

CLAIMS

What is claimed is:

1. A system for delivering a processing solution, the system comprising:
a bioprocess container containing a concentrated processing solution, the concentrated
5 processing solution produced at a first site;
a processing area having at least one processing unit at a second site different from the
first site; and
a pipe connecting the bioprocess container to the at least one processing unit, the pipe
having a valve to allow the concentrated processing solution to flow from the bioprocess
10 container to the at least one processing unit to combine the concentrated processing solution with
a biopolymer-containing solution produced in the at least one processing unit,
wherein the processing solution is at least one of a buffer and media.
2. The system of claim 1, further comprising a controller connected to the at least
15 one processing unit,
wherein the concentrated processing solution is provided based on a determination by the
controller that the processing solution is required when the determination is communicated from
the second site to the first site.
- 20 3. The system of claim 1 or claim 2, wherein the system is configured to dilute the
concentrated processing solution prior to combining with the biopolymer containing solution.
4. The system of any of claims 1-3, wherein the processing solution is one of Tris,
Tris-Base, Tricine, HEPES, MOPS, PIPES, TAPS, bicine, BES, TES, cacodylate, MES, acetate,
25 MKP, ADA, ACES, glycinamide, acetamidoglycine, acetic acid, citric acid, glycine, glycine
glycinate, sodium phosphate, ethanol, hydrochloric acid, sodium hydroxide, guanidinium
chloride, guanidine hydrochloride, sodium chloride, and a combination of any of these.
5. The system of any of claims 1-4, wherein the bioprocess container includes an
30 inner layer for contacting the processing solution and an outer layer configured to support the
inner layer.

6. The system of any of claims 1 and 3-5, further comprising a controller configured to determine a bioburden of the processing solution.

5

7. The system of any of claims 1-6, comprising a dilution liquid supply, wherein the concentrated processing solution from the bioprocess container and at least one of water and buffer from the dilution liquid supply is added to an inlet of an inline processing solution dilution system to result in a diluted processing solution.

10

8. A method for delivering a processing solution, the method comprising providing a concentrated processing solution in a bioprocess container, the concentrated processing solution being produced at a first site; and

combining the concentrated processing solution with a biopolymer-containing solution produced in a bioreactor at a second site different from the first site, wherein the processing solution is at least one of a buffer and media.

15

9. The method of claim 8, wherein the concentrated processing solution is provided based on a determination that the concentrated processing solution is required and the determination is communicated from the second site to the first site.

20

10. The method of claim 8 or claim 9, further comprising diluting the concentrated processing solution prior to combining with the biopolymer containing solution.

25

11. The method of any of claims 8-10, wherein the processing solution is one of Tris, Tris-Base, Tricine, HEPES, MOPS, PIPES, TAPS, bicine, BES, TES, cacodylate, MES, acetate, MKP, ADA, ACES, glycineamide, acetamidoglycine, acetic acid, citric acid, glycine, glycine glycinate, sodium phosphate, ethanol, hydrochloric acid, sodium hydroxide, guanidinium chloride, guanidine hydrochloride, sodium chloride, and a combination of any of these.

30

12. The method of any of claims 8-11, wherein the bioprocess container comprises an inner layer for product contact and an outer layer configured to support the inner layer.

13. The method of any of claims 8-12, further comprising determining a bioburden of the processing solution.

14. The method of any of claims 8-13, further comprising transporting the bioprocess container containing the processing solution from the first site to the second site.

15. A pharmaceutical production facility comprising:
a buffer storage area capable of receiving at least one bioprocess container configured to contain a concentrated processing solution;
a processing area having at least one processing unit;
a wall separating the buffer storage area from the processing area; and
at least one pipe having a first end in the buffer storage area and a second end in the processing area, the first end configured to connect to at least one bioprocess container of the at least one bioprocess container, and the second end configured to connect to at least one processing unit of the at least one processing unit.

16. The pharmaceutical production facility of claim 15, wherein the at least one pipe has a valve.

17. The pharmaceutical production facility of claim 15 or claim 16, wherein the at least one bioprocess container includes an inner layer for contacting the processing solution and an outer layer configured to support the inner layer.

18. The pharmaceutical production facility of any of claims 15-17, further comprising a platform in the buffer storage area, the platform being configured to support the at least one bioprocess container,
the at least one bioprocess container including a plurality of bioprocess containers,

the platform having a first level configured to support at least one bioprocess container of the plurality of bioprocess containers and a second level configured to support at least one bioprocess container of the plurality of bioprocess containers,

5 wherein the platform is configured to allow a user to place a bioprocess container of the plurality of bioprocess containers onto the platform using a forklift, and the platform being configured to allow a user to remove the respective bioprocess container from the platform using the forklift.

10 19. The pharmaceutical production facility of claim 18, further comprising a plurality of inlets spaced apart along the platform, each inlet being connected to the at least one pipe, and each inlet being configured to be connected to an outlet of a bioprocess container of the plurality of bioprocess containers.

15 20. The pharmaceutical production facility of any of claims 15-19, wherein the processing area is configured as a cleanroom environment.