

TRACKING MATERIAL GENEALOGY

FIELD OF THE INVENTION

[0001] The present disclosure relates generally to tracking the flow of material throughout a manufacturing process. More specifically, the present disclosure relates to generation of a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process having continuous steps.

BACKGROUND OF THE INVENTION

[0002] Manufacturing pharmaceuticals requires processing input materials (e.g., raw materials, semi-processed materials) received from various suppliers or processed on-site through preliminary processing steps into a batch of finished product through a series of steps. The input materials may comprise raw materials received from multiple different suppliers, and each batch of raw material may be associated with a different lot or batch number. United States Food and Drug Administration (FDA) regulations and Good Manufacturing Practices (GMP) require that each finished batch of drug product be associated with an inventory report detailing the genealogy of the finished batch of drug product.

[0003] An inventory report detailing the genealogy of a finished batch of drug product tracks information, such as the quantity, material number and feed input batch ID, of each input material that went into the finished batch of drug product. The material number can be used to determine exactly what type of input material went into the finished batch of drug product and which supplier it came from. The feed input batch ID can be used to determine the exact shipment of raw material received from said supplier, which can identify when the shipment of raw material was manufactured, when the shipment of raw material was shipped, when the shipment of raw material was received, and/or how the shipment of raw material was transported. Specifying the list of input materials of a finished batch of drug product in the inventory report is referred to as specifying the “material genealogy” of said batch of finished drug product.

SUMMARY OF THE INVENTION

[0004] According to an exemplary embodiment, a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising: for each step of the plurality of steps of the manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step; inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0005] According to another exemplary embodiment, a system comprising: for each step of a plurality of steps of a manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process: at least one feeder tank for storing input material input into the respective step; at least one pump for controlling the input of the input material from the at least one feeder tank into the respective step; and one or more sensors disposed on said at least one feeder tank and/or at least one pump and configured to generate data regarding the at least one feeder tank and/or the at least one pump; at least one processor, wherein the at least one processor receives at least some of the data generated by the one or more sensors; and at least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by the at least one processor, cause

the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via the manufacturing process, the method comprising: for each step of the plurality of steps of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step, wherein the setting data includes the at least some of the data generated by the one or more sensors for the respective step; inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0006] According to another exemplary embodiment, at least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by at least one processor, cause the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising: for each step of the plurality of steps of the manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step; inputting the data into a computational sub-model configured to model how

the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0007] It is noted that techniques for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process having various different features are disclosed herein and these features may be combined in various different configurations, including configurations not specifically illustrated or discussed. Although several different combinations of such features are described herein, a person having ordinary skill in the art will realize that further such combinations not explicitly described herein are also possible and enabled by the present disclosure and are within the scope of the present application. Additionally, although various techniques are disclosed herein for attaining the disclosed features, a person having ordinary skill in the art will realize that some modifications to the disclosed techniques may be possible and within the scope of the disclosed techniques. It is also to be understood that the phraseology and terminology employed herein are for the purpose of description and should not be regarded as limiting.

BRIEF DESCRIPTION OF THE DRAWINGS

[0008] Various aspects, techniques, and embodiments of the present technology disclosed herein are described below with reference to the accompanying drawings. It should be appreciated that the figures are not necessarily drawn to scale. Items appearing in multiple figures may be indicated by the same reference numeral. For purposes of clarity, not every component may be labeled in every figure. Features of the present technology will become more apparent, and techniques for how to attain the features of the present technology, will be better understood by reference to the following detailed description considered in conjunction with the accompanying drawings, wherein:

[0009] FIG. 1 is an example schematic diagram of a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein.

[0010] FIG. 2 is an example schematic diagram of a first step of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0011] FIG. 3A is an example schematic diagram illustrating example buffer tanks of a first feeder tank at a first time, in accordance with some embodiments of the technology described herein.

[0012] FIG. 3B is an example schematic diagram illustrating the example buffer tanks of FIG. 3A at a second time, in accordance with some embodiments of the technology described herein.

[0013] FIG. 4 is an example schematic diagram of a multi-step manufacturing process, in accordance with some embodiments of the technology described herein.

[0014] FIG. 5 is a flowchart of an example method for generating a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein.

[0015] FIG. 6 is an example schematic diagram illustrating aspects of a process for generating an intermediate record comprising genealogy information of a product subsequent to completion of a first step of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0016] FIG. 7A is an example schematic diagram illustrating aspects of a process for generating a report comprising genealogy information of a product subsequent to completion

of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0017] FIG. 7B is an example schematic diagram illustrating aspects of assigning virtual identifiers to a product subsequent to completion of respective steps of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0018] FIG. 8A is an example schematic diagram of an intermediate record for a first step of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0019] FIG. 8B is an example schematic diagram of an intermediate record for a second step of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0020] FIG. 8C is an example schematic diagram of an intermediate record for a third step of a manufacturing process, in accordance with some embodiments of the technology described herein.

[0021] FIG. 9 is an example schematic diagram of a system for generating a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein.

[0022] FIG. 10 is an example schematic diagram illustrating applications that comprise a system for generating a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein.

[0023] FIG. 11 is a block diagram detailing aspects of a controller that performs aspects of the techniques for tracking material genealogy described herein.

DETAILED DESCRIPTION OF THE INVENTION

[0024] Provided herein are exemplary implementations of techniques for tracking material genealogy of a finished batch of drug product. In particular, aspects of the technology include techniques for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process having a plurality of continuous steps. The genealogy information of the report may include at least one manufacturing parameter (e.g., material number, feed input batch ID, and/or quantity) of each material present in the product after completion of the plurality of steps.

[0025] As noted herein, the FDA and GMP require that each finished batch of drug product be associated with an inventory report detailing the genealogy of the finished batch of drug product. Specifying the list of input materials of a finished batch of drug product in the inventory report (e.g., indicating the material number, feed input batch ID, and quantity of each input material in the finished batch of drug product) is referred to as specifying the “material genealogy” of a particular batch of finished drug product.

[0026] The input materials may comprise raw materials input into the manufacturing process and processed in the manufacturing process. The input materials may comprise semi-processed material created from one or more raw materials (e.g., by combining two or more raw materials and/or processing one or more raw materials). Where the input material comprises a semi-processed material, the semi-processed material may have an assigned feed input batch ID, and the one or more raw materials from which the semi-processed material is made comprise their own batch IDs. The feed input batch ID of the semi-processed material may associate the semi-processed material with batch IDs of the one or more raw materials from which the semi-processed material is made.

[0027] Compiling the material genealogy of a batch of finished drug product can be complicated, for example, when manufacturing a drug involves multiple continuous steps. Within a single continuous step, input materials are introduced into the step through feeder tanks. As the feeder tanks run low, they are replenished with additional input materials. Each time the feeder tanks are replenished, they may be replenished with a batch of input material bearing a different feed input batch ID. Each continuous step of the manufacturing process may comprise multiple feeder tanks, and one or more of the feeder tanks may be replenished with a new batch of input material at least once during the processing of the single continuous

step. In some instances, it can take hours (e.g., up to 5 hours) to process a batch of drug product through a single continuous step.

[0028] Where previously drug products were typically manufactured in batches which do not require replenishing feeder tanks mid-step, specifying the material genealogy of a batch of finished drug product could be done rather easily. However, specifying the material genealogy of a batch of finished drug product manufactured using continuous manufacturing practices is considerably more complicated, as the material genealogy must take into account the times at which feeder tanks were replenished mid-process and the expected amount of time it would take for such replenished material to propagate through the manufacturing process. Thus, the inventors have recognized a need for techniques for tracking material genealogy of a drug product manufactured using one or more continuous manufacturing processes.

[0029] In addition, manufacturing a drug product can involve multiple continuous steps. For example, in some embodiments, manufacturing a drug product can be performed in at least three continuous steps. Between each step, intermediate product is collected in isolation tanks before being processed in the next continuous step. The intermediate product collected in the isolation tank may then be fed into the next continuous step.

[0030] The inventors have recognized that tracking material genealogy of a finished batch of drug product is difficult due to (1) the continuous nature of each step of the manufacturing process and (2) the fact that the manufacturing process includes multiple such continuous steps. Therefore, the inventors have developed techniques for automatically tracking material genealogy of a finished batch of drug product. For example, there are provided herein methods for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process comprising a plurality of steps performed sequentially. Each respective step comprises a continuous sub-process. The techniques include performing, for each step (1) receiving data indicating a plurality of characteristics (e.g., a set of materials used for the respective step, setting data indicative of a setting of at least one manufacturing component used for the respective step such as pump speed, a time when a feeder tank was refilled, etc.) associated with the continuous sub-process of the respective step, inputting the data into a computational sub-model (e.g., a residence time distribution model for the particular step) configured to

model how the set of materials used for the respective step propagate through the respective step, and receiving an intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step as output. The techniques further include generating, based on at least the intermediate record of a last step, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process. The genealogy information of the report includes at least one manufacturing parameter (e.g., material number, feed input batch ID, quantity) of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0031] FIG. 1 is an example schematic diagram of a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein. The report 100 illustrated in FIG. 1 may be referred to as a material genealogy report. The report 100 details the genealogy of a finished batch of drug product. In particular, the report comprises genealogy information of manufacturing materials used to manufacture a product after completion of a plurality of continuous steps of a manufacturing process.

[0032] As shown in FIG. 1, the report 100 includes a number of rows pertaining to each input material present in the finished batch of drug product. For each input material, the report 100 identifies a material number, a batch identifier, and a quantity of the input material present in the finished batch of drug product. The report 100 shown in the illustrated embodiment provides the quantity of each input material in kilograms, however other units of quantity are possible.

[0033] As described herein, the material number can be used to determine exactly what type of input material went into the finished batch of drug product and which supplier it came from. For example, the material number may be used to retrieve such information from a database storing information that corresponds a material number to a particular type of material and/or supplier. The batch identifier, also referred to herein as a “feed input batch ID” can be used to determine the exact shipment of raw material received from said supplier, which can be used to identify when the shipment of raw material was manufactured, when the shipment of raw material was shipped, when the shipment of raw material was received,

and/or how the shipment of raw material was transported. For example, the batch identifier may be used to retrieve such information from a database storing information that corresponds the batch identifier to a particular shipment of raw material. In some embodiments, the input material comprises a raw material, and the feed input batch ID can directly correspond the input material to the information regarding the raw material. In some embodiments, the input material comprises a semi-processed material comprising one or more raw materials, and the feed input batch ID can correspond the input material to respective batch IDs of the one or more raw materials from which the semi-processed material is made, and the respective batch IDs of the one or more raw materials can be used to retrieve the information regarding the one or more raw materials.

[0034] As described herein, compiling the material genealogy of a finished batch of drug product can be complicated when manufacturing of the finished batch of drug product involves multiple continuous steps. FIG. 2 is an example schematic diagram of a first step of a manufacturing process, in accordance with some embodiments of the technology described herein. In the illustrated embodiment of FIG. 2, a first step (“Step 1”) of a manufacturing process for manufacturing a drug is illustrated.

[0035] Within each single continuous “step”, drug product is processed from left to right. At various stages in the process of the step, input materials are introduced into the step via feeder tanks. As shown in the illustrated embodiment, feeder tanks through which input material is fed into the step are illustrated schematically. In the illustrated embodiment of FIG. 2, step 1 comprises two feeder tanks, however other configurations are possible.

[0036] Each feeder tank may be coupled to a respective pump for feeding the input material of the feeder tank into the step. For example, as shown schematically in FIG. 2, a first feeder tank is coupled to a first pump for feeding input material from the first feeder tank into a first mixer. A second feeder tank of FIG. 2 is coupled to a second pump for feeding input material from the second feeder tank into the first mixer. The input material in the second feeder tank may be a same or different type of material (e.g., having a different material number) than an input material in the first feeder tank. The input material in the first and second feeder tanks may have different feed input batch IDs.

