Claims

1. A manufacturing system for biopharmaceuticals comprising:

at least one inputting device directly connected to at least one inoculum expansion device through at least one piece of tubing and a connector that does not include a shake flask incubation device, wherein the direct connection contains a sensor that controls a transfer of a material from the at least one inputting device to the at least one inoculum expansion device;

said at least one inoculum expansion device is connected to at least one production stage bioreactor device through at least one piece of tubing and a connector;

said at least one production stage bioreactor device is connected to at least one primary recovery device through at least one piece of tubing and a connector;

said at least one primary recovery device is directly connected to at least one capturing device by at least one piece of tubing and a connector;

said at least one capturing device is connected to at least one ultrafiltration and diafiltration device through at least one piece of tubing and a connector;

said at least one ultrafiltration and diafiltration device connected to the capturing device is connected to at least one polishing membranes device through at least one piece of tubing and a connector;

said at least one polishing membranes device is connected to at least one polishing using cation exchange device through at least one piece of tubing and a connector;

said at least one polishing using cation exchange device is connected to at least one virus reduction filtration device through at least one piece of tubing and a connector; and

said at least one virus reduction filtration device is connected to at least one ultrafiltration and diafiltration device through at least one piece of tubing and a connector;

said at least one ultrafiltration and diafiltration device connected to the virus reduction filtration device is connected to at least one automated bulk fill device through at least one piece of tubing and a connector,

wherein the device can be from at least two different manufacturers and wherein the system is configured to be switchable for difference processes.

2. The manufacturing system of claim 1, wherein at least one device is not made for single-use.

3. The manufacturing system of claim 1, wherein the system is operated as a closed system.

4. The manufacturing system of claim 1, further comprising at least one sensor capable of controlling flow of material between two devices.

5. The manufacturing system of claim 1, wherein the system is automated.

6. The manufacturing system of claim 1, wherein at least one device can be in more than one room.

7. The manufacturing system of claim 1, further comprising at least one disposable bag that can be used to dispose of at least one device, tubing or connector.

8. A method of making biopharmaceuticals comprising:

directly connecting at least one inputting device to at least one inoculum expansion device using at least one piece of tubing and a connector such that material can directly pass from the inputting device to the inoculum expansion device without a shake flask incubation step, wherein the direct connection contains a sensor that controls passing of material from the at least one inputting device to the at least one inoculum expansion device;

connecting said at least one inoculum expansion device to at least one production stage bioreactor device using at least one piece of tubing and a connector such that material can pass from the inoculum expansion device to the production stage bioreactor device;

connecting said at least one production stage bioreactor device to at least one primary recovery device using at least one piece of tubing and a connector such that material can pass from the production stage bioreactor device to the primary recovery device;

connecting said at least one primary recovery device directly to at least one capturing device using at least one piece of tubing and a connector such that material can pass from the primary recovery device to the capturing device;

connecting said at least one capturing device to at least one ultrafiltration and diafiltration device using at least one piece of tubing and a connector such that material can pass from the capturing device to the ultrafiltration and diafiltration device;

connecting said at least one ultrafiltration and diafiltration device to at least one polishing membranes device using at least one piece of tubing and a connector such that material can pass from the ultrafiltration and diafiltration device to the polishing membrane device;

connecting said at least one polishing membranes device to at least one polishing using cation exchange device using at least one piece of tubing and a connector such that material can pass from the polishing membranes device to the polishing using cation exchange device; and

connecting said at least one polishing using cation exchange device to at least one virus reduction filtration device using at least one piece of tubing and a connector such that material can pass from the polishing using cation exchange device to the virus reduction filtration device;

wherein the device can be from at least two different manufacturers and wherein the system is configured to be switchable for difference processes.

9. The method of claim 9, further comprising:

connecting said at least one virus reduction filtration device to at least one ultrafiltration and diafiltration device such that material can pass from the virus reduction filtration device to the ultrafiltration and diafiltration device; and

connecting said at least one ultrafiltration and diafiltration device to at least one automated bulk fill device such that material can pass from the ultrafiltration and diafiltration device to the automated bulk fill device.

