

Description

Title of the Invention

SAFETY MANAGEMENT SYSTEM IN CELL PROCESSING FACILITY

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Technical Field

The present invention relates to a safety management system in a cell processing facility and especially to a safety management system which can ensure safety regarding an operator or a product in a cell processing facility.

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Background Art

In a case where various organs or tissues become defected, dysfunctional, or malfunctioning, it is required to transplant a cell or a tissue to regenerate a lost function. Medical technology for reconstructing an organ or a tissue function is comprehensively called "regenerative medicine." In the regenerative medicine, a human cellular and tissue based product (hereinafter referred to as product) manufactured by carrying out preparation such as processing or cultivation of a human cellular and tissue is used.

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For preparation of the product, a guarantee that the product is biologically clean is required because the product is transplanted to a human without carrying out final sterilization of the product under the condition where pollution by a dust or a microscopic organism from outside is prevented.

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The product is manufactured by biologically clean operation and a high quality which requires a guarantee of biological cleanliness similarly to a medical injection solution or the like is required.

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A facility for manufacturing such a product (called a cell processing facility (CPF) or a cell processing center (CPC)) mainly consists of a bio-clean room (BCR) necessary for preparation of a cell or a tissue to manufacture a human cellular and tissue based product which is a cell or a tissue required for regeneration medicine, and is a facility for receiving a

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raw material, manufacturing, examining and testing, storing, or the like. The CPF is provided in a university, a hospital, a corporation, or the like.

5 The CPF is configured by combining chambers partitioned small and from a viewpoint of ensuring the biological cleanliness, an operator in each chamber is caused to operate independently and is isolated from outside.

10 Operation by the operators of the CPF must be carried out following a predetermined procedure or quality demanded for a cellular and tissue based product used for the regenerative medicine cannot be ensured. According to an idea of quality assurance of good manufacturing practice (GMP) or the like, operation of the CPF must be carried out following a procedure predetermined by an order (manufacturing order of a cellular
15 and tissue based product). Because regulated operational activity by the operator becomes a standard, later-described abnormalities by the operator is judged as a departure from the standard if the activity by the operator is managed by a computer system.

20 Therefore, a computer system tends to be introduced into the CPF for various management controls and a system for appropriately realizing various management has been proposed. In the Japanese Unexamined Patent Application Publication No. 2004-290140, a management system regarding cultivation of a cell and a management method regarding cultivation of a cell
25 are disclosed.

Meanwhile, this type of a computer system includes, for example,

(1) a computer system for collecting and managing an
30 environment value such as temperature, humidity, chamber pressure, and number of floating particles of the facility,

(2) a computer system for collecting and managing a function value such as temperature, number of floating particles, and concentration of carbon dioxide of a
35 manufacturing equipment of the facility,

(3) a computer system for collecting and managing record of entrance and exit into and from the facility or each chamber,

and

(4) a computer system for collecting information of manufacturing orders and manufacturing records of the facility.

Moreover, there is a fire alarm system required for a
5 building.

For example, the computer system of (1) or (2) monitors the chamber for operation or function of the manufacturing equipment (e.g., temperature/humidity/room pressure/cleanliness/concentration of carbon dioxide) and adjusts the
10 equipment such as an air conditioner or issues a warning in a case where the target departs from a management standard value.

The computer system of (3) carries out record management of the entrance of the facility or each chamber, for example, carries out unlocking operation of the door by reading an IC
15 card or by a biometric authentication and record management of the operator. For example, if there is information that an operator entered a chamber at 13:00 but there is no record of the operator leaving the chamber after 22:00, it is judged that there is abnormality regarding safety of the operator and a
20 warning is issued.

Moreover, the computer system of (4) is aimed at managing a manufacturing order of a product and a record. For example, if there is a record that an operation A was carried out at 14:00 and an operation B was to be recorded within 10 minutes by the
25 following manufacturing order from the system in a normal operation but there is no record that shows operation B has been carried out by an operator even after one hour, his condition can be used as a warning judgment information for safety of operators and a warning can be issued. This is called audit
30 trail and carries out a series of operation recording to which exact time stamp (date and time automatically stamped by the computer) is attached.