[0037] As shown in FIG. 2, the input material fed into the step 1 via the respective feeder tanks is fed into a first mixer. The material, which is now referred to herein as intermediate

material to refer to a material that has been processed through at least a portion of at least one step of the manufacturing process, may be mixed in the first mixer, for example, using an activator pump. In the illustrated embodiment of FIG. 2, the intermediate material is fed from the first mixer to a second mixer where the intermediate material is further mixed, for example, using a base pump. The intermediate material is then fed from the second mixer to a first plug flow reactor (PFR). Subsequently, the intermediate material is fed from the first plug flow reactor into a surge vessel, also referred to herein as an isolation tank. The isolation tank collects the finished batch of material at the end of step 1.

[0038] As a respective feeder tank runs low on input material to feed into the step, it is replenished with additional input material. Each time the feeder tanks are replenished, they may be replenished with a batch of input material bearing a different feed input batch ID. For example, a material having a first batch identifier may be fed from the first feeder tank into the first mixer for a first duration of the first step that is less than a total duration of the first step. At the conclusion of the first duration, a second material having a second batch identifier may be fed from the first feeder tank into the first mixer for a second duration that is less than the total duration of the first step. The second material may be a same type of material as the first material (e.g., having a same material number). However, the second material may have a different batch identifier than the first material. In some embodiments, the second material may be a different type of material than the first material (e.g., due to a change in the manufacturing process mid-step). The techniques described herein for tracking material genealogy of a batch of drug product determine a quantity of the first material and a quantity of the second material in the batch of drug product at the conclusion of the first step.

[0039] FIGS. 3A-3B illustrate aspects of replenishing a feeder tank with additional input material during the first step. For example, FIG. 3A is an example schematic diagram illustrating example buffer tanks of a first feeder tank at a first time, in accordance with some embodiments of the technology described herein. For simplicity, some components of the first step are omitted from FIGS. 3A-3B. In the illustrated embodiment of FIGS. 3A-3B, the first feeder tank comprises multiple buffer tanks, each having input material therein. At the first time illustrated in FIG. 3A, a first batch of input material (e.g., having a first feed input batch ID) is fed into the first mixer from a first buffer tank of the first feeder tank. This may

be achieved by activating at least one valve between the first buffer tank and the first mixer such that material is able to flow from the first buffer tank to the first mixer.

[0040] The first feeder tank further comprises a second buffer tank having a second batch of input material. The second batch of input material may be a same type of material as the first batch of input material in the first buffer tank (e.g., having a same material number), but may have a different feed input batch ID. At the first time illustrated in FIG. 3A, the second batch of material in the second buffer tank is unable to flow into the first mixer due to the configuration of the at least one valve which blocks flow of the second batch of input material in the second buffer tank into the mixer.

[0041] FIG. 3B is an example schematic diagram illustrating the example buffer tanks of FIG. 3A at a second time, in accordance with some embodiments of the technology described herein. Subsequent to the first time, the material in the first buffer tank may become depleted. At that time, the step may be configured for enabling material from the second buffer tank to flow into the first mixer. This may be achieved by activating the at least one valve to allow the second batch of material to flow from the second buffer tank into the first mixer, as shown in FIG. 3B.

[0042] In this way, input material is continuously fed into the first step throughout the duration of the first step despite depletion of a first buffer tank. The step may therefore be considered a “continuous” step. That is, for the duration of the first step, input materials are constantly being fed into the step and constantly being fed out of the sub-process into the isolation tank. Due to the constant flow of material into the first step, feeder tanks for a particular material may need to be replenished with a new batch of material during the first step.

[0043] Similar to the feeder tanks, the isolation tank may comprise multiple buffer tanks. For example, the first step may be configured such that, initially, a first buffer tank receives the intermediate product output from the first step. When the first buffer tank is full, a second buffer tank may receive the intermediate product output from the first step. When the second buffer tank is full, a third buffer tank may receive the intermediate product output from the first step, and so forth. The isolation tank may comprise any suitable number of buffer tanks (e.g., at least two, at least five, at least ten). The intermediate product collected in each buffer tank may be assigned a respective virtual identifier, as described herein. For example, the

batch of intermediate product collected in a first buffer tank may be assigned VID001_A and the batch of intermediate product collected in the second buffer tank may be assigned VID001_B, and so forth.

[0044] As shown in FIG. 2, Step 1 of the manufacturing process may include a plurality of sensors. In some embodiments, a system configured to perform the techniques described herein comprises, for each step of a plurality of steps of a manufacturing process, one or more sensors. The one or more sensors may comprise respective sensors associated with different components of the manufacturing process (e.g., respective feeder tanks, respective pumps, respective mixers, etc.). The one or more sensors can generate data associated with one or more of the components of the manufacturing process, for example, throughout a duration of Step 1. In some embodiments, the data generated by the one or more sensors comprise time series data that track one or more conditions of a manufacturing component of Step 1 throughout a duration of Step 1.

[0045] The data generated by the one or more sensors can be input into the computational sub-model, as described herein, for Step 1. For example, the setting data input into the computational model described herein may comprise at least some of the data generated by the one or more sensors. As described herein, the computational sub-model for Step 1 can be used to generate a record comprising genealogy information of an intermediate batch of drug product at the completion of Step 1. By using the data generated by the one or more sensors in the computational sub-model to generate the record, generation of the record comprising the genealogy information accounts for “live” data representing the actual operating conditions of Step 1. Instead of only generating the report based on target operating parameters representing the manner in which the manufacturing process is intended to operate (e.g., desired pump speeds, desired replenishment times of input material into a feeder tank), the computational sub-models use data indicative of how the manufacturing process is actually performed by use of the data from the one or more sensors. The resulting report indicating the material genealogy of a finished batch of drug product is therefore more accurate, as it accounts for actual operating conditions of the manufacturing process which may include unintentional or unforeseen deviations from target operating conditions. In addition, the techniques for generating the report indicating the material genealogy of the finished batch of drug product are less labor-intensive to generate, as they automatically

account for deviation from desired operating conditions when generating the report instead of requiring a manual correction after the fact.

[0046] In the illustrated embodiment of FIG. 2, each feeder tank of Step 1 comprises at least one sensor configured to track one or more conditions of the respective feeder tank throughout a duration of Step 1. The sensor may track one or more conditions of the respective feeder tank to which it is coupled. For example, the sensor may track a characteristic of the input material in the feeder tank, such as volume, weight, or another suitable characteristic. The one or more conditions of the feeder tank may be tracked by the sensor over the duration of the respective step. That is, the data generated by the sensor comprises time series data representative of the characteristic (e.g., volume, weight, etc., of the input material in the feeder tank) of the respective step. In this manner, the sensor can track the characteristic of the feeder tank over time and deviation from a desired value can be detected. The data generated by the sensor coupled to the feeder tank may be indicative of at least one time during the duration of the respective step at which the feeder tank is replenished with a new batch of input material. For example, by detecting an increase in volume and/or weight of input material in the feeder tank (which may be over a threshold increase), it can be determined that the feeder tank has been replenished. The determined time at which the feeder tank is replenished can be used to detect any deviation from a target time at which the feeder tank is desired to be replenished under target operating conditions. The deviation from target replenishment time can be input into the computational sub-model for Step 1, so that the computational model can accurately track the material genealogy of the intermediate batch of drug product at the completion of Step 1 in view of the deviation in target replenishment time.

[0047] Each pump of Step 1 may also comprise one or more sensors configured to track one or more conditions of the respective pump throughout a duration of Step 1. A respective sensor may track one or more conditions of the respective pump to which it is coupled. For example, the respective sensor may track the pump speed of the respective pump to which it is coupled, for example, over the duration of the respective step. That is, the data generated by the sensor comprises time series data representative of the pump speed of the respective pump throughout the duration of the respective step. In this manner, the sensor can track the pump speed over the duration of the respective step and deviation from a desired pump speed

can be detected. The deviation from target pump speed can be input into the computational sub-model for Step 1, so that the computational model can accurately track the material genealogy of the intermediate batch of drug product at the completion of Step 1 in view of the deviation in pump speed.

[0048] The use of the one or more sensors shown in FIG. 2 is exemplary, and other configurations are possible. For example, fewer than all of the components of Step 1 may have a sensor associated with the component. In some embodiments, additional steps (e.g., all) of the manufacturing process may comprise one or more sensors associated with one or more (e.g., all) of the components (e.g., respective feeder tanks, respective pumps, respective mixers) of the respective steps. For simplicity in illustration, the one or more sensors are omitted from FIGS. 3A-3B, which illustrate aspects of the manufacturing process.

[0049] Each step of the manufacturing process may take a number of hours to complete. For example, it may take up to five hours to completely fill the isolation tank that collects the output of continuous step 1. During the duration of a single continuous step, one or more feeder tanks of the step may need to be replenished one or more times.

[0050] Manufacturing a finished batch of drug product may involve multiple steps. For example, in some embodiments, a manufacturing process for manufacturing a drug product comprises three (e.g., at least three, exactly three) continuous steps like that of step 1 illustrated in FIG. 2. FIG. 4 is an example schematic diagram of a multi-step manufacturing process, in accordance with some embodiments of the technology described herein.

[0051] The example schematic diagram of FIG. 4 illustrates a manufacturing process for manufacturing a product (e.g., a finished batch of drug product). In the illustrated embodiment of FIG. 4, the manufacturing process comprises multiple steps. Each step of the manufacturing process comprises a continuous subprocess of the manufacturing process. For example, the manufacturing process includes the first step ("step 1") illustrated in FIG. 2 and described herein.

[0052] The manufacturing process illustrated by the schematic diagram of FIG. 4 illustrates the flow of material through the manufacturing process. The flow of material is from left to right in each row. For example, the manufacturing process may begin at step 1 where input material is fed into step 1 via first and second feeder tanks. As described herein, intermediate material is fed out of step 1 into an isolation tank ("surge vessel" in FIG. 4). At the

completion of step 1, the intermediate batch of drug product at the completion of step one is fed into the next step of the manufacturing process.

[0053] As shown in FIG. 4, the intermediate batch of drug product in the surge vessel of step 1 is fed into an intermediate processing sub-step (“intermediate processing sub-step A”). As described herein, the surge vessel of step 1 may comprise multiple buffer tanks. The intermediate product in the surge vessel of step 1 may be fed into a subsequent step one buffer tank at a time. For example, the intermediate product in the first buffer tank of the isolation tank may be fed into a subsequent step until the first buffer tank becomes depleted, at which point the intermediate product in the second buffer tank of the isolation tank may begin feeding into the subsequent step.

[0054] The intermediate processing sub-steps of the manufacturing process differs from the steps (e.g., steps 1-3) of the manufacturing process in that new materials are introduced into the product at steps 1-3 while new materials are not introduced into the product at the intermediate processing sub-steps A-C. The intermediate processing sub-step may perform additional filtering and/or processing of the intermediate batch of drug product before feeding the intermediate batch of drug product into a second step. For example, intermediate processing sub-step A comprises a first nanofiltration tank for performing nanofiltration of the intermediate batch of drug product prior to feeding the intermediate batch of drug product into the second step of the manufacturing process.

[0055] Subsequently, the manufacturing process comprises a second step (“step 2” in FIG. 4). The second step may be configured similar to the first step described herein. However, in the second step, the intermediate batch of drug product produced at the first step acts as a source of input material for the second step. That is, the intermediate batch of drug product produced at the first step is fed into the second step via a feeder tank and pump into a third mixer of the second step. As described herein, the intermediate batch of drug product produced at the first step may be fed into the second step one buffer tank at a time. Additional input material is fed into the second step via a third feeder tank coupled to a corresponding third pump. Processing of material through the second step proceeds in the same or similar manner as the first step described herein. An output of the second step is collected in an isolation tank (“surge vessel”) for the second step. The surge vessel of the second step may

comprise multiple buffer tanks which are filled sequentially and assigned respective virtual identifiers.

