airflow path that both surrounds and partially penetrates (flows through) a portion of the reagents fluid reservoir. The cold airflow path is generated by an adjacent cold thermal assembly. The cold zone also contains a condensation control means for the control and removal of condensation within the cold zone.

Both the warm zone and cold zone further comprise a segregated independently controlled gas environment. In the warm zone this helps to provide for specific gas concentrations that influence dissolved gases present in cell culture media such as oxygen and carbon dioxide through fluid surface gas exchange. The adjustment and/or maintenance of dissolved gases is influential in terms of biological performance, including examples such as the delivery of oxygen and the maintenance of a target pH for the cell culture. The control of dissolved gases within the culture media is achieved through the recirculation of culture media across a gas exchange membrane (such as silicone tubing) whereby the concentration of dissolved gases within the culture fluid responds to the concentration gradient between the fluid and the surrounding gaseous environment. By adjusting the environment, the level of dissolved gases within the culture fluid is simultaneously adjusted.

The automated cell culture and tissue engineering system is configured with a movable thermal barrier assembly that, during installation of a cell culture cassette, serves to lock the cassette within the system operational interface and in doing so, forms the warm zone and the cold zone and keeps these two zones thermally and physically separated. Insulating mechanisms are provided to ensure that the warm zone and cold zone are insulated from each other and do not influence either the cell culture or the properties of the stored reagents. The movable thermal barrier assembly creates and defines portions of the borders of each of the warm zone and the cold zone.

The system heating and cooling assemblies, as well as operational robotics are contained/positioned separate to that of the cassette receiving area of the system, which is beneficial not to interfere with warm airflow or cold airflow paths and their function. Further, the heating assembly is segregated to be separate and insulated from the cooling assembly. The system heating assembly is configured to generate and regulate the temperature of the continuous warm high airflow path for several days as is required and further can quickly adjust for any temperature drop that may occur due to the entrance of cooler room temperature air during opening and inspection of the system. The configuration and shape of the system helps to provide for a warm airflow path to be directed solely at the bioreactor module and continually circulate around and through it. The cold thermal assembly is configured to continually remove heat as airflow in the cold zone is continually

drawn through a cold thermal assembly and the air temperature is reduced. The cold zone is configured to have a channeled airflow, that is, the cold airflow path follows structural features including airflow channels, airflow baffles and air flow vents to help carry the cooled air through the cold zone around and partially through the reagents fluid reservoir and further through an optional adjacent cold reservoir external to the reagents fluid reservoir. These structural features help to prevent and minimize any blockage of the return air (by filled fluids bags) traveling toward to the cold thermal assembly.

The provision of a separate warm zone and separate cold zone minimizes the amount and location of condensation that may form within the system as the system is only subjected to condensation in the cold zone which has a mechanism to effectively prevent, control and remove condensation.

The disclosure in examples comprises an automated cell culture and tissue engineering system that comprises a closed automated cell culture cassette for the one of more of cell source isolation, cell proliferation/expansion, cell differentiation, cell isolation, cell labelling, cell purification, cell washing and cell seeding onto scaffolds for tissue formation (product formation). In examples, the cells are mammalian. In further examples, human cells. The type of cell or tissue is not limiting. In one non-limiting example, pluripotent stem cells, such as embryonic stem cells and induced pluripotent stem (iPS) cells, may be cultured and expanded for cell replacement therapy.

The automated cell culture cassette is in examples a closed, single-use disposable cassette comprising one or more sterile bioreactor modules fluidly connected to a reagent fluids reservoir. The sterile bioreactor is loaded with desired cells and/or tissue and connected to the reagent fluid reservoir which is preloaded to contain the required fluid reagents. The sterility of the cassette is maintained throughout.

The automated cell culture cassette is operatively employed within an automated cell culture and tissue engineering system along with a dedicated software program to deliver and track a desired process(es). Suitable non limiting automated cell culture and tissue engineering systems are described in U.S. 8,492,140; U.S. 9,701,932; U.S. 9,534,195; U.S. 9,499,780; and U.S. 9,783,768 (the contents of each of these U.S. patents is incorporated by reference in their entireties).

