REACTOR SYSTEMS

RELATED APPLICATIONS

This application claims priority to U.S. Ser. No. 61/453,099 filed Mar. 15, 2011.

FIELD OF DISCLOSURE

This disclosure relates to equipment utilized to manufacture chemical agents, particularly biopharmaceuticals.

BACKGROUND INFORMATION

This disclosure relates to equipment having reaction vessels used to manufacture chemical and/or biological products such as biopharmaceuticals. For instance, fermenters commonly provide a reaction vessel for cultivation of microbial organisms or mammalian, insect, or plant cells to produce such products. Currently available systems do not provide for simple removal of the components of a reaction from a reaction container and cleaning of equipment after a reaction is completed. The systems described herein solve these problems by providing a custom geometry, and optionally a sterile container used for reactions (e.g., biological, chemical), that does not require cleaning and re-sterilization after use is solved by the system described herein. The system also provides for ease of use in loading and unloading the disposable reaction container from a holder (e.g., an external jacket system).

SUMMARY OF THE DISCLOSURE

~~The systems described herein comprise: a mobile single-use disposable reaction container that may be housed within a holding system (e.g., external jacket system). In some embodiments, reactor systems comprising a mobile carriage assembly; a disposable reaction container removably attached to the carriage assembly; and, a carriage holder into which the mobile carriage assembly may be removably inserted are provided. In certain embodiments, the carriage holder comprises a heat transfer jacket. The mobile carriage may optionally comprise at least one implement selected from the group consisting of at least one wheel or track, an implement providing for fixably attaching the~~

The systems described herein comprise: a) a mobile carriage assembly holder comprising an interior into which a mobile carriage assembly may be removably inserted, the holder comprising: i) a receiving implement comprising at least one wheel or track for receiving the mobile carriage assembly; and, ii) a door for securing the mobile carriage assembly within the interior of the holder following insertion of the mobile carriage assembly into the holder; b) a mobile carriage assembly comprising: i) at least one primary mobility implement comprising at least one wheel or track for moving the mobile carriage assembly prior to insertion of the mobile carriage assembly into the holder; ii) secondary mobility implements, each secondary mobility element comprising at least one wheel or track, wherein: 1) the secondary mobility implements are not in contact with the ground prior to or following insertion of the mobile carriage assembly into the holder; 2) at least one secondary mobility implement is proximal to the receiving implement and at least one secondary mobility implement is distal from the receiving implement prior to insertion of the mobile carriage assembly into the holder; 3) the secondary mobility implements provide for insertion of the mobile carriage assembly into the holder, and removal of the mobile carriage assembly from the holder, using the receiving implement of the holder; and, iii) a shaft and impellar assembly; and, c) a disposable reaction container removably attached to the mobile carriage assembly that, when removably attached to the mobile carriage assembly: 1) comprises an interior chamber in which reaction components may be reacted with one another; 2) encloses the shaft and impellar assembly; and, 3) separates the reaction components from the external environment.

In some embodiments, the carriage holder comprises a heat transfer jacket. In some embodiments, the disposable reaction container comprises a sparge. In some embodiments, the holder: i. provides for heating and/or cooling of the reaction components within the reaction container; ii. comprises a door for maintaining the reaction container separated from the exterior of the holder; and/or, iii. comprises one or more anti-swirl and/or heat exchange baffles. In some embodiments, the reaction is selected from the group consisting of a chemical process, a pharmaceutical process, and a biological process. In some embodiments, the biological process is selected from the group consisting of microbiological culture, mammalian cell culture, and plant cell culture. In some embodiments, the reaction is at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, combination thereof. In some embodiments, the holder comprises one or more vertical seams at which the holder may be opened and/or closed and

further comprises one or more vertical hinges that may be positioned approximately opposite the one or more vertical seams.