[0056] The intermediate batch of drug product in the surge vessel of step 2 is fed into a subsequent intermediate processing sub-step (intermediate processing sub-step B). For example, the intermediate batch of drug product of step 2 may be fed into the intermediate processing sub-step B one buffer tank at a time. The intermediate processing sub-step B may perform additional filtering and/or processing of the intermediate batch of drug product, like intermediate processing sub-step A, before feeding the intermediate batch of drug product into a third step. For example, intermediate processing sub-step B comprises a second nanofiltration tank for performing nanofiltration of the intermediate batch of drug product prior to feeding the intermediate batch of drug product into the third step of the manufacturing process.

[0057] Subsequently, the manufacturing process comprises a third step (“step 3” in FIG. 4). The third step may be configured similar to the first and second steps. For example, the intermediate batch of drug product produced at the second step acts as a source of input material for the third step. That is, the intermediate batch of drug product produced at the second step is fed into the third step via a feeder tank and pump into a fifth mixer of the third step. This feeder tank of the third step comprises the input material fed into the respective steps from the first and second feeder tanks of the first step and the third feeder tank of the second step. The intermediate batch of drug product produced at the second step may be fed into the third step one buffer tank at a time, as described herein. Additional input material is fed into the fifth mixer of the third step via a fourth feeder tank. Processing of material through the third step proceeds in the same or similar manner as the first and second steps described herein. An output of the third step is collected in an isolation tank (“surge vessel”) for the third step. The isolation tank of the third step may comprise multiple buffer tanks, which may be filled sequentially and assigned respective virtual identifiers.

[0058] In some embodiments, the manufacturing process of FIG. 4 proceeds to one or more additional steps and/or intermediate processing sub-steps. For example, the output of third step may be fed into an intermediate processing sub-step (intermediate processing sub-step C) for additional filtering and/or processing. The output of the third step may be fed into the

intermediate processing sub-step C one buffer tank at a time. The end product of the manufacturing process may be isolated.

[0059] The end product of the manufacturing process is the finished batch of drug product. As shown in FIG. 4, the manufacturing process comprises multiple steps. Each step may comprise one or more feeder tanks for inputting input materials into the respective step. One or more of the respective feeder tanks may input input material of different types into the respective step. Each of the steps of the manufacturing process may be continuous, that is, having material flowing into and out of the step throughout the duration of the step such that input material fed into the step must be replenished with additional input material having a different feed input batch ID during the completion of the step. Accordingly, the end product of the manufacturing process comprises a finished batch of drug product having multiple input materials of different types (e.g., different material numbers). In addition, the finished batch of drug product may have multiple input materials of a same type (e.g., a same material number) but from a different batch (e.g., having different feed input batch IDs). The respective materials in the finished batch of drug product may be present in different quantities. The quantities of each material present in the finished batch drug product are dependent on a number of settings of the manufacturing components of the manufacturing process, such as pump speeds, time when feeder tanks and/or buffer tanks are replenished with additional input material, tank sizes, and/or pipe diameters.

[0060] Tracking the material genealogy of the intermediate batches of drug product at the completion of each continuous step of the manufacturing process and the finished batch of drug product after completion of all of the steps is challenging due to the multiple steps of the manufacturing process and their continuous nature. However, such information is necessary to generate the genealogy reports required under the FDA and GMP. Accordingly, the inventors have developed techniques for automatically tracking the material genealogy of a batch of drug product. For example, FIG. 5 is a flowchart of an example method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process comprising a plurality of sequentially performed steps, in accordance with some embodiments of the technology described herein. As shown and described with respect to FIG. 4, for example, the manufacturing process comprises a plurality of steps and each step may be continuous.

Therefore, the plurality of steps of the manufacturing process may be considered to comprise continuous sub-processes of the overall manufacturing process.

[0061] The example method 500 illustrated in FIG. 5 begins at act 502 where, for a respective step of a plurality of steps of a manufacturing process, data indicating a plurality of characteristics of the respective step are received. The respective step may be the first step of the plurality of steps. Accordingly, the process 500 may begin by receiving the data indicating the plurality of characteristics of the first step (e.g., “step 1” illustrated in FIGS. 2 and 4).

[0062] The plurality of characteristics of the respective step are associated with the continuous sub-process of the respective step. For example, the plurality of characteristics may comprise a set of materials used for the respective step (e.g., a set of materials in the respective feeder tanks of the respective step that are fed into the respective step during completion of the continuous sub-process). The set of materials may be indicated by material number, feed batch input ID, and/or initial quantity. In some embodiments, the plurality of characteristics for a respective step comprises time series data indicating a time period during which an input material of the set of input materials is introduced into a respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step. For example, the data received at act 502 may comprise event frame data comprising the time series data described herein.

[0063] In some embodiments, feeding input material into a respective step comprises feeding input material into the respective step for a duration of the first step. Feeding input material into the step for the duration of the first step may comprise feeding a first batch of a first input material of a set of materials having a first batch identifier into the respective step for a first time period. At the end of the first time period, the feeder tank may be replenished with a second batch of the first input material having a second batch identifier. In particular, the second batch comprises the same type of input material as the first batch (e.g., having a same material number) but may comprise a different batch identifier than the first batch. Replenishing the feeder tank with the second batch of input material may comprise filling the feeder tank with additional input material at an end of the first duration. In some embodiments, as described herein, replenishing the feeder tank with the second batch of input

material comprises activating a valve that allows input material from a second buffer tank of the first feeder tank to feed input material into the step (e.g., as described with respect to FIGS. 3A-3B). The second batch of the first input material may be fed into the respective step for a second time period that is less than the duration of the respective step and subsequent to the first time period. The second time period may begin at the end of the first time period. The plurality of characteristics received at act 502 may include the respective time periods during which different batches of input material are fed into the respective step.

[0064] The plurality of characteristics associated with the continuous sub-process of the respective step may further comprise setting data indicative of a setting of at least one manufacturing component used for the respective step. For example, the at least one manufacturing component may comprise a pump, a tank (e.g., a feeder tank, a buffer tank, a mixer tank, etc.), a pipe, or other component of the respective step. The setting data may comprise a pump speed of a respective pump of the respective step (e.g., a first pump coupled to the first feeder tank, a second pump coupled to the second feeder tank, an activator pump coupled to the first mixer, a base pump coupled to the second mixer, etc.). For example, the setting data may comprise time series data indicating pump speeds of the respective pumps throughout a duration of the step. The setting data may comprise a time when a respective tank was refilled (e.g., a time when a respective feeder tank was refilled, a time when a respective buffer tank was refilled). The setting data may comprise a time when a respective tank was coupled to a mixer (e.g., a time when the at least one valve described herein was activated to couple respective buffer tank to a mixer to allow material from the respective buffer tank to flow into the mixer via the valve). The setting data may comprise at least some of the data generated by the one or more sensors of a respective step, as described herein.

[0065] Subsequently, the method 500 proceeds to act 504 where the data received at act 502 is input into a computational sub-model for the respective step. The computational sub-model may be configured to model how the set of materials used for the respective step propagate through the respective step. In some embodiments, the computational sub-model models how liquid materials disperse and propagate through the respective step based on setting data for the respective step (e.g., pump speeds, tank sizes, and/or pipe diameters used throughout the respective step).

[0066] For example, the computational sub-model may comprise a residence time distribution model for the respective step. A residence time distribution model determines the probability distribution of the time that a piece of material is likely to spend in a process. In a manufacturing process such as that described herein which use pumps to pump material into the respective steps, the speed of the pump impacts the residence time distribution model. Accordingly, pump speed is one of the plurality of characteristics input into the computational sub-model.

[0067] The residence time distribution model may determine, for each portion of material, how long that portion of material spends in the step before being output into the isolation tank. By knowing the length of time a portion of material spends in a step and an initial time when the portion of material is input into the step, the computational sub-model can determine whether the portion of material is in the isolation tank at completion of the step.

[0068] The computational sub-model may generate, based on which materials are determined to be in the isolation tank at the end of the respective step, an intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step. Accordingly, at act 506, the method 500 receives an intermediate record as output from the computational sub-model.

[0069] For example, FIG. 8A is an example schematic diagram of a plurality of intermediate records for a first step of a manufacturing process, in accordance with some embodiments of the technology described herein. Specifically, FIG. 8A shows three intermediate records, associated with virtual identifiers VID001_A, VID001_B, and VID001_C respectively. As described herein, the isolation tank of step 1 may comprise multiple buffer tanks. During processing of step 1, a first buffer tank is filled with the intermediate product generated during step 1 until full, at which point the intermediate product generated during step 1 is input to a second buffer tank, and so forth. An intermediate record may be generated for a batch of intermediate material within one buffer tank and may be assigned a respective virtual identifier. For example, as shown in FIG. 8A, material within a first buffer tank is associated with a first intermediate record assigned virtual identifier VID001_A, material within a second buffer tank is associated with a second intermediate record assigned virtual

identifier VID001_B, and material within a third buffer tank is associated with a third intermediate record assigned virtual identifier VID001_C.

[0070] Even as one buffer tank is in the process of being filled with intermediate material output from step 1, another buffer tank may be in the process of being emptied into step 2. So for example, as the second buffer tank is being filled, the first buffer tank may be in the process of being emptied into step 2; as the third buffer tank is being filled, the second buffer tank may be in the process of being emptied into step 2, and so forth. When the third buffer tank is being emptied into step 2, the intermediate material output of step 1 may be routed back to the (now empty) first buffer tank. Accordingly, at that point of time, a virtual identifier VID001_D (not shown) may be assigned to a new batch of intermediate material being collected within the first buffer tank. In this way, the virtual identifier associated with each buffer tank may not be static but may change over time as new batches are cycled through each buffer tank. Although in the illustrated embodiment three buffer tanks are described, more or fewer buffer tanks may be implemented, in some embodiments.

[0071] The intermediate records 810 of FIG. 8A each comprise a plurality of rows indicating, for each material present in a respective buffer tank of the isolation tank at the completion of the first step, a material number, a batch identifier, and a quantity (in KG). As described herein, the material number may be used to retrieve additional information stored in a database corresponding to that material number (e.g., type of material, supplier, etc.). The batch identifier may be used to retrieve additional information stored in a database corresponding to that batch identifier (e.g., when the batch was manufactured, when the batch was shipped, when the batch was received, how the batch was transported, etc.).

[0072] As shown in FIG. 8A, the intermediate record VID001_A for step 1 indicates that the intermediate product within the first buffer tank comprises 8 KG of a first material A₁ associated with batch identifier B₁, and 20 KG of a second material A₂ associated with batch identifier B₃. Similarly, the intermediate record VID001_C for step 1 indicates that the intermediate product within the third buffer tank comprises 15 KG of the first material A₁ associated with batch identifier B₂, and 3 KG of the second material A₂ associated with batch identifier B₄. The intermediate record VID001_B indicates that two different batches (e.g., with batch identifiers B₁ and B₂) of the first material A₁ are present in the intermediate product in the second buffer tank. During processing of the intermediate product within the second

buffer tank, the first material A_1 may be fed into the first step via a first feeder tank. During completion of the first step, the first batch B_1 of material A_1 may become depleted and replenished with a second batch B_2 of material A_1 . Accordingly, the intermediate product in the second buffer tank at the end of step 1 comprises multiple batches of the same material.

[0073] The intermediate record $VID001_B$ further indicates that the intermediate product in the second buffer tank at the end of step 1 comprises a second material A_2 . Two different batches (as indicated by different batch identifiers B_3 and B_4) of the second material A_2 are present in the intermediate product at the end of the first step. This is due to replenishing of a second feeder tank configured to feed the second material A_2 into the first step during completion of the first step with a new batch of material A_2 during processing of the intermediate product that is within the second buffer tank. Accordingly, the intermediate product in the second buffer tank comprises multiple materials and for each material, multiple batches of that material.