However, although the above-mentioned computer system used in the CPF may issue a warning of departure from a management
35 value regarding each information collection, the system does not recognize the each information collection as information for understanding safety condition of the operator or product

in the facility.

The present invention is aimed at providing a safety method and an apparatus regarding an operator or a product in a cell processing facility.

5 More specifically, firstly, the present invention is aimed at causing personnel carrying out operation in the facility to escape more safely in the case of a disaster.

Further, secondly, the present invention is aimed at providing a system which can display the best method such as
10 containing a product under operation (e.g., in a case where there is virus or the like) as much as possible to prevent spread of the product depending on the condition of the site.

Thirdly, the present invention is aimed at providing a system which can show appropriate action so that a product
15 manufactured in the CPF, which is a custom-made product and therefore production thereof is generally stopped once the production is interrupted by a disaster or the like, can be kept manufactured in another facility as much as possible.

20 Disclosure of the Invention

The present invention has been made to solve at least part of the above-described problems and can be realized as the following configuration example.

25 That is, a safety management system in a cell processing facility according to the present invention firstly includes an information management system part for correlating a manufacturing information (including operator, operation room, date of operation, process information, used equipment,
30 manufacturing record, or the like) with a manufacturing number of a product in each process of product manufacturing in the cell processing facility for management, a monitoring system part for recording environmental condition data (including temperature, humidity, pressure, cleanliness, or the like) of
35 an operation equipment including the operation room with an arbitrary time interval, an environmental condition monitoring means for generating a matrix information including process

information from the information management system of the operation equipment and an environmental condition data from the monitoring system and for monitoring whether or not the environmental condition data obtained by the matrix information is within a certain threshold, an alarming means for issuing a warning corresponding to deviation of the detected environmental condition data from the threshold in a case where an operation equipment out of a certain threshold which indicates abnormality in the environmental condition data in the matrix information is detected, and a database for storing warning processing data in advance corresponding to the environmental condition data level out of a threshold which corresponds to the operation process, wherein the alarming means obtains operation process of the operation equipment out of the threshold from the information management system, reads out the warning processing data which corresponds to the operation process in advance from the database, and causes a warning processing including product processing support corresponding to the environmental condition data level out of the threshold to be independently displayed on each monitor which is collateral to the operation equipment along with the warning.

Moreover, in the above-described configuration, the database stores an evacuation route data for an operator of each operation equipment corresponding to the environmental condition data level out of the threshold along with the warning and the alarming means has a function to display and instruct an evacuation route for an operator in a case where evacuation of the operator is required corresponding to the environmental condition data level when the warning is issued on a monitor collateral to the operation room which corresponds to the environmental condition out of the threshold.

Further, in the above-described configuration, in the safety management system in a cell processing facility, the database stores data for instructing a securement method of a product under production in each operation process of each operation equipment corresponding to the environmental

condition data level out of the threshold along with the warning and the warning means can display the securement method of the product on a monitor in the operation room corresponding to the environmental condition out of the threshold.

5 Further, in the above-described configuration, the database stores data for instructing a littering prevention method of a product corresponding to the environmental condition data level out of the threshold along with the warning and can display the littering prevention method which
10 corresponds to the warning level requiring littering prevention of the product under production on the monitor of the operation room corresponding to the environmental condition out of the threshold.

 In addition, in the above-described configuration, the
15 monitoring system part can input data from an external alarming system out of the cell processing facility via a communication line, the database stores warning processing data of each operation process of each operation room corresponding to the warning level which corresponds to the data from outside of the
20 facility, and the warning means causes each monitor collateral to the operation equipment to individually display a warning processing corresponding to the operation process in each operation room corresponding to the data from outside of the facility.

25 According to the above-described safety management system in a cell processing facility, abnormality to safety in the CPF can be prognosed as much as possible in advance and notified to the personnel concerned. Then, it becomes possible to take safer measures than a conventional system by setting
30 standards for handling of a product or action by an operator according to the alarm or warning.

Brief Description of the Drawings

35 [FIG. 1] A block diagram showing an overall configuration of a safety management system in a cell processing facility according to the present invention.

[FIG. 2] A configuration example of a cell processing facility to which the safety management system is applied.

