SYSTEMS AND METHODS FOR COORDINATING MANUFACTURING OF CELLS FOR PATIENT-SPECIFIC IMMUNOTHERAPY

CROSS-REFERENCE TO RELATED APPLICATIONS

[0001] This application claims priority to US Provisional Application No. 63/013,942, filed on April 22, 2020, US Provisional Application No. 63/155,711, filed March 2, 2021, and US Provisional Application No. 63/159,806, filed March 11, 2021, each of which is incorporated herein by reference in its entirety for all purposes.

BACKGROUND

[0002] Treatment of bulky, refractory cancers using adoptive transfer of tumor infiltrating lymphocytes (TILs) represents a powerful approach to therapy for patients with poor prognoses. Gattinoni, *et al.*, *Nat. Rev. Immunol.* **2006,** *6,* 383-393. A large number of TILs are required for successful immunotherapy, and a robust and reliable process is needed for commercialization. This has been a challenge to achieve because of technical, logistical, and regulatory issues with cell expansion. IL-2-based TIL expansion followed by a "rapid expansion process" (REP) has become a preferred method for TIL expansion because of its speed and efficiency. Dudley, *et al.*, *Science* **2002,** *298,* 850-54; Dudley, *et al.*, *J. Clin. Oncol.* **2005,** *23,* 2346-57; Dudley, *et al.*, *J. Clin. Oncol.* **2008**, *26,* 5233-39; Riddell, *et al.*, *Science* **1992,** *257,* 238-41; Dudley, *et al.*, *J. Immunother.* **2003**, *26,* 332-42. REP can result in a 1,000-fold expansion of TILs over a 14-day period, although it requires a large excess (*e.g.*, 200-fold) of irradiated allogeneic peripheral blood mononuclear cells (PBMCs, also known as mononuclear cells (MNCs)), often from multiple donors, as feeder cells, as well as anti-CD3 antibody (OKT3) and high doses of IL-2. Dudley, *et al., J. Immunother.* **2003,** *26,* 332-42. TILs that have undergone an REP procedure have produced successful adoptive cell therapy following host immunosuppression in patients with melanoma.

SUMMARY

[0002a] In one aspect, the present disclosure refers to a method for manufacturing a cell therapy product comprising tumor infiltrating lymphocytes (TILs) to be used in a composition for treating a patient having cancer, the method comprising:

receiving, at a computing device, a request for manufacturing the cell therapy product, from at least a portion of a solid tumor obtained from the patient or a first population of cells obtained from the solid tumor, using a selected multi-step cell expansion process, the request including acceptance criteria for manufactured cell therapy product at each of a plurality of steps during the selected multi-step cell expansion process;

generating, by the computing device, a container label based on the request, the container label comprising information associated with:

(a) a manufacturing order received from a treatment facility requesting the cell therapy product, including an order-specific identifier,

(b) the patient, including a patient-specific identifier,

(c) the treatment facility requesting the manufacturing of the cell therapy product,

(d) the selected multi-step cell expansion process; and

(e) a manufacturing facility where the cell therapy product is to be manufactured;

determining, by the computing device, a schedule for manufacturing the cell therapy product at the manufacturing facility based on

(i) a time of receipt of the solid tumor or the first population of cells and

(ii) the selected multi-step cell expansion process;

generating, by the computing device, a manufacturing label to be affixed to a manufacturing container to be used during the selected multi-step cell expansion process, the manufacturing label comprising information associated with:

(a) the manufacturing order, including the order-specific identifier,

(b) the patient, including the patient-specific identifier,

(c) the selected multi-step cell expansion process or a step thereof and

(f) quality of manufactured cell therapy product;

initiating the selected multi-step cell expansion process to manufacture the cell therapy product in accordance with the schedule;

performing quality control assays to determine acceptance parameters at each of a plurality of time points during the selected multi-step cell expansion process;

at each of the plurality of time points generating, by the computing device, a respective updated manufacturing label, to be affixed to the manufacturing container, corresponding to a respective one of the plurality of time points, the updated manufacturing label comprising information associated with

(a) the manufacturing order, including the order-specific identifier,

(b) the patient, including the patient identifier,

(c) the selected multi-step cell expansion process and

(ee) updated information associated with quality of manufactured cell therapy product comprising the determined acceptance parameters at a corresponding time point;

determining an adjusted schedule, by the computing device, for manufacturing the cell therapy product based on whether the acceptance parameters at a given time point read from the updated manufacturing label meet the acceptance criteria at the given time point; and

completing the selected multi-step cell expansion process in accordance with the adjusted schedule to manufacture the cell therapy product.

