records are considered reliable, trustworthy, and equivalent to paper records. Part 11 defines rules for various record-keeping processes, including but not limited to validation, protection, access controls, personnel controls, reproduction, auditing, and others. One challenge of automated systems is maintaining compliance with Part 11.

[0008] The benefits of automation may not be fully realized without appropriate automated control. The present application provides technical solutions to technical problems related to automated control of automated cell engineering systems.

Summary of the Invention

[0009] According to a first aspect of the present invention, there is provided a method for controlling an automated cell engineering system configured to produce a cell culture. The method includes establishing, by an automated process control system, a network connection with the automated cell engineering system; receiving, via the network connection, process information from the automated cell engineering system, the process information including one or more of temperature information, pH information, glucose concentration information, oxygen concentration information, component identification information and optical density information; and providing a control signal to cause the automated cell engineering system to adjust one or more process parameters of the automated cell engineering based on the process information.

[0010] According to a second aspect of the present invention, there is provided a method for controlling a plurality of automated process control systems via a central control system. The method includes establishing network connections with a plurality of computer systems corresponding to a plurality of automated process control systems, each configured to control a plurality of automated cell engineering systems configured for production of cell cultures; accessing, by the central control systems, control information history of a first computer system from the plurality of computer systems; and providing to the first computer system at least one of a cell culture growth protocol update and a cell engineering software update.

[0011] According to a third aspect of the present invention, there is provided a method for automated production of a cell culture performed by an automated cell engineering system. The method includes initiating a cell culture growth protocol within the automated cell engineering system; monitoring process information of the cell culture growth protocol; adjusting one or more parameters of the cell culture growth protocol based on the monitoring; arresting the cell culture growth protocol and recording a stage within the protocol at which the arresting occurred; and re-initiating the cell culture growth protocol at the stage within the cell culture growth protocol.

[0012] According to a fourth aspect of the present invention, there is provided a method for utilizing excess capacity within a network of automated cell engineering systems configured for automated production of cell cultures. The method includes receiving, from

a plurality of automated process control systems within the network, measures of excess capacity of the automated cell engineering systems; determining a capacity requirement according to patient requirements for a cell culture; matching the capacity requirement to

a selected automated cell engineering system according to the measures of excess capacity; and transferring a biological sample to the selected cell engineering system for production of a cell culture.

[0013] According to a fifth aspect of the present invention, there is provided a method for automated production of a cell culture performed by an automated cell engineering system. The method includes initiating a cell culture growth protocol within the automated cell engineering system; receiving, from an authorized user, an updated cell culture delivery requirement; and adjusting one or more parameters of the cell culture growth protocol based on the updated cell culture delivery requirement.

[0014] According to a sixth aspect of the present invention, there is provided a method for automated production of a cell culture performed by an automated cell engineering system. The method includes initiating a cell culture growth protocol within the automated cell engineering system; monitoring one or more parameters of the cell culture growth protocol; projecting, according to the monitoring, a cell culture delivery date; and alerting an authorized user in advance of the cell culture delivery date.

Brief Description of the Figures

[0015] FIG. 1 shows a generalized manufacturing process for a cell culture.

[0016] FIG. 2 shows a lab space containing exemplary cell engineering systems as described in embodiments herein.

[0017] FIG. 3 shows a cell culture production process that can be performed in a cell engineering system as described in embodiments herein.

[0018] FIGS. 4A-4C show an overview of an automated cell engineering system . FIG. 4A shows an automated cell engineering system in the closed configuration. FIG. 4B shows a Cassette that can be inserted into the automated cell engineering system . FIG. 4C shows an automated cell engineering system in the open configuration.

[0019] FIGS. 4D-4E show the location and orientation of a cell culture chamber utilized in an automated cell engineering system .

[0020] FIG. 4F shows a more detailed view of the cell culture chamber utilized in an automated cell engineering system .

[0021] FIG. 4G shows a process flow legend for an automated cell engineering system .

[0022] FIGS. 5A-5E show another configuration of an automated cell engineering system as described in embodiments herein. FIG. 5A shows a disposable cassette that can be loaded into the automated cell engineering system . FIG. 5B shows an automated cell engineering system in the open configuration. FIG. 5C shows the cassette loaded into the automated cell engineering system. FIG. 5D shows the automated cell engineering system in a closed configuration. FIG. 5E shows a detailed view of a cassette for use with the automated cell engineering system .

[0023] FIG. 5F shows the use of a syringe and a bag to sample from the cassette.

[0024] FIG. 6 shows the incorporation of an electroporation unit with a cell engineering system, in accordance with embodiments hereof.