[FIG. 3] A configuration example of a safety management system applied to one of operation rooms.

5 [FIG. 4] A configuration block diagram showing a part of a monitoring system in the safety management system.

[FIG. 5] A configuration example of an information management system.

10 [FIG. 6] An example of matrix data generated by the safety management system.

[FIG. 7] A screen display example of an evacuation guidance warning.

[FIG. 8] A screen display example of a product littering prevention support.

15 [FIG. 9] An example of warning processing data by change in pressure.

[FIG. 10] An example of warning processing data when there is a small fire.

20 Best Mode for Carrying out the Invention

Hereinafter, the present invention will be explained in detail using an embodiment shown in figures. However, the embodiment is just an example for explanation and various
25 modifications can be adopted without departing from the scope and spirit of the invention.

A configuration example of a cell processing facility (CPF) to which the present invention is applied is shown in FIG. 2. As shown in the figure, a CPF 10 mainly consists of a bio
30 clean room (BCR) required for preparation of a cell or a tissue for manufacturing of a human cellular and tissue based product which is a cell and tissue necessary in regenerative medicine and is configured by combining small rooms such as a raw material safekeeping room 12 for receiving and keeping a raw material,
35 a preparation room 13, a test agent preparation room 14, a cell preparation room 16, a sterilization test room 18, an examination and test room 20, a cold storage room 22, a

sterilization room 24, a management room 26 where a computer equipment is provided, or the like.

A safety management system 30 applied in such CPF 10 basically includes following processing parts.

5 (a) An information management system part for instructing content of an operation or a procedure thereof to an operator and for recording a result of the operation (e.g., by a computer system) is provided. Existence of the operator in a room is indirectly judged by including management of time
10 and operation history by an operator.

 (b) A monitoring system part for collecting and managing environment inside a room where an operator is working (e.g., temperature, humidity, number of floating particles, and pressure) is provided. Change in pressure inside the room
15 caused by opening and closing of a door by entrance of the operator, change in the number of particles in the room, temporary change in room temperature or humidity are analyzed.

 (c) A monitoring system part for collecting and managing function of a machine or equipment provided to manufacture a product (e.g., temperature of an incubator, temperature of a
20 refrigerator, or number of floating particles of a safety cabinet) is provided.

 (d) A system for collecting and managing public external danger information all the time is provided.

25 (e) A system for collecting and managing information from an instrument for detecting an indication of a disaster in advance (e.g., a seismic instrument, a smoke detector, monitoring record by a camera, and a fire detector) is provided to the CPF.

30 (f) A system for managing an automatic recording of entrance and exit into/from a room by an operator (e.g., an IC card, an IC tag, or a biometric authentication) is provided.

 Then, a system for notifying a degree of safety of an operator (degree of danger), quality or degree of safety of a
35 product or the like (product or a raw material of a product or the like) by mathematically analyzing management data of (a) to (f) (or a combination of part thereof) is provided. For

notification, warning process according to the degree of danger such as an action level (e.g., operators must immediately evacuate from the CPF), a warning level (operators gather in the periphery of evacuation doors to wait and see), or the like is carried out.

An overall notional configuration of the safety management system is shown in FIG. 1. This basically includes a monitoring system part 36 for obtaining an environmental condition data 34 (34a, 34b, 34c, ...) indicating when, where, and what environmental condition (temperature, humidity, pressure, fire information, or the like) each of operation rooms 32a, 32b, ... (the raw material safekeeping room 12, the test agent preparation room 14, the cell preparation room 16, the sterilization test room 18, the examination and test room 20, the cold storage room 22, the management room 26, or the like) is in and an information management system part 38 for managing when, where and who is doing what operation in each of operation rooms 32 (32a, 32b, ...).

FIG. 3 shows a configuration example of the safety management system applied to one of the operation rooms 32. Five computer system processing parts are provided between the operation room 32 and the computer management room 26 and a computer system processing part for integrating all of them is provided in the computer management room 26.

First, to monitor entrance and exit into and from the operation room 32 by an operator, a reading antenna 42 for an IC tag 40 carried by an operator is provided and a first computer 44 for inputting a detection signal of entrance and exit into and from the room is provided. The first computer 44 specifies an operator by the IC tag 40, correlates the operator with the operation room 32, and records date and time of entrance and exit into and from the room. Therefore, this configures a room entrance and exit management system processing part 46.

