[0005] Accordingly, there exists a need to provide an electronic based record that can reduce the chances of human error and provide a harmonized record across various packaging sites that can efficiently scale without going through the tedious approval process.

SUMMARY

[0005a] In an aspect, the present disclosure refers to a method for generating an executable batch record for a clinical trial study, the method comprising: at a first electronic device associated with a production facilitator: displaying a user interface for inputting batch record information comprising packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer; receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator; producing a preliminary batch record based on the information input by the user associated with the production facilitator; at a second electronic device associated with a pharmaceutical batch customer: displaying a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record; receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and in accordance with receiving the approval of the preliminary batch record producing an executable batch record for a producer to execute.

[0005b] In an aspect, the present disclosure refers to an electronic system, comprising: one or more processors; a memory; and one or more programs, wherein the one or more programs are stored in the memory and configured to be executed by the one or more processors, the one or more programs including instructions for: at a first electronic device associated with a production facilitator: displaying a user interface for inputting batch record information comprising at least packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer; receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator; producing a preliminary batch record that based on the information input by the user associated with the production facilitator; at a second electronic device associated with a pharmaceutical batch customer: displaying a customer user interface

that comprises the preliminary batch record and an interface for approving the preliminary batch record; receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and in accordance with receiving the approval of the preliminary batch record producing an executable batch record for a producer to execute.

[0005c] In an aspect, the present disclosure refers to a non-transitory computer-readable storage medium storing one or more programs, the one or more programs comprising instructions, which when executed by one or more processors of one or more electronic devices having a display, cause the one or more electronic devices to: at a first electronic device associated with a batch record facilitator: display a user interface for inputting batch record information comprising at least packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer; receive the packaging instructions, the bill of materials, and the lot assignment from a user associated with the batch record facilitator; produce a preliminary batch record that based on the information input by the user associated with the batch record facilitator; at a second electronic device associated with a pharmaceutical batch customer: display a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record; receive an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and in accordance with receiving the approval of the preliminary batch record produce an executable batch record for a producer to execute.

[0006] Examples of the present disclosure include systems and methods for a computer based system for generating a standardized executable batch record. Such a system is designed to allow the executable batch record to be used across multiple packaging sites (including domestic and international packaging sites), generate an executable batch record that requires minimal manual updates at a packaging site, and reduce duplicative approvals by the company in charge of the clinical trial studies. Additionally, because the study batch record is maintained and approved on a centralized system, if the company conducting the study would like to produce additional batches of output materials (*e.g.*, produce a second run of output materials for further clinical trial studies), then the system can generate a new executable batch record based on the existing study batch record and study information (*e.g.*, without having to regenerate a new study batch record). Furthermore, the system can

maintain an audit history that tracks the actions of individuals as they interact with the system.

[0007] Examples of the present disclosure include systems and methods for generating an executable batch record for a clinical trial study. For example, in one or more examples, the method can include, at a first electronic device associated with a production facilitator, displaying a user interface (UI) for inputting batch record information, the UI including at least packaging instructions, a bill of materials, and a lot assignment. In one or more examples, the batch record information can include a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical customer. In one or more examples, the method can further include, at the first electronic device, receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator. In one or more examples, the method can further include, producing a preliminary batch record based on the information input by the user associated with the production facilitator. In one or more examples, the method can further include, at a second electronic device associated with a pharmaceutical batch customer, displaying a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record. In one or more examples, the method can further include, at the second electronic device,

receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer. In one or more examples, the method can further include, in accordance with receiving the approval of the preliminary batch record producing an executable batch record for a producer to execute.

[0008] Examples of the present disclosure can further include an electronic system for generating an executable batch record for a clinical trial study. The electronic system can include one or more processors, a memory, and one or more programs, the one or more programs stored in the memory and configured to be executed by the one or more processors. According to examples of the present disclosure, the one or more programs can include instructions for at a first electronic device associated with a production facilitator, displaying a user interface (UI) for inputting batch record information, the UI including at least packaging instructions, a bill of materials, and a lot assignment. In such examples, the batch record information can include a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical customer. In such examples, the one or more programs can further include instructions for, at the first electronic device, receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator. In such examples, the one or more programs can further include instructions for producing a preliminary batch record based on the information input by the user associated with the production facilitator. In one or more examples, the one or more programs can further include instructions for, at a second electronic device associated with a pharmaceutical batch customer, displaying a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record. In one or more examples, the one or more programs can further include instructions for, at the second electronic device, receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer. In one or more examples, the one or more programs can further include instructions for, in accordance with receiving the approval of the preliminary batch record, producing an executable batch record for a producer to execute.

[0009] Examples of the present disclosure can further include non-transitory computer-readable storage medium storing one or more programs, the one or more programs comprising instructions, which when executed by one or more processors of one or more electronic devices having a display, cause the one or more electronic devices to perform a method. In one or more examples, the method can include at a first electronic device

CLAIMS

1. A method for generating an executable batch record for a clinical trial study, the method comprising:

at a first electronic device associated with a production facilitator:

displaying a user interface for inputting batch record information comprising packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer;

receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator;

producing a preliminary batch record based on the information input by the user associated with the production facilitator;

at a second electronic device associated with a pharmaceutical batch customer:

displaying a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record;

receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and

in accordance with receiving the approval of the preliminary batch record producing an executable batch record for a producer to execute.

2. The method of claim 1, wherein the user associated with the pharmaceutical batch customer is configured to approve the preliminary batch record without editing the preliminary batch record.

