[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 disposed outside of the container includes 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, an enclosed space defined 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 disposed outside of the container includes a flexible seal assembly wall with an interior surface, the flexible seal assembly wall fixedly attached to the container wall, 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

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 disposed outside of the container including a flexible seal assembly wall with an interior surface, the flexible seal assembly wall fixedly attached to the container wall, 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, an enclosed space defined 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 disposed outside of the container and including a flexible seal assembly wall with an interior surface, the flexible seal assembly wall fixedly attached to the container wall, 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

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 9, 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, the seal assembly being disposed outside of the container and including a seal assembly wall fixedly attached to the wall of the container, the seal assembly wall and a barrier disposed exterior of the seal assembly wall defining an enclosed space;

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.