This disclosure also provides methods for carrying out a reaction such as a chemical process, pharmaceutical process, and/or biological process (e.g., microbiological culture, mammalian cell culture, plant cell culture, at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, combination thereof) using such systems, as well as reaction products produced using such methods.

~~v. optionally comprises one or more anti-swirl and / or heat exchange baffle(s).~~ ~~In some embodiments, a mobile carriage assembly to which a disposable reaction container may be removably attached, the mobile carriage assembly comprising at least one wheel and / or track and an implement for mixing the components of the reaction in the reaction chamber, is provided. Exemplary of such embodiments may be those shown in Figs. 1 and 2. Such a mobile carriage assembly may be placed into a holder as, for example, described herein to carry out a reaction within the disposable reaction container (Fig. 3).~~

~~The reactor systems described herein may be used to carry out any of a variety of reactions, such as a chemical process, a pharmaceutical process, and / or a biological process (or combinations thereof). Exemplary biological processes may include, for example, microbiological culture, mammalian cell culture, and plant cell culture. In some embodiments, the reaction may be used in at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, combination thereof, or the like for use in, for example, for the prevention and / or treatment of a disease (e.g., as a vaccine). Also provided are methods for carrying out such reactions using the reactor systems described herein. The products of such reactions are also provided by this disclosure. Additional embodiments and advantages of these systems are described below.~~

BRIEF DESCRIPTION OF THE DRAWINGS

Figure 1. Exemplary carriage assembly.

Figure 2. Exemplary carriage assembly with reversibly attached reaction container (4). **Figure 3.** Exemplary carriage assembly and holder (e.g., external jacket system) and exemplary tracks (8) for reversibly inserting carriage assembly (optionally also comprising reaction container) into holder.

Figure 4. Exemplary reactor system in which carriage assembly is contained within holder and separated from exterior by door (7).

disposable reaction container to the carriage, an implement providing for fixably attaching the carriage to the holder, and an implement for mixing the components of the reaction. The implement for mixing the components of the reaction may be, for example, an agitator that optionally comprises a shaft and impeller that is incorporated in the reaction container and that connects to a drive mechanism fixably attached to the carriage. The disposable reaction container may comprise a sterile, sealable interior chamber in which reaction components may be reacted with one another; may be reversibly fixably attached to the mobile carriage assembly; may be removed from the mobile carriage assembly after the reaction is complete; may separate the contents of the reaction from the external environment after removal from the mobile carriage assembly; and / or, incorporate a sparge or other accessory. In certain embodiments, the holder may comprise a receiving implement with which the carriage may be inserted into and optionally affixed to the holder; maintain the desired geometry of the disposable reaction container, optionally including reaction container anti-swirl baffles; provide for heating and / or cooling of the reaction components within the reaction container; comprise a door for maintaining the reaction container separated from the exterior of the holder; and / or, comprise one or more anti-swirl and / or heat exchange baffles. In some embodiments, the receiving implement comprises one or more wheels or tracks. Other features of these reactor systems will be apparent from the description provided herein including, for example, Figures 1 -4. Thus, in some embodiments, the reactor systems may comprise:

1) a mobile carriage assembly;

2) a disposable reaction container removably attached to the carriage assembly; and,

3) a holder with a heat transfer jacket (e.g., external jacket system) comprising an opening into which the carriage (e.g., and reaction container) may be removably inserted;

wherein:

a) the mobile carriage assembly optionally comprises [at least one of]:

i. at least one implement providing mobility to the carriage, such as one or more wheels or tracks;

ii. at least one implement providing for fixably attaching the disposable reaction container to the carriage; and,

iii. at least one implement providing for fixably attaching the carriage to the holder;

iv. one or more implements such as an agitator that optionally comprises a shaft and impellar fixably attached to the carriage and providing for mixing of the contents of the reaction within the reaction container;

b) the disposable reaction container:

i. provides a sterile, sealable interior chamber in which reaction components may be reacted with one another,

