

WHAT IS CLAIMED:

1. A method of facilitating real-time monitoring of conditions within a vial during a lyophilization process occurring within a lyophilization chamber, the method comprising:
for each time interval of a plurality of time intervals during the lyophilization process, determining (i) a current value of a temperature within the lyophilization chamber and external to the vial using a temperature sensor, and (ii) a current value of a pressure within the lyophilization chamber and external to the vial using a pressure sensor; and
after each time interval of the plurality of time intervals,
determining, by one or more processors, current values of one or more conditions within the vial, at least by (i) applying the current values of the temperature and the pressure within the lyophilization chamber as inputs to a heat and mass transfer balance model, and (ii) solving for a current value of a temperature within the vial, and
one or both of
causing, by the one or more processors, a display device to display the current values of the one or more conditions within the vial to a user, and
controlling, by the one or more processors and based on the current values of the one or more conditions within the vial, (i) the temperature within the lyophilization chamber and/or (ii) the pressure within the lyophilization chamber.
2. The method of claim 1, wherein determining the current values of the one or more conditions within the vial further comprises solving for a current amount of water removed from, or remaining within, a product within the vial.
3. The method of claim 1 or 2, wherein determining the current value of the temperature within the lyophilization chamber comprises determining a current value of a temperature of a shelf that supports the vial within the lyophilization chamber.
4. The method of any one of claims 1 through 3, wherein determining the current values of the one or more conditions within the vial comprises applying the current values of the temperature and the pressure within the lyophilization chamber, and one or more properties of the lyophilization chamber and/or the vial, as inputs to the heat and mass transfer balance model.
5. The method of claim 4, wherein the one or more properties of the lyophilization chamber and/or the vial include a heat and mass transfer coefficient associated with the lyophilization chamber and the vial.
6. The method of any one of claims 1 through 5, wherein determining the current values of the one or more conditions within the vial comprises applying the current values of the temperature and the pressure within the lyophilization chamber, and one or more properties of a product within the vial, as inputs to the heat and mass transfer balance model.
7. The method of claim 6, wherein the one or more properties of the product include a cake resistance

of the product.

8. The method of any one of claims 1 through 7, comprising controlling the temperature and/or the pressure within the lyophilization chamber by using the current values of the one or more current conditions within the vial to provide one or more feedback signals to one or more controllers.

9. The method of any one of claims 1 through 8, comprising causing the display device to display the current values of the one or more conditions within the vial to the user.

10. The method of claim 9, comprising:
causing the display device to dynamically update one or more graphs indicating changes over time of (i) the temperature and the pressure within the lyophilization chamber, and/or (ii) the conditions within the vial.

11. The method of any one of claims 1 through 10, further comprising, after each time interval of the plurality of time intervals:

predicting, by the one or more processors, one or more future values of the one or more conditions within the vial corresponding to one or more future time intervals; and

causing, by the one or more processors, the display device to display the one or more future values of the one or more conditions within the vial to the user.

12. The method of claim 11, wherein predicting the one or more future values includes assuming a constant temperature and pressure within the lyophilization chamber over the one or more future time intervals.

13. A system comprising:
a lyophilization chamber configured to hold a vial;
a temperature sensor configured to measure a temperature within the lyophilization chamber and external to the vial;
a pressure sensor configured to measure a pressure within the lyophilization chamber and external to the vial;
and

a computing system configured to
for each time interval of a plurality of time intervals during a lyophilization process occurring within the lyophilization chamber, obtain (i) a current value of the temperature within the lyophilization chamber from the temperature sensor, and (ii) a current value of the pressure within the lyophilization chamber from the pressure sensor, and

after each time interval of the plurality of time intervals,

determine current values of one or more conditions within the vial, at least by (i) applying the current value of the temperature and the pressure within the lyophilization chamber as inputs to a heat and mass transfer balance model, and (ii) solving for a current value of a temperature within the vial, and

one or both of

cause a display device to display the current values of the one or more conditions within the vial to a user, and

control, based on the current values of the one or more conditions within the vial, (i) the temperature within the lyophilization chamber and/or (ii) the pressure within the lyophilization chamber.

14. The system of claim 13, wherein determining the current values of the one or more conditions within the vial further includes solving for a current amount of water removed from, or remaining within, a product within the vial.