10. The method of claim 9, wherein the method is automated.

11. The method of claim 10, wherein the method is automated.

12. A manufacturing system for biopharmaceuticals comprising:

at least one inputting device directly connected to at least one inoculum expansion device through at least one piece of tubing and a connector that does not include a shake flask incubation device, wherein the direct connection contains a sensor that controls a transfer of a material from the at least one inputting device to the at least one inoculum expansion device;

said at least one inoculum expansion device is connected to at least one production stage perfusion device through at least one piece of tubing and a connector;

said at least one production stage perfusion device is connected directly to at least one volume exchange device through at least one piece of tubing and a connector;

said at least one volume exchange device is connected to at least one continuous filtration device through at least one piece of tubing and a connector;

said at least one continuous filtration device is connected to at least one virus reduction filtration device through at least one piece of tubing and a connector;

said at least one virus reduction filtration device is connected to at least one ultrafiltration and diafiltration device through at least one piece of tubing and a connector; and

said at least one ultrafiltration and diafiltration device connected to the virus reduction filtration device is connected to at least one automated bulk fill device through at least one piece of tubing and a connector,

wherein the device can be from at least two different manufacturers and wherein the system is configured to be switchable for difference processes.

13. The manufacturing system of claim 14, wherein at least one device is not made for single-use.

14. The manufacturing system of claim 14, wherein the system is operated as a closed system.

15. The manufacturing system of claim 14, further comprising at least one sensor capable of controlling flow of material between two devices.

16. The manufacturing system of claim 14, wherein the system is automated.

17. The manufacturing system of claim 14, wherein at least one device can be in more than one room.

18. The manufacturing system of claim 14, further comprising at least one disposable bag that can be used to dispose of at least one device, tubing or connector.

19. A method of making biopharmaceuticals comprising:

directly connecting at least one inputting device to at least one inoculum expansion device using at least one piece of tubing and a connector such that material can pass directly from the inputting device to the inoculum expansion device without a shake flask incubation

step, wherein the direct connection contains a sensor that controls passing of material from the at least one inputting device to the at least one inoculum expansion device;

connecting said at least one inoculum expansion device to at least one production stage perfusion device using at least one piece of tubing and a connector such that material can pass from the inoculum expansion device to the production stage perfusion device;

connecting said at least one production stage perfusion device directly to at least one volume exchange device using at least one piece of tubing and a connector such that material can pass from the production stage perfusion device to the volume exchange device;

connecting said at least one volume exchange device to at least one continuous purification device using at least one piece of tubing and a connector such that material can pass from the volume exchange device to the continuous purification device;

connecting said at least one continuous purification device to at least one virus reduction filtration device using at least one piece of tubing and a connector such that material can pass from the continuous purification device to the virus reduction filtration device;

connecting said at least one virus reduction filtration device to at least one ultrafiltration and diafiltration device using at least one piece of tubing and a connector such that material can pass from the virus reduction filtration device to the ultrafiltration and diafiltration device; and

connecting said at least one ultrafiltration and diafiltration device to at least one automated bulk fill device using at least one piece of tubing and a connector such that material can pass from the ultrafiltration and diafiltration device to the automated bulk fill device.

20. A manufacturing system for biopharmaceuticals comprising:

at least one inputting device directly connected to at least one inoculum expansion device through at least one piece of tubing and a connector that does not include a shake flask

incubation device, wherein the direct connection contains a sensor that controls a transfer of a material from the at least one inputting device to the at least one inoculum expansion device;

said at least one inoculum expansion device is connected to at least one production stage bioreactor device through at least one piece of tubing and a connector;

said at least one production stage bioreactor device is connected to at least one primary recovery device through at least one piece of tubing and a connector;

said at least one primary recovery device is directly connected to at least one volume exchange device through at least one piece of tubing and a connector;

said at least one volume exchange device is connected to at least one continuous purification device through at least one piece of tubing and a connector;

said at least one continuous purification device is connected to at least one virus reduction filtration device through at least one piece of tubing and a connector;

said at least one virus reduction filtration device is connected to at least one ultrafiltration and diafiltration device through at least one piece of tubing and a connector; and

said at least one ultrafiltration and diafiltration device connected to the virus reduction filtration device is connected to at least one automated bulk fill device through at least one piece of tubing and a connector,

wherein the device can be from at least two different manufacturers and wherein the system is configured to be switchable for difference processes.

21. The manufacturing system of claim 23, wherein at least one device is not made for single-use.

22. The manufacturing system of claim 23, wherein the system is operated as a closed system.

23. The manufacturing system of claim 23, further comprising at least one sensor capable of controlling flow of material between two devices.

24. The manufacturing system of claim 23, wherein the system is automated.

25. The manufacturing system of claim 23, wherein at least one device can be in more than one room.

26. The manufacturing system of claim 23, further comprising at least one disposable bag that can be used to dispose of at least one of device, tubing or connector.