Embedded sensors within the cell culture cassette, provide real-time biofeedback and enable automatic adjustment in bioprocessing to accommodate natural variations in cell source behaviour. The entire bioprocess is contained within the disposable cassette to ensure maximum patient and operator safety and to streamline logistics. Further, in order to

successfully support multiple biological steps in a cell process sequence, the cassette bioreactor(s) are integrated in combination with biosensor feedback within one or more interlinked bioreactors, to provide a highly intuitive system with precise control at each cell and tissue stage. This comprehensive level of automation enable technically feasible and economical scale-up, patient-scale cell manufacturing capabilities and allows streamlined production of cell therapies under good manufacturing practice (GMP) conditions thus meeting the unique challenges of different autologous and allogeneic clinical applications of cell and tissue therapy.

Advantageously, the cell culture cassette is installed and operationally retained within the cell culture and tissue engineering system housing in a manner that the bioreactor module resides solely in the distinct warm zone and the reagents fluid reservoir resides solely in a distinct cold zone. The installation of the cell culture cassette into the system is via the actuation and locking of a movable thermal barrier assembly that environmentally isolates the first thermal zone from the second thermal zone with respect to temperature, gases and humidity. The cell culture cassette comprises the bioreactor module with attached reagents fluids reservoir. While this combination into a single cell culture cassette is more user friendly, it poses more of a challenge with respect to creating separate and distinct environmental zones for the bioreactor module and for the reagents fluid reservoir versus a more simplistic design based on physically separate bioreactor module and reservoir that can be located in separate environmental zones.

The disclosure provides dedicated airway paths within the warm zone and the cold zone ensuring controlled distribution of temperature/gas is provided about the bioreactor module housing the cell culture(s) and about the reagents fluid reservoir in a manner to preclude points of distortions of uniformity in each zone.

In examples of the disclosure is a cell culture and tissue engineering system comprising two distinct independent thermal airflows, a first airflow comprising a high velocity warm airflow for directing at and around a bioreactor module of a cell culture cassette, and a second airflow comprising a cold airflow for circulating around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate substantially (these zones in examples are not hermetically sealed relative to each other) and cannot intermingle.

In examples the first airflow and said second airflow are contained within a cell culture cassette receiving area of said system.

In examples, the cell culture cassette receiving area is separate from operational, heating and cooling assemblies of the system.

In examples the cell culture cassette receiving area defines a warm zone that comprises the high velocity warm airflow.

In examples the warm zone comprises substantially homogeneous temperature within the warm zone.

In examples the cell culture cassette receiving area defines a cold zone that comprises the cold airflow, said cold zone positioned beneath the warm zone.

In examples the cold zone comprises a means for reducing or eliminating condensation.

In examples a thermal platform separates the warm zone from the cold zone. In examples, the thermal platform contains seals.

In examples of the disclosure is a method for maintaining a controlled thermal environment for biological processes within a bioreactor module of a cell culture cassette, the method comprising:

directing a first airflow comprising a high velocity warm airflow at and around the bioreactor module, and simultaneously circulating a cold air flow around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate and cannot intermingle.

In one aspect, the present disclosure refers to a method for maintaining a controlled thermal environment for biological processes within a bioreactor module of a cell culture cassette, the method comprising:

creating and maintaining a distinct high velocity warm airflow at and around the bioreactor module, and simultaneously creating and circulating a distinct cold air flow around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate and cannot intermingle.

According to an example of the disclosure is a cell culture and tissue engineering system comprising a thermal zone architecture for providing a more consistent and controlled environment for facilitating biological processes, wherein the system comprises:

a distinct warm zone compartment that retains a bioreactor module while continuously circulating a high velocity warm airflow path around and directed at and around the bioreactor module; and

a distinct cold zone compartment that retains a reagents fluid reservoir functionally connected to the bioreactor module, while continuously circulating a cold airflow path around and through the reagents fluid reservoir.

