~~Claims~~

CLAIMS

1. A system for the growth of biologics comprising:

a perfusion seed train or a fed-batch bioreactor seed train;

a bioreactor subsystem comprising at least two bioreactors ~~and at least one~~fed from the perfusion seed train or ~~a~~the fed-batch bioreactor seed train ~~of fed-batch incubators; and~~;

at least two harvest subsystems, wherein each harvest subsystem is configured to be in fluid communication with each of the bioreactors in the bioreactor subsystem, ~~alone~~individually or in combination; and

at least one purification subsystem, wherein the at least one purification subsystem is configured to be in fluid communication with each of the at least two harvest subsystems individually or in combination, wherein the at least one purification subsystem is downstream from the at least two harvest subsystems.

~~2.~~ A system as defined in claim 1, further comprising a flow control assembly positioned in between the at least two bioreactors and the at least two harvest subsystems, the flow control assembly being configured to selectively control flow of a fluid from a first bioreactor to a first harvest subsystem and from the first bioreactor to a second harvest subsystem, the flow control assembly also being configured to control flow of a fluid from a second bioreactor to the first harvest subsystem and from the second bioreactor to the second harvest subsystem.

2.

~~3.~~ A system as defined in claim 1, ~~further comprising~~wherein the system comprises at least ~~one~~two purification ~~subsystem~~subsystems, wherein ~~each~~at least one purification subsystem is ~~in fluid communication with each of the harvest subsystems, alone or in combination.~~

~~4. A system as defined in claim 3, wherein at least one of the purification subsystems is~~ configured to produce a different biologic than at least one other purification subsystem.

3.

~~5.~~ A system as defined in claim 1, configured to process more than 100 batches per year.

4.

~~6.~~ A system as defined in claim 1, wherein at least one of the bioreactors is 6000 L or larger.

5.

~~7.~~ A system as defined in claim 1, wherein the bioreactor subsystem comprises at least one fed-batch bioreactor.

6. ~~A~~

~~8.~~ The system as defined in claim 1 ~~further comprising a buffer distribution system comprising:~~

~~at least one buffer dilution device which accepts~~ , wherein the at least two ~~inputs (i) and (ii), wherein (i) is a buffer concentrate source stream and (ii) is a sterile water for injection source stream;~~

~~at least one buffer dilution device which delivers a buffer mixture comprising (i) and (ii) to a buffer mixture distribution manifold;~~

~~wherein at least one buffer mixture distribution manifold may be used to control parameters of the buffer mixture delivered to each of a plurality of destinations independently, the parameters including at least one of the following: flow rate or concentration; and~~

~~wherein the buffer mixture is not stored before delivery to any of the plurality of destinations.~~

~~9. A system as defined in claim 8, comprising:~~

~~a first buffer dilution device, wherein the buffer mixture output from the first buffer dilution device is delivered to at least one downstream buffer dilution device as input (i), wherein the input (i) of any buffer dilution device downstream of the first buffer dilution device may be partially diverted to another buffer dilution device or to at least one buffer mixture distribution manifold; and~~

~~wherein at least two buffer mixture distribution manifolds distribute buffer of a different concentration.~~

~~10. A system as defined in claim 8, wherein at least two buffer dilution devices deliver buffer of about the same concentration to at least one buffer distribution manifold.~~

~~**11.** A system defined as in claim 8, wherein at least one buffer destination comprises a media preparation subsystem, a cell culture subsystem, the bioreactor subsystem, one of the~~ harvest subsystems~~, and/or a purification subsystem.~~

~~**12.** A building comprising the system as defined in claim 1.~~

~~**13.** A building as defined in claim 12, wherein the building includes~~ feed at least two purification subsystems ~~and each of~~, wherein the at least two purification subsystems ~~comprise:~~

~~three chromatography column stations and three chromatography skid stations in a first room;~~

~~a chromatography column station and a chromatography skid station in a second adjacent room; and~~

~~a maintenance area accessible from either the first room or the second room;~~

~~wherein the maintenance area is accessible from the first and second rooms by airlocks and is further accessible from the remainder of the building by another airlock.~~

~~**14.** A building as defined in claim 13, wherein the second room further comprises a filling device.~~

~~**15.** A building as defined in claim 12, wherein the bioreactor subsystem comprises a plurality of bioreactor stations in one room, wherein some or all of the stations~~ are ~~filled with a bioreactor.~~

~~**16.** A building as defined in claim 15, wherein at least one bioreactor station is not filled with a bioreactor.~~

7. ~~A building~~operated in parallel.