27. A method of making biopharmaceuticals comprising:

directly connecting at least one inputting device to at least one inoculum expansion device using at least one piece of tubing and a connector such that material can directly pass from the inputting device to the inoculum expansion device without a shake flask incubation step, wherein the direct connection contains a sensor that controls passing of material from the at least one inputting device to the at least one inoculum expansion device;

connecting said at least one inoculum expansion device to at least one production stage bioreactor device using at least one piece of tubing and a connector such that material can pass from the inoculum expansion device to the production stage bioreactor device;

connecting said at least one production stage bioreactor device to at least one primary recovery device using at least one piece of tubing and a connector such that material can pass from the production stage bioreactor device to the primary recovery device;

directly connecting said at least one primary recovery device to at least one volume exchange device using at least one piece of tubing and a connector such that material can pass from the primary recovery device to the volume exchange device;

connecting said at least one volume exchange device to at least one continuous purification device using at least one piece of tubing and a connector such that material can pass from the volume exchange device to the continuous purification device;

connecting said at least one continuous purification device to at least one virus reduction filtration device using at least one piece of tubing and a connector such that material can pass from the continuous purification device to the virus reduction filtration device;

connecting said at least one virus reduction filtration device to at least one ultrafiltration and diafiltration device using at least one piece of tubing and a connector such that material can pass from the virus reduction filtration device to the ultrafiltration and diafiltration device; and

connecting said at least one ultrafiltration and diafiltration device to at least one automated bulk fill device using at least one piece of tubing and a connector such that material can pass from the ultrafiltration and diafiltration device to the automated bulk fill device.

28. A manufacturing system for biopharmaceuticals comprising:

at least one inputting device directly connected to at least one inoculum expansion device through at least one piece of tubing and a connector that does not include a shake flask incubation device, wherein the direct connection contains a sensor that controls a transfer of a material from the at least one inputting device to the at least one inoculum expansion device;

said at least one inoculum expansion device is connected to at least one production stage perfusion device through at least one piece of tubing and a connector;

said at least one production stage perfusion device is directly connected to at least one volume exchange device through at least one piece of tubing and a connector;

said at least one volume exchange device is connected to at least one continuous purification device through at least one piece of tubing and a connector;

said at least one continuous purification device is connected to at least one virus reduction filtration device through at least one piece of tubing and a connector;

said at least one virus reduction filtration device is connected to at least one ultrafiltration and diafiltration device through at least one piece of tubing and a connector; and

said at least one ultrafiltration and diafiltration device is connected to at least one automated bulk fill device through at least one piece of tubing and a connector.

29. The manufacturing system of claim 32, wherein the device can be from at least two different manufacturers.

30. The manufacturing system of claim 32, wherein at least one device is not made for single-use.

31. The manufacturing system of claim 32, wherein there the system operated as a closed system.

32. The manufacturing system of claim 32, further comprising at least one sensor capable of controlling flow of material between two devices.

33. The manufacturing system of claim 32, wherein the system is automated.

34. The manufacturing system of claim 32, wherein at least one device can be in more than one room.

35. The manufacturing system of claim 32, further comprising at least one disposable bag that can be used to dispose of at least one device, tubing or connector.

36. A method for manufacturing biopharmaceuticals comprising:

directly connecting at least one inputting device to at least one inoculum expansion device using at least one piece of tubing and a connector such that material can directly pass from the inputting device to the inoculum expansion device without a shake flask incubation

step, wherein the direct connection contains a sensor that controls passing of material from the at least one inputting device to the at least one inoculum expansion device;

connecting said at least one inoculum expansion device to at least one production stage bioreactor device using at least one piece of tubing and a connector such that material can pass from the inoculum expansion device to the production stage bioreactor device;

connecting said at least one production stage bioreactor device to at least one primary recovery device using at least one piece of tubing and a connector such that material can pass from the production stage bioreactor device to the primary recovery device;

directly connecting said at least one primary recovery device to at least one volume exchange device using at least one piece of tubing and a connector such that material can pass from the primary recovery device to the volume exchange device;

connecting said at least one volume exchange device to at least one continuous purification device using at least one piece of tubing and a connector such that material can pass from the volume exchange device to the continuous purification device;

connecting said at least one continuous purification device to at least one virus reduction filtration device using at least one piece of tubing and a connector such that material can pass from the continuous purification device to the virus reduction filtration device;

connecting said at least one virus reduction filtration device to at least one ultrafiltration and diafiltration device using at least one piece of tubing and a connector such that material can pass from the virus reduction filtration device to the ultrafiltration and diafiltration device; and

connecting said at least one ultrafiltration and diafiltration device to at least one automated bulk fill device using at least one piece of tubing and a connector such that material can pass from the ultrafiltration and diafiltration device to the automated bulk fill device.

