CLAIMS

1. A buffer management system comprising:

a supply of concentrated buffer solution;

a dilution skid, the dilution skid including a single use manifold and a control unit, the single use manifold in fluid communication with the supply of concentrated buffer solution, the manifold adapted to be placed in fluid communication with a source of water for injection (WFI), the control unit configured to operate the dilution skid to selectively mix the supply of concentrated buffer solution with an amount of WFI from the source of WFI in the single use manifold to produce a diluted buffer solution;

a biocontainer assembly, the biocontainer assembly including a biocontainer bag and a fill level sensor, the biocontainer bag defining a storage volume, the biocontainer bag in fluid communication with the manifold of the dilution skid for storing diluted buffer solution therein, the fill level sensor configured to generate a fill level signal indicative of a volume of material within the storage volume of the biocontainer bag, and the fill level sensor in communication with the control unit of the dilution skid to transmit the fill level signal thereto;

wherein the control unit is configured to maintain a predetermined minimum volume of diluted buffer solution in the storage volume of the biocontainer bag based upon the fill level signal received from the fill level sensor.

2. The buffer management system according to claim 1, wherein the biocontainer assembly includes a shelf having a support surface configured to support the biocontainer bag, the support surface disposed at an oblique angle with respect to a horizontal axis, and wherein the fill level sensor comprises a capacitive fill level sensor, the capacitive fill level sensor mounted to the support surface.

3. The buffer management system according to claim 2, wherein the oblique angle at which the support surface is disposed is in a range between five degrees and forty-five degrees.

4. The buffer management system according to claim 2, wherein the oblique angle at which the support surface is disposed is in a range between fifteen degrees and thirty-five degrees.

5. The buffer management system according to any one of claim 2 to claim 4, wherein the shelf includes an upper end and a lower end, the lower end being disposed vertically below the upper end, and wherein the shelf includes a bag cradle mounted to the lower end, the bag cradle including an angled support surface configured to receive therein a bottom end of the biocontainer bag.

6. The buffer management system according to any one of claim 2 to claim 5, wherein the shelf includes an underside surface, and wherein the capacitive fill level sensor is mounted to the underside surface.

7. The buffer management system according to claim 6, wherein the underside surface of the shelf defines a recess, the capacitive fill level sensor disposed within the recess, and wherein the shelf includes a cover plate, the cover plate mounted to the underside of the shelf such that the cover plate is over the recess.

8. The buffer management system according to any one of claim 2 to claim 7, wherein the capacitive fill level sensor comprises a strip sensor configured to detect fill levels along the strip over a predetermined length.

9. The buffer management system according to any one of claim 2 to claim 7, wherein the capacitive fill level sensor comprises a plurality of fill level sensors arranged in spaced relationship to each other, a first fill level sensor being disposed at a first position corresponding to the predetermined maximum fill volume, and a second fill level sensor being disposed at a second position corresponding to the predetermined minimum fill volume.

10. The buffer management system according to any one of claim 1 to claim 9, wherein the single use manifold includes a buffer characteristic sensor, the buffer characteristic sensor configured to detect a value of a buffer characteristic of the diluted buffer solution in the single use manifold 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, wherein the control unit is configured to determine whether the diluted buffer solution is within a predetermined tolerance range of a given specification for a desired buffer based upon the buffer characteristic signal, and wherein the control unit is configured to selectively adjust a volumetric ratio of concentrated buffer solution to WFI flowing through the through the single use manifold based upon the buffer characteristic signal.

11. A buffer management system comprising:

at least one workstation configured to support a supply of concentrated buffer solution;

an inline dilution skid having a first pump body, a second pump body, a manifold, and a control unit,

the manifold operably arranged with the first pump body and the second pump body, the manifold including a buffer inlet line, a water for injection (WFI) inlet line, and a discharge line in fluid communication with both the buffer inlet line and the WFI inlet line, the buffer inlet line in selective fluid communication with the supply of concentrated buffer solution, the WFI inlet line adapted to be placed in fluid communication with a source of WFI, the manifold including a first pump head and a second pump head, the first pump head disposed in the buffer inlet line and operably arranged with the first pump body to selectively generate a fluid displacement within the buffer inlet line by operating the first pump body, and the second pump head disposed in the WFI inlet line and operably arranged with the second pump body to selectively generate a fluid displacement within the WFI inlet line by operating the second pump body, and

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 to produce a quantity of diluted buffer solution;

a biocontainer assembly including a biocontainer bag and a fill level sensor, the biocontainer bag defining a storage volume, the biocontainer bag in fluid communication with the manifold of the dilution skid for storing diluted buffer solution therein, the fill level sensor configured to generate a fill level signal indicative of a volume of material within the storage volume of the biocontainer bag, and the fill level sensor in communication with the control unit of the dilution skid to transmit the fill level signal thereto;

wherein the control unit is configured to stop production of the diluted buffer solution once a predetermined maximum volume of diluted buffer solution is in the storage volume of the biocontainer bag based upon the fill level signal received from the fill level sensor.

12. The buffer management system according to claim 11, wherein the 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.

13. The buffer management system according to claim 11 or claim 12, 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.

14. The buffer management system according to any one of claim 11 to claim 13, wherein the manifold incudes a drain junction and a waste line, the drain junction in fluid communication with the discharge line, and the waste line being in fluid communication with the discharge line via the drain junction.

15. The buffer management system according to claim 14, 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 line and the waste line such that the WFI line is in fluid communication with the waste line via the second drain junction.

16. The buffer management system according to claim 15, wherein the buffer inlet line is in fluid communication with the waste line.

17. The buffer management system according to claim 15 or claim 16, 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 line, and the second drain junction.

18. The buffer management system according to any one of claim 11 to claim 17, wherein said at least one workstation is configured to support a plurality of supplies of concentrated buffer solution, wherein the buffer inlet line includes a plurality of buffer inlet ports in fluid communication with a respective one of the plurality of supplies of concentrate buffer solution, wherein the discharge line includes a plurality of buffer discharge ports in fluid communication therewith, the plurality of buffer discharge ports corresponding to the plurality of buffer inlet ports, and wherein the manifold further includes a respective control valve associated with each one of the buffer inlet ports and the buffer discharge ports, each control valve in electrical communication with the control unit to selectively occlude the respective one of the buffer inlet ports or buffer discharge ports, the buffer management system further comprising:

a plurality of biocontainer assemblies including a biocontainer bag and a fill level sensor, the plurality of biocontainer assemblies corresponding to the number of supplies of concentrated buffer solutions, the plurality of buffer discharge ports in respective fluid communication with the biocontainer bag of a different one of the plurality of biocontainer assemblies, the fill level sensor of each one of the biocontainer assemblies configured to configured to detect the volume of material within the respective biocontainer bag and to generate a fill level signal indicative of the detected volume of material within the respective biocontainer bag, each of the fill level sensors in electrical communication with the control unit to transmit the respective fill level signal thereto.

19. The buffer management system according to claim 18, wherein the control unit is configured to maintain a predetermined minimum volume of diluted buffer solution in the storage volume of each biocontainer bag based upon the fill level signal received from the fill level sensor.

20. The buffer management system according to claim 18 or claim 19, wherein each biocontainer assembly includes a shelf having a support surface configured to support the biocontainer bag, the support surface disposed at an oblique angle with respect to a horizontal axis, and wherein the fill level sensor comprises a capacitive fill level sensor, the capacitive fill level sensor mounted to the support surface.