[0002b] In one aspect, the present disclosure refers to a method for manufacturing a cell therapy product comprising tumor infiltrating lymphocytes (TILs) for treatment of cancer, the method comprising:

receiving, at a computing device, an indication that a solid tumor obtained from a patient having the cancer or a first population of cells comprising TILs obtained from the solid tumor obtained from the patient has been received at a manufacturing facility for manufacturing the cell therapy product using a selected multi-step cell expansion process;

generating, by the computing device, a manufacturing label to be affixed to a manufacturing container to be used during a multi-step cell expansion process for manufacturing the cell therapy product from at least a portion of the obtained solid tumor or the first population of cells, the manufacturing label comprising information associated with:

(a) a manufacturing order received from a treatment facility requesting the cell therapy product, including an order-specific identifier,

(b) the patient, including a patient-specific identifier,

(c) the selected multi-step cell expansion process and

(d) quality of manufactured cell therapy product;

initiating the multi-step cell expansion process to manufacture the cell therapy product;

performing a quality control assay to determine acceptance parameters for the manufactured cell therapy product at each of a plurality of time points during the selected multi-step cell expansion process;

receiving, at the computing device, the acceptance parameters for the manufactured cell therapy product at each of the plurality of time points;

reading, by the computing device, the manufacturing label at each of the plurality of time points; and

for each step of the multi-step cell expansion process, generating, by the computing device, a warning signal when:

information relating to the patient on the manufacturing label for the step does not match the information relating to the patient on the manufacturing label for an immediately preceding manufacturing step, or

acceptance parameters on the manufacturing label for a given time point in the selected multi-step cell expansion process do not meet acceptance criteria for the given time point in the selected multi-step cell expansion process.

BRIEF DESCRIPTION OF DRAWINGS

[0003] FIG. 1 schematically depicts various stages in a treatment of a patient using adoptive cell therapy using TILs including various steps for manufacturing allogenic TILs.

[0004] FIG. 2A shows the timeline for a GEN 3 process for TIL manufacturing.

1. **CLAIMS**

What is claimed is:

~~1. A method of manufacturing a cell therapy product by expanding a population of cells obtained from a tumor from a patient into the cell therapy product, the method comprising:~~

~~receiving, by a computing device, a cell order request to expand the population of cells for the patient;~~

~~generating, by the computing device, cell order identifier including a patient-specific identifier associated with the cell order request;~~

~~initiating a process to manufacture the cell therapy product, the process comprising:~~

~~after receiving the population of cells at a manufacturing facility, dynamically scheduling, by the computing device, patient treatment events, the dynamic scheduling being dependent on acceptance parameters for subsequently obtained expansion cell therapy product,~~

~~initiating expansion of the cell therapy product from at least some of the obtained population of cells using a cell expansion technique and determining acceptance parameters for the expansion cell therapy product,~~

~~determining whether the acceptance parameters for the expansion cell therapy product meet certain acceptance criteria,~~

~~in response to a determination that that the acceptance parameters for the expansion cell therapy product meet the acceptance criteria, completing the initial expansion of cell therapy, and~~

~~in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria, rescheduling, by the computing device, the patient treatment events and completing a subsequent expansion of cell therapy product,~~

~~wherein the rescheduling the patient treatment events is performed based on a clinically determined time gap between an infusion of the expanded cell therapy product in the patient and patient treatment events prior to or subsequent to the infusion of the expanded cell therapy product in the patient.~~

2. A method for manufacturing a cell therapy product by expanding a population of cells obtained from a tumor from a patient into the cell therapy product, the method comprising:

receiving a population of cells from the patient at a manufacturing facility based on a cell order request to manufacture the cell therapy product for the patient;

generating, by a computing device, a cell order identifier including a patient-specific identifier associated with the cell order request;

initiating a process to manufacture the cell therapy product, the process comprising:

after receiving the population of cells at the manufacturing facility, scheduling, by the computing device, patient treatment events,

initiating expansion of the cell therapy product from at least some of the population of cells using a cell expansion technique and determining acceptance parameters for the expansion cell therapy product at a first time point and at a second time point subsequent to the first time point,

determining whether acceptance parameters for the expansion cell therapy product meet acceptance criteria associated with a corresponding time point,

in response to a determination that the acceptance parameters for the expansion cell therapy product meet the acceptance criteria at the first time point, continuing the expansion of cell therapy product from the at least some of the obtained cell therapy product using the cell expansion technique up to the second time point, and

in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at the second time point:

determining whether re-performing the expansion of the cell therapy product using the cell expansion technique is feasible from the first time point based on the acceptance parameters at the second time point,

in response to a determination that the re-performing is feasible, re-performing the expansion of the cell therapy product from at least some of the cell therapy product obtained at the second time point using the cell expansion technique from the first time point to obtain the cell therapy product,

estimating, by the computing device, a time of completion of the expansion of the cell therapy product following the re-performing of the expansion of the cell therapy product from the first time point, and

rescheduling, by the computing device, the patient treatment events and completing a subsequent expansion of cell therapy product from the first time point,

wherein the rescheduling of the patient treatment events is performed based on the estimated time of completion of the expansion of the cell therapy product and a timing of patient treatment events prior to or subsequent to an infusion of the expanded cell therapy product in the patient.

3. The method of any one of claims 1-2, wherein the cell therapy product comprises T cells.

4. The method of any one of claims 1-2, wherein the cell therapy product comprises tumor infiltrating lymphocytes (TILs).

5. The method of any one of claims 1-2, wherein the patient treatment events include one or more of an inpatient stay time period, resection date, lymphodepletion date, infusion date for infusing the patient with the cell therapy product and IL-2 treatment date.

6. The method of any one of claims 1-2, wherein the determining whether the acceptance parameters for the expansion cell therapy product meet the acceptance criteria comprises determining the acceptance parameters for the expansion cell therapy product at a plurality of time points following the initiation of the expansion of the obtained cell therapy product, the plurality of time points including the first and the second time points.