15. The system of claim 13 or 14, wherein the temperature within the lyophilization chamber includes a temperature of a shelf that supports the vial within the lyophilization chamber.

16. The system of any one of claims 13 through 15, wherein the computing system is configured to determine the current values of the one or more conditions within the vial at least by applying (i) the current values of the temperature and the pressure within the lyophilization chamber, (ii) one or more properties of the lyophilization chamber and/or the vial, and (iii) one or more properties of a product within the vial, as inputs to the heat and mass transfer balance model.

17. The system of claim 16, wherein the one or more properties of the lyophilization chamber and/or the vial include a heat transfer coefficient associated with the lyophilization chamber and the vial, and wherein the one or more properties of the product include a cake resistance of the product.

18. The system of any one of claims 13 through 17, further comprising:
one or more controllers configured to control the temperature within the lyophilization chamber,
wherein the computing system is configured to control the temperature and/or the pressure within the lyophilization chamber by using the current values of the one or more current conditions within the vial to provide one or more feedback signals to the one or more controllers.

19. The system of any one of claims 13 through 18, further comprising:
the display device,
wherein the computing system is configured to cause the display device to display the current values of the one or more conditions within the vial to the user.

20. The system of claim 19, wherein the computing system is configured to cause the display device to dynamically update one or more graphs indicating changes over time of (i) the temperature and the pressure within the lyophilization chamber, and/or (ii) the conditions within the vial.

21. The system of any one of claims 13 through 20, wherein the computing system is further configured to, after each time interval of the plurality of time intervals:
predict one or more future values of the one or more conditions within the vial corresponding to one or more

future time intervals; and

cause the display device to display the one or more future values of the one or more conditions within the vial to the user.

22. One or more non-transitory computer-readable media storing instructions that, when executed by one or more processors, cause the one or more processors to:

for each time interval of a plurality of time intervals during a lyophilization process, determine (i) a current value of a temperature within the lyophilization chamber and external to the vial using a temperature sensor, and (ii) a current value of a pressure within the lyophilization chamber and external to the vial using a pressure sensor; and

after each time interval of the plurality of time intervals,

determine current values of one or more conditions within the vial, at least by (i) applying the current values of the temperature and the pressure within the lyophilization chamber as inputs to a heat and mass transfer balance model, and (ii) solving for a current value of a temperature within the vial, and

one or both of

cause a display device to display the current values of the one or more conditions within the vial to a user, and

control, based on the current values of the one or more conditions within the vial, (i) the temperature within the lyophilization chamber and/or (ii) the pressure within the lyophilization chamber.

23. The one or more non-transitory computer-readable media of claim 22, wherein determining the current values of the one or more conditions within the vial further includes solving for a current amount of water removed from, or remaining within, a product within the vial.

24. The one or more non-transitory computer-readable media of claim 22 or 23, wherein determining the current values of the one or more conditions within the vial includes applying the current values of the temperature and the pressure within the lyophilization chamber, (ii) one or more properties of the lyophilization chamber and/or the vial, and (iii) one or more properties of a product within the vial, as inputs to the heat and mass transfer balance model.

25. The one or more non-transitory computer-readable media of claim 24, wherein the one or more properties of the lyophilization chamber and/or the vial include a heat transfer coefficient associated with the lyophilization chamber and the vial, and wherein the one or more properties of the product include a cake resistance of the product.

26. The one or more non-transitory computer-readable media of any one of claims 22 through 25, wherein the instructions cause the one or more processors to control the temperature and/or the pressure within the lyophilization chamber by using the current values of the one or more current conditions within the vial to provide one or more feedback signals to one or more controllers.

27. The one or more non-transitory computer-readable media of any one of claims 22 through 26, wherein the instruction cause the one or more processors to:

cause the display device to display the current values of the one or more conditions within the vial to the user.

28. The one or more non-transitory computer-readable media of claim 27, wherein the instructions cause the one or more processors to:

cause the display device to dynamically update one or more graphs indicating changes over time of (i) the temperature and the pressure within the lyophilization chamber, and/or (ii) the conditions within the vial.

29. The one or more non-transitory computer-readable media of any one of claims 22 through 28, wherein the instructions further cause the one or more processors to, after each time interval of the plurality of time intervals:

predict one or more future values of the one or more conditions within the vial corresponding to one or more future time intervals; and

cause the display device to display the one or more future values of the one or more conditions within the vial to the user.