CLAIMS

1. A manifold for a buffer management system, the manifold comprising:

a mixing junction;

a buffer inlet line, the buffer inlet line in fluid communication with the mixing junction;

a water for injection (WFI) inlet line, the WFI inlet line in fluid communication with the mixing junction;

a discharge line, the discharge line in fluid communication with both the buffer inlet line and the WFI inlet line via the mixing junction;

a first pump component, the first pump component disposed in the buffer inlet line, the first pump component configured to be operably arranged with a first pump motor to selectively generate a fluid displacement within the buffer inlet line;

a second pump component, the second pump component disposed in the WFI inlet line, the second pump component configured to be operably arranged with a second pump motor to selectively generate a fluid displacement within the WFI inlet line;

a buffer characteristic sensor, the buffer characteristic sensor disposed in the discharge line, the buffer characteristic sensor configured to detect a value of a buffer characteristic of a fluid in the discharge line and to generate a buffer characteristic signal indicative of the sensed value for the buffer characteristic;

wherein the buffer inlet line includes a plurality of buffer inlet ports in fluid communication therewith, the WFI inlet line includes a water port in fluid communication therewith, and the discharge line includes a plurality of buffer discharge ports in fluid communication therewith;

wherein the buffer inlet line, the WFI inlet line, the mixing junction, the discharge line, and the first and second single use pump components are connected together as a single use part.

2. The manifold according to claim 1, wherein ~~the buffer inlet line includes a plurality of buffer inlet ports in fluid communication therewith, the WFI inlet line includes a water port in fluid communication therewith, and the discharge line includes a plurality of buffer discharge ports in fluid communication therewith,~~ the plurality of buffer discharge ports ~~corresponding~~ corresponds to the plurality of buffer inlet ports.

3. The manifold according to claim 2, wherein the buffer inlet line, the WFI inlet line, and the discharge line comprise tubing adapted to be selectively occluded by a pinch valve externally mounted thereto.

4. The manifold according to any one of claim 1 to claim 3, further comprising:

a drain junction, the drain junction in fluid communication with the discharge line;

a waste line, the waste line being in fluid communication with the discharge line via the drain junction;

wherein the drain junction and the waste line are connected to and part of the single use part.

5. The manifold according to claim 4, wherein the buffer characteristic sensor comprises a first buffer characteristic sensor, the manifold further comprising:

a second buffer characteristic sensor, the second buffer characteristic sensor disposed in the waste line, the second buffer characteristic sensor configured to detect a value of the buffer characteristic of a fluid in the waste line and to generate a second buffer characteristic signal indicative of the sensed value for the buffer characteristic in the waste line.

6. The manifold according to claim 5, wherein the first buffer characteristic sensor and the second buffer characteristic sensor both comprise a conductivity sensor.

7. The manifold according to claim 5 or claim 6, wherein the drain junction comprises a first drain junction, the manifold further comprising:

A second drain junction, the second drain junction in fluid communication with both the WFI inlet line and the waste line such that the WFI inlet line is in fluid communication with the waste line via the second drain junction.

8. The manifold according to claim 7, wherein the buffer inlet line is in fluid communication with the waste line.

9. The manifold according to claim 7 or claim 8, further comprising:

a third drain junction, the third drain junction in fluid communication with, and interposed between, the buffer inlet line and the WFI inlet line;

wherein the buffer inlet line is in fluid communication with the waste line via the third drain junction, the WFI inlet line, and the second drain junction.

10. A dilution skid comprising:

a first pump body and a second pump body;

a control unit, the control unit in electrical communication with the first pump body and the second pump body, the control unit being configured to selectively operate the first pump body and the second pump body;

a single use manifold according to claim 1, the single use manifold operably arranged with the first pump body and the second pump body, the manifold including a first inlet line, a second inlet line, and a discharge line in fluid communication with both the first inlet line and the second inlet line, the manifold including a first pump head and a second pump head, the first pump head disposed in the first inlet line and operably arranged with the first pump body to selectively generate a fluid displacement within the first inlet line by operating the first pump body, and the second pump head disposed in the second inlet line and operably arranged with the second pump body to selectively generate a fluid displacement within the second inlet line by operating the second pump body.