37. A method to manufacture a biopharmaceutical product comprising:

inserting a material into an inoculum device for processing;

transferring the material from the inoculum device to an inoculum expansion device for further processing, wherein inoculum device is directly connected to the inoculum expansion device without a shake flask incubation step, wherein the direct connection contains a sensor that controls the transfer of the material from the at least one inoculum device to the at least one inoculum expansion device;

then transferring the material from the inoculum expansion device to a production stage bioreactor device for further processing;

then transferring the material from the production stage bioreactor device to a primary recovery device for further processing;

then transferring the material directly from the primary recovery device to a capturing device for further processing;

then transferring the material from the capturing device to an ultrafiltration and diafiltration device for further processing;

then transferring the material from the ultrafiltration and diafiltration device to a polishing membrane device for further processing;

then transferring the material from the polishing membrane device to a polishing using cation exchange device for further processing;

then transferring the material from the polishing using cation exchange device to a virus reduction filtration device for further processing;

then transferring the material from the virus reduction filtration device to an ultrafiltration and diafiltration device for further processing; and

then transferring the material from the ultrafiltration and diafiltration device to an automated bulk fill device to obtain the biopharmaceutical product.

38. A method to manufacture a biopharmaceutical product comprising:

inserting a material into an inoculum device for processing;

transferring the material from the inoculum device to an inoculum expansion device for further processing, wherein inoculum device is directly connected to the inoculum expansion device without a shake flask incubation step, wherein the direct connection contains a sensor that controls the transfer of the material from the at least one inoculum device to the at least one inoculum expansion device;

then transferring the material from the inoculum expansion device to a production stage perfusion device for further processing;

then directly transferring the material from the production stage perfusion device to a volume exchange device for further processing;

then transferring the material from the volume exchange device to a continuous filtration device for further processing;

then transferring the material from the continuous filtration device to a virus reduction filtration device for further processing;

then transferring the material from the virus reduction filtration device to an ultrafiltration and diafiltration device for further processing; and

then transferring the material from the ultrafiltration and diafiltration device to an automated bulk fill device to obtain the biopharmaceutical product.

39. A method to manufacture a biopharmaceutical product comprising:

inserting a material into an inoculum device for processing;

transferring the material from the inoculum device to an inoculum expansion device for further processing, wherein inoculum device is directly connected to the inoculum expansion device without a shake flask incubation step, wherein the direct connection contains a sensor that controls the transfer of the material from the at least one inoculum device to the at least one inoculum expansion device;

then transferring the material from the inoculum expansion device to a production stage bioreactor device for further processing;

then directly transferring the material from the production stage bioreactor device to a primary recovery device for further processing;

then transferring the material from the primary recovery device to a volume exchange device for further processing;

then transferring the material from the volume exchange device to a continuous purification device for further processing;

then transferring the material from the continuous purification device to a virus reduction filtration device for further processing;

then transferring the material from the virus reduction filtration device to an ultrafiltration and diafiltration device for further processing; and

then transferring the material from the ultrafiltration and diafiltration device to an automated bulk fill device to obtain the biopharmaceutical product.

40. A method to manufacture a biopharmaceutical product comprising:

inserting a material into an inoculum device for processing;

transferring the material from the inoculum device to an inoculum expansion device for further processing, wherein inoculum device is directly connected to the inoculum expansion

device without a shake flask incubation step, wherein the direct connection contains a sensor that controls the transfer of the material from the at least one inoculum device to the at least one inoculum expansion device;

then transferring the material from the inoculum expansion device to a production stage perfusion device for further processing;

then directly transferring the material from the production stage perfusion device to a volume exchange device for further processing;

then transferring the material from the volume exchange device to a continuous purification device for further processing;

then transferring the material from the continuous purification device to a virus reduction filtration device for further processing;

then transferring the material from the virus reduction filtration device to an ultrafiltration and diafiltration device for further processing; and

then transferring the material from the ultrafiltration and diafiltration device to an automated bulk fill device to obtain the biopharmaceutical product.