TITLE OF THE INVENTION

Method for management of cell processing process, and processing tool kit therefor

BACKGROUND OF THE INVENTION

1. Field of the Invention

The present invention relates to a method for the management of a cell processing process to be performed in an aseptic manipulation area, such as a biohazard safety cabinet, by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample, such as a human or animal sample, and a culture medium; and a plurality of processing tools including an unused container, such as an unused dish and an unused centrifuge tube, and a chemical agent, wherein a processing tool kit is prepared in advance of the cell processing process in such a manner as to allow a set of selectively combined processing tools including the unused dish and/or the unused centrifuge tube to be enclosed therein, and then carried into and opened within the aseptic manipulation area to take out the combined processing tools therefrom so as to perform the cell processing process using the combined processing tools as unused processing tools. The present invention also relates to a processing tool kit for use in the method.

More specifically, the present invention relates to a method for the management of a cell processing process to be performed in an aseptic manipulation area, such as a biohazard safety cabinet, by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample and a culture medium; a processing tool kit prepared in advance of the cell processing process in such a manner as to allow a set of selectively combined processing tools including the unused dish and/or the unused centrifuge tube to be enclosed therein; and a separate processing tool including a chemical agent, wherein kit identification data associated with tool identification data which is uniquely assigned to each of the combined processing tools enclosed in the processing tool kit, and appended to an IC tag attached to a corresponding one of the combined processing tools, is pre-appended to an IC tag attached to the processing tool kit, and process-instruction data configured to indicate an instruction for the cell processing process and associated with at least a plurality of biological-material identification

data uniquely assigned to respective ones of a plurality of the biological materials, a plurality of stage identification data uniquely assigned to respective ones of a plurality of stages of the cell processing process, a plurality of the tool identification data uniquely assigned to respective ones of the combined and separate processing tools, and a plurality of the kit identification data uniquely assigned to respective ones of a plurality of the processing tool kits, is pre-stored in a computer-operated data processing unit communicatably connected to the wireless reading unit, whereafter, in response to reading the kit identification data appended to the processing tool kit, using a wireless reading unit, such as a reader, an arbitrary one of the plurality of kit identification data associated with the process-instruction data is chosen and cross-checked with the read kit identification data, through the data processing unit, and cross-check data indicative of whether the two cross-checked data are coincident with each other is output from the data processing unit, whereby, when it is confirmed that the output cross-check data indicates coincidence between the two cross-checked data, an operator involved in the cell processing process is permitted to carry the processing tool kit into the aseptic processing area and open the processing tool kit to take out the combined processing tools so as to perform the cell processing process using the combined processing tools as unused processing tools. The present invention also relates to a processing tool kit for use in the above method.

2. Description of the Related Art

Recent years, in the field of therapeutic medical researches, a medical technique of culturing a cell collected from a biological body to regenerate impaired biological tissues, so-called "regenerative medical technique", have been actively studied. The regenerative medical technique involves a need to increase the number of cells associated with at least one sample up to a given value (e.g., a value required for an intended therapy) through cell culture. In conjunction with the cell culture, a cell processing process including a task of replacing a container for subculture or the like is performed at least several times, using a large number of processing tools, e.g., several hundred or more containers and a wide variety of chemical agents depending in intended purposes, as shown in FIGS. 10 and 11. In such a case, as might be expected, it is required to allow the cell processing process to be performed according to a strict

operating procedure so as to eliminate a risk of cross-contamination between respective containers or operation rooms, and avoid the occurrence of human errors, while promoting higher efficiency therein [see, for example, JP 2004-016194A (hereinafter referred to as "Patent Publication 1")]. Moreover, differently from a process of manufacturing industrial products or food products, in the stage of increasing the number of cells up to a required value through cell culture after completion of the cell processing process, a record or history of each cell has to be strictly handled throughout the entire cell culture stage, in view of a process management [see, for example, "Kinetic Assessment in consideration of Heterogeneous Characteristics in Human Tissue Culture, and Bioprocess Design", Masahiro Kinooka and Masahito Taya (School of Engineering Science of Graduated School, Osaka University, Japan), August/12/2003, Autumn Meeting of Japan Chemical Industry Association (hereinafter referred to as "Non-Patent Publication 1")]. Therefore, it is recommended to perform the cell processing process including a task of replacing a culture medium, a task of centrifugation and a task of subinoculation, in a facility compliant with the GMP (Good Manufacturing Practice) Regulations related to investigational new drugs, according to a specific standard operating procedure (SOP) based on the GMP Regulations [see, for example, "Air-Conditioning Equipment and Plant Systems", Hitachi Plant Technical Review, No. 11, December/2005, pp 10-11 (hereinafter referred to as "Non-Patent Publication 2")].