Moreover, a bar code reader 48 for specifying a cell to be processed and an operation terminal 50 having an input board are provided in the operation room 32. The operation terminal 50 displays content of an operation based on an instruction

(operation instruction) 54 supplied through a second computer 52 on the management room side, inputs an operation record or achievement record, and causes the second computer 52 to output a manufacturing record data 56 (refer to FIG. 1) such as a product
5 name, manufacturing number, process name, operation room number, and operator's name. Therefore, the bar code reader 48, the operation terminal 50, and the second computer 52 configure the information management system part 38.

Further, a room pressure sensor 58, a room temperature
10 sensor 60, a humidity sensor 62, and a floating particle sensor 64 are provided inside the operation room 32 to collect and manage the environmental condition data 34 such as pressure, temperature, humidity, and the number of floating particles in the operation room. A third computer 66 for inputting these
15 detection signals is provided in the computer management room 26 and the environmental condition data 34 is recorded and kept in chronological order. This system processing part is a room inner environment monitoring system part 36A. Here, change in pressure caused by opening and closing of a door when an operator
20 enters into and exits from the room, change in the number of floating particles in the room, and temporary change in temperature and humidity can be analyzed.

Further, a temperature sensor 68 and a floating particle
25 sensor 70 for detecting the temperature and the number of floating particles of an incubator or a safety cabinet provided in the operation room 32 are provided to collect and manage function of a machine or equipment provided to manufacture a product (for example, temperature of the incubator, temperature of the refrigerator, number of floating particles in the safety
30 cabinet). Of course, it is needless to say that environmental condition data such as temperature of other equipment such as a freezer or a refrigerator (not shown) can be detected. Meanwhile, a fourth computer 72 for inputting a sensor signal is provided on the computer management room 26 side. Therefore,
35 they configure a machinery monitoring system part 36B.

A configuration example where the room inner environment monitoring system part 36A and the machinery monitoring system

part 36B are applied to a plurality of operation rooms is shown in FIG. 4. To, for example, the raw material safekeeping room 12 of each of the operation rooms 32, equipment such as a freezer 12A, a refrigerator 12B, or the like is collateral. Temperature of the collateral equipment is measured by a sensor and is taken as chronological data by the third and the fourth computers 66 and 72 for monitoring. Similarly, in the test agent preparation room 14, cleanliness of the safety cabinet 14A for carrying out preparation operation of a test agent is detected and at the same time temperature, humidity, pressure, cleanliness, or the like in the room is measured by a sensor. In the cell preparation room 16, cleanliness of the safety cabinet 16A which is a storage facility and temperature and concentration of carbon dioxide of the incubator 16B are measured. Temperature, humidity, pressure, and cleanliness in the room are also measured and taken as chronological data by the computers 66 and 72 in a similar manner. In other operation rooms 32 (not shown), environmental condition data assumed to be necessary depending on the operation content are measured and are taken by the computers 66 and 72 as chronological data. The computers for monitoring 66 and 72 include function of a current value display, a trend display, an alarm display, and an action to be taken display in each of the operation rooms 32 and they can be displayed on a screen. Moreover, the computers have an alarm standard value and an action to be taken standard value as an internally set value, compare the standard value with the current value, and depending on the deviation level thereof, can issue the alarm display or the action to be taken display in a phased manner. Further, the computers can output the alarm to outside and issue an alarm by a different display or by sound.

Further, as shown in FIG. 3, in addition to the above-mentioned monitoring system parts 36A and B, a monitoring camera 74 is provided in the operation room 32 and image processing is carried out by a fifth computer 76 so that the fifth computer provides a visual management system. Further, a fire detector 78 or a smoke detector 80 is provided in the operation room 32 and an alarm can be issued by a fire alarm

system 82 of the computer management room 26 in a case a fire breaks out.

Here, each of the sensors in the operation room 32 and the computer system parts of the computer management room 26
5 are connected via a relay plate 84 and sensing data of the plurality of operation rooms 32 are inputted into each of the computers 44, 52, 66, 72, and 76 via the relay plate so that management of condition of the plurality of operation rooms 32 is carried out.