3. The method of any of claim 1 or claim 2, wherein receiving the packaging instructions further comprises:

receiving packaging instructions in a first language;

determining whether the first language is used at the production site;

in accordance with a determination that the first language is not used at the production site, generating a translation of the packaging instructions corresponding to a second language used at the production site.

4. The method of any of claims 1-3, wherein receiving the lot assignment further comprises:

receiving a quantity of output materials to be manufactured, each output material corresponding to one or more input materials;

accessing an inventory of a production site;

for each output material, assigning a first supplier lot number based on at least one of a first supplier lot size or a first supplier lot expiration date determined from the inventory; and

for each input material, assigning a second supplier lot number based on at least one of a second supplier lot size or a second supplier lot expiration date determined from the inventory.

5. The method of claim 4, further comprising, generating a second executable batch record for the clinical trial study, comprising:

receiving, at the first electronic device, a second lot assignment associated with the production site comprising:

receiving a second quantity of output materials to be manufactured, each output material corresponding to one or more input materials;

accessing the inventory of the production site;

for each output material, assigning a third supplier lot number based on at least one of a third supplier lot size or a third supplier lot expiration date determined from the inventory of the production site;

for each input material, assigning a fourth supplier lot number based on at least one of a fourth supplier lot size or a fourth supplier lot expiration date determined from the inventory of the production site;

producing a second preliminary batch record that is based on the information input by the user associated with the production facilitator;

receiving, from the second electronic device, an approval of the second preliminary batch record; and

in accordance with receiving the approval of the second preliminary batch record producing a second executable batch record for the producer to execute.

6. The method of any of claims 1-5, further comprising, at the first electronic device:

receiving customer data associated with the pharmaceutical batch customer;

receiving study information for the clinical trial study, the clinical trial study associated with the customer data; and

receiving output material information, the output material information corresponding to one or more output materials associated for the clinical trial study.

7. The method of claim 6, wherein receiving the bill of materials further comprises:

importing at least a portion of the output material information to the bill of materials;

receiving a quantity associated with each of the one or more output materials and corresponding input materials from the output material information; and

assign a customer identifier based on the customer inventory.

8. The method of any of claim 6 or claim 7, wherein the study information comprises packaging sites, study languages, destination countries, output materials, dosage codes, business units, approvers, or a combination thereof.

9. The method of any of claims 6-8, wherein the output material information comprises output materials, input materials, drug categorizations, alternative materials, a storage temperature, time out environment details, humidity control details, light control details, label details or a combination thereof.

10. The method of any of claims 1-9, wherein the executable batch record is accessed by the user associated with the production facilitator prior to being accessed by the producer.

11. The method of any of claims 1-10, further comprising causing to present an audit history, the audit history corresponding to a list of actions associated with inputting the batch record information and receiving the approval of the preliminary batch record.

12. The method of any of claims 1-11, further comprising:

receiving, at the first electronic device, study information for the clinical trial study, the study information comprising one or more customer approvers, the one or more customer approvers comprising the user associated with the pharmaceutical batch customer;

determining whether the batch record information comprises blinding information;

in accordance with a determination that the batch record information comprises blinding information, causing to present, at the second electronic device, a restricted view of the preliminary batch record that omits the blinding information to the user associated with the pharmaceutical batch customer,

wherein the user associated with the pharmaceutical batch customer is configured to be blinded.

13. The method of claim 12, wherein the blinding information comprises a medication list, an identification number, a kit number, a start sequence number, an end sequence number, or a combination thereof.

14. The method of any of claim 12 or claim 13, wherein the one or more customer approvers further comprises a second user associated with the pharmaceutical batch customer, wherein the second user associated with the pharmaceutical batch customer is configured to not be blinded.

15. The method of claim 14, further comprising:

in accordance with the determination that the batch record information comprises blinding information, causing to present to the second user associated with the pharmaceutical batch customer, an unrestricted view of the executable batch record that includes the blinding information.

16. An electronic system, comprising:

one or more processors;

a memory; and

one or more programs, wherein the one or more programs are stored in the memory and configured to be executed by the one or more processors, the one or more programs including instructions for:

at a first electronic device associated with a production facilitator:

displaying a user interface for inputting batch record information comprising at least packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer;

receiving the packaging instructions, the bill of materials, and the lot assignment from a user associated with the production facilitator;

producing a preliminary batch record that based on the information input by the user associated with the production facilitator;

at a second electronic device associated with a pharmaceutical batch customer:

displaying a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record;

receiving an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and

in accordance with receiving the approval of the preliminary batch record producing an executable batch record for a producer to execute.

17. A non-transitory computer-readable storage medium storing one or more programs, the one or more programs comprising instructions, which when executed by one or more processors of one or more electronic devices having a display, cause the one or more electronic devices to:

at a first electronic device associated with a batch record facilitator:

display a user interface for inputting batch record information comprising at least packaging instructions, a bill of materials, and a lot assignment, wherein the user interface comprises a selection of inventory associated with a production site and a selection of inventory associated with a pharmaceutical batch customer;

receive the packaging instructions, the bill of materials, and the lot assignment from a user associated with the batch record facilitator;

produce a preliminary batch record that based on the information input by the user associated with the batch record facilitator;

at a second electronic device associated with a pharmaceutical batch customer:

display a customer user interface that comprises the preliminary batch record and an interface for approving the preliminary batch record;

receive an approval of the preliminary batch record from a user associated with the pharmaceutical batch customer; and

in accordance with receiving the approval of the preliminary batch record produce an executable batch record for a producer to execute.