The Patent Publication 1 includes a description to the effect that "a cell subculture technique is generally essential in a cell culture stage for increasing the number of cells up to a given value, wherein it is necessary to perform cumbersome/complicated cell processing tasks, such as a task of replacing a culture medium received in a container, and a task of re-inoculating an unused medium (i.e., new medium) serving as a subculture medium, with cells". The Patent Publication 1 further discloses a system designed such that identification data, such as a barcode, appended to a culture container is read to manage the culture container so as to provide enhanced efficiency in the cell processing tasks which would otherwise be required to be handled by an experienced operator depending on intended purposes, to suppress the occurrence of serious accidents, such as cross-contamination between respective containers or operation rooms.

The Non-Patent Publication 1 includes a description to the effect that: "in view of

heterogeneous growth characteristics of plural types of cells each associated with a different sample, a cell processing process may include a non-flowchart-based sub-process, so-called "deviant sub-process", wherein a stage of replacing between containers to divide cells into a plurality of groups and a culture stage are monitored, and, depending on growth characteristics of a specific type of cells, the replacement stage and the culture stage for the specific type of cells are performed at a timing earlier or later than a cell processing process for other types of cells, on a case-by-case basis".

The Non-Patent Publication 2 includes a description to the effect that "in the above case, it is obligated to prepare an SOP for a software area (process management and quality management), in addition to planning, designing and construction of a hardware area (cell processing facilities), and implementation of validation, based on the GMP Regulations related to investigational new drugs".

Most of an entire cell processing process is strictly performed on a biohazard safety cabinet or a cell processing task table, formed with an aseptic manipulation area, on a step-by-step basis, according to a required operating procedure. Thus, in a cell processing process consisting of at least several stages, a plurality of processing materials required for each of the stages, such as a biological material and a plurality of processing tools, are carried into the aseptic manipulation area to process a cell. Then, after completion of the cell processing process, the processing materials are sorted into a waste material, and a useful material to be preserved. For example, if it is necessary to preserve the useful material in a frozen state (i.e., cryopreserve the useful material), the useful material will be transported to an area equipped with a freezer, such as a preservation room. As for the waste material, a disposable waste material will be transported, for example, to a waste room located in a vicinity of the aseptic manipulation area. Subsequently, a plurality of processing materials required for a next cycle of cell processing process are carried into the aseptic manipulation area to perform the cell processing process in the same manner.

Therefore, in the cell processing process consisting of at least several stages, a processing tool including an unused container, such as an unused dish and an unused centrifuge tube, and a chemical agent, which are to be carried into the aseptic manipulation area as a part of the

processing materials, will be significantly increased in type and number. Moreover, most of a set of selectively combined processing tools, such as unused containers for use in the cell processing process, are formed as a disposable type in view of preventing cross-contamination, and thereby a waste material resulting from such a disposable processing tool will also be increased in type and number. As a result, it is necessary to take a lot of time for one cycle of cell processing process. Moreover, it cannot be said that there is not any risk that a used processing tool to be discarded is erroneously mixed with and used as an unused processing tool.

Thus, it has been expected to provide a system capable of allow one cycle of cell processing process to be rapidly completed without misidentification between an unused processing tool and a used processing tool, using a processing tool kit which is prepared to allow a set of selectively combined processing tools including an unused dish and/or an unused centrifuge tube to be enclosed therein, and intended to be carried into and opened within an aseptic manipulation area so as to take out the combined processing tools therefrom.