10 Further, in this embodiment, it is enabled to input data from an external alarming system part 85 outside of the cell processing facility via a communication line (network) 83 and weather information or earthquake information can be taken into the safety management system.

15 The monitoring system by the monitoring camera 74, the fire alarm system 82, and a system by the external alarming system part 85 configure a third monitoring system part 36C.

Here, the second computer 52 of the information management system part 38 transmits display of content of
20 operation based on the instruction (operational instruction) 54 (refer to FIG. 1) to the operation terminal 50, takes operation record or achievement record inputted by the operation terminal 50, and correlates manufacturing information including the operator, operation room, date of
25 operation, used equipment, manufacturing record with the product number of a product in each product manufacturing process (cell cultivation process, cell preparation process, cell observation process, cell shipping process) in the cell processing facility for management.

30 One of the roles of the information management system part 38 is to manage overall processes between a hospital (research facility) 86 and the CPF 10 from collection of specimen to cell cultivation process until finally a product is administered. Processing procedure here is shown in FIG. 5.

35 That is, the hospital 86 (research facility) and the CPF 10 are connected by an information network 88 and input of a specimen collection processing S1 is carried out using a

computer in the hospital (research facility) 86 as an input terminal. This processing includes procedures such as reception, collection of specimen, screening, and request for cultivation.

5 On the CPF 10 side, if the request for cultivation is confirmed, the specimen is transferred into the CPF 10 and a specimen reception processing S2 is carried out using a computer provided in the CPF 10. In the specimen collection processing S2, reception test of the specimen is carried out and if the
10 received cell is appropriate, a manufacturing plan is made. According to the making of the manufacturing plan, required material is received and the material thus received is registered and then the process proceeds to the following cell preparation and cultivation processing S3.

15 In the cell preparation and cultivation processing S3, authentication of an instruction drawn up by the manufacturing plan is carried out and according to the instruction, preparation of a raw material, operation, recording of achievement, and confirmation of a record are carried out for
20 processing of preparation and cultivation. If cultivation is complete, the process proceeds to a conservation processing S4 of the cell thus cultivated and processing such as confirmation of conservation, storage, and stocktaking is carried out. Moreover, shipping processing S5 is carried out when a shipping
25 request from the hospital (research facility) 86 is received and if the shipping request is received, confirmation of the requested cell is carried out and the cell is packed to be shipped to the hospital (research facility) 86.

 Meanwhile, in the hospital (research facility) 86, a
30 specimen administration processing S6 is to be carried out and the shipping request for the cultivated cell is made to the CPF 10 side on the basis of an administration plan. The cultivated cell thus transferred by the request is administered after confirmation of a patient.

35 By such a series of processing, continued operation from collection of a specimen to cultivation of a cell and administration of a specimen is carried out between the hospital

(research facility) 86 and the CPF 10.

In the instruction 54 drawn up above, specific operation content is instructed when cultivation and preparation of a target specimen is carried out. In the cell cultivation operation, operation procedures exactly following the instruction must be carried out. Therefore, in each of operation rooms in the CPF 10, environmental condition in each operation process following the instruction is regulated.

Therefore, in the present embodiment, an environmental condition monitoring means for generating a matrix information including a process information from the information management system part and an environmental condition data from the monitoring system and for monitoring whether or not the environmental condition data 34 obtained by the matrix information is within a certain threshold is provided. The environmental condition monitoring means includes an integrated computer 90 for carrying out input and output communication among the computers 44, 52, 66, 72, 76, and 82 of each system part including the room entrance and exit management system part 46, the information management system part 38, and the monitoring system part 36, as shown in FIG. 3. The integrated computer 90 at least obtains data from the information management system part 38 and the monitoring system part 36, generates a matrix data 92 including an environmental condition data column such as temperature in each of the operation rooms (preparation room, test agent preparation room, safekeeping room, cultivation room, or the like) for each operation process (cell cultivation process, cell cultivation process, cell observation process, cell shipping process, or the like) regulated in the instruction and retains the matrix data in a database 96 (refer to FIG. 1), as shown in FIG. 6. That is, a data sheet 94A in the cell cultivation process enumerates names of each operation room in a header line in horizontal direction, enumerates environmental condition data items (temperature, pressure, fire, earthquake, or the like) in a header line in vertical direction, and is allowed to display measured environmental condition data under cell cultivation

process in this matrix chart. This is prepared for each operation process (94B, 94C, ...).