[0074] The virtual identifiers $VID001_A$, $VID001_B$, and $VID001_C$ serve as a cross-reference for the intermediate records and the information therein. For example, the virtual identifier of the intermediate record 810 “ $VID001_A$ ” may be used in subsequent records to refer to the information within the first intermediate record $VID001_A$, as described herein. A correspondence between the virtual identifier of a particular record and the genealogy information regarding the materials described in that record may be stored in a database.

[0075] Acts 502-506 may be performed for each step of the plurality of steps of the manufacturing process. Accordingly, at act 508, it is determined whether additional steps of the plurality of steps of the manufacturing process are remaining.

[0076] If, at act 508, it is determined that additional steps remain, the method 500 returns through the “Yes” branch to act 502 where data indicating a plurality of characteristics for a subsequent respective step of the manufacturing process is obtained. Acts 502-506 may repeat for each subsequent step of the plurality of steps until acts 502-506 have been performed for each step of the manufacturing process and no additional steps remain.

[0077] For example, acts 502-506 may be performed for the second step of the manufacturing process described herein (e.g., with respect to FIG. 4) subsequent to performing acts 502-506 for the first step. Acts 502-506 may then be performed for the third

step of the manufacturing process described herein (e.g., with respect to FIG. 4) subsequent to performing acts 506 for the second step.

[0078] FIGS. 8B-8C illustrate example schematic diagrams of intermediate records for the second and third steps of a manufacturing process. For example, FIG. 8B is an example schematic diagram of two intermediate records for a second step of a manufacturing process associated with virtual identifiers VID002_A and VID002_B, in accordance with some embodiments of the technology described herein. Similar to step 1, VID002_A may be associated with an intermediate record for a batch of intermediate product in a first buffer tank that collects the output of step 2, while VID002_B may be associated with an intermediate record for a batch of intermediate product in a second buffer tank that collects the output of step 2. The intermediate records indicate genealogy information of materials present in an intermediate product within a respective buffer tank at the completion of the second step. For example, the intermediate record 820 indicates a material number, batch identifier, and quantity of each material present in the intermediate product at the completion of the second step.

[0079] As shown in FIG. 8B, the intermediate records 820 for step 2 references the virtual identifiers VID001_{A-C} of the first intermediate records 810. For example, the intermediate record VID002_A indicates that the intermediate product within the first buffer tank collecting output from step 2 includes 28 KG of the intermediate product output from step 1 associated with virtual identifier VID001_A, and 9 KG of the intermediate product output from step 1 associated with virtual identifier VID001_B. Similarly, the intermediate record VID002_B indicates that the intermediate product within the second buffer tank collecting output from step 2 includes 15 KG of the intermediate product output from step 1 associated with virtual identifier VID001_B, and 18 KG of the intermediate product output from step 1 associated with virtual identifier VID001_C. By referencing VID001_{A-C}, the second intermediate records 820 for the second step indicates that the intermediate product at the completion of step 2 includes all of the materials indicated in the first intermediate records 810 without having to specifically reference each of the materials. The virtual identifiers VID001_{A-C} may be used to identify each of the materials and their genealogy information indicated in the first intermediate records 810. In some embodiments, each of the materials and their genealogy information indicated by the first intermediate record 810 may be explicitly included in the

second intermediate record 820 instead of being referenced by their respective virtual identifier. As shown in FIG. 8B, the second intermediate records 820 include virtual identifiers VID002_{A-B} which may be used in subsequent records to refer to the information within the second intermediate records 820. VID002_A may be assigned to the intermediate product in a first buffer tank of the isolation tank of step 2 and VID002_B may be assigned to the intermediate product in a second buffer tank of the isolation tank of step 2. As discussed above for step 1, the virtual identifier associated with each buffer tank may not be static but may change over time as new batches are cycled through each buffer tank.

[0080] As shown in FIG. 8B, the intermediate product at the completion of the second step includes all of the materials present in the intermediate product at the completion of the first step in addition to additional materials added to the product during the second step. For example, a third type of material (indicated by material number A₃) may be added to the second step via a third feeder tank, as described herein. Multiple different batches (as indicated by batch identifiers B₅ and B₆) of the third material A₃ are present in the intermediate product at the completion of the second step (e.g., due to replenishing the third feeder tank with a new batch of input material during completion of the second step).

[0081] FIG. 8C is an example schematic diagram of intermediate records for a third step of a manufacturing process, in accordance with some embodiments of the technology described herein. Specifically, FIG. 8C shows two intermediate records, associated with virtual identifiers VID003_A and VID003_B, respectively. The intermediate record 830 indicates genealogy information of materials present in an intermediate product at the completion of the third step. For example, the intermediate record 830 indicates a material number, batch identifier, and quantity of each material present in the intermediate product at the completion of the third step.

[0082] As shown in FIG. 8C, the intermediate records 830 references the virtual identifiers VID002_{A-B} of the second intermediate record 820. By referencing VID002_{A-B}, the third intermediate record 830 for the third step indicates that the intermediate product at the completion of step 3 includes all of the materials indicated in the second intermediate record 820 without having to specifically reference each of the materials. The virtual identifiers VID002_{A-B} may be used to identify each of the materials and their genealogy information indicated in the second intermediate record 820. In some embodiments, each of the materials

and their genealogy information indicated by the first intermediate record 810 and/or second intermediate record 820 may be explicitly included in the third intermediate record 830 instead of being referenced by the virtual identifiers. As shown in FIG. 8C, the third intermediate record 830 includes virtual identifiers VID003_{A-B} which may be used in subsequent records to refer to the information within the third intermediate record 830. For example, VID003_A may refer to the intermediate batch of product in a first buffer tank of the isolation tank of step 3 and VID003_B may refer to the intermediate batch of product in a second buffer tank of the isolation tank of step 3. Also as discussed above for steps 1 and 2, the virtual identifier associated with each buffer tank may not be static but may change over time as new batches are cycled through each buffer tank.

[0083] As shown in FIG. 8C, the third intermediate record 830 references the virtual identifiers VID002 of the second intermediate record 820. As described herein, the second intermediate record 820 references the first intermediate record 810, so materials present in the intermediate product after completion of the third step include the materials fed into the first step (e.g., via the first and second feeder tanks), the materials fed into the second step (e.g., via the third feeder tank), and the materials fed into the third step (e.g., via the fourth feeder tank). For example, a fourth type of material (indicated by material number A₄) may be added to the third step via a fourth feeder tank, as described herein. Multiple different batches (as indicated by batch identifiers B₇ and B₈) of the fourth material A₄ are present in the intermediate product at the completion of the third step (e.g., due to replenishing the fourth feeder tank with a new batch of input material during completion of the third step).

[0084] As shown in FIGS. 8A-8C, the intermediate records of subsequent steps of the manufacturing process may reference earlier steps of the manufacturing process (e.g., using virtual identifiers). Accordingly, in some embodiments, the data input into the computational sub-model of a subsequent step may include genealogy information of the intermediate product after completion of a prior step. This may be performed by inputting the intermediate record of a prior step into the computational sub-model of a subsequent step.

[0085] If, at act 508, it is determined that no additional steps of the manufacturing process remain, the method 500 proceeds through the “No” branch to act 510 where a report is generated comprising genealogy information of manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process. For

example, the genealogy information of the report generated at act 508 may comprise at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process. The manufacturing parameter may include a material number, a batch identifier, and/or a quantity of each material present in the product after completion of the plurality of steps.

[0086] Report 100 illustrated in FIG. 1 is an example of a report that may be generated at act 508. For example, report 100 indicates a material number, a batch identifier, and a quantity (in KG) of each material present in a finished batch of drug product after completion of a plurality of steps of a manufacturing process (e.g., the manufacturing process shown and described in FIG. 4). As described herein, the material number and batch identifier may be used to determine additional information about each material present in the finished batch of drug product.

[0087] Generating the report at act 508 is performed based on at least an intermediate record of a last step. Referring to the example manufacturing process described herein (e.g., with reference to FIG. 4), “step 3” may be a last step of the manufacturing process. An third intermediate record 830 may therefore be the intermediate record of the last step on which the report generated at act 508 is based. For example, where the third step is the last step of the manufacturing process, the third intermediate record 830 indicates each of the materials present in the finished batch of product as well as genealogy information for each of the materials. The report 100 may be generated by replacing the virtual identifiers VID002_{A-B} with the information the virtual identifiers represent (e.g., the information in the appropriate second intermediate record 820). As the second intermediate record also includes virtual identifiers, VID001_{A-C}, the virtual identifiers VID001_{A-C} included in the second intermediate record may also be replaced with the information the virtual identifier represents in the first report. Thus, the report 100 may be generated based on at least the intermediate record of the last step of the plurality of steps. When the intermediate record of the last step comprises a reference to the intermediate record of one or more steps of the plurality of steps preceding the last step (e.g., the virtual identifier described herein), generating the report comprising the genealogy information is further based on the intermediate records of said one or more steps preceding the last step.

[0088] It should be appreciated that the virtual identifiers may not be used in some embodiments. Further, in some embodiments, the virtual identifiers in the intermediate records may be replaced prior to generating the report comprising genealogy information of materials in the finished batch of drug product after completion of all of the steps of the manufacturing process at act 508. For example, the intermediate record for the last step may be generated without using virtual identifiers. In particular, generating the intermediate record for the last step may include replacing any existing virtual identifiers with the information to which they correspond. In such embodiments where the intermediate record for the last step does not contain any virtual identifiers, the intermediate record for the last step may be the report generated at act 508.

[0089] Accordingly, the method 500 provides a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process comprising a plurality of continuous steps. The method described herein overcomes the challenge of tracking material genealogy throughout a multi-step manufacturing process where each step is continuous (e.g., having material fed into and output of the step throughout the step such that input materials must be replenished with new batches during completion of the step). The use of the computational sub-model to generate reports indicating material genealogy information for the intermediate product at the completion of each step eliminates the need to determine material genealogy information via a cumbersome manual process. Rather, by inputting certain data (e.g., set of materials used, time frames indicating when such materials are input into a feeder tank, pump speeds, pipe diameters, etc.) into the computational sub-model at each step, the composition of an end-product of each step can be determined automatically.

[0090] The method for generating the report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process may be embodied in software. For example, aspects of the technology described herein include at least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by at least one processor, cause the at least one processor to perform any of the methods described herein.

[0091] Aspects of the technology described herein further include systems comprising the at least one processor and the at least one non-transitory computer-readable storage medium.

The system may comprise one or more (e.g., all) of the components of the manufacturing process illustrated in FIG. 4. For example, the system may comprise one or more pumps, one or more feeder tanks, one or more isolation tanks, etc. FIG. 4 illustrated a controller 1100. The system may comprise at least one controller 1100. The controller 1100 may contain at least one processor and memory having instructions that, when executed by the at least one processor, execute the methods described herein (e.g., method 500). The controller 1100 further comprises the sub-components described herein with respect to FIG. 11.

[0092] FIG. 6 is an example schematic diagram illustrating aspects of a process for generating an intermediate record comprising genealogy information of a product subsequent to completion of a first step of a manufacturing process, in accordance with some embodiments of the technology described herein. In particular, FIG. 6 illustrates a schematic diagram of a process for generating genealogy information of manufacturing materials in a product after completion of a first step of a manufacturing process.

[0093] As shown in FIG. 6, and described herein, step 1 of the manufacturing process includes a plurality of “feeds” of input material into the step. That is, step 1 comprises a plurality of feeder tanks that feed input material into step 1. The input material from the feeds is input into a plug flow reactor (PFR) and processed in the PFR. The processed material is output from the PFR and into a surge vessel, also referred to herein as an isolation tank. The contents of the isolation tank (e.g., the intermediate material and their genealogy information) are assigned a virtual identifier, as described herein. In particular, the isolation tank may comprise multiple buffer tanks, and the contents of each buffer tank may be assigned a respective virtual identifier. In the illustrated embodiment, the contents of the isolation tank after completion of the first step are assigned a virtual identifier “VID001.”