Japanese Patent No. 3706128 (hereinafter referred to as "Patent Publication 2") discloses a regenerative medical technique of collecting a given volume (e.g., several cc) of a sample (e.g., bone marrow) in an undifferentiated state, from one donor who is a patient, and increasing the number of mesenchymal stem cells contained in the sample, from about 10^3 or 10^4 up to about 10^7 or 10^8, so as to therapeutically administer the cells to the patient. FIGS. 10 and 11 show a typical example of a required number of processing tools required for culturing an autologous cell to be administered to a patient who is a donor of the cell in a regenerative medical therapy, such as a dish and/or a centrifuge tube serving as a part of processing materials. The number of processing tools per person required for a cell processing process and a preceding process of creating a culture medium using peripheral blood for an autologous serum to be used in increasing the number of cells by cell culture, is enormous, specifically 300 or more only for the unused dish or about 250 only for the centrifuge tube.

Although the system disclosed in the Patent Publication 1 is adapted to check culture procedures and conditions associated with a specific cell to be subjected to a primary culture stage and a subculture stage, so as to meet a minimum need for preventing misidentification and cross-contamination, it is not intended to manage a large number and various types of processing

tools accurately without error. Thus, it is obvious that this system can manage only a limited number of processing tools, and requires a relatively long period of time for one cycle of cell processing process. Moreover, if such a large number of processing tools are handled based on this system, a time required for the cell processing process will be significantly extended, and a task of sorting the processing materials into a useful material and a waste material after completion of the cell processing process will become extremely complicated. This is likely to cause the occurrence of misidentification between the useful material and the waste material. In the worst case, the waste material is likely to be erroneously identified and re-used as an unused material, to cause an impermissible cross-contamination incident.

SUMMARY OF THE INVENTION

In view of the above circumstances, it is an object of the present invention to provide a cell processing process management method capable of managing a processing material quickly and accurately without error to prevent biological hazards, using a processing tool kit as the processing material together with a separate processing tool, such as a chemical agent, wherein the processing tool kit is prepared in such a manner that two or more selected from a large number of unused containers required for a cell processing process to be performed in an aseptic manipulation area are enclosed therein as a set of selectively combined processing tools, and assigned with kit identification data associated with a plurality of tool identification data uniquely assigned to respective ones of the combined processing tools.

It is another object of the present invention to provide a processing tool kit for use in the cell processing process management method.

Just for reference, JP 2004-262617A (hereinafter referred to as "Patent Publication 3") discloses a data management system using a method for the management of a large number of articles, such as a stock of components. The data management system is designed such that identification data configured to identify each of a plurality of components is appended to an IC tag attached to a corresponding one of the components, and identification data configured to identify a container for transporting the components together is appended to an IC tag attached to the container, together with the respective identification data of the components, wherein the

components are selectively managed on a container-by-container basis during management in a warehouse, and on a component-by-component basis after they are taken out of the container. More specifically, the management method comprises: pre-inputting spare-part identification data configured to identify each of a plurality of spare parts which have passed an inspection, into a spar-part IC tag attached to a corresponding one of the spare parts; pre-inputting container identification data configured to identify a container for transporting the spare parts together, into a container IC tag attached to the container, together with the respective spare-part identification data of the spare parts; and reading and processing the spare-part and container identification data from the container IC tags to perform a stock, quality, asset or distribution management of the spare parts.

Although a relationship between the container and each of the spare parts superficially seems to be similar to a relationship between the processing tool kit and each of the combined processing tools in the present invention, the container-to-spare part relationship is no more than a relationship between a transport container and an article to be transported by the transport container, and each of the respective spare-part identification data input in the spare-part IC tags are not associated with the container identification data input in the container IC tag. That is, the container identification data and the spare-part identification data are used for the stock management, etc., in such a manner that the container identification data and the spare-part identification data are input into the container IC tag and the spare-part IC tag, independently, or the respective spare-part identification data of the spare parts contained in the container are simply input in only the container IC tag, together with the container identification data.

The Patent Publication 3 does not include any description and suggestion about a technique of: pre-inputting, into a computer-operated data processing unit, task instruction data associated with identification data, such as the container identification data input in the container IC tag of the container containing the plurality of spare parts; reading the container identification data of the container in use of the container and/or the spare parts contained in the container, causing the data processing unit to cross-check the read identification data with the task instruction data; and handling the spare parts while monitoring the cross-check result.