~~**17.** The~~ system as defined in claim ~~16~~1, wherein ~~at least one of~~ the ~~bioreactor stations not filled with a bioreactor and at least one of the bioreactor stations filled with a bioreactor are configured to maintain fluid communication with a flow control assembly, the flow control assembly being configured to selectively control the flow of a fluid from any one of~~ at least two ~~bioreactor stations to any one of~~ bioreactors feed the at least two harvest subsystems~~.~~

8. ~~A building~~, wherein the at least two harvest subsystems are operated in parallel.

9. The system as defined in claim 1, wherein the at least one purification subsystem comprises at least one chromatography column station.

~~**18.** The~~ The system as defined in claim ~~12, further comprising logistics corridors, personnel areas, packing areas, shipping areas, and/or receiving areas.~~

~~**19.** A building as defined in claim 12, configured to meet Leadership in Energy and Environmental Design certification standards.~~

20. A building as defined in claim 12, comprising:

a plurality of motion, temperature, and/or moisture sensors distributed on, in, and/or around equipment in9, wherein the building; and

a monitoring system configured to track the outputs of the plurality of sensors and generate records and/or alerts responsive to outputs departing from predetermined ranges.

21. A process for the growth of biologics in the system of claim 1 comprising the steps of:

growing a cell mass;

harvesting material comprising (i) the cells or (ii) components of the cells;

10. passing a first portion of the harvested material to a first at least one purification subsystem; comprises three chromatography column stations.

passing a second portion of the harvested material to a second

11. The system as defined in claim 1, wherein the at least one purification subsystem; comprises a pre-viral train.

producing a first product via the first

12. The system as defined in claim 11, wherein the pre-viral train comprises at least one chromatography column station.

13. The system as defined in claim 1, wherein the at least one purification subsystem; and comprises a post-viral train.

producing a second product via the second

14. The system as defined in claim 13, wherein the post-viral train comprises at least one chromatography column station.

15. The system as defined in claim 1, wherein the at least one purification subsystem. comprises a pre-viral train and a post-viral train.

16. The system as defined in claim 15, wherein the pre-viral train and the post-viral train are configured such that one of the pre-viral train and the post-viral train comprises at least one chromatography column station, wherein the at least one chromatography column station comprises at least one chromatography column, wherein the at least one chromatography column is configured such that it can be transferred from the pre-viral train to the post-viral train or from the post-viral train to the pre-viral train.

17. A system for the growth of biologics comprising:

a perfusion seed train or a fed-batch bioreactor seed train;

a bioreactor subsystem comprising at least two bioreactors fed from the perfusion seed train or the fed-batch bioreactor seed train;

at least two harvest subsystems, wherein each harvest subsystem is configured to be in fluid communication with each of the bioreactors in the bioreactor subsystem individually or in combination, wherein each harvest subsystem is

downstream from the at least two bioreactors, wherein each harvest subsystem receives the effluent of the at least two bioreactors;

at least one purification subsystem, wherein the at least one purification subsystem is configured to be in fluid communication with each of the at least two

harvest subsystems individually or in combination, wherein the at least one purification subsystem is downstream from the at least two harvest subsystems, wherein the at least one purification subsystem is downstream from the at least two harvest subsystems, wherein the at least one purification subsystem comprises at least one chromatography column station;

a flow control assembly positioned in between the at least two bioreactors and the at least two harvest subsystems, the flow control assembly being configured to selectively control flow of a fluid from a first bioreactor to a first harvest subsystem and from the first bioreactor to a second harvest subsystem, the flow control assembly also being configured to control flow of a fluid from a second bioreactor to the first harvest subsystem and from the second bioreactor to the second harvest subsystem; and

wherein the bioreactor subsystem, the at least two harvest subsystems, and the at least one purification subsystem are selectively operable such that one or more subsystems are operable while one or more subsystems are not operating.

18. The system as defined in claim 17, wherein the at least one purification subsystem comprises three chromatography column stations.

19. The system as defined in claim 17, wherein the at least one purification subsystem comprises a pre-viral train.

20. The system as defined in claim 19, wherein the pre-viral train comprises the at least one chromatography column station.

21. The system as defined in claim 17, wherein the at least one purification subsystem comprises a post-viral train.

22. The system as defined in claim 21, wherein the post-viral train comprises the at least one chromatography column station.

23. The system as defined in claim 17, wherein the at least one purification subsystem comprises a pre-viral train and a post-viral train.

24. The system as defined in claim 23, wherein the pre-viral train and the post-viral train are configured such that one of the pre-viral train and the post-viral train comprises the at least one chromatography column station; wherein the at least one chromatography column station comprises at least one chromatography column, wherein the at least one chromatography column is configured such that it can be transferred from the pre-viral train to the post-viral train or from the post-viral train to the pre-viral train.