7. The method of claim 6, wherein the rescheduling of patient treatment events comprises rescheduling the patient treatment events in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points.

8. The method of claim 6, wherein the rescheduling of patient treatment events comprises terminating the patient treatment events in response to a determination that the acceptance

parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination.

9. The method of claim 6, wherein in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination, terminating the subsequent expansion of cell therapy product.

10. The method of claim 9, wherein determining acceptance parameters for the expansion cell therapy product comprise one or more of determination of viability, sterility, cell count, mycoplasma count, CD3 count, result of an Endotoxin assay, and a result of a Gram stain assay.

11. The method of claim 10, wherein the cell expansion technique comprises a rapid expansion step, and

the method further comprises:

determining whether the acceptance parameters for the expansion cell therapy product meet the acceptance criteria prior to the rapid expansion step; and

in response to a determination that the acceptance parameters for the expansion cell therapy product meet the acceptance criteria, scheduling a lymphodepletion date at a date prior to the completion of the manufacturing of the expanded cell therapy product, scheduling an infusion date at a date following the completion of the manufacturing of the expanded cell therapy product, and scheduling an IL-2 treatment date following the infusion date.

12. The method of any one of claims 1-2, wherein the cell expansion technique includes culturing the cell therapy product in a single closed container bioreactor.

13. The method of claim 2, wherein estimating the time of completion of the expansion of the cell therapy product following the re-performing of the expansion of the cell therapy product from the first time point comprises determining the time needed for completing the expansion process from the first time point based on one or both of the acceptance parameters at the second

time point and the acceptance parameters associated with a population of cells used for re-performing the expansion of the cell therapy product from the first time point.

14. The method of any one of claims 1-2, wherein cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting, upon receiving the cell order request, a confirmation, including one or both of the patient-specific identifier and the cell order identifier, to the hospital-side interface that the cell order request associated with the patient has been received.

15. The method of claim 14, further comprising scheduling a set of dates corresponding to a plurality of time points, including the first and second time points, for determining whether acceptance parameters for the expansion cell therapy product meet the acceptance criteria during expansion of the cell therapy product depending on the cell expansion technique and when the cell order request is received.

16. The method of claim 14, further comprising transmitting, upon rescheduling the patient treatment events, to the hospital-side interface an updated schedule for the patient treatment events associated with the patient-specific identifier.

17. The method of claim 16, further comprising:

transmitting, to a logistics interface, a pick-up order associated with the patient-specific identifier based on the time of completion; and

transmitting, to a hospital-side interface, a schedule for the patient treatment events associated with the patient-specific identifier based on the time of completion.

18. The method of claim 17, further comprising: in response to a determination that re-performing of the expansion of the cell therapy product from the first time point is feasible:

disassociating, by the computing device, the cell order identifier from the patient-specific identifier, and

generating, by the computing device, a new cell order identifier associated with the cell order request and associating the new cell order identifier with the patient-specific identifier.

19. The method of claim 18, wherein the cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting the patient-specific identifier including the new cell order identifier and the estimated time of completion of the expansion of the cell therapy product to the hospital-side interface.

20. The method of claim 18, further comprising:

generating, by the computing device, a new schedule for shipping and logistics events associated with the patient treatment events based on the rescheduling of the patient treatment events, and

transmitting the new schedule of shipping and logistics events associated the patient-specific identifier including the new cell order identifier to a logistics interface based on the rescheduling of shipping and logistics events.

21. The method of claim 18, further comprising:

associating, by the computing device, with the patient-specific identifier at each time point at which the determination of whether acceptance parameters meet the certain acceptance criteria is made, the new cell order identifier including fields corresponding to each respective time point and a result of the determination.

22. The method of claim 21, wherein the scheduling comprises:

scheduling, by the computing device, the patient treatment events based on the patient-specific identifier including the new cell order identifier.

23. The method of claim 21, further comprising, in response to a determination that the re-performing is not possible, canceling, by the computing device, the patient treatment events scheduled subsequent to the second time point.

24. The method of claim 23, further comprising transmitting the cancellation of patient treatment events to a hospital-side interface and a logistics interface.

25. The method of claim 24, further comprising, in response to a determination that the re-performing is not feasible, destroying the expanded cell therapy product and disassociating the patient-specific identifier from the cell order identifier.

26. A method of treating the patient with the expansion cell therapy product obtained by the method of claim 1 in accordance with the rescheduled patient treatment events.

27. A method of manufacturing a cell therapy product for a patient, the method comprising:

receiving, at a computing device, a cell order request to manufacture the cell therapy product for the patient, manufacturing slots at a plurality of manufacturing facilities for manufacturing the cell therapy product, wherein the manufacturing slots for a respective manufacturing facility are received at the computing device from a manufacturer computer subsystem associated with the respective manufacturing facility, and a preliminary schedule of patient treatment events for treating the patient with the cell therapy product;

determining and displaying in a scheduling user interface, by the computing device, a plurality of available manufacturing slots for manufacturing the cell therapy product based on the preliminary schedule of patient treatment events;

after selection of one of the available manufacturing slots, performing, at a medical facility, a procedure on the patient to obtain a solid tumor from the patient in accordance with the preliminary schedule of patient treatment events and the available manufacturing slot;