That is, differently from the objects and after-mentioned elements and functions of the

present invention, the Patent Publication 3 is directed to a processing method for allowing a plurality of spare parts to be manageably carried in (i.e., stored in) and carried out of a warehouse or the like in such a manner as to selectively manage the spare parts as a whole when they are contained in a container or the like, and on a spare part-by-spare part basis after they are taken out of the container or the like.

In order to achieve the above objects, as set forth in the appended claim 1, according to a first aspect of the present invention, there is provided a method of managing a cell processing process to be performed in an aseptic manipulation area by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample and a culture medium; a processing tool kit prepared in advance of the cell processing process in such a manner as to allow a set of selectively combined processing tools including an unused dish and/or an unused centrifuge tube to be enclosed therein; and a separate processing tool including a chemical agent. The method comprises: pre-appending, to a wireless communication device attached to the processing tool kit, kit identification data assigned to the processing tool kit and associated with tool identification data which is uniquely assigned to each of the combined processing tools enclosed in the processing tool kit, and appended to a wireless communication device attached to a corresponding one of the combined processing tools; pre-storing, in a computer-operated data processing unit, process-instruction data configured to indicate an instruction for the cell processing process and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of a plurality of the biological materials, a plurality of stage identification data uniquely assigned to respective ones of a plurality of stages of the cell processing process, a plurality of the tool identification data uniquely assigned to respective ones of the combined and separate processing tools, and a plurality of the kit identification data uniquely assigned to respective ones of a plurality of the processing tool kits; causing a wireless reading unit communicatably connected to the data processing unit, to read the kit identification data pre-appended to the kit tool; and causing the data processing unit to choose an arbitrary one of the plurality of kit identification data associated with the process-instruction data, and cross-check the read kit identification data with the arbitrary kit identification data so as to output cross-check data indicative of whether the two

cross-checked data are coincident with each other, whereby, when it is confirmed that the output cross-check data indicates coincidence between the two cross-checked data, an operator involved in the cell processing process is permitted to carry the processing tool kit into the aseptic processing area.

As set forth in the appended claim 2, according to a second aspect of the present invention, there is provided a method of managing a cell processing process to be performed in an aseptic manipulation area by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample and a culture medium; a processing tool kit prepared in advance of the cell processing process in such a manner as to allow a set of selectively combined processing tools including an unused dish and/or an unused centrifuge tube to be enclosed therein; and a separate processing tool including a chemical agent, wherein the processing material is carried into the aseptic manipulation area by an operator involved in the cell processing process. The method comprises the steps of: pre-appending, to a wireless communication device attached to each of the combined processing tools to be enclosed in the processing tool kit, tool identification data uniquely assigned to each of the combined processing tools; pre-appending, to a wireless communication device attached to the processing tool kit, kit identification data assigned to the processing tool kit and associated with the respective tool identification data of the combined processing tools; pre-storing, in a computer-operated data processing unit, process-instruction data configured to indicate an instruction for the cell processing and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of a plurality of the biological materials, a plurality of stage identification data uniquely assigned to respective ones of a plurality of stages of the cell processing process, a plurality of the tool identification data uniquely assigned to respective ones of the combined and separate processing tools, and a plurality of the kit identification data uniquely assigned to respective ones of a plurality of the processing tool kits; causing a wireless reading unit communicatably connected to the data processing unit, to read the kit identification data pre-appended to the wireless communication device attached to the processing tool kit to be carried in the aseptic manipulation area; and causing the data processing unit to choose an arbitrary one of the plurality of kit identification data associated with the process-instruction data,

and cross-check the read kit identification data with the arbitrary kit identification data so as to output a result of a determination on whether the two cross-checked data are coincident with each other, in the form of cross-check data, whereby: when the output cross-check data indicates coincidence between the two cross-checked data, the operator is permitted to carry the processing tool kit into the aseptic processing area, after causing the data processing unit to associate a specific one of the plurality of biological-material identification data with the respective tool identification data of the combined processing tools enclosed in the processing tool kit; and, when the output cross-check data indicates non-coincidence between the two cross-checked data, the operator is instructed to perform an error handling while stopping the task of carrying the processing tool kit into the aseptic processing area.