ii. may be reversibly fixably attached to the carriage such that one or more of the implements of the carriage may be coupled to the reaction container (e.g., agitator (e.g., the shaft and impellar being affixed to a motor on the carriage and providing for mixing of the contents of the reaction within the reaction container)) while others may be positioned outside the reaction container (e.g., the baffle(s)) and / or other components of the system);

iii. may be removed from the carriage after the reaction is complete, optionally keeping the contents of the reaction separated from the external environment (e.g., under sterile conditions); and,

iv. optionally comprises a sparge (e.g., gas introduction device); and,

c) the holder [may]:

i. comprises an receiving implement (e.g., one or more tracks) with which the carriage may be inserted into and optionally affixed to the holder;

ii. maintains the desired geometry (e.g., shape) of the disposable reaction container, optionally including reaction container anti-swirl baffles;

iii. provides for heating and / or cooling of the reaction components within the reaction container;

iv. comprises a door for maintaining the carriage and reaction container separated from the exterior of the holder (e.g., locking the carriage / reaction container within the holder); and,

CLAIMS

What is claimed is:

1. A reactor system comprising:
    a. a mobile carriage assembly comprising:
        i) a carriage platform;
        ii) at least one primary wheel and at least one secondary wheel;
        iii) a shaft and impellar assembly attached to the carriage platform;
    b. a disposable reaction container removably attached to the carriage platform; and,
    c. a mobile carriage assembly holder into which the mobile carriage assembly may be removably inserted, the holder comprising one or more wheels and/or tracks for receiving the mobile carriage assembly;

    wherein:

    the mobile carriage assembly may be removably inserted into and removed from the holder using the secondary wheel of the mobile carriage assembly and the one or more wheels and/or tracks for receiving the mobile carriage assembly.

2. The reactor system of claim 1 wherein the carriage holder comprises a heat transfer jacket.

3. The reactor system of claims 1 or 2, wherein the disposable reaction container:
    a. comprises a sterile, sealable interior chamber in which reaction components may be reacted with one another;
    b. may be removed from the mobile carriage assembly after the reaction is complete;
    c. functions to separate the contents of the reaction separated from the external environment after removal from the mobile carriage assembly; and / or,
    d. comprises a sparge.

4. The reactor system of any one of claims 1-3 wherein the holder:
    i. is configured to maintain the desired geometry of the disposable reaction container, optionally including reaction container anti-swirl baffles;
    ii. is configured to provide for heating and / or cooling of the reaction components within the reaction container;
    iii. comprises a door for maintaining the reaction container separated from the exterior of the holder; and / or,
    iv. comprises one or more anti-swirl and / or heat exchange baffles.

5. The reactor system of any one of claims 1-4 wherein the reaction is selected from the group consisting of a chemical process, a pharmaceutical process, and a biological process.

6. The reactor system of claim 5 wherein the biological process is selected from the group consisting of microbiological culture, mammalian cell culture, and plant cell culture.

7. The reactor system of claim 5 wherein the reaction is at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, or combination thereof.

8. The reactor system of any one of claims 1-7 wherein the holder comprises one or more vertical seams at which the holder may be opened and / or closed and further comprises one or more vertical hinges.

9. The reactor system of claim 8 wherein the one or more vertical hinges are positioned approximately opposite the one or more vertical seams.

~~10. A method for carrying out a reaction using a reactor system of any one of claims 1-9.~~

11. The method of claim 10 wherein the reaction is selected from the group consisting of a chemical process, a pharmaceutical process, and a biological process.

12. The method of claim 11 wherein the biological process is selected from the group consisting of microbiological culture, mammalian cell culture, and plant cell culture.

13. The method of claim 10 wherein the reaction is at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, or combination thereof.

14. A mobile carriage assembly to which a disposable reaction container may be removably attached, the mobile carriage assembly comprising a carriage platform, at least one primary wheel for moving the carriage assembly and at least one secondary wheel, and an implement for mixing the components of the reaction in the reaction container, the implement being attached to the carriage platform; and wherein the carriage platform is capable of removably attaching the disposable reaction container.