transferring the obtained solid tumor to a manufacturing facility corresponding to the available manufacturing slot in accordance with the available manufacturing slot;

initiating, upon receiving the obtained solid tumor at the manufacturing facility, manufacturing of the cell therapy product from at least a portion of the obtained solid tumor using a cell expansion technique;

determining, during the manufacturing of the cell therapy product, acceptance parameters for the manufactured cell therapy product at a first time point and a second time point subsequent to the first time point and whether the acceptance parameters meet acceptance criteria associated with a corresponding time point, the acceptance parameters being determined based on a result of an assay associated with the corresponding time point;

modifying, by the computing device, a manufacturing schedule for manufacturing of the cell therapy product, manufacturing slots corresponding to the manufacturing facility, and the preliminary schedule of patient treatment events based on whether the acceptance criteria at one or both of the first and second time points are met; and

completing the manufacturing of the cell therapy product in accordance with the modified manufacturing schedule if the acceptance criteria at both the first and second time points are met.

28. The method of claim 27, further comprising transferring the manufactured cell therapy product to the medical facility.

29. The method of claim 27, further comprising, upon receiving the cell order request, generating, by the computing device, a patient-specific identifier associated with the patient and the cell order request.

30. The method of claim 29, further comprising automatically generating, by the computing device, a shipping label for a container for the obtained solid tumor, the shipping label comprising the patient-specific identifier, the cell order request, the manufacturing slot and the manufacturing facility corresponding to the available manufacturing slot.

31. The method of claim 30, further comprising automatically generating, by the computing device, a manufacturing label for the container for the obtained solid tumor, the manufacturing label comprising a time point corresponding to a manufacturing process being used for manufacturing the cell therapy product when the manufacturing label is generated, a container-identifying bar code, the patient-specific identifier, manufacturing steps completed at the time point, acceptance parameters associated with the completed processes, and a manufacturing process being performed at the time point.

32. The method of claim 27, wherein the cell therapy product comprises T-cells.

33. The method of claim 27, wherein the cell therapy product comprises tumor infiltrating lymphocytes (TILs).

~~34. The method of claim 27, wherein the patient treatment events include one or more of an inpatient stay time period, resection date, lymphodepletion date, infusion date for infusing the patient with the cell therapy product and IL-2 treatment date.~~

~~35. The method of claim 27, wherein the determining whether the acceptance parameters for the manufactured cell therapy product meet the acceptance criteria comprises determining the acceptance parameters for the manufactured cell therapy product at a plurality of time points following the initiation of the expansion of the received cell therapy product, the plurality of time points including the first and the second time points.~~

~~36. The method of claim 35, further comprising: rescheduling, by the computing device, the patient treatment events and completing a subsequent expansion of cell therapy product, wherein the rescheduling of patient treatment events comprises rescheduling the patient treatment events in response to a determination that the acceptance parameters for the manufactured cell therapy product do not meet the acceptance criteria at any of the plurality of time points.~~

~~37. The method of claim 35, wherein the rescheduling of patient treatment events comprises terminating the patient treatment events in response to a determination that the acceptance parameters for the manufactured cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination.~~

~~38. The method of claim 35, wherein in response to a determination that the acceptance parameters for the manufactured cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination, terminating the subsequent expansion of cell therapy product.~~

~~39. The method of claim 38, wherein determining acceptance parameters for the manufactured cell therapy product comprise one or more of determination of viability, sterility, cell count, mycoplasma count, CD3 count, result of an Endotoxin assay, and a result of a Gram stain assay.~~

~~40. The method of claim 39, wherein the cell expansion technique comprises a rapid expansion step, and~~

~~the method further comprises:~~

~~determining whether the acceptance parameters for the manufactured cell therapy product meet the acceptance criteria prior to the rapid expansion step; and~~

~~in response to a determination that the acceptance parameters for the manufactured cell therapy product meet the acceptance criteria, scheduling a lymphodepletion date at a date prior to the completion of the manufacturing of the cell therapy product, scheduling an infusion date at a date following the completion of the manufacturing of the cell therapy product, and scheduling an IL-2 treatment date following the infusion date.~~

~~41. The method of claim 27, wherein the cell expansion technique includes culturing the cell therapy product in a single closed container bioreactor.~~

~~42. The method of claim 27, further comprising: estimating, by the computing device, a time of completion of the expansion of the cell therapy product, wherein estimating the time of completion of the expansion of the cell therapy product following a re-performing of the expansion of the cell therapy product from the first time point comprises determining the time needed for completing the expansion process from the first time point based on one or both of the acceptance parameters at the second time point and the acceptance parameters associated with a population of cells used for re-performing the expansion of the cell therapy product from the first time point.~~

~~43. The method of claim 27, wherein cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting, upon receiving the cell order request, a confirmation, including one or both of the patient-specific identifier and the cell order identifier, to the hospital-side interface that the cell order request associated with the patient has been received.~~

~~44. The method of claim 43, further comprising scheduling a set of dates corresponding to a plurality of time points, including the first and second time points, for determining whether acceptance parameters for the manufactured cell therapy product meet the acceptance criteria during expansion of the cell therapy product depending on the cell expansion technique and when the cell order request is received.~~