Here, the matrix data 92 in FIG. 6 is a virtual one and practically may be one which outputs the environmental condition data 34 in each of the operation rooms 32 for each operation process in the integrated computer 90 in response to a request. Display data of each matrix data 92 indicates the environmental condition data 34 from the monitoring system part 36 which momentarily changes. The data is displayed on the integrated computer 90 and at the same time only data part corresponding to the operation process carried out by the operation terminal 50 of each of the operation rooms 32 may be cut to be output and displayed.

The integrated computer 90 monitors whether or not the environmental condition data obtained by the matrix data 92 is within a certain threshold. For this, the integrated computer 90 compares a threshold including a standard value of an environmental condition regulated by the instruction 54 or an equipment manual with the environmental condition data which is being measured to obtain deviation therebetween, activates a concentrated alarm panel 98 depending on the deviation level, and activates an alarm panel 100 or a speaker 102 in a corresponding operation room. Similarly, in a case where there is a fire or an earthquake, depending on the scale of the fire or the earthquake, the concentrated alarm panel 98 is started and the alarm panel 100 or the speaker 102 is activated. Then, at the same time, the alarm is also displayed on the operation terminal 50 in each of the operation rooms 32. That is, the integrated computer 90 and the alarm panels 98 and 100 configure a means for issuing a warning depending on the deviation between the detected environmental condition data and the threshold in a case where an operation equipment out of a certain threshold indicating abnormality in the environmental condition data in the matrix data information is detected. The alarming means obtains an operation process in an operation equipment including the operation room 32, which is out of the threshold, from the information management system part 38, reads out a

warning processing data corresponding to the operation process in advance from the database 96, and causes the warning processing including a product processing instruction corresponding to the environmental condition data level out of the threshold along with the warning to be independently displayed on each monitor which is collateral to the operation equipment. Content of the warning differs depending on each operation process or on the level of the warning. Therefore, appropriate warnings to an operator matching the change in the environmental condition and the operation process or the operation room are databased in advance in the database 96 including the integrated computer 90 and the integrated computer 90 judges an appropriate warning processing corresponding to the location where a problem occurred to carry out safety management.

Type of data for warning stored in the database 96 includes the following. That is, an evacuation route data for an operator in each operation equipment corresponding to the environmental condition data level out of the threshold along with the warning is stored in the database 96 and the integrated computer 90 which configures the alarming means instructs an evacuation route for an operator by a monitor display in a case where evacuation of the operator is required depending on the environmental condition data level when a warning is issued on the monitor of the operation terminal 50 collateral to the operation room 32 which corresponds to an environmental condition out of the threshold. This, for example, causes an overhead view of the CPF 10 and current location, and the evacuation route to be displayed and at the same time causes an action display such as "Disaster strikes. Follow the evacuation route to immediately evacuate from the facility" to be displayed on the operation terminal 50.

Moreover, the database 96 stores data for instructing a securement method of a product under production in each operation process for each operation equipment including the operation room depending on the environmental condition data level out of the threshold along with the warning and the

alarming means can display the securement method of the product on the monitor of the operation terminal 50 in the operation room 32 corresponding to the environmental condition out of the threshold. For example, action display such as "Disaster strikes. (A) Discard Chemical A currently under usage according to the procedure for discarding. (B) Ensure Chemical B currently under preparation according to the procedure" is displayed on the operation terminal 50, as shown in FIG. 8.

Further, the database 96 stores data for instructing a littering prevention method of a product corresponding to the environmental condition data level out of the threshold along with the warning and can display the littering prevention method of the product which corresponds to the warning level requiring littering prevention of the product under production on the monitor of the operation room corresponding to the environmental condition out of the threshold. This generates a matrix data in advance by types of the operation rooms 32 and the size of deviation of measured pressure from the standard value for example, reads out data describing handling procedures in other concerning areas depending on the detected deviation, and displays the data on the operation terminal 50 as shown in FIG. 9.