[0094] The process illustrated in FIG. 6 includes inputting data into a computational sub-model for the first step of the manufacturing process and outputting data from the computation sub-model for the first step. As shown in FIG. 6, input data to the computational sub-model for step 1 comprises initial conditions and process inputs and measures of the first step. For example, the input data may include the set of materials used for the respective step and setting data indicative of a setting of at least one manufacturing component used for the first step. Such information can include pump speeds, pipe diameters, materials fed into the step including material numbers and/or feed input batch IDs, time series data indicating a

duration during which a particular material is fed into the first step, which may be in the form of event frames, as described herein, and/or valve activity (e.g., indicating a time when a valve is opened/closed to allow/restrict flow of material from a buffer tank into the step).

[0095] The output of the computational sub-model for the step comprises contents of one or more components of the step. For example, the output of the computational sub-model includes information regarding contents of the surge vessel (also referred to herein as the “isolation tank”) at the end of the first step. The information regarding the contents of the surge vessel can be reflected in an intermediate report comprising genealogy information of the materials present in the intermediate product after completion of the first step. The output of the computational sub-model may further comprise information regarding contents of other equipment in the step. For example, the computational sub-model may comprise a residence time distribution model which estimates residence time of portions of material throughout the step. By understanding the residence time of portions of material throughout the step, the computational sub-model can determine what material and what quantity thereof is present in each part (e.g., piece of equipment) of the step at a particular time. Such information may be used to generate error reports and/or to prepare the equipment for a subsequent round of the manufacturing process.

[0096] As described herein, a manufacturing process for manufacturing a finished batch of drug product may comprise a plurality of sequentially performed steps. A computational sub-model may be used for each of the plurality of steps to determine genealogy information of the product subsequent to completion of the respective step. FIG. 7A is an example schematic diagram illustrating aspects of a process for generating a report comprising genealogy information of a product subsequent to completion of a manufacturing process. The manufacturing process of FIG. 7A corresponds to the manufacturing process illustrated and described in FIG. 4. FIG. 7A illustrates that a discrete computational sub-model may be used for determining the genealogy information of a product at each step, including intermediate processing sub-steps A-C. The intermediate processing sub-steps may perform filtration, isolation, and/or processing steps (e.g., nanofiltration, as indicated by “NF” in FIG. 7A). The output of each model (e.g., genealogy information of the materials produced at the end of a respective step and/or a report comprising such information) may be assigned a respective virtual identifier (e.g., VID001_A, VID001_B, VID002_e, VID002_e, VID003_A, and so forth).

[0097] FIG. 7B is an example schematic diagram illustrating aspects of assigning virtual identifiers to a product subsequent to completion of respective steps of a manufacturing process, in accordance with some embodiments of the technology described herein. As described herein, the output of each model for each respective step may be assigned a virtual identifier (e.g., VID001). For example, each respective fill of a buffer tank of an isolation tank may be assigned a respective virtual identifier (e.g., VID001_A, VID001_B, VID001_C, and so forth). A first continuous manufacturing (CM) step may be assigned VID001. A first nanofiltration (NF) intermediate processing sub-step (intermediate processing sub-step A) following the first CM step may be assigned VID001'. As the first NF intermediate processing sub-step follows the CM step, the contents of the product at the completion of the first NF intermediate processing sub-step depend on the contents of the product at the completion of the first CM step. That is, the contents output from the first CM step are input into the first NF intermediate processing sub-step, so the virtual identifier VID001' for the first NF intermediate processing sub-step may take the virtual identifier VID001 of the first CM step into account. As the manufacturing process proceeds through the additional CM steps and NF intermediate processing sub-steps, each subsequent step must take into account all of the steps that precede it. At the completion of the manufacturing process (e.g., at completion of the third CM step), the isolated batch of finished drug product is assigned a final virtual identifier VID003'. The final virtual identifier VID003' takes into account the output of each step completed in the manufacturing process. A report indicating genealogy information (e.g., material number, feed input batch ID, quantity) for each material in the finished batch of drug product may be generated based on the final virtual identifier VID006.

[0098] FIG. 9 is an example schematic diagram of a system for generating a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein. The system 900 illustrated in FIG. 9 is a material tracking system configured to perform the techniques for tracking material genealogy of a product described herein. The system 900 provides a platform to store and execute the material tracking models described herein. The system 900 may be accessed via a web user interface (UI) using a web browser.

[0099] As shown in FIG. 9, the system 900 comprises a historian platform 910, an interface platform 920, and a model platform 930. Each of the components of the system are

configured to communicate with each other. For example, the interface platform 920 may be configured to communicate with the historian platform 910 (e.g., to request data from the historian platform 910) and the historian platform 910 is configured to provide data to the interface platform 920. The interface platform 920 is configured to provide data to and receive data from the model platform 930. The interface platform 920 may therefore serve as an interface between the historian platform 910 and the model platform 930.

[0100] The historian platform 910 is a source of data for the interface platform 920, which provides the data to the model platform 930. In particular, the historian platform 910 may comprise a data historian (e.g., an OSi Pi Data historian, as one example). The historian platform 910 may be configured to provide time-series data to the interface platform 920 that can be used as model input. The historian platform 910 may comprise a data source provider that allows retrieval of asset framework data (e.g., PI OLEDB Enterprise Provider) and a data source provider that allows retrieval of time-series data from a data archive (e.g., PI OLEDB Provider). The historian platform 910 keeps track of which input materials (each associated with a material number and feed input batch ID) are introduced into the feeder tanks of a respective step while processing a drug product at the respective step.

[0101] The historian platform 910 generates data structures that are processed by the interface platform 920, and thereafter used by the model platform 930 to produce genealogy information. In particular, the data structures produced by the historian platform 910 are referred to as “event frames.” An event frame is a time window of information extending from a start of a step until an end of a step. An event frame time window starts when a respective buffer tank of an isolation tank begins to fill with intermediate product output from a respective step. The event frame ends when the buffer tank of the isolation tank is filled (e.g., no additional material is fed out from the step into the respective buffer tank). A subsequent event frame may begin when intermediate material is fed out from the step into a second buffer tank of the isolation tank. The event frame comprises time series data representative of all of the inputs into the step during the time window of the event frame. For example, the event frame comprises time series data representative of pump speeds of each pump operating during the time window. The event frame comprises information representative of when a batch of input material is depleted and when a new batch of input material is fed into the step.

[0102] As described herein, the historian platform communicates the event frame data to an interface platform 920. The interface platform 920 receives the event frame data from the historian platform 910. The interface platform 920 may optionally perform processing on the event frame data received from the historian platform 910 before passing the event frame data to the model platform 930. An example embodiment of the interface platform is the business automation workflow (BAW) software produced by IBM.

[0103] The interface platform 920 may comprise a programmable operating system that allows for providing the output of one software application to another software application, thus configuring the two software applications to work together. The interface platform 920 may monitor model execution by the model platform 930. The interface platform 920 may further complete user tasks relating to the material genealogy tracking processes described herein. For example, a user interface may be provided as part of the system for interfacing with the interface platform 920. Via the user interface, a user may monitor, manage, and document completion of model tasks.

[0104] The model platform 930 comprises software configured to execute a model. For example, the model platform 930 comprises software configured to execute the computational sub-models for the respective steps of the manufacturing process described herein. The model platform 930 receives the processed event frame data provided by the interface platform 920 and executes the one or more models based on the event frame data. In particular, the model platform 930 may run a residence time distribution model on the input data to generate material genealogy information of a batch of intermediate product that results from a single run of a continuous step. The model platform 930 may then send the results of the model execution back to the interface platform 920. This process may be repeated for each batch of event frame data generated by the historian platform 910. For example, the model platform 930 may execute a respective model on event frame data corresponding to each respective step of the manufacturing process and send the results of the model execution back to the interface platform 920 for each step.

[0105] The model's task requires modeling how long it will take for input materials introduced into a feeder tank to propagate through the entire continuous step and end up in the batch of intermediate product collected in the isolation tank at the end of the step. For instance, consider a batch of product being processed through continuous step 1. The output

of this batch is collected in an isolation tank at the end of step 1. Assume step 1 starts running at time T_0 and ends at time T_F . Assume further that at time T_0 , a certain feeder tank A was initially filled with input material bearing feed input batch ID “X” but that at time T_N in the middle of the continuous step 1 (i.e., $T_0 < T_N < T_F$), the feeder tank A’s supply of X material was exhausted, and feeder tank A was switched to provide input material bearing feed input batch ID “Y.”

[0106] The model’s task is to model how liquid materials disperse and propagate during the processing of step 1 in order to estimate the number of kilograms of “X” material vs. the number of kilograms of “Y” material that ended up in the isolation tank at the end of step 1, when processing concludes at time T_F . The model must do this not only for materials X and Y and feeder tank A, but also for all feeder tanks that provide input materials at any point into step 1. This task requires taking into account pump speeds, tank sizes, diameter of pipes, etc. throughout step 1.

[0107] The output of the model platform is a material genealogy of the product collected in the isolation tank at the end of step 1. This process may be repeated for the remaining steps of the manufacturing process order to arrive at a final material genealogy of the finished drug product at the end of the last step of the manufacturing process.

[0108] The interface platform 920 receives the results of the model execution from the model platform 930. In some embodiments, the results of the model execution for each respective step comprises an intermediate record comprising genealogy information of each material present in an intermediate batch of drug product after completion of the respective step, as described herein. The interface platform 920 may compile the report comprising genealogy information of each material present in a finished batch of drug product based on the intermediate records for each step. The interface platform 920 may update inventory information based on the materials indicated as used in the manufacturing process. For example, material genealogy reports may be used to update SAP for inventory reconciliation and to record the material genealogy.

[0109] In some embodiments, the system (e.g., the interface platform 920) may raise investigations based detection of logical errors such as missing virtual identifiers or mismatched batches. In addition, the system is capable of re-executing the computational model to revise and/or generate new intermediate records (e.g., an updated intermediate

record for a respective step of the manufacturing process). For example, a user may detect an error in operating conditions (e.g., a leak in a tank resulting in missing material) that the model did not account for in an initial execution of the model. The user can re-execute the model with the additional information regarding the error (e.g., information regarding the missing material) so that the intermediate report generated by the model accounts for the error in operating conditions raised by the user.

[0110] For example, one or more sensors may be associated with each respective step of the manufacturing process. The one or more sensors may track one or more conditions of one or more components of the respective step (e.g., at least one feeder tank configured to store input material that is input into the respective step, at least one pump configured to pump the input material into the respective step). In some embodiments, there is a sensor disposed on each pump of a respective step. The sensor may track one or more conditions of the respective pump to which it is coupled. For example, the sensor may track the pump speed of the respective pump to which it is coupled, for example, over the duration of the respective step. That is, the data generated by the sensor comprises time series data representative of the pump speed of the respective pump over the duration of the respective step. In this manner, the sensor can track the pump speed over the duration of the respective step and deviation from a desired pump speed can be detected.

[0111] In some embodiments, there is a sensor disposed on each respective feeder tank of a respective step. The sensor may track one or more conditions of the respective feeder tank to which it is coupled. For example, the sensor may track a characteristic of the input material in the feeder tank, such as volume, weight, or other suitable characteristic. The one or more conditions of the feeder tank may be tracked by the sensor over the duration of the respective step. That is, the data generated by the sensor comprises time series data representative of the characteristic (e.g., volume, weight, etc., of the input material in the feeder tank) of the respective step. In this manner, the sensor can track the characteristic of the feeder tank over time and deviation from a desired value can be detected. For example, the data generated by the sensor coupled to the feeder tank may be indicative of at least one time during the duration of the respective step at which the feeder tank is replenished with a new batch of input material. For example, by detecting an increase in volume and/or weight of input material in the feeder tank (which may be over a threshold increase), it can be determined

that the feeder tank has been replenished. The determined time at which the feeder tank is replenished can be used to detect any deviation from a target time at which the feeder tank is desired to be replenished.