~~45. The method of claim 44, further comprising transmitting, upon rescheduling the patient treatment events, to the hospital-side interface an updated schedule for the patient treatment events associated with the patient-specific identifier.~~

~~46. The method of claim 45, further comprising:~~

~~transmitting, to a logistics interface, a pick-up order associated with the patient-specific identifier based on the time of completion; and~~

~~transmitting, to a hospital-side interface, a schedule for the patient treatment events associated with the patient-specific identifier based on the time of completion.~~

~~47. The method of claim 46, further comprising: in response to a determination that re-performing of the expansion of the cell therapy product from the first time point is feasible:~~

~~disassociating, by the computing device, the cell order identifier from the patient-specific identifier, and~~

~~generating, by the computing device, a new cell order identifier associated with the cell order request and associating the new cell order identifier with the patient-specific identifier.~~

~~48. The method of claim 47, wherein the cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting the patient-specific identifier including the new cell order identifier and an estimated time of completion of the expansion of the cell therapy product to the hospital-side interface.~~

~~49. The method of claim 48, further comprising:~~

~~generating, by the computing device, a new schedule for shipping and logistics events associated with the patient treatment events based on the rescheduling of the patient treatment events, and~~

~~transmitting the new schedule of shipping and logistics events associated the patient-specific identifier including the new cell order identifier to a logistics interface based on the rescheduling of shipping and logistics events.~~

~~50. The method of claim 49, further comprising:~~

~~associating, by the computing device, with the patient-specific identifier at each time point at which the determination of whether acceptance parameters meet the acceptance criteria is made, the new cell order identifier including fields corresponding to each respective time point and a result of the determination.~~

~~51. The method of claim 50, wherein the scheduling comprises:~~

~~scheduling, by the computing device, the patient treatment events based on the patient-specific identifier including the new cell order identifier.~~

~~52. The method of claim 51, further comprising, in response to a determination that the re-performing is not possible, canceling, by the computing device, the patient treatment events scheduled subsequent to the second time point.~~

~~53. The method of claim 52, further comprising transmitting the cancellation of patient treatment events to a hospital-side interface and a logistics interface.~~

~~54. The method of claim 53, further comprising, in response to a determination that the re-performing is not feasible, destroying the expanded cell therapy product and disassociating the patient-specific identifier from the cell order identifier.~~

~~55. A method of treating the patient with the manufactured cell therapy product obtained by the method of claim 27 in accordance with the rescheduled patient treatment events.~~

56. A method for manufacturing a cell therapy product, the method comprising:

receiving, at a manufacturing facility, a solid tumor obtained from a patient;

generating, by a computing device, a manufacturing label for a manufacturing container to be used in a process for manufacturing the cell therapy product from at least a portion of the obtained solid tumor using a cell expansion technique, the manufacturing label comprising information associated with the patient, the manufacturing process and quality of manufactured cell therapy product;

initiating a process to manufacture the cell therapy product, the process comprising:

performing, at a medical facility, a procedure on the patient to obtain a solid tumor from the patient,

transferring the obtained solid tumor to a manufacturing facility,

after receiving the obtained solid tumor at the manufacturing facility, dynamic scheduling, by the computing device, patient treatment events, the dynamic scheduling being dependent on acceptance parameters for subsequently obtained expansion cell therapy product,

initiating expansion of the cell therapy product from at least some of the obtained solid tumor using a cell expansion technique and determining acceptance parameters for the expansion cell therapy product at a plurality of time points,

performing a quality control assay to determine acceptance parameters for the manufactured cell therapy product at the plurality of time points;

receiving, at the computing device, the acceptance parameters for the manufactured cell therapy product;

generating, by the computing device, an updated manufacturing label corresponding to each of the plurality of time points, the updated manufacturing label comprising updated information associated with quality of manufactured cell therapy product, the updated information comprising the acceptance parameters at a corresponding time point;

reading, by the computing device, the updated manufacturing label at each of the plurality of time points; and

completing expansion of the cell therapy product based on information read from the updated manufacturing label at each of the plurality of time points.

57. The method of claim 56, further comprising providing, by the computing device, a warning signal if:

information relating to the patient on the updated manufacturing label for a subsequent manufacturing step does not match the information relating to the patient on the manufacturing label for an immediately preceding manufacturing step, or

acceptance parameters on the updated manufacturing label for a given time point in the manufacturing process do not meet acceptance criteria for that time point in the manufacturing process,

wherein the acceptance parameters comprise one or more of viability, sterility, cell count, mycoplasma count, CD3 count, a result of an endotoxin assay, and a result of a Gram stain assay.

58. The method of claim 56, wherein information relating to the patient comprises a patient-specific identifier and a cell order identifier associated with a cell order request to manufacture the cell therapy product for the patient.

59. The method of claim 56, wherein the cell expansion technique includes culturing the cell therapy product in a single closed container bioreactor.

60. The method of claim 56, wherein the manufacturing label comprises a barcode encoding the information associated with the patient, the manufacturing process and quality of manufactured cell therapy product.

61. The method of claim 57, further comprising scheduling a set of dates corresponding to a plurality of time points, including a first time point and a second time point subsequent to the first time point, for determining whether acceptance parameters for the manufactured cell therapy product meet the acceptance criteria during the manufacturing process depending on the cell expansion technique being used and when a cell order request is received at the manufacturing facility.