Fig. 10 shows an example where content of action in a case of a small fire is databased. As understood from the figure, in a case where a fire breaks out in the preparation and cultivation room 1, the fact that fire broke out may be displayed on the operation terminal 50 in the site of the fire, content of action for other operation rooms may be adjusted and set depending on the distance from the site of fire, and content of action corresponding to the fire level may be read out from the database 96 and displayed on each operation terminal 50 for instruction.

Here, same is applied to a case where data from outside of the cell processing facility (natural disaster information) is inputted from the external alarming system part 85 via a communication line (information network 88). Warning processing data in each operation process for each operation

room corresponding to the warning level depending on the outside-of-facility data is stored in the database 96 and the warning processing corresponding to the outside-of-facility data for the operation process in each operation room is independently displayed on each monitor collateral to the operation equipment by the integrated computer 90 which configures the warning means.

As explained above, according to the safety management system in a cell processing facility according to the present invention, it becomes possible to carry out a warning processing corresponding to an environmental condition data level out of the threshold which corresponds to the operation process of the cell preparation and cultivation operation by the information management system part, the monitoring system part, the environmental condition monitoring means, and the warning means. Therefore, it becomes possible to accurately carry out a safety measure for an operator working in the CPF 10 or a product.

Industrial Availability

The present invention can be used as a safety management system which can secure safety of an operator or a product in a cell processing facility carrying out regenerative medicine.

Claims

1. A safety management system in a cell processing facility comprising:

5 an information management system part for correlating a manufacturing information including operator, operation room, date of operation, used equipment, manufacturing record, or the like with a manufacturing number of a product in each process of product manufacturing in the cell processing facility for
10 management;

a monitoring system part for recording environmental condition data including temperature, humidity, pressure, cleanliness, or the like of an operation equipment including the operation room with an arbitrary time interval;

15 an environmental condition monitoring means for generating a matrix information including process information from the information management system of the operation equipment and an environmental condition data from the monitoring system and for monitoring whether or not the
20 environmental condition data obtained by the matrix information is within a certain threshold;

an alarming means for issuing a warning corresponding to deviation of the detected environmental condition data from the threshold in a case where an operation equipment out of a certain
25 threshold which indicates abnormality in the environmental condition data in the matrix information is detected; and

a database for storing warning processing data corresponding to the environmental condition data level out of a threshold which corresponds to the operation process in
30 advance, wherein

the alarming means obtains operation process of the operation equipment out of the threshold from the information management system part, reads out the warning processing data which corresponds to the operation process in advance from the
35 database, and causes a warning processing including product processing support corresponding to the environmental condition data level out of the threshold to be displayed

independently on each monitor which is collateral to the operation equipment along with the warning.

2. The safety management system in a cell processing facility according to claim 1, wherein the database stores an evacuation route data for an operator of each operation equipment corresponding to the environmental condition data level out of the threshold along with the warning and the alarming means has a function to display and instruct an evacuation route for an operator in a case where evacuation of the operator is required corresponding to the environmental condition data level when the warning is displayed on a monitor collateral to the operation room which corresponds to the environmental condition out of the threshold.

3. The safety management system in a cell processing facility according to claim 1, wherein the database stores data for instructing a securement method of a product under production in each operation process of each operation equipment corresponding to the environmental condition data level out of the threshold along with the warning and the warning means can display a securement method of the product on a monitor in the operation room corresponding to the environmental condition out of the threshold.

4. The safety management system in a cell processing facility according to claim 1, wherein the database stores data for instructing a littering prevention method of a product corresponding to the environmental condition data level out of the threshold along with the warning and can display the littering prevention method which corresponds to the warning level requiring littering prevention of the product under production on the monitor of the operation room corresponding to the environmental condition out of the threshold.

5. The safety management system in a cell processing facility according to claim 1, wherein the monitoring system

part can input data from an external alarming system part out of the cell processing facility via a communication line, the database stores warning processing data of each operation process of each operation room corresponding to the warning level which corresponds to the data from outside of the facility, and the warning means causes each monitor collateral to the operation equipment to display a warning processing corresponding to the operation process in each operation room corresponding to the data from outside of the facility.

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