As set forth in the appended claim 3, preferably, the method set forth in the appended claim 2 further includes the step of, when the output cross-check data indicates coincidence between the two cross-checked data, allowing the operator to confirm the output cross-check data indicative of the coincidence, and then causing the data processing unit to associate a specific one of the plurality of biological-material identification data with the respective tool identification data of the combined processing tools enclosed in the processing tool kit, whereafter the operator is permitted to carry the processing tool kit into the aseptic processing area and open the processing tool kit so as to take out the combined processing tools from the opened processing tool kit.

As set forth in the appended claim 4, preferably, in the method set forth in the appended claim 2 or 3, after the error handling is performed while stopping the task of carrying the processing tool kit into the aseptic processing area, the operator is permitted to restart the task of carrying the processing tool kit into the aseptic processing area.

As set forth in the appended claim 5, preferably, the method set forth in any one of the appended claims 2 to 4 further includes the step of causing the data processing unit to instruct display means provided in the aseptic processing area to display the output cross-check data.

As set forth in the appended claim 6, according to a third aspect of the present invention, there is provided a processing tool kit which comprises: a set of selectively combined unused processing tools including an unused dish and/or an unused centrifuge tube, wherein the

combined unused processing tools are enclosed therein in advance of a cell processing process to be performed in an aseptic processing area, and used in the cell processing process together with a biological material consisting of a cell associated with a specific sample and a culture medium, and a separate processing tool including a chemical agent; and a wireless communication device attached thereto while having kit identification data assigned to the processing tool kit and appended thereto, wherein the kit identification data is associated with tool identification data which is uniquely assigned to each of the combined unused processing tools and appended to a wireless communication device attached to a corresponding one of the combined unused processing tools.

As set forth in the appended claim 7, according to a fourth aspect of the present invention, there is provided a processing tool kit for use in a cell processing system, wherein the cell processing system includes: a computer-operated data processing unit pre-storing therein process-instruction data configured to indicate an instruction for a cell processing process and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of biological materials to be subjected to the cell processing process, and a plurality of kit identification data uniquely assigned to respective ones of a plurality of the processing tool kits required for the cell processing process; and a wireless reading unit communicatably connected to the data processing unit. The processing tool kit comprises: a set of selectively combined unused processing tools enclosed therein; and a wireless communication device attached to each of the combined unused processing tools while having tool identification data uniquely assigned to each of the combined unused processing tools and appended thereto, wherein the wireless reading unit is adapted to read the kit identification data pre-appended to the processing tool kit, and the data processing unit is adapted to choose an arbitrary one of the plurality of kit identification data associated with the process-instruction data, and cross-check the read kit identification data with the arbitrary kit identification data, to output a result of a determination on whether the two cross-checked data are coincident with each other, in the form of cross-check data, wherein, when it is conformed that the output cross-check data indicates coincidence between the two cross-checked data, an operator involved in the ell processing process is permitted to carry the processing tool kit having the combined unused processing tools

enclosed therein, into an aseptic processing area, and open the processing tool kit so as to take out the combined unused processing tools from the opened processing tool kit, after causing the data processing unit to associate a specific one of the plurality of biological-material identification data with the respective tool identification data appended to the wireless communication devices attached to the combined unused processing tools.

In a specific embodiment of the present invention, the aseptic manipulation area for the cell processing process is preferably equipped with: a biohazard safety cabinet which has a receiving space for manipulating therein the processing material for use in the cell processing process, such as the processing tool kit, and an insertion opening for allowing an operator to carry the processing material in/out of the receiving space therethrough; and an operation desk which have a wireless reading unit, such as a reader, a wireless antenna, and a touch panel-type display unit. Alternatively, the aseptic manipulation area may include a cell processing task table installed in a cell processing room and managed to keep surroundings in an aseptic condition, or
may be a cell processing room itself wherein an operation desk is installed thereoutside, and an operator performs a remote manipulation using a manipulator or the like. In either case, the aseptic manipulation area is preferably designed to allow an operator to reliably perform each task, while using the wireless reading unit (e.g., a reader) to read the identification data, such as an ID number pre-appended to the wireless communication device (e.g., an IC tag) attached to the processing material carried in or out of the aseptic manipulation area, and cross-checking the read identification data with a specific one of the plurality of the identification data associated with the process-instruction data including the plurality of pre-stored kit identification data and others.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 is a schematic diagram generally showing an operation of a cell processing system utilizing a management method of the present invention.