In examples, the distinct cold zone compartment further comprises a means for reducing or eliminating condensation.

In examples, the warm zone compartment further comprises a distinct gas environment to that of the cold zone compartment.

According to a further example of the disclosure is an automated system for cell culture and tissue engineering that retains a cell culture cassette in two distinct temperature and gas controlled environments, wherein a biological reactor component of the cassette is

operatively retained in a substantially homogeneous warm airflow zone with controlled gas concentrations, and wherein a reagents fluid reservoir component of the cassette resides in a substantially homogeneous cold airflow zone, wherein the warm airflow zone is distinctly separated from the cold airflow zone, and wherein the cold airflow zone further comprises a means for preventing or eliminating undesirable moisture accumulation therein.

According to a further example of the disclosure is a cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette in a more consistently controlled environment for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a warm zone configured for circulating a warm airflow path surrounding the bioreactor module;

a cold zone configured for circulating a cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module solely within the warm zone and the reagents fluid reservoir solely within the cold zone.

In another aspect, the present disclosure refers to a cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a warm zone configured to circulate a warm airflow path surrounding the bioreactor module;

a cold zone configured to circulate a cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module within the warm zone and the reagents fluid reservoir within the cold zone.

According to a further example of the disclosure is a cell culture cassette comprising:

- a bioreactor module having a bottom part attached with a reagents fluid reservoir;
- the reagents fluid reservoir comprising a fluids bag container having open air ducts located on front and back walls of the reservoir.

In examples, the fluids bag container comprises a roof and floor, the roof comprising baffles extending downwardly.

In examples, the cassette further comprises a layer of thermal insulation positioned in between the bottom of the bioreactor module and the roof of the fluids bag container, said layer of thermal insulation insulating against migration of heat from the bioreactor module.

In examples, the reagents fluid reservoir is attached via port connections positioned on the roof of said fluids bag container and unobstructed by said layer of thermal insulation.

In examples, the reagents fluid reservoir further comprises snap tabs for attaching to the bioreactor module.

According to a further example of the disclosure is a reagents fluid reservoir for connection to a bioreactor module, the reagents fluid reservoir comprising a fluids bag container having open air ducts located on front and back walls of the reservoir.

In examples, the fluids bag container comprises a roof and floor, the roof comprising baffles extending downwardly.

According to an example of the disclosure is an automated cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette in a more consistently controlled environment for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a warm zone configured for circulating a tangential warm airflow path surrounding the bioreactor module;

a cold zone configured for circulating a tangential cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module solely within the warm zone and the reagents fluid reservoir solely within the cold zone.

In another aspect, the present disclosure refers to an automated cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a housing comprising an outer shell cover and an inner shell body, wherein the outer shell cover encloses a front opening of the inner shell body in an enveloped manner when the system is closed;

a warm zone including a heating assembly configured to circulate a tangential warm airflow path surrounding the bioreactor module;

a cold zone including a cold thermal assembly configured to circulate a tangential cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module within the warm zone and the reagents fluid reservoir within the cold zone.

In any of the aforementioned examples, the system and method may comprise one or more controllers and associated software, sensors, and user interface.

Non-limiting examples are as follows:

1A. A cell culture and tissue engineering system comprising two distinct independent thermal airflows, a first airflow comprising a high velocity warm airflow for directing at and around a bioreactor module of a cell culture cassette, and a second airflow comprising a cold airflow for circulating around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate and cannot intermingle.

1B. The system of item 1A, wherein said first airflow and said second airflow are contained within a cell culture cassette receiving area of said system.

1C. The system of item 1B, wherein said cell culture cassette receiving area defines a warm zone that comprises the high velocity warm airflow.

1D. The system of item 1C, wherein said warm zone comprises substantially homogeneous temperature within the warm zone.

1E. The system of item 1B, 1C or 1D, wherein said cell culture cassette receiving area defines a cold zone that comprises the cold airflow, said cold zone positioned beneath the warm zone.

1F. The system of item 1E, wherein said cold zone comprises a means for reducing or eliminating condensation.

1G. The system of item 1F, wherein a thermal platform separates the warm zone from the cold zone.

1H. A method for maintaining a controlled thermal environment for biological processes within a bioreactor module of a cell culture cassette, the method comprising:

directing a first airflow comprising a high velocity warm airflow at and around the bioreactor module, and simultaneously circulating a cold air flow around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate and cannot intermingle.

1J The method of item 1H using the system of any one of items 1A to 1H.

2A. A cell culture and tissue engineering system comprising a thermal zone architecture for providing a more consistent and controlled environment for facilitating biological processes, wherein the system comprises:

a distinct warm zone compartment that retains an bioreactor module while continuously circulating a high velocity warm airflow path around and directed at and around the bioreactor module; and

a distinct cold zone compartment that retains a reagents fluid reservoir functionally connected to the bioreactor module, while continuously circulating a cold airflow path around and through the reagents fluid reservoir.

2B. The system of item 2A, wherein the distinct cold zone compartment further comprises a means for reducing or eliminating condensation.

2C. The system of item 2A or 2B, wherein said warm zone compartment further comprises a distinct gas environment to that of the cold zone compartment.

2D A method for maintaining a controlled environment for biological processes within a bioreactor and for maintaining fluids required for the bioreactor at a cool temperature for stability, the method comprising the use of the system of any one of items 2A to 2C.

3A. An automated system for cell culture and tissue engineering that retains a cell culture cassette in two distinct temperature and gas controlled environments, wherein a biological reactor component of the cassette is operatively retained in a substantially homogeneous warm airflow zone with controlled gas concentrations, and wherein a reagents fluid reservoir component of the cassette resides in a substantially homogeneous cold airflow zone, wherein the warm airflow zone is distinctly separated from the cold airflow zone, and wherein the cold airflow zone further comprises a means for preventing or eliminating undesirable moisture accumulation therein.

3B. A method for maintaining a controlled environment for biological processes within a bioreactor and for maintaining fluids required for the bioreactor at a cool temperature for stability, the method comprising the use of the system of item 3A.

1. A cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette in a more consistently controlled environment for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a warm zone configured for circulating a warm airflow path surrounding the bioreactor module;

a cold zone configured for circulating a cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module solely within the warm zone and the reagents fluid reservoir solely within the cold zone.

2. The cell culture and tissue engineering system of item 1, wherein said cold zone further comprises a condensation control means for minimizing and eliminating undesirable moisture accumulation therein.

3. The cell culture and/or tissue engineering system of item 1 or 2, wherein said warm zone and said cold zone each comprise a substantially segregated gas environment.

4. The cell culture and tissue engineering system of item 1, 2 or 3, said system having a housing comprising an outer shell cover and an inner shell body, wherein the outer shell cover encloses a front opening of the inner shell body in an enveloped manner when the system is closed.

5. The cell culture and tissue engineering system of item 5, wherein said outer shell cover is connected to the inner shell body for rotation while the inner shell body remains stationary, the outer shell cover rotates along an outer arc of the inner shell body to expose the front opening of the inner shell body for access thereto and stops rotating when the outer shell cover nests the inner shell body.

6. The cell culture and tissue engineering system of item 4 or 5, wherein said front opening of the inner shell body comprises a periphery with an inflatable sealing means for a sealing engagement with an inside surface of the outer shell body when the system is closed.

7. The cell culture and tissue engineering system of item 6, wherein said periphery comprises a U shaped channel for retaining said inflatable sealing means.

8. The cell culture and tissue engineering system of item 7, wherein the sealing means comprises an elastomeric tube that fits within the U shaped channel, the elastomeric tube being substantially flat when the system is open and the sealing means activated upon closing the system to introduce an inflation pressure into the cavity of the inflatable seal causing

displacement of the seal to effect a positive seal between the outer shell cover and the front opening of the inner shell body.

10. The cell culture and tissue engineering system of item 9, wherein said outer shell cover is configured as an arc-shaped body that helps to direct the circulating warm airflow path surrounding the bioreactor module and also helps to direct the circulating cold airflow path surrounding the reagents fluid reservoir.

11. The cell culture and tissue engineering system of item 10, wherein said arc-shaped body comprises a plurality of thermal cells to act as an exterior thermal barrier.

12. The cell culture and tissue engineering system of any one of items 4 to 11, wherein the movable thermal barrier assembly is disposed on an operational robotics interface positioned within the front opening of the inner shell body.

13. The cell culture and tissue engineering system of item 12, wherein said operational robotics interface is connected to associated internal robotics and comprises valve actuators, peristaltic pumps and related control systems for mating with corresponding connections on the cell culture cassette.

14. The cell culture and tissue engineering system of any one of items 4 to 11, wherein said movable thermal barrier assembly comprises:

- a pair of spaced apart levered arms internally connected at either side of the operational robotics interface that support a central thermal platform with an associated upper handrail

15. The cell culture and tissue engineering system of item 14, wherein said movable thermal barrier assembly is movable from a first raised position for installing the cell culture cassette, to a second lowered position that locks and retains the cell culture cassette against the operational robotics interface for accurate alignment and retention thereto and simultaneously isolating the warm zone from the cold zone.

16. The cell culture and tissue engineering system of item 15, wherein said upper handrail is sized to closely conform to dimensions of the cell culture cassette and provide a gripping means to lock the cassette into position for operation or to raise the thermal platform.

17. The cell culture and tissue engineering system of item 14, 15 or 16, wherein recesses are provided on the operational robotics interface adjacent said levered arms for providing operator controlled access to open the assembly.

18. The cell culture and tissue engineering system of any one of items 14 to 17, wherein said thermal platform extends forward and radiates from around the cell culture cassette to the outer shell cover.

19. The cell culture and tissue engineering system of item 18, wherein the thermal platform comprises a flexible outer seal at its front outer boundary to accommodate relative motion between the thermal platform and the outer shell cover and a flexible inner seal that is directly adjacent to the cell culture cassette.

20. The cell culture and tissue engineering system of item 19, wherein the flexible inner seal accommodates mounting tolerances of the cell culture cassette.

21. The cell culture and tissue engineering system of item 19 or 20, wherein said flexible outer seal and the said flexible inner seal are elastomeric and impermeable to vapor.

22. The cell culture and tissue engineering system of item 21, wherein said flexible outer seal and the said flexible inner sear are wiper-style seals.

23. The cell culture and tissue engineering system of any one of items 14 to 22, wherein when in the locked position the thermal platform comprises part of the lower surface boundary of the warm zone and part of the upper surface boundary of the cold zone.

24. The cell culture and tissue engineering system of any one of items 14 to 18, wherein the inner shell body comprises a floor supporting a tray with forward cantilevered ledge that supports part of a bottom surface of the cell culture cassette.

24a. The cell culture and tissue engineering system of item 24, wherein an airflow duct is defined by the floor and the tray.

25. The cell culture and tissue engineering system of any one of items 4 to 24, wherein a heating assembly is provided in an upper section of the inner shell body generates warm air directed at the bioreactor module.

26. The cell culture and tissue engineering system of item 25, wherein the heating arrangement comprises a high capacity linear fan operably connected to a heated airflow director to generate and direct a high velocity warm airflow path.

27. The cell culture and tissue engineering system of item 26, wherein the high tangential warm airflow path surrounding the bioreactor module promotes uniformity of temperature of the warm zone and thus of biological processes within the bioreactor.

28. The cell culture and tissue engineering system of item 27, wherein the high tangential velocity warm airflow path surrounding the bioreactor module helps to maintain the bioreactor internal temperature at about 35°C, at about 36°C, at about 37°C, at about 38°C or at about 39°C.

28a. The cell culture and tissue engineering system of item 28, wherein gases are selectively introduced into the warm zone.

28b. The cell culture and tissue engineering system of item 28a, wherein gases comprise one or more of oxygen, carbon dioxide and nitrogen.

28c. The cell culture and tissue engineering system of item 28a or 28b, wherein the warm zone comprises sensors in the in the warm airflow path for monitoring the gases.

28d. The cell culture and tissue engineering system of item 28c, wherein the sensors are operatively connected to a PID (proportional integral derivative) controller providing feedback control of gases.

29. The cell culture and tissue engineering system of any one of items 4 to 28, wherein a cold thermal assembly forms the rear of the inner shell body and generates and controls the cold zone airflow path surrounding the reagent fluid reservoir for enhanced reagent stability.

30. The cell culture and tissue engineering system of item 29, wherein said cold thermal assembly comprises a cold sink array that comprises a plurality of cold sinks compressed with a peltier device to a hot sink for transfer of heat to the hot sink.

31. The cell culture and tissue engineering system of item 30, wherein compression is spring compression utilizing a Peltier solid-state device comprising an array of spring compression bolts each comprising coil springs, the hot sink acting as a heat conductive path for heat removal.

32. The cell culture and tissue engineering system of item 31, wherein said Peltier solid-state device functions to pump heat from the cold sinks to the hot sink for subsequent heat transfer to an ambient environment.

33. The cell culture and tissue engineering system of any one of items 30 to 32, wherein each cold sink array is segmented into functional units comprising a cold sink and associated axial fan.

34. The cell culture and tissue engineering system of item 33, wherein the axial fan has an axial flow configuration.

35. The cell culture and tissue engineering system of item 33 or 34, wherein the cold sink comprises a vertical fin structure.

36. The cell culture and tissue engineering system of any one of items 29 to 35, further comprising thermal insulation to inhibit heat from returning to the cold sink from the hot sink.

37. The cell culture and tissue engineering system of any one of items 2 to 36, wherein said condensation control means comprises a moisture transport material enclosed within a

duct connected to the hot sink, the moisture transport material collecting and moving any condensate that may form and that travels down the cold sink and through to the hot sink where it is evaporated.

38. The cell culture and tissue engineering system of item 37, wherein said condensation control means minimizes and eliminates undesirable microbial contamination from moisture accumulation.

39. The cell culture and tissue engineering system of any one of items 29 to 38, wherein the cold thermal assembly can be unhinged from the bottom of the inner shell body to hang in an open configuration for cleaning.

40. The cell culture and tissue engineering system of item 39, wherein the cold sink array and associated axial fan may be uncoupled for cleaning.

41. The cell culture and tissue engineering system of item 40, wherein the hot sink fan and associated cowling may be unlatched from an upper portion of the inner shell body and raised into an open configuration for cleaning.

42. The cell culture and tissue engineering system of any one of items 1 to 41, wherein the reagent fluids reservoir is fluidly connected to the bioreactor module via top mounted port connections for mating with ports on an underside of the bioreactor module.

43. The cell culture and tissue engineering system of item 42, wherein the reagent fluids reservoir further comprises snap tabs for reversible attachment to the bioreactor module.

44. The cell culture and tissue engineering system of item 43, wherein the reagent fluids reservoir accommodates reagents required for biological processes and accommodates the retention of waste products eliminated from the bioreactor module.

45. The cell culture and tissue engineering system of item 44, wherein the reagent fluids reservoir comprises a fluid bags container for storing a plurality of separate reagents and for storing the waste products.

46. The cell culture and tissue engineering system of item 45, wherein said plurality of separate reagents are stored in reagent bags.

47. The cell culture and tissue engineering system of item 46, wherein the waste products are stored in reagent bags.

48. The cell culture and tissue engineering system of item 46 or 47, wherein said reagent bags are flexible reagent bags.

49. The cell culture and tissue engineering system of any one of items 44 to 48, wherein the reagent fluids reservoir further comprises open air ducts located at the top of front and

back walls such that the open air ducts are positioned above said reagent bags providing cold airflow directly above the reagent bags.

50. The cell culture and tissue engineering system of item 49, further wherein the reagent fluids reservoir comprises a roof with downwardly extending baffles to help direct the cold airflow above and across the reagent bags.

51. The cell culture and tissue engineering system of item 50, wherein said cell culture cassette further comprises a layer of thermal insulation positioned in between said bioreactor module and said reagent fluids reservoir, said layer of thermal insulation insulating against any migration of heat from the bioreactor module.

52. A cell culture cassette comprising:

- a bioreactor module having a bottom part attached with a reagents fluid reservoir;
- the reagents fluid reservoir comprising a fluids bag container having open air ducts located on front and back walls of the reservoir.

53. The cell culture cassette of item 52, wherein the fluids bag container comprises a roof and floor, the roof comprising baffles extending downwardly.

54. The cell culture cassette of item 52 or 53, wherein the cassette further comprises a layer of thermal insulation positioned in between the bottom of the bioreactor module and the roof of the fluids bag container, said layer of thermal insulation insulating against migration of heat from the bioreactor module.

55. The cell culture cassette of any one of items 53 or 54, wherein the reagents fluid reservoir is attached via port connections positioned on the roof of said fluids bag container and unobstructed by said layer of thermal insulation.

56. The cell culture cassette of item 55, wherein the reagents fluid reservoir further comprises snap tabs for attaching to the bioreactor module.

57. An automated cell and tissue culture engineering system comprising the cell culture cassette of any one of items 52 to 56.

57a. The automated system of item 57, wherein the cassette comprises one or more sensors linked to a logic means.

58. A reagents fluid reservoir for connection to a bioreactor module, the reagents fluid reservoir comprising a fluids bag container having open air ducts located on front and back walls of the reservoir.

59. The reagents fluid reservoir of item 57, further wherein the fluids bag container comprises a roof and floor, the roof comprising baffles extending downwardly.

60. A cell culture cassette comprising a bioreactor module and a reagents fluid reservoir according to item 58 or 59.

61. An automated cell culture and tissue engineering system for receiving and operationally supporting an automated cell culture cassette in a more consistently controlled environment for biological processes, the cell culture cassette comprising a bioreactor module and a reagents fluid reservoir, the system comprising:

a warm zone configured for circulating a tangential warm airflow path surrounding the bioreactor module;

a cold zone configured for circulating a tangential cold airflow path surrounding the reagents fluid reservoir; and

a movable thermal barrier assembly for thermally isolating said warm zone from said cold zone upon installation of the cell culture cassette, and for securing the bioreactor module solely within the warm zone and the reagents fluid reservoir solely within the cold zone.

62. A method for maintaining a controlled thermal environment for biological processes within a bioreactor module of a cell culture cassette, the method comprising:

creating and maintaining a distinct high velocity warm airflow at and around the bioreactor module, and simultaneously creating and circulating a distinct cold air flow around and through a reagents fluid reservoir operatively connected to the bioreactor module,

wherein said first airflow and said second airflow are separate and cannot intermingle.

Brief Description of the Drawings:

The following description of typical aspects described herein will be better understood when read in conjunction with the appended drawings. For the purpose of illustrating the invention, there are shown in the drawings aspects which are presently typical. It should be understood, however, that the invention is not limited to the precise arrangements and instrumentalities of the aspects shown in the drawings. It is noted that like reference numerals refer to like elements across different embodiments as shown in the drawings and referred to in the description.

The description herein will be more fully understood in view of the following drawings:

Figure 1 illustrates a cross section of one embodiment of a cell culture and tissue engineering system of the invention showing a cell culture cassette engaged to operational robotics with the thermal barrier assembly in a locked position;