CLAIMS

1. A reactor system comprising:

a) a mobile carriage assembly holder comprising an interior into which a mobile carriage assembly may be removably inserted, the holder comprising:

i) a receiving implement comprising at least one wheel or track for receiving the mobile carriage assembly; and,

ii) a door for securing the mobile carriage assembly within the interior of the holder following insertion of the mobile carriage assembly into the holder;

b) a mobile carriage assembly comprising:

i) at least one primary mobility implement comprising at least one wheel or track for moving the mobile carriage assembly prior to insertion of the mobile carriage assembly into the holder;

ii) secondary mobility implements, each secondary mobility element comprising at least one wheel or track, wherein:

1) the secondary mobility implements are not in contact with the ground prior to or following insertion of the mobile carriage assembly into the holder;

2) at least one secondary mobility implement is proximal to the receiving implement and at least one secondary mobility implement is distal from the receiving implement prior to insertion of the mobile carriage assembly into the holder;

3) the secondary mobility implements provide for insertion of the mobile carriage assembly into the holder, and removal of the mobile carriage assembly from the holder, using the receiving implement of the holder; and,

iii) a shaft and impellar assembly; and,

c) a disposable reaction container removably attached to the mobile carriage assembly that, when removably attached to the mobile carriage assembly:

1) comprises an interior chamber in which reaction components may be reacted with one another;

2) encloses the shaft and impellar assembly; and,

3) separates the reaction components from the external environment.

2. The reactor system of claim 1 wherein the carriage holder comprises a heat transfer jacket.

3. The reactor system of claim 1 wherein the disposable reaction container comprises a sparge.

4. The reactor system of claim 1 wherein the holder:

i. provides for heating and/or cooling of the reaction components within the reaction container;

ii. comprises a door for maintaining the reaction container separated from the exterior of the holder; and/or,

iii. comprises one or more anti-swirl and/or heat exchange baffles.

5. The reactor system of claim 1 wherein the reaction is selected from the group consisting of a chemical process, a pharmaceutical process, and a biological process.

6. The reactor system of claim 5 wherein the biological process is selected from the group consisting of microbiological culture, mammalian cell culture, and plant cell culture.

7. The reactor system of claim 5 wherein the reaction is at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, combination thereof.

8. The reactor system of claim 1 wherein the holder comprises one or more vertical seams at which the holder may be opened and/or closed and further comprises one or more vertical hinges.

9. The reactor system of claim 8 wherein the one or more vertical hinges are positioned approximately opposite the one or more vertical seams.

10. A method for carrying out a reaction, the method comprising using a reactor system of claim 1.

11. The method of claim 10 wherein the reaction is selected from the group consisting of a chemical process, a pharmaceutical process, and a biological process.

12. The method of claim 11 wherein the biological process is selected from the group consisting of microbiological culture, mammalian cell culture, and plant cell culture.

13. The method of claim 10 wherein the reaction is at least one step of a process for the production of a composition comprising a peptide, protein, nucleic acid, complex thereof, combination thereof.

14. A reaction product produced using a method of claim 10.

15. A reaction product produced using a reactor system of claim 1.

16. The reactor system of claim 1 wherein the primary mobility element comprises one or more tracks.

17. The reactor system of claim 16 wherein the primary mobility element comprises one or more wheels.

18. The reactor system of claim 1 wherein the primary mobility element comprises one or more tracks.

19. The reactor system of claim 1 wherein each of the primary mobility element and the secondary mobility element comprises one or more wheels.

20. The reactor system of claim 1 wherein the receiving implement comprises one or more tracks.

21. The reactor system of claim 1 wherein the secondary mobility element comprises one or more wheels.

22. The reactor system of claim 1 wherein the receiving implement comprises one or more wheels.