FIG. 2 is a table showing one example of task items in each stage of the operation of the cell processing system in FIG. 1.

FIG. 3 is a schematic diagram showing a room/equipment layout of a cell processing center

equipped with a cell processing/culture room and others, in the cell processing system in FIG. 1.

FIG. 4 is a perspective view showing one example of a biohazard safety cabinet for use in a cell processing process utilizing the management method of the present invention.

FIG. 5 is a top plan view showing a processing tool kit according to one embodiment of the present invention, wherein a set of selectively combined processing tools, such as a dish, a centrifuge tube and a pipette, are enclosed in the processing tool kit, and tool identification data uniquely assigned to each of the combined processing tools is appended to an IC tag attached to a corresponding one of the combined processing tools.

FIG. 6 is a schematic diagram showing a processing material including the processing tool kit, for use in the cell processing process utilizing the management method of the present invention.

FIG. 7 is a flowchart showing tasks in respective stages, such as stages of production, storage, preparation and use of a processing tool kit, in the cell processing process utilizing a management method according to one embodiment of the present invention.

FIG. 8 is a flowchart showing tasks in respective stages, such as stages of production, storage, preparation and use of a processing tool kit, in the cell processing process utilizing the management method according to the embodiment of the present invention.

FIG. 9 is a schematic diagram showing an instruction sheet No. 4 as one example of process-instruction data for use in the cell processing process utilizing the management method according to the embodiment of the present invention.

FIG. 10 is a schematic diagram showing the number of processing tools per person required for a cell processing process for a stem cell obtained from bone marrow.

FIG. 11 is a schematic diagram showing the number of processing tools per person required for a process of preparing a culture solution from peripheral blood.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The present invention will now be specifically described based on an embodiment thereof.

FIG. 1 is a schematic diagram generally showing an operation of a cell processing system which is performed in a medical or research center, a cell processing center and a processing-tool

manufacturer (i.e., a supplier of unused processing tools) by utilizing a management method according to the present invention.

Assuming the processes illustrated in FIGS. 10 and 11, a sample to be subjected to a cell processing process is collected from a patient (donor) in a medical or research center, and data about the collected sample (i.e., sample data) is registered together with data about the donor (i.e., donor data) in the medical or research center. Then, the collected sample (i.e., biological material) is delivered to a cell-culture acceptance office of a GMP-compliant cell processing center (CPC) together with culture request data. In the cell-culture acceptance office of the CPC, the collected sample is subjected to an acceptance test, and then the sample data, the donor data and the culture request data are registered as acceptance test data. In parallel, a new (i.e., unused) processing tool which includes a separate unused processing tool and a processing tool kit prepared to allow a set of selectively combined unused processing tools to be enclosed therein, is produced by a processing-tool manufacturer, and transported to the cell-culture acceptance office of the CPC. In the cell-culture acceptance office of the CPC, the accepted unused processing tool is registered. Then, the sample (i.e., biological material) is subjected to a cell processing process, using the unused processing tool in an aseptic manipulation area of the CPC. Then, after completion of the required cell processing process, the processed sample (i.e., processed biological material) is subjected to a preservation and/or delivery treatments according to predetermined procedures, and then packed in a container or the like. Subsequently, the container containing the processed sample (i.e., processed biological material) will be delivered from the CPC to the medical or research center, and administered to the patient (i.e., the donor).

The above tasks are required to be performed according to a specific standard operating procedure (SOP) compliant with the GMP Regulations. FIG. 2 is a table showing one specific example of tasks to be performed according to such an SOP. As shown in the example illustrated in FIG. 2, in a sample collection stage in advance of a cell processing stage and a cell culture stage, a donor ID number is created in such a manner as to associated with data of a sample (i.e., biological material). Then, in a culture acceptance stage, process-instruction data, such as an instruction sheet, is created in such a manner as to be associated with identification data to be appended to an IC tag which is attached to each of the biological material associated

with the donor ID number, and a processing tool, which are used as a processing material when each task designated in the instruction sheet is performed in the cell processing process. The instruction sheet fundamentally indicates data about a processing material required for each of a plurality of stages of the cell processing process, task items to be performed in each of the stages, and others, as will be described in detail later.

FIG. 3 shows one example of a cube-shaped cell processing center (CPC) 100 utilizing the management method of the present invention. FIG. 3 illustrates a movement route for a user or operator, which is required to pass through a dressing or undressing room, a transport route for a processing material including a biological material and a processing tool, which is required to pass through a pass box, and a transport route for a waste material to be discarded after completion of the cell processing process according to the instruction sheet. The cell processing center 100 has a preservation room 120, a preparation room 130 and a cell processing/culture room 140, each of which is equipped with an essential apparatus (301 to 306) and a substation (201 to 203), i.e., a data terminal of the cell processing system, to be used at least for performing the cell processing process, and a management room 110 equipped with at least a base station which is a data processing unit for managing the entire cell processing system. Typically, the present invention relates to a method for management of a cell processing process to be performed in a biohazard safety cabinet 303 (hereinafter referred to simply as "safety cabinet 303") installed in the cell processing/culture room 140 in FIG. 3 to serve as an aseptic manipulation area, and a processing tool kit for used in the management method.

FIG. 4 is a perspective view showing one example of an aseptic manipulation area to be used during a cell processing process utilizing the management method of the present invention, which corresponds to the safety cabinet 303 illustrated in FIG. 3.

FIG. 5 is a top plan view showing a processing tool kit according to one embodiment of the present invention. As shown in FIG 5, the processing tool kit has a set of selectively combined processing tools, such as a dish, a centrifuge tube and a pipette for use in a cell processing process, which are enclosed therein, wherein tool identification data uniquely assigned to each of the combined processing tools is appended to an IC tag attached to a corresponding one of the combined processing tools, and kit identification data uniquely assigned to the processing tool

kit is appended to an IC tag attached to the processing tool kit, in such a manner as to be associated with respective tool identification data of the combined processing tools. Data corresponding to the kit identification data associated with respective tool identification data of the combined processing tools is pre-stored in an after-mentioned data processing unit 204.

For example, the safety cabinet 303 may be formed in a cubic shape which has a front wall provided with an openable/closable shutter, and internally has a receiving space 314 for performing a cell processing process therein. In the safety cabinet 303 provided with the shutter, the front wall is formed with an insertion opening for allowing a user or operator to carry a processing material in/out of the receiving space 314 therethrough. FIG. 4 shows a state when a biological material (such as a cell associated with a donor's sample to be subjected to a cell processing, and a culture medium) contained in a biological-material container 321, and a processing tool kit 319 having an unused dish and an unused centrifuge tube enclosed therein and required for the cell processing process, are placed in the receiving space 312, together with individual containers (such as a dish 320 and a centrifuge tube 322 taken out from an additional processing tool kit by opening the additional processing tool kit), and a chemical-agent container 321 (which is a separate processing tool). The centrifuge tube 322 is used for purification/separation, for example, using a centrifugal machine disposed adjacent to the safety cabinet 303 in FIG. 3. In this specification, the biological material and the processing tool will be referred to collectively as "processing material".

The cell processing/culture room 140 in FIG. 3 may be equipped with an incubator 306 for use in primary culture and subculture, and a waste room or chamber 305 provided with a reader adapted to read a tool ID number (serving as tool identification data) uniquely assigned to a used processing tool (such as a used biological-material container 321) to be discarded as a waste material after completion of a cell processing process. In a cell processing process using the safety cabinet 303 in the above cell processing/culture room 140, an operator 318 involved in the cell processing process (hereinafter referred to as "cell-processing operator") performs a required task according to a procedure manual, such as an instruction sheet, displayed on a touch panel-type display unit 328, while visually checking the receiving space 314.

For example, in an operation of carrying, in the receiving space 314, a plurality of required

processing materials, such as a biological material, a processing tool kit having a set of selectively combined unused processing tools enclosed therein, and a separate processing tool, the operator 318 carries the processing materials through the insertion opening 316 one by one.

An IC tag 324 is attached to each of the processing materials (including a set of selectively combined processing tools enclosed in the processing tool kit), and an ID number uniquