[0006] As set forth in more detail below, the present disclosure provides an improved injector embodying advantageous alternatives to the conventional devices and methods discussed above.

Summary

[0007] According to an aspect of the present disclosure, an injector includes a container, a seal assembly, a fluid delivery system, and an actuator. The container includes a container wall with an interior surface. The wall of the container defines a bore, and the container further includes a stopper that is moveable along the bore. The seal assembly includes a flexible seal assembly wall with an interior surface, the interior surfaces of ~~a~~ the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall to define an enclosed space between the flexible wall and the barrier. The fluid delivery system includes a sterile container needle having a point disposed only through the barrier in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the flexible wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir. The sterile container needle is attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state. The actuator is adapted to move the container needle from the storage state to the delivery state.

[0007A] According to another aspect of the present disclosure, an injector includes a container, a seal assembly, a fluid delivery system, and an actuator. The container includes a container wall with an interior surface. The wall of the container defines a bore, and the container further includes a stopper that is moveable along the bore. The seal assembly includes a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall, the stopper, and the seal assembly wall defining a closed sterile reservoir adapted to be filled with a medical fluid or drug product. The fluid delivery system includes a sterile container needle having a point disposed only partially through the seal assembly wall in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the seal assembly wall into the sterile reservoir in a delivery state such that

the sterile container needle is in fluid communication with the reservoir. The sterile container needle is attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state. The actuator is adapted to move the container needle from the storage state to the delivery state.

[0008] According to another aspect of the present disclosure, a method of assembling an injector includes filling a sterile reservoir of a container with a medical fluid or drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container, mechanically coupling a sterile fluid delivery system to the container under sterile conditions, the fluid delivery system not in fluid communication with the reservoir in a storage state and in fluid communication with the reservoir in a delivery state, and assembling the remainder of the injector under clean room conditions.

Brief Description of the Drawings

[0009] The disclosure will be more fully understood from the following description taken in conjunction with the accompanying drawings. Some of the figures may have been simplified by the omission of selected elements for the purpose of more clearly showing other elements. Such omissions of elements in some figures are not necessarily indicative of the presence or absence of particular elements in any

We claim:

1. An injector comprising:

a container including a container wall with an interior surface;

a seal assembly including a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall to define an enclosed space between the flexible wall and the barrier;

a fluid delivery system comprising a sterile container needle having a point disposed only through the barrier in a storage state, and disposed through the flexible wall into the sterile reservoir in a delivery state,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state; and

an actuator that is adapted to move the container needle from the storage state to the delivery state.

2. The injector of claim 1, wherein the connector is press fit onto the container.

3. The injector of any one of the preceding claims, wherein the connector is a first connector of a pair of connectors, a second connector of the pair of connectors being attached to the container, the first and second of the pair of connectors mechanically coupled to secure the sterile container needle to the container in the storage state.

4. The injector of claim 3, wherein the first and second connectors each comprise one of a pair of facing surfaces, the facing surfaces abutting to limit

movement of the first and second connectors axially along a longitudinal axis of the sterile container needle.

5. The injector of any one of claims 3 to 4, wherein the first and second connectors engage to rotatably couple the pair of connectors to secure the sterile container needle to the container in the storage state.

6. The injector of any one of claims 3 to 5, wherein the first and second connectors threadingly engage to couple the pair of connectors to secure the sterile container needle to the container in the storage state.

7. The injector of any one of claims 3 to 6, wherein the container comprises a rim disposed about an opening, the seal assembly being disposed over the opening in the container, and the second connector comprising a rim and disposed over the seal assembly, the container further comprising a crimp ring formed about the rim of the container and the rim of the second connector with the seal assembly disposed between the rims to secure the seal assembly between the rim of the container and the rim of the second connector.

8. The injector of claim 7, wherein the second connector has a passage therethrough, the sterile container needle disposed through the passage in the second connector and through the barrier in the storage state.

9. The injector of any one of claims 3 to 8, wherein the first connector comprises a collar disposed continuously about the sterile connector needle.

10. The injector of any one of claims 3 to 8, wherein the first connector comprises a collar disposed discontinuously about the sterile connector needle.

11. The injector of any one of the preceding claims, wherein the wall of the container comprises a rigid wall.

12. The injector of any one of the preceding claims, wherein the wall of the container defines a bore, and the container further comprises a stopper that is moveable along the bore.

13. The injector of any one of the preceding claims, wherein the container wall defines a bore with an opening in fluid communication with a first end of the bore, and the flexible wall defines a septum disposed across the opening and fixedly attached to the container wall.

14. The injector of any one of the preceding claims, wherein the fluid delivery system comprises sterile flexible tubing connected at a first end to the container needle and a second end to a sterile injection needle received within a sterile cover that closes off the sterile injection needle.

15. The injector of any one of the preceding claims, wherein the actuator is adapted to delay movement of the container needle from the storage state to the delivery state after an input is received.

16. The injector of claim 15, further comprising a mechanical, electro-mechanical, or electrical input device coupled to the actuator.

17. The injector of any one of the claims 1 to 16, wherein the medical fluid or drug product comprises a volume of an erythropoiesis stimulating agent.

18. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of a granulocyte colony-stimulating factor.

19. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of a TNF blocker.

20. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of a pegylated granulocyte colony-stimulating factor.

21. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of interleukin-receptor specific antibody.

22. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of IGF-receptor (Insulin Growth Factor receptor) specific antibody.

23. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of TGF-specific antibody.

24. The injector of any one of claims 1 to 16, wherein the medical fluid or drug product comprises a volume of PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) - specific antibody.

25. A method of assembling an injector, the method comprising:

filling a sterile reservoir of a container with a medical fluid or drug product under sterile conditions, the reservoir defined by an interior surface of a wall of the container;

mechanically coupling a sterile fluid delivery system to the container under sterile conditions, the fluid delivery system not in fluid communication with the reservoir in a storage state and in fluid communication with the reservoir in a delivery state; and

assembling the remainder of the injector under clean room conditions.

26. The method of claim 25, wherein the step of filling the sterile reservoir follows the step of mechanically coupling the sterile fluid delivery system to the container.

27. The method of any one of claims 25 to 26, wherein the step of mechanically coupling the sterile fluid delivery system to the container follows the step of filling the sterile reservoir.

28. The method of any one of claims 25 to 27, wherein the step of mechanically coupling the sterile fluid delivery system occurs within a fill/finish suite.

29. The method of any one of claims 25 to 28, wherein assembling the remainder of the injector comprises:

attaching the fluid delivery system to an actuator under clean room conditions, the actuator adapted to change the state of the fluid delivery system from the storage state to a delivery state.

30. A subassembly comprising:

a container including a container wall with an interior surface;

a seal assembly including a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier

disposed exterior of the seal assembly wall to define an enclosed space between the flexible wall and the barrier; and

a fluid delivery system comprising a sterile container needle having a point disposed only through the barrier in a storage state, and disposed through the flexible wall into the sterile reservoir in a delivery state,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state.

31. The subassembly of claim 30, wherein the connector is press fit onto the container.

32. The subassembly of any one of claims 30 to 31, wherein the connector is a first connector of a pair of connectors, a second connector of the pair of connectors being attached to the container, the first and second of the pair of connectors mechanically coupled to secure the sterile container needle to the container in the storage state.

33. The subassembly of claim 32, wherein the first and second connectors each comprise one of a pair of facing surfaces, the facing surfaces abutting to limit movement of the first and second connectors axially along a longitudinal axis of the sterile container needle.

34. The subassembly of claim 33, wherein the first and second connectors engage to rotatably couple the pair of connectors to secure the sterile container needle to the container in the storage state.

35. The subassembly of any one of claims 33 to 34, wherein the first and second connectors threadingly engage to couple the pair of connectors to secure the sterile container needle to the container in the storage state.

36. The subassembly of any one of claims 32 to 35, wherein the container comprises a rim disposed about an opening, the seal assembly being disposed over the opening in the container, and the second connector comprising a rim and disposed over the seal assembly, the container further comprising a crimp ring formed about the rim of the container and the rim of the second connector with the seal assembly disposed between the rims to secure the seal assembly between the rim of the container and the rim of the second connector.

37. The subassembly of claim 36, wherein the second connector has a passage therethrough, the sterile container needle disposed through the passage in the second connector and through the barrier in the storage state.

38. The subassembly of any one of claims 32 to 35, wherein the first connector comprises a collar disposed continuously about the sterile connector needle.

39. The subassembly of any one of claims 32 to 35, wherein the first connector comprises a collar disposed discontinuously about the sterile connector needle.

40. An injector comprising:

a container including a container wall with an interior surface;

a seal assembly including a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product;

a fluid delivery system comprising a sterile container needle having a point disposed only partially through the seal assembly wall in a storage state, and disposed through the seal assembly wall into the sterile reservoir in a delivery state,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state; and

an actuator that is adapted to move the container needle from the storage state to the delivery state.

41. The injector of claim 40, wherein the connector is press fit onto the container.

42. The injector of any one of claims 40 to 41, wherein the connector is a first connector of a pair of connectors, a second connector of the pair of connectors being attached to the container, the first and second of the pair of connectors mechanically coupled to secure the sterile container needle to the container in the storage state.

43. The injector of claim 42, wherein the first and second connectors each comprise one of a pair of facing surfaces, the facing surfaces abutting to limit movement of the first and second connectors axially along a longitudinal axis of the sterile container needle.

44. The injector of claim 43, wherein the first and second connectors engage to rotatably couple the pair of connectors to secure the sterile container needle to the container in the storage state.

45. The injector of any one of claims 43 to 44, wherein the first and second connectors threadingly engage to couple the pair of connectors to secure the sterile container needle to the container in the storage state.

46. The injector of any one of claims 42 to 45, wherein the container comprises a rim disposed about an opening, the seal assembly being disposed over the opening in the container, and the second connector comprising a rim and disposed over the seal assembly, the container further comprising a crimp ring formed about the rim of the container and the rim of the second connector with the seal assembly disposed between the rims to secure the seal assembly between the rim of the container and the rim of the second connector.

47. The injector of claim 46, wherein the second connector has a passage therethrough, the sterile container needle disposed through the passage in the second connector in the storage state.

48. The injector of any one of claims 42 to 47, wherein the first connector comprises a collar disposed continuously about the sterile connector needle.

49. The injector of any one of claims 42 to 48, wherein the first connector comprises a collar disposed discontinuously about the sterile connector needle.

We claim:

1. An injector comprising:

a container including a container wall with an interior surface, wherein the wall of the container defines a bore, and the container further comprises a stopper that is moveable along the bore;

a seal assembly including a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall and the seal assembly wall defining a closed sterile reservoir filled with a medical fluid or drug product, and a barrier disposed exterior of the seal assembly wall to define an enclosed space between the flexible wall and the barrier;

a fluid delivery system comprising a sterile container needle having a point disposed only through the barrier in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the flexible wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state; and

an actuator that is adapted to move the container needle from the storage state to the delivery state.

2. An injector comprising:

a container including a container wall with an interior surface, wherein the wall of the container defines a bore, and the container further comprises a stopper that is moveable along the bore;

a seal assembly including a flexible seal assembly wall with an interior surface, the interior surfaces of the container wall, the stopper, and the seal assembly wall defining a closed sterile reservoir adapted to be filled with a medical fluid or drug product;

a fluid delivery system comprising a sterile container needle having a point disposed only partially through the seal assembly wall in a storage state such that the sterile container needle is not in fluid communication with the reservoir, and disposed through the seal assembly wall into the sterile reservoir in a delivery state such that the sterile container needle is in fluid communication with the reservoir,

the sterile container needle attached to a connector, the connector mechanically coupled to the container to secure the sterile container needle to the container with the needle in the storage state; and

an actuator that is adapted to move the container needle from the storage state to the delivery state.