11. The dilution skid according to claim 10, further comprising:

a plurality of control valves, each one of the plurality of control valves in electrical communication with the control unit and in operable relationship with the manifold to selectively occlude at least one of the first inlet line, the second inlet line, and the discharge line.

12. The dilution skid according to claim 11, further comprising:

a cabinet, the cabinet defining an interior cavity and having an exterior surface, the first pump body and the second pump body disposed within the interior cavity of the cabinet, and the single use manifold removably mounted to the exterior surface of the cabinet such that the manifold is in operable arrangement with the first pump body and the second pump body.

13. The dilution skid according to claim 11 or claim 12, wherein the single use manifold includes a buffer characteristic sensor, the buffer characteristic sensor disposed in the discharge line, the buffer characteristic sensor configured to detect a value of a buffer

characteristic of a fluid in the discharge line and to generate a buffer characteristic signal indicative of the sensed value for the buffer characteristic, the buffer characteristic sensor in electrical communication with the control unit to transmit the buffer characteristic signal thereto, the control unit being configured to control the operation of at least one of the first pump body and the second pump body based upon the buffer characteristic signal received from the buffer characteristic sensor.

14. The dilution skid according to claim 13, wherein the control unit is configured to control at least one of a pump speed and a volume displacement of at least one of the first pump body and the second pump body to adjust a volumetric ratio of a buffer solution flowing through the first inlet line and an amount of water for injection (WFI) flowing through the second inlet line and being blended together in the discharge line.

15. The dilution skid according to claim 13 or claim 14, wherein the control unit is configured to generate an alarm when the buffer characteristic signal is outside of a predetermined tolerance range.

16. The dilution skid according to any one of claim 11 to claim 15, wherein the first inlet line includes a plurality of first inlet ports in fluid communication therewith, the second inlet line includes a second inlet port in fluid communication therewith, and the discharge line includes a plurality of discharge ports in fluid communication therewith, the plurality of discharge ports corresponding to the plurality of first inlet ports, and wherein each of the first inlet ports, the second inlet port, and the discharge ports has associated therewith one of the plurality of control valves in operable relationship to selectively occlude the respective one of the first inlet ports, the second inlet port, and the discharge ports.

17 The dilution skid according to claim 16, wherein the single use manifold includes a drain junction and a waste line, the drain junction in fluid communication with the discharge line, and the waste line in fluid communication with the discharge line via the drain junction, and wherein the waste line has associated therewith one of the control valves to selectively occlude the waste line.

18. The dilution skid according to claim 17, wherein the single use manifold includes a buffer characteristic sensor, the buffer characteristic sensor disposed in the waste line, the buffer characteristic sensor configured to detect a value of a buffer characteristic of a fluid in the waste line and to generate a buffer characteristic signal indicative of the sensed

value for the buffer characteristic, the buffer characteristic sensor in electrical communication with the control unit to receive the buffer characteristic signal therefrom, the control unit configured to determine whether the liquid passing through the waste line is within a predetermined tolerance range of a given specification for a desired buffer based upon the buffer characteristic signal and to occlude the waste line via said one of the control valves when the fluid in the waste line is within the predetermined tolerance range.

19. A method of using a buffer management system, the method comprising:

drawing an amount of buffer concentrate and an amount of water for injection (WFI) to an inline dilution skid including a manifold according to any one of claim 1 to claim 9;

mixing the amount of buffer concentrate and the amount of WFI in the manifold of the inline dilution skid to form a diluted buffer solution;

sensing, at the inline dilution skid, a buffer characteristic of the diluted buffer solution;

transmitting a buffer characteristic signal indicative of a value for the sensed buffer characteristic to a control unit;

using the control unit to determine whether the diluted buffer solution is within a predetermined tolerance range for a selected buffer recipe based upon the buffer characteristic signal;

discharging the diluted buffer solution from the discharge line of the manifold of the inline dilution skid to a biocontainer once the control unit determines the diluted buffer solution is within the predetermined tolerance range.

20. The method according to claim 19, further comprising:

discharging the diluted buffer solution from the inline dilution skid through a waste line of the manifold when the control unit determines the diluted buffer solution is outside of the predetermined tolerance range;

using the controller to adjust at least one of a buffer pump drawing the amount of buffer concentrate to the inline dilution skid and a WFI pump drawing the amount of WFI to the inline dilution skid based upon the buffer characteristic signal.