[0112] The data generated by the one or more sensors can be input into the computational sub-models for the respective steps described herein. For example, the setting data described herein comprises at least some of the data generated by the one or more sensors, in some embodiments. In this manner, the computational sub-model accounts for “live” data representing the operation of the manufacturing process. Instead of only operating on target operating parameters representing the manner in which the manufacturing process is intended to operate (e.g., desired pump speeds, desired replenishment times), the computational sub-models use data indicative of how the manufacturing process is actually performed. The resulting report indicating the material genealogy of a finished batch of drug product is therefore more accurate, as it accounts for actual operating conditions of the manufacturing process. In addition, the techniques for generating the report indicating the material genealogy of the finished batch of drug product is less labor-intensive to generate, as it automatically accounts for deviation from desired operating characteristics when generating the report instead of requiring a manual correction after the fact.

[0113] FIG. 10 is an example schematic diagram illustrating applications that comprise a system for generating a report comprising genealogy information of a product manufactured via a manufacturing process, in accordance with some embodiments of the technology described herein. The schematic diagram of FIG. 10 illustrates applications performed by the components of the example system 900 described herein. For example, FIG. 10 illustrates the historian platform (e.g., OSIsoft PI Data Historian in the illustrated embodiment) which generates event frame data. The event frame data generated by the historian platform is communicated to the interface platform (e.g., Business Automated Workflow in the illustrated embodiment) which processes the data. For example, in the illustrated embodiment, BAW connects to OSIsoft PI using SQL Server linked servers and retrieves event frames that describe the data related to unit operations that is relevant for the model execution. Event frames contain attribute data and specify the PI Points that should be retrieved for the event frame time period. When an event frame is closed (i.e., complete), it is associated to a unique human readable label called a Virtual Identifier (VID). The attributes,

time-series data and VID are then written to a file and forwarded to the model platform (e.g., Domino in the illustrated embodiment) as an input of the model execution.

[0114] As described herein, the processed event frame data can be communicated by the interface platform to the model platform (e.g., Domino Platform in the illustrated embodiment) which may execute the model based on the event frame data. For example, in the illustrated embodiment, BAW integrates with Domino by invoking the model execution and retrieving the results. Model configuration and data from the previous model execution are stored within Domino and automatically provided to the model on execution. The full data set used during each model execution is stored in Domino. The results generated by the model executions are stored by BAW in a SQL Server database. The SQL server is a relational database management system.

[0115] The SQL Server database serves as the database for the material tracking process. Where possible, the system does not duplicate source system data. Rather, it stores metadata that allows the system to retrieve source system data on demand.

[0116] As shown in FIG. 10, the system may further comprise one or more user interfaces for interacting with one or more components of the system. For example, the system illustrated in FIG. 10 comprises a plurality of user interfaces that may allow a user to perform one or more the following functions.

[0117] The system may allow a user to perform near real-time and historical material tracking process monitoring. For example, BAW provides users with a UI to view real-time insights, including the VIDs that have been ingested by the system, the status of model executions, and the information pertaining to investigations on a model execution. Historical model executions and isolated batches can be inspected for the same information. Domino provides users with a UI to view the historical model execution data stored within the application.

[0118] The system may allow a user to perform straight-through processing workflow management. For example, the system handles all straight-through processing workflow and ETL tasks related to retrieving and storing data from OSIsoft PI, executing models, and receiving and storing data from models. BAW periodically retrieves event frames and automatically triggers the workflow when an event frame is closed.

[0119] The system may allow a user to perform investigation workflow management. For example, if an event occurs in the continuous manufacturing process that affects the execution of the material tracking model, this event will be captured in the system by an end user. BAW provides users with a UI to open new investigations, and to link to them any model executions that are affected. If there is a Trackwise record related to the event, it will be referenced in the BAW investigation. The investigation process allows users to access the Domino UI and manually re-execute any models impacted by the investigation. Once re-run and verified, the updated model execution results are incorporated by BAW into the SQL Server database.

[0120] The system may allow a user to perform automated investigation logging. For example, BAW can also be configured to flag investigations automatically when events or data meet certain conditions. These investigations can then be followed up on by users.

[0121] The system may allow a user to perform user task management. For example, BAW automatically assigns tasks to users (or teams) as part of the workflow management process. BAW provides users with a UI for viewing pending tasks assigned to them (or to their team) and for claiming a task. Once a task is claimed by a user, it will not be available to other users (or team members). Users can complete claimed tasks via task-specific UIs. Two-person verification (2PV) tasks have been included in the workflows for activities deemed to be critical. BAW manages these 2PV tasks and ensures that a user that completed the original task cannot complete the 2PV of that task. BAW also provides users with UIs for viewing the task history related to isolated batches and the list of tasks completed by the users themselves.

[0122] The system may allow a user to generate a material tracking genealogy report. For example, as described herein, BAW provides a report that is generated for an isolated batch which incorporates the data from the related model executions. The report contains a list of feed input batch IDs and their related quantities that are contained in the isolated batch. It also contains a list of feed input batch IDs and quantities that were diverted to waste.

[0123] The system may allow a user to generate an SAP inventory report. For example, BAW provides a report that is generated for an isolated batch which incorporates the data from the related model executions. The report lists all feed input batches and the quantities of those feed input batches associated with the isolated batch to be used to update SAP for

inventory reconciliation. If material is diverted during the period of the isolated batch the report will list the batches and quantities to be associated with the divert process order.

[0124] The system may allow a user to generate residual reports and/or audit trail reports. For example, a Power BI report may be generated from the system to monitor the performance of residuals across model runs for the same step to identify trends. A Power BI report may be generated from the system that lists electronic records and BAW and/or Domino configuration changes performed by non-system users, and lists electronic signatures associated to the approval of BAW tasks.

[0125] The system may assist with compliance with one or more federal, state, and/or local laws. The system may be a closed system with data integrity controls in place such as role-based security, automatic data audit trail capture, and human-readable reporting and views of system data. The system provides a robust, controlled, automated, and, if needed, manual workflow management environment for implementing material tracking requirements under this regulation. The SQL Server database maintains a complete history for the material tracking genealogy, including material mass fractions, for each batch created by the continuous manufacturing process. The data can be recalled and presented in human-readable format in a variety of ways, including via reports or visual inspection in the system's user interface.

[0126] FIG. 11 is a block diagram detailing aspects of a controller that performs techniques for tracking material genealogy according to exemplary one or more embodiments. The controller 1100 may include one or more processors 1110 that implement the example method shown in FIG. 5, for example. Instructions processed by the one or more processors 1110 to implement the method 500 may be stored in non-transitory computer-readable media such as non-volatile storage 1120, for example. Any one or more processors 1110 may be referred to as "a processor," and subsequent reference to "the processor" should be interpreted to refer to any one or more of the processors 1110. That is, different ones of the processors 1110 may implement different aspects of the method 500 and other processes discussed herein. Memory 1130 may store genealogy information generated by the process, such as the intermediate records and/or the genealogy report, as well as other data. A display 1140 may display the output of implementing the method 500 shown in FIG. 5 (e.g., one or more intermediate records and/or the report indicating genealogy information of materials in

the finished batch of drug product subsequent to completion of the plurality of steps of the manufacturing process).

[0127] The technology described herein can have any of the configurations described below.

[0128] (1) A method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising: for each step of the plurality of steps of the manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step; inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0129] (2) The method of (1), wherein, for a second step of the plurality of steps, at least some of the data indicating the plurality of characteristics associated with the continuous sub-process of the second step comprises at least some information in the intermediate record for a first step preceding the second step in the plurality of steps.

[0130] (3) The method of (1), wherein the plurality of characteristics of the respective step comprises a pump speed for each pump of a plurality of pumps that feed material into the respective step.

[0131] (4) The method of (3), wherein the plurality of characteristics of the respective step comprises time series data indicating a time period during which an input material of the set of materials is introduced into the respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step.

[0132] (5) The method of (1), wherein a first step of the plurality of steps comprises feeding input material into the first step for a duration of the first step and feeding the input material into the first step comprises: feeding a first batch of a first input material of the set of materials having a first batch identifier into the first step for a first time period that is less than the duration of the first step; and feeding a second batch of the first input material having a second batch identifier different than the first batch identifier into the first step for a second time period that is less than the duration of the first step and subsequent to the first time period.

[0133] (6) The method of (5), wherein the intermediate report indicates a quantity of the first input material having the first batch identifier and a quantity of the first input material having the second batch identifier present in an end product of the first step.

[0134] (7) The method of (5), wherein the second time period begins at an end of the first time period.

[0135] (8) The method of (1), wherein the computational sub-model models how liquid materials disperse and propagate based on pump speeds, tank sizes, and pipe diameters used throughout a respective step of the plurality of steps of the manufacturing process.

[0136] (9) The method of (1), wherein the computational sub-model comprises a residence time distribution model.

[0137] (10) The method of (1), wherein the plurality of steps of the manufacturing process comprises at least three steps.

[0138] (11) The method of (1), wherein the at least one manufacturing parameter comprises a material number, a batch identifier, and a quantity of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0139] (12) The method of (1), wherein when the intermediate record of the last step comprises a reference to the intermediate record of one or more steps of the plurality of steps

preceding the last step, generating the report comprising the genealogy information is further based on the intermediate records of said one or more steps preceding the last step.

[0140] (13) The method of (1), further comprising re-executing the computational sub-model for at least one of the plurality of steps based on user input indicating a detected error in the manufacturing process, wherein re-executing the computational sub-model comprises inputting data regarding the detected error in the manufacturing process to the computational sub-model and receiving an updated intermediate record as output from the computational sub-model.

[0141] (14) The method of (1), wherein the setting data includes at least some of the data generated by one or more sensors for the respective step, the one or more sensors being disposed on at least one feeder tank for storing input material input into the respective step and/or on at least one pump for controlling the input of the input material from the at least one feeder tank into the respective step and the one or more sensors being configured to generate data regarding the at least one feeder tank and/or the at least one pump

[0142] (15) The method of (14), wherein the one or more sensors for each respective step track one or more conditions of the at least one feeder tank and/or the at least one pump over a duration of the respective step.

[0143] (16) The method of (15), wherein the one or more conditions of the at least one pump comprise a pump speed of the at least one pump and the data generated by the one or more sensors for each respective step comprises time series data representative of the pump speed of the at least one pump over the duration of the respective step.

[0144] (17) The method of (15), wherein the one or more conditions of the at least one feeder tank comprises a volume of input material in the at least one feeder tank and the data generated by the one or more sensors for each respective step comprises time series data representative of the volume of input material in the at least one feeder tank over the duration of the respective step.

[0145] (18) The method of (17), wherein the data generated by the one or more sensors is indicative of at least one time during the duration of the respective step at which the at least one feeder tank is replenished with a new batch of input material.

[0146] (19) A system comprising: for each step of a plurality of steps of a manufacturing process, wherein each respective step comprises a continuous sub-process of the

manufacturing process: at least one feeder tank for storing input material input into the respective step; at least one pump for controlling the input of the input material from the at least one feeder tank into the respective step; and one or more sensors disposed on said at least one feeder tank and/or at least one pump configured to generate data regarding the at least one feeder tank and/or the at least one pump; at least one processor, wherein the at least one processor receives at least some of the data generated by the one or more sensors; and at least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by the at least one processor, cause the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via the manufacturing process, the method comprising: for each step of the plurality of steps of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step, wherein the setting data includes the at least some of the data generated by the one or more sensors for the respective step; inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0147] (20) The system of (19), wherein, for a second step of the plurality of steps, at least some of the data indicating the plurality of characteristics associated with the continuous sub-process of the second step comprises at least some information in the intermediate record for a first step preceding the second step in the plurality of steps.