62. The method of claim 61, further comprising integrating with a logistics interface, receiving courier status information via a courier computing subsystem, wherein courier status

~~information includes and in response to receiving the courier status information, determining shipping schedule for shipping the manufactured cell therapy product based on the determined schedule of manufacturing and generating a shipping label for a shipping container containing the manufactured cell therapy product.~~

~~63. The method of claim 61, further comprising transmitting a shipping request to a logistics facility based on the determined shipping schedule.~~

~~64. The method of claim 61, further comprising generating a shipping label for a shipping container containing the manufactured cell therapy product before performing a final quality control assay, the shipping label being indicative that the manufactured cell therapy product is not releasable unless a result of the final quality control assay indicates that the corresponding acceptance parameters meet the corresponding acceptance criteria.~~

~~65. The method of claim 57, further comprising:~~

~~upon determining that the acceptance parameters for the manufactured cell therapy product meet the acceptance criteria, determining a completion date for the manufacturing of the cell therapy;~~

~~generating, by the computing device, a schedule for patient treatment events corresponding to a use of the cell therapy product for treating a patient based on the completion date;~~

~~transmitting, to a logistics interface, a pick-up order based on the completion date; and~~

~~transmitting, to a hospital-side interface, the schedule for the patient treatment events.~~

~~66. The method of claim 57, wherein the cell therapy product comprises T-cells.~~

~~67. The method of claim 57, wherein the cell therapy product comprises tumor infiltrating lymphocytes (TILs).~~

~~68. The method of claim 57, wherein the patient treatment events include one or more of an inpatient stay time period, resection date, lymphodepletion date, infusion date for infusing the patient with the cell therapy product and IL-2 treatment date.~~

~~69. The method of claim 57, wherein the determining whether the acceptance parameters for the expansion cell therapy product meet the acceptance criteria comprises determining the acceptance parameters for the expansion cell therapy product at a plurality of time points following the initiation of the expansion of the obtained cell therapy product, the plurality of time points including the first and the second time points.~~

~~70. The method of claim 69, further comprising: rescheduling, by the computing device, the patient treatment events and completing a subsequent expansion of cell therapy product, wherein the rescheduling of patient treatment events comprises rescheduling the patient treatment events in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points.~~

~~71. The method of claim 69, wherein the rescheduling of patient treatment events comprises terminating the patient treatment events in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination.~~

~~72. The method of claim 69, wherein in response to a determination that the acceptance parameters for the expansion cell therapy product do not meet the acceptance criteria at any of the plurality of time points because of contamination, terminating the subsequent expansion of cell therapy product.~~

~~73. The method of claim 72, wherein determining acceptance parameters for the expansion cell therapy product comprise one or more of determination of viability, sterility, cell count, mycoplasma count, CD3 count, result of an Endotoxin assay, and a result of a Gram stain assay.~~

74. The method of claim 73, wherein the cell expansion technique comprises a rapid expansion step, and

the method further comprises:

determining whether the acceptance parameters for the expansion cell therapy product meet the acceptance criteria prior to the rapid expansion step; and

in response to a determination that the acceptance parameters for the expansion cell therapy product meet the acceptance criteria, scheduling a lymphodepletion date at a date prior to the completion of the manufacturing of the cell therapy product, scheduling an infusion date at a date following the completion of the manufacturing of the cell therapy product, and scheduling an IL-2 treatment date following the infusion date.

75. The method of claim 56, wherein the cell expansion technique includes culturing the cell therapy product in a single closed container bioreactor.

76. The method of claim 56, wherein estimating the time of completion of the expansion of the cell therapy product following a re-performing of the expansion of the cell therapy product from the first time point comprises determining the time needed for completing the expansion process from the first time point based on one or both of the acceptance parameters at the second time point and the acceptance parameters associated with a population of cells used for re-performing the expansion of the cell therapy product from the first time point.

77. The method of claim 58, wherein cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting, upon receiving the cell order request, a confirmation, including one or both of the patient-specific identifier and the cell order identifier, to the hospital-side interface that the cell order request associated with the patient has been received.

78. The method of claim 77, further comprising scheduling a set of dates corresponding to a plurality of time points, including the first and second time points, for determining whether acceptance parameters for the expansion cell therapy product meet the acceptance criteria during

~~expansion of the cell therapy product depending on the cell expansion technique and when the cell order request is received.~~

~~79. The method of claim 78, further comprising transmitting, upon rescheduling the patient treatment events, to the hospital-side interface an updated schedule for the patient treatment events associated with the patient-specific identifier.~~

~~80. The method of claim 79, further comprising:~~

~~transmitting, to a logistics interface, a pick-up order associated with the patient-specific identifier based on the time of completion; and~~

~~transmitting, to a hospital-side interface, a schedule for the patient treatment events associated with the patient-specific identifier based on the time of completion.~~

~~81. The method of claim 80, further comprising: in response to a determination that re-performing of the expansion of the cell therapy product from the first time point is feasible:~~

~~disassociating, by the computing device, the cell order identifier from the patient-specific identifier, and~~

~~generating, by the computing device, a new cell order identifier associated with the cell order request and associating the new cell order identifier with the patient-specific identifier.~~