3. The injector of claim 2, wherein the connector is press fit onto the container.

4. The injector of any one of claims 2 to 3, wherein the connector is a first connector of a pair of connectors, a second connector of the pair of connectors being attached to the container, the first and second of the pair of connectors mechanically coupled to secure the sterile container needle to the container in the storage state.

5. The injector of claim 4, wherein the first and second connectors each comprise one of a pair of facing surfaces, the facing surfaces abutting to limit movement of the first and second connectors axially along a longitudinal axis of the sterile container needle.

6. The injector of claim 5, wherein the first and second connectors engage to rotatably couple the pair of connectors to secure the sterile container needle to the container in the storage state.

7. The injector of any one of claims 5 to 6, wherein the first and second connectors threadingly engage to couple the pair of connectors to secure the sterile container needle to the container in the storage state.

8. The injector of any one of claims 4 to 7, wherein the container comprises a rim disposed about an opening, the seal assembly being disposed over the opening in the container, and the second connector comprising a rim and disposed over the seal assembly, the container further comprising a crimp ring formed about the rim of the container and the rim of the second connector with the seal assembly disposed between the rims to secure the seal assembly between the rim of the container and the rim of the second connector.

9. The injector of claim 8, wherein the second connector has a passage therethrough, the sterile container needle disposed through the passage in the second connector in the storage state.

10. The injector of any one of claims 4 to 9, wherein the first connector comprises a collar disposed continuously about the sterile connector needle.

11. The injector of any one of claims 4 to 10, wherein the first connector comprises a collar disposed discontinuously about the sterile connector needle.

12. The injector of any one of claims 1 to 11, wherein the bore comprises an opening in fluid communication with a first end of the bore, and the flexible wall defines a septum disposed across the opening and fixedly attached to the container wall.

13. The injector of any one of claims 1 to 12, wherein the fluid delivery system comprises sterile flexible tubing connected at a first end to the container needle and a second end to a sterile injection needle received within a sterile cover that closes off the sterile injection needle.

14. The injector of any one of the claims 1 to 13, wherein the medical fluid or drug product comprises a volume of: an erythropoiesis stimulating agent, a granulocyte colony-stimulating factor, a TNF blocker, a pegylated granulocyte colony-stimulating factor, an interleukin-receptor specific antibody, IGF-receptor (Insulin Growth Factor receptor) specific antibody, a TGF-specific antibody, a PCSK9 (Proprotein Convertase Subtilisin/Kexin Type 9) - specific antibody.

15. A method of assembling the injector of any one of claims 1 to 14, the method comprising:

filling the sterile reservoir of the container with the medical fluid or drug product under sterile conditions, the reservoir defined by the interior surface of the wall of the container, the stopper, and the seal assembly;

mechanically coupling the fluid delivery system to the container under sterile conditions, the fluid delivery system not in fluid communication with the reservoir in the storage state and in fluid communication with the reservoir in the delivery state; and

assembling the remainder of the injector under clean room conditions.

16. The method of claim 15, wherein the step of filling the sterile reservoir follows the step of mechanically coupling the sterile fluid delivery system to the container.

17. The method of any one of claims 15 to 16, wherein the step of mechanically coupling the sterile fluid delivery system to the container follows the step of filling the sterile reservoir.

18. The method of any one of claims 15 to 17, wherein the step of mechanically coupling the sterile fluid delivery system occurs within a fill/finish suite.

19. The method of any one of claims 15 to 18, wherein assembling the remainder of the injector comprises:

attaching the fluid delivery system to the actuator under clean room conditions, the actuator adapted to change the state of the fluid delivery system from the storage state to a delivery state.