[0148] (21) The system of (19), wherein the plurality of characteristics of the respective step comprises a pump speed for each pump of the at least one pump for the respective step.

[0149] (22) The system of (21), wherein the plurality of characteristics of the respective step comprises time series data indicating a time period during which an input material of the set of materials is introduced into the respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step.

[0150] (23) The system of (19), wherein a first step of the plurality of steps comprises feeding the input material from the at least one feeder tank for the first step into the first step for a duration of the first step and feeding the input material into the first step comprises: feeding a first batch of a first input material of the set of materials having a first batch identifier into the first step for a first time period that is less than the duration of the first step; and feeding a second batch of the first input material having a second batch identifier different than the first batch identifier into the first step for a second time period that is less than the duration of the first step and subsequent to the first time period.

[0151] (24) The system of (23), wherein the intermediate report indicates a quantity of the first input material having the first batch identifier and a quantity of the first input material having the second batch identifier present in an end product of the first step.

[0152] (25) The system of (23), wherein the second time period begins at an end of the first time period.

[0153] (26) The system of (19), wherein the computational sub-model models how liquid materials disperse and propagate based on pump speeds, tank sizes, and pipe diameters used throughout a respective step of the plurality of steps of the manufacturing process.

[0154] (27) The system of (19), wherein the computational sub-model comprises a residence time distribution model.

[0155] (28) The system of (19), wherein the plurality of steps of the manufacturing process comprises at least three steps.

[0156] (29) The system of (19), wherein the at least one manufacturing parameter comprises a material number, a batch identifier, and a quantity of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0157] (30) The system of (19), wherein when the intermediate record of the last step comprises a reference to the intermediate record of one or more steps of the plurality of steps preceding the last step, generating the report comprising the genealogy information is further based on the intermediate records of said one or more steps preceding the last step.

[0158] (31) The system of (19), wherein the one or more sensors for each respective step track one or more conditions of the at least one feeder tank and/or the at least one pump over a duration of the respective step.

[0159] (32) The system of (31), wherein the one or more conditions of the at least one pump comprise a pump speed of the at least one pump and the data generated by the one or more sensors for each respective step comprises time series data representative of the pump speed of the at least one pump over the duration of the respective step.

[0160] (33) The system of (31), wherein the one or more conditions of the at least one feeder tank comprises a volume of input material in the at least one feeder tank and the data generated by the one or more sensors for each respective step comprises time series data representative of the volume of input material in the at least one feeder tank over the duration of the respective step.

[0161] (34) The system of (33), wherein the data generated by the one or more sensors is indicative of at least one time during the duration of the respective step at which the at least one feeder tank is replenished with a new batch of input material.

[0162] (35) The system of (19), wherein the method further comprises re-executing the computational sub-model for at least one of the plurality of steps based on user input indicating a detected error in the manufacturing process, wherein re-executing the computational sub-model comprises inputting data regarding the detected error in the manufacturing process to the computational sub-model and receiving an updated intermediate record as output from the computational sub-model.

[0163] (36) At least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by at least one processor, cause the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising: for each step of the plurality of steps of the manufacturing process,

wherein each respective step comprises a continuous sub-process of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising: a set of materials used for the respective step; and setting data indicative of a setting of at least one manufacturing component used for the respective step; inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0164] (37) The at least one non-transitory computer-readable storage medium of (36), wherein, for a second step of the plurality of steps, at least some of the data indicating the plurality of characteristics associated with the continuous sub-process of the second step comprises at least some information in the intermediate record for a first step preceding the second step in the plurality of steps.

[0165] (38) The at least one non-transitory computer-readable storage medium of (36), wherein the plurality of characteristics of the respective step comprises a pump speed for each pump of a plurality of pumps that feed material into the respective step.

[0166] (39) The at least one non-transitory computer-readable storage medium of (38), wherein the plurality of characteristics of the respective step comprises time series data indicating a time period during which an input material of the set of materials is introduced into the respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step.

[0167] (40) The at least one non-transitory computer-readable storage medium of (36), wherein a first step of the plurality of steps comprises feeding input material into the first step for a duration of the first step and feeding the input material into the first step comprises: feeding a first batch of a first input material of the set of materials having a first batch identifier into the first step for a first time period that is less than the duration of the first step; and feeding a second batch of the first input material having a second batch identifier different than the first batch identifier into the first step for a second time period that is less than the duration of the first step and subsequent to the first time period.

[0168] (41) The at least one non-transitory computer-readable storage medium of (40), wherein the intermediate report indicates a quantity of the first input material having the first batch identifier and a quantity of the first input material having the second batch identifier present in an end product of the first step.

[0169] (42) The at least one non-transitory computer-readable storage medium of (40), wherein the second time period begins at an end of the first time period.

[0170] (43) The at least one non-transitory computer-readable storage medium of (36), wherein the computational sub-model models how liquid materials disperse and propagate based on pump speeds, tank sizes, and pipe diameters used throughout a respective step of the plurality of steps of the manufacturing process.

[0171] (44) The at least one non-transitory computer-readable storage medium of (36), wherein the computational sub-model comprises a residence time distribution model.

[0172] (45) The at least one non-transitory computer-readable storage medium of (36), wherein the plurality of steps of the manufacturing process comprises at least three steps.

[0173] (46) The at least one non-transitory computer-readable storage medium of (36), wherein the at least one manufacturing parameter comprises a material number, a batch identifier, and a quantity of each material present in the product after completion of the plurality of steps of the manufacturing process.

[0174] (47) The at least one non-transitory computer-readable storage medium of (36), wherein when the intermediate record of the last step comprises a reference to the intermediate record of one or more steps of the plurality of steps preceding the last step, generating the report comprising the genealogy information is further based on the intermediate records of said one or more steps preceding the last step.

[0175] (48) The at least one non-transitory computer-readable storage medium of (36), wherein the method further comprises re-executing the computational sub-model for at least one of the plurality of steps based on user input indicating a detected error in the manufacturing process, wherein re-executing the computational sub-model comprises inputting data regarding the detected error in the manufacturing process to the computational sub-model and receiving an updated intermediate record as output from the computational sub-model.

[0176] (49) The at least one non-transitory computer-readable storage medium of (36), wherein the setting data includes at least some of the data generated by one or more sensors for the respective step, the one or more sensors being disposed on at least one feeder tank for storing input material input into the respective step and/or on at least one pump for controlling the input of the input material from the at least one feeder tank into the respective step and the one or more sensors being configured to generate data regarding the at least one feeder tank and/or the at least one pump.

[0177] (50) The at least one non-transitory computer-readable storage medium of (49), wherein the one or more sensors for each respective step track one or more conditions of the at least one feeder tank and/or the at least one pump over a duration of the respective step.

[0178] (51) The at least one non-transitory computer-readable storage medium of (50), wherein the one or more conditions of the at least one pump comprise a pump speed of the at least one pump and the data generated by the one or more sensors for each respective step comprises time series data representative of the pump speed of the at least one pump over the duration of the respective step.

[0179] (52) The at least one non-transitory computer-readable storage medium of (50), wherein the one or more conditions of the at least one feeder tank comprises a volume of input material in the at least one feeder tank and the data generated by the one or more sensors for each respective step comprises time series data representative of the volume of input material in the at least one feeder tank over the duration of the respective step.

[0180] (53) The at least one non-transitory computer-readable storage medium of (53), wherein the data generated by the one or more sensors is indicative of at least one time during the duration of the respective step at which the at least one feeder tank is replenished with a new batch of input material.

[0181] Techniques operating according to the principles described herein may be implemented in any suitable manner. The processing and decision blocks of the flow charts above represent steps and acts that may be included in algorithms that carry out these various processes. Algorithms derived from these processes may be implemented as software integrated with and directing the operation of one or more single- or multi-purpose processors, may be implemented as functionally-equivalent circuits such as a Digital Signal Processing (DSP) circuit or an Application-Specific Integrated Circuit (ASIC), or may be implemented in any other suitable manner. It should be appreciated that the flow charts included herein do not depict the syntax or operation of any particular circuit or of any particular programming language or type of programming language. Rather, the flow charts illustrate the functional information one skilled in the art may use to fabricate circuits or to implement computer software algorithms to perform the processing of a particular apparatus carrying out the types of techniques described herein. It should also be appreciated that, unless otherwise indicated herein, the particular sequence of steps and/or acts described in each flow chart is merely illustrative of the algorithms that may be implemented and can be varied in implementations and embodiments of the principles described herein.

[0182] Accordingly, in some embodiments, the techniques described herein may be embodied in computer-executable instructions implemented as software, including as application software, system software, firmware, middleware, embedded code, or any other suitable type of computer code. Such computer-executable instructions may be written using any of a number of suitable programming languages and/or programming or scripting tools, and also may be compiled as executable machine language code or intermediate code that is executed on a framework or virtual machine.

[0183] When techniques described herein are embodied as computer-executable instructions, these computer-executable instructions may be implemented in any suitable manner, including as a number of functional facilities, each providing one or more operations to complete execution of algorithms operating according to these techniques. A “functional facility,” however instantiated, is a structural component of a computer system that, when integrated with and executed by one or more computers, causes the one or more computers to perform a specific operational role. A functional facility may be a portion of or an entire software element. For example, a functional facility may be implemented as a function of a

process, or as a discrete process, or as any other suitable unit of processing. If techniques described herein are implemented as multiple functional facilities, each functional facility may be implemented in its own way; all need not be implemented the same way.

Additionally, these functional facilities may be executed in parallel and/or serially, as appropriate, and may pass information between one another using a shared memory on the computer(s) on which they are executing, using a message passing protocol, or in any other suitable way.

[0184] Generally, functional facilities include routines, programs, objects, components, data structures, etc. that perform particular tasks or implement particular abstract data types.

Typically, the functionality of the functional facilities may be combined or distributed as desired in the systems in which they operate. In some implementations, one or more functional facilities carrying out techniques herein may together form a complete software package. These functional facilities may, in alternative embodiments, be adapted to interact with other, unrelated functional facilities and/or processes, to implement a software program application.

[0185] Some exemplary functional facilities have been described herein for carrying out one or more tasks. It should be appreciated, though, that the functional facilities and division of tasks described is merely illustrative of the type of functional facilities that may implement the exemplary techniques described herein, and that embodiments are not limited to being implemented in any specific number, division, or type of functional facilities. In some implementations, all functionality may be implemented in a single functional facility. It should also be appreciated that, in some implementations, some of the functional facilities described herein may be implemented together with or separately from others (i.e., as a single unit or separate units), or some of these functional facilities may not be implemented.

[0186] Computer-executable instructions implementing the techniques described herein (when implemented as one or more functional facilities or in any other manner) may, in some embodiments, be encoded on one or more computer-readable media to provide functionality to the media. Computer-readable media include magnetic media such as a hard disk drive, optical media such as a Compact Disk (CD) or a Digital Versatile Disk (DVD), a persistent or non-persistent solid-state memory (e.g., Flash memory, Magnetic RAM, etc.), or any other suitable storage media. Such a computer-readable medium may be implemented in any

suitable manner. As used herein, “computer-readable media” (also called “computer-readable storage media”) refers to tangible storage media. Tangible storage media are non-transitory and have at least one physical, structural component. In a “computer-readable medium,” as used herein, at least one physical, structural component has at least one physical property that may be altered in some way during a process of creating the medium with embedded information, a process of recording information thereon, or any other process of encoding the medium with information. For example, a magnetization state of a portion of a physical structure of a computer-readable medium may be altered during a recording process.

[0187] Further, some techniques described above comprise acts of storing information (e.g., data and/or instructions) in certain ways for use by these techniques. In some implementations of these techniques—such as implementations where the techniques are implemented as computer-executable instructions—the information may be encoded on a computer-readable storage media. Where specific structures are described herein as advantageous formats in which to store this information, these structures may be used to impart a physical organization of the information when encoded on the storage medium. These advantageous structures may then provide functionality to the storage medium by affecting operations of one or more processors interacting with the information; for example, by increasing the efficiency of computer operations performed by the processor(s).