~~82. The method of claim 81, wherein the cell order request to expand cell therapy product is received from a hospital-side interface, and the method further comprises transmitting the patient-specific identifier including the new cell order identifier and an estimated time of completion of the expansion of the cell therapy product to the hospital-side interface.~~

~~83. The method of claim 82, further comprising:~~

~~generating, by the computing device, a new schedule for shipping and logistics events associated with the patient treatment events based on the rescheduling of the patient treatment events, and~~

~~transmitting the new schedule of shipping and logistics events associated the patient-specific identifier including the new cell order identifier to a logistics interface based on the rescheduling of shipping and logistics events.~~

~~84. The method of claim 81, further comprising:~~

~~associating, by the computing device, with the patient-specific identifier at each time point at which the determination of whether acceptance parameters meet the certain acceptance criteria is made, the new cell order identifier including fields corresponding to each respective time point and a result of the determination.~~

~~85. The method of claim 84, wherein the scheduling comprises:~~

~~scheduling, by the computing device, the patient treatment events based on the patient-specific identifier including the new cell order identifier.~~

~~86. The method of claim 85, further comprising, in response to a determination that the re-performing is not possible, canceling, by the computing device, the patient treatment events scheduled subsequent to the second time point.~~

~~87. The method of claim 86, further comprising transmitting the cancellation of patient treatment events to a hospital-side interface and a logistics interface.~~

~~88. The method of claim 87, further comprising, in response to a determination that the re-performing is not feasible, destroying the expanded cell therapy product and disassociating the patient-specific identifier from the cell order identifier.~~

~~89. A method of treating the patient with the expansion cell therapy product obtained by the method of claim 56 in accordance with the rescheduled patient treatment events.~~

1. A method for manufacturing a cell therapy product comprising tumor infiltrating lymphocytes (TILs) to be used in a composition for treating a patient having cancer, the method comprising:

receiving, at a computing device, a request for manufacturing the cell therapy product, from at least a portion of a solid tumor obtained from the patient or a first population of cells obtained from the solid tumor, using a selected multi-step cell expansion process, the request including acceptance criteria for manufactured cell therapy product at each of a plurality of steps during the selected multi-step cell expansion process;

generating, by the computing device, a container label based on the request, the container label comprising information associated with:

(a) a manufacturing order received from a treatment facility requesting the cell therapy product, including an order-specific identifier,

(b) the patient, including a patient-specific identifier,

(c) the treatment facility requesting the manufacturing of the cell therapy product,

(d) the selected multi-step cell expansion process; and

(e) a manufacturing facility where the cell therapy product is to be manufactured;

determining, by the computing device, a schedule for manufacturing the cell therapy product at the manufacturing facility based on

(i) a time of receipt of the solid tumor or the first population of cells and

(ii) the selected multi-step cell expansion process;

generating, by the computing device, a manufacturing label to be affixed to a manufacturing container to be used during the selected multi-step cell expansion process, the manufacturing label comprising information associated with:

(a) the manufacturing order, including the order-specific identifier,

(b) the patient, including the patient-specific identifier,

(c) the selected multi-step cell expansion process or a step thereof and

(f) quality of manufactured cell therapy product;

initiating the selected multi-step cell expansion process to manufacture the cell therapy product in accordance with the schedule;

performing quality control assays to determine acceptance parameters at each of a plurality of time points during the selected multi-step cell expansion process;

at each of the plurality of time points generating, by the computing device, a respective updated manufacturing label, to be affixed to the manufacturing container, corresponding to a respective one of the plurality of time points, the updated manufacturing label comprising information associated with

(a) the manufacturing order, including the order-specific identifier,

(b) the patient, including the patient identifier,

(c) the selected multi-step cell expansion process and

(ee) updated information associated with quality of manufactured cell therapy product comprising the determined acceptance parameters at a corresponding time point;

determining an adjusted schedule, by the computing device, for manufacturing the cell therapy product based on whether the acceptance parameters at a given time point read from the updated manufacturing label meet the acceptance criteria at the given time point; and

completing the selected multi-step cell expansion process in accordance with the adjusted schedule to manufacture the cell therapy product.

2. The method of claim 1, further comprising, for each step of the selected multi-step cell expansion process, providing, by the computing device, a warning signal when:

information relating to the patient on the updated manufacturing label for a given step does not match the information relating to the patient on the manufacturing label for a preceding step, or

acceptance parameters on the updated manufacturing label for a given time point in the selected multi-step cell expansion process do not meet acceptance criteria for the given time point in the selected multi-step cell expansion process,

wherein the acceptance parameters comprise one or more of viability, sterility, cell count, mycoplasma count, CD3 count, a result of an endotoxin assay, and a result of a Gram stain assay.

3. The method of claim 1, wherein the selected multi-step cell expansion process includes culturing the TILs obtained from the solid tumor or the first population of cells in a closed container bioreactor.

4. The method of claim 1, wherein the manufacturing label comprises a barcode encoding the information associated with the patient, the selected multi-step cell expansion process and quality of manufactured cell therapy product.

5. The method of claim 1, wherein determining the schedule for manufacturing the cell therapy product comprises scheduling a set of dates corresponding to a plurality of time points, including a first time point and a second time point subsequent to the first time point, for determining whether acceptance parameters for the manufactured cell therapy product meet the acceptance criteria during the selected multi-step cell expansion process to manufacture the cell therapy product depending on the selected multi-step cell expansion process and when the manufacturing order is received at the manufacturing facility.

6. The method of claim 1, further comprising receiving courier status information via the computing device;

in response to receiving the courier status information, determining shipping schedule for shipping the manufactured cell therapy product based on the adjusted schedule of manufacturing, and

generating a shipping label for a shipping container containing the manufactured cell therapy product.

7. The method of claim 6, further comprising transmitting, by the computing device, a shipping request to a logistics facility based on the determined shipping schedule.

8. The method of claim 1, further comprising:

upon determining that the acceptance parameters for the manufactured cell therapy product meet the acceptance criteria, by the computing device, determining a completion date for the manufacturing of the cell therapy product;

generating, by the computing device, a schedule for patient treatment events corresponding to a use of the cell therapy product for treating a patient based on the completion date;

transmitting, by the computing device, to a logistics interface, a pick-up order based on the completion date; and

transmitting, by the computing device, to a hospital-side interface, the schedule for the patient treatment events.

9. The method of claim 1, wherein the manufacturing label further comprises a given time point corresponding to a given step of the selected multi-step cell expansion process when the manufacturing label is generated, a container-identifying code, steps completed at the given time point, acceptance parameters associated with the completed steps, and a step to be performed at or after the given time point.

10. The method of claim 1, wherein the manufacturing label comprises a graphical identification code encoding

(a) a manufacturing order received from a treatment facility requesting the cell therapy product,

(b) the patient, including a patient identifier,

(c) the selected multi-step cell expansion process and

(d) quality of manufactured cell therapy product,

the graphical identification code being one of a 1-dimensional barcode and a 2-dimensional barcode.

11. The method of claim 1, further comprising generating a contingent shipping label for a shipping container containing the cell therapy product before performing a final quality control assay, the contingent shipping label being indicative that the cell therapy product

is not releasable unless a result of the final quality control assay indicates that the acceptance parameters meet acceptance criteria.

12. A method for manufacturing a cell therapy product comprising tumor infiltrating lymphocytes (TILs) for treatment of cancer, the method comprising:

receiving, at a computing device, an indication that a solid tumor obtained from a patient having the cancer or a first population of cells comprising TILs obtained from the solid tumor obtained from the patient has been received at a manufacturing facility for manufacturing the cell therapy product using a selected multi-step cell expansion process;

generating, by the computing device, a manufacturing label to be affixed to a manufacturing container to be used during a multi-step cell expansion process for manufacturing the cell therapy product from at least a portion of the obtained solid tumor or the first population of cells, the manufacturing label comprising information associated with:

(a) a manufacturing order received from a treatment facility requesting the cell therapy product, including an order-specific identifier,

(b) the patient, including a patient-specific identifier,

(c) the selected multi-step cell expansion process and

(d) quality of manufactured cell therapy product;

initiating the multi-step cell expansion process to manufacture the cell therapy product;

performing a quality control assay to determine acceptance parameters for the manufactured cell therapy product at each of a plurality of time points during the selected multi-step cell expansion process;

receiving, at the computing device, the acceptance parameters for the manufactured cell therapy product at each of the plurality of time points;

reading, by the computing device, the manufacturing label at each of the plurality of time points; and

for each step of the multi-step cell expansion process, generating, by the computing device, a warning signal when:

information relating to the patient on the manufacturing label for the step does not match the information relating to the patient on the manufacturing label for an immediately preceding manufacturing step, or

acceptance parameters on the manufacturing label for a given time point in the selected multi-step cell expansion process do not meet acceptance criteria for the given time point in the selected multi-step cell expansion process.

13. The method of claim 12, wherein the acceptance parameters comprise one or more of viability, sterility, cell count, mycoplasma count, CD3 count, a result of an endotoxin assay, and a result of a Gram stain assay.

14. The method of claim 12, further comprising generating, by the computing device, an updated manufacturing label corresponding to each of the plurality of time points, the updated manufacturing label further comprising updated information associated with quality of manufactured cell therapy product, the updated information comprising the acceptance parameters at a corresponding time point.

15. The method of claim 12, wherein the warning signal comprises:

when information relating to the patient on the manufacturing label for the manufacturing step does not match the information relating to the patient on the manufacturing label for the immediately preceding manufacturing step, a prevention signal preventing performance of subsequent steps in the multi-step cell expansion process.

16. The method of claim 12, wherein the warning signal comprises:

if acceptance parameters on the manufacturing label for a given time point in the selected multi-step cell expansion process do not meet acceptance criteria for that time point in the selected multi-step cell expansion process, an alert signal indicating that the acceptance criteria for the given time point are not met.

17. The method of claim 16, wherein the alert signal causes the computing device to generate an updated manufacturing label comprising updated information associated with quality of manufactured cell therapy product, the updated information comprising the acceptance parameters at the given time point.

18. The method of claim 17, further comprising reading the updated manufacturing label and determining, based on the updated information, whether additional processing of the manufactured cell therapy product can be performed to meet the acceptance criteria at that time point.

19. The method of claim 18, further comprising controlling, by the computing device, the multi-step cell expansion process to enable the additional processing of the manufactured cell therapy product to meet the acceptance criteria at the given time point.