[0188] In some, but not all, implementations in which the techniques may be embodied as computer-executable instructions, these instructions may be executed on one or more suitable computing device(s) operating in any suitable computer system, or one or more computing devices (or one or more processors of one or more computing devices) may be programmed to execute the computer-executable instructions. A computing device or processor may be programmed to execute instructions when the instructions are stored in a manner accessible to the computing device or processor, such as in a data store (e.g., an on-chip cache or instruction register, a computer-readable storage medium accessible via a bus, a computer-readable storage medium accessible via one or more networks and accessible by the device/processor, etc.). Functional facilities comprising these computer-executable instructions may be integrated with and direct the operation of a single multi-purpose programmable digital computing device, a coordinated system of two or more multi-purpose computing device sharing processing power and jointly carrying out the techniques described

herein, a single computing device or coordinated system of computing device (co-located or geographically distributed) dedicated to executing the techniques described herein, one or more Field-Programmable Gate Arrays (FPGAs) for carrying out the techniques described herein, or any other suitable system.

[0189] A computing device may comprise at least one processor, a network adapter, and computer-readable storage media. A computing device may be, for example, a desktop or laptop personal computer, a personal digital assistant (PDA), a smart mobile phone, a server, or any other suitable computing device. A network adapter may be any suitable hardware and/or software to enable the computing device to communicate wired and/or wirelessly with any other suitable computing device over any suitable computing network. The computing network may include wireless access points, switches, routers, gateways, and/or other networking equipment as well as any suitable wired and/or wireless communication medium or media for exchanging data between two or more computers, including the Internet. Computer-readable media may be adapted to store data to be processed and/or instructions to be executed by processor. The processor enables processing of data and execution of instructions. The data and instructions may be stored on the computer-readable storage media.

[0190] A computing device may additionally have one or more components and peripherals, including input and output devices. These devices can be used, among other things, to present a user interface. Examples of output devices that can be used to provide a user interface include printers or display screens for visual presentation of output and speakers or other sound generating devices for audible presentation of output. Examples of input devices that can be used for a user interface include keyboards, and pointing devices, such as mice, touch pads, and digitizing tablets. As another example, a computing device may receive input information through speech recognition or in other audible format.

[0191] Embodiments have been described where the techniques are implemented in circuitry and/or computer-executable instructions. It should be appreciated that some embodiments may be in the form of a method, of which at least one example has been provided. The acts performed as part of the method may be ordered in any suitable way. Accordingly, embodiments may be constructed in which acts are performed in an order

different than illustrated, which may include performing some acts simultaneously, even though shown as sequential acts in illustrative embodiments.

[0192] Various aspects of the embodiments described above may be used alone, in combination, or in a variety of arrangements not specifically discussed in the embodiments described in the foregoing and is therefore not limited in its application to the details and arrangement of components set forth in the foregoing description or illustrated in the drawings. For example, aspects described in one embodiment may be combined in any manner with aspects described in other embodiments.

[0193] Use of ordinal terms such as “first,” “second,” “third,” etc., in the claims to modify a claim element does not by itself connote any priority, precedence, or order of one claim element over another or the temporal order in which acts of a method are performed, but are used merely as labels to distinguish one claim element having a certain name from another element having a same name (but for use of the ordinal term) to distinguish the claim elements.

[0194] Also, the phraseology and terminology used herein is for the purpose of description and should not be regarded as limiting. The use of “including,” “comprising,” “having,” “containing,” “involving,” and variations thereof herein, is meant to encompass the items listed thereafter and equivalents thereof as well as additional items.

[0195] The word “exemplary” is used herein to mean serving as an example, instance, or illustration. Any embodiment, implementation, process, feature, etc. described herein as exemplary should therefore be understood to be an illustrative example and should not be understood to be a preferred or advantageous example unless otherwise indicated.

[0196] To clarify the use of and to hereby provide notice to the public, the phrases “at least one of <A>, , . . . and <N>” or “at least one of <A>, , . . . <N>, or combinations thereof” or “<A>, , . . . and/or <N>” are defined by the Applicant in the broadest sense, superseding any other implied definitions hereinbefore or hereinafter unless expressly asserted by the Applicant to the contrary, to mean one or more elements selected from the group comprising A, B, . . . and N. In other words, the phrases mean any combination of one or more of the elements A, B, . . . or N including any one element alone or the one element in combination with one or more of the other elements which may also include, in combination, additional elements not listed.

[0197] While various embodiments have been described, it will be apparent to those of ordinary skill in the art that many more embodiments and implementations are possible. Accordingly, the embodiments described herein are examples, not the only possible embodiments and implementations. Furthermore, the advantages described above are not necessarily the only advantages, and it is not necessarily expected that all of the described advantages will be achieved with every embodiment.

CLAIMS

We claim:

1. A method for generating a report comprising genealogy information of manufacturing materials used to manufacture a liquid product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising:

for each step of the plurality of steps of the manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process: receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising:

a set of liquid materials used for the respective step; and

setting data indicative of a setting of at least one manufacturing component used for the respective step;

inputting the data into a computational sub-model configured to model how the set of liquid materials used for the respective step propagates through the respective step; and

receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and

generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

2. The method of claim 1, wherein, for a second step of the plurality of steps, at least some of the data indicating the plurality of characteristics associated with the continuous sub-process of the second step comprises at least some information in the intermediate record for a first step preceding the second step in the plurality of steps.

3. The method of claim 1, wherein the plurality of characteristics of the respective step comprises a pump speed for each pump of a plurality of pumps that feed material into the respective step.
4. The method of claim 3, wherein the plurality of characteristics of the respective step comprises at least one of time series data indicating a time period during which an input material of the set of materials is introduced into the respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step.
5. The method of claim 1, wherein a first step of the plurality of steps comprises feeding input material into the first step for a duration of the first step and feeding the input material into the first step comprises:
- feeding a first batch of a first input material of the set of materials having a first batch identifier into the first step for a first time period that is less than the duration of the first step; and
 - feeding a second batch of the first input material having a second batch identifier different than the first batch identifier into the first step for a second time period that is less than the duration of the first step and subsequent to the first time period.
6. The method of claim 5, wherein the intermediate report indicates a quantity of the first input material having the first batch identifier and a quantity of the first input material having the second batch identifier present in an end product of the first step.
7. The method of claim 5, wherein the second time period begins at an end of the first time period.

8. The method of claim 1, wherein the computational sub-model models how liquid materials disperse and propagate based on pump speeds, tank sizes, and pipe diameters used throughout a respective step of the plurality of steps of the manufacturing process.
9. The method of claim 1, wherein the computational sub-model comprises a residence time distribution model.
10. The method of claim 1, wherein the plurality of steps of the manufacturing process comprises at least three steps.
11. The method of claim 1, wherein the at least one manufacturing parameter comprises a material number, a batch identifier, and a quantity of each material present in the product after completion of the plurality of steps of the manufacturing process.
12. The method of claim 1, wherein when the intermediate record of the last step comprises a reference to the intermediate record of one or more steps of the plurality of steps preceding the last step, generating the report comprising the genealogy information is further based on the intermediate records of said one or more steps preceding the last step.
13. The method of claim 1, further comprising re-executing the computational sub-model for at least one of the plurality of steps based on user input indicating a detected error in the manufacturing process, wherein re-executing the computational sub-model comprises inputting data regarding the detected error in the manufacturing process to the computational sub-model and receiving an updated intermediate record as output from the computational sub-model.
14. A system comprising:
for each step of a plurality of steps of a manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process:
at least one feeder tank for storing liquid input material input into the respective step;

at least one pump for controlling the input of the input material from the at least one feeder tank into the respective step; and

one or more sensors disposed on said at least one feeder tank or on said at least one pump and configured to generate data regarding the at least one feeder tank or the at least one pump;

at least one processor, wherein the at least one processor receives at least some of the data generated by the one or more sensors; and

at least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by the at least one processor, cause the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a liquid product manufactured via the manufacturing process, the method comprising:

for each step of the plurality of steps of the manufacturing process:

receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising:

a set of materials used for the respective step; and

setting data indicative of a setting of at least one manufacturing component used for the respective step, wherein the setting data includes the at least some of the data generated by the one or more sensors for the respective step;

inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and

receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and

generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.

15. The system of claim 14, wherein for a second step of the plurality of steps, at least some of the data indicating the plurality of characteristics associated with the continuous sub-process of the second step comprises at least some information in the intermediate record for a first step preceding the second step in the plurality of steps.

16. The system of claim 14, wherein the plurality of characteristics of the respective step comprises a pump speed for each pump of the at least one pump for the respective step.

17. The system of claim 16, wherein the plurality of characteristics of the respective step comprises at least one of time series data indicating a time period during which input material of the set of input materials is introduced into the respective step, a quantity of the input material introduced into the respective step, a material number of the input material introduced into the respective step, and a batch identifier of the input material introduced into the respective step.

18. The system of claim 14, wherein a first step of the plurality of steps comprises feeding the input material from the at least one feeder tank for the first step into the first step for a duration of the first step and feeding the input material into the first step comprises:

feeding a first batch of a first input material of the set of materials having a first batch identifier into the first step for a first time period that is less than the duration of the first step; and

feeding a second batch of the first input material having a second batch identifier different than the first batch identifier into the first step for a second time period that is less than the duration of the first step and subsequent to the first time period.

19. The system of claim 18, wherein the intermediate report indicates a quantity of the first input material having the first batch identifier and a quantity of the first input material having the second batch identifier present in an end product of the first step.

20. The system of claim 14, wherein the computational sub-model comprises a residence time distribution model.

21. The system of claim 14, wherein the one or more sensors for each respective step track one or more conditions of the at least one feeder tank or the at least one pump over a duration of the respective step.

22. The system of claim 21, wherein the one or more conditions of the at least one pump comprise a pump speed of the at least one pump and the data generated by the one or more sensors for each respective step comprises time series data representative of the pump speed of the at least one pump over the duration of the respective step.

23. The system of claim 21, wherein the one or more conditions of the at least one feeder tank comprises a volume of input material in the at least one feeder tank and the data generated by the one or more sensors for each respective step comprises time series data representative of the volume of input material in the at least one feeder tank over the duration of the respective step.

24. The system of claim 23, wherein the data generated by the one or more sensors is indicative of at least one time during the duration of the respective step at which the at least one feeder tank is replenished with a new batch of input material.

25. At least one non-transitory computer-readable storage medium having instructions encoded thereon that, when executed by at least one processor, cause the at least one processor to perform a method for generating a report comprising genealogy information of manufacturing materials used to manufacture a liquid product manufactured via a manufacturing process, the manufacturing process comprising a plurality of steps performed sequentially, the method comprising:

for each step of the plurality of steps of the manufacturing process, wherein each respective step comprises a continuous sub-process of the manufacturing process:

receiving data indicating a plurality of characteristics associated with the continuous sub-process of the respective step of the plurality of steps, the plurality of characteristics comprising:

- a set of liquid materials used for the respective step; and

- setting data indicative of a setting of at least one manufacturing component used for the respective step;

inputting the data into a computational sub-model configured to model how the set of materials used for the respective step propagate through the respective step; and

- receiving an intermediate record as output from the computational sub-model, the intermediate record indicating genealogy information of at least some of the manufacturing materials used to manufacture the product after completion of the continuous sub-process of the respective step; and

- generating, based on at least the intermediate record of a last step of the plurality of steps of the manufacturing process, the report comprising the genealogy information of the manufacturing materials used to manufacture the product after completion of the plurality of steps of the manufacturing process, wherein the genealogy information of the report comprises at least one manufacturing parameter of each material present in the product after completion of the plurality of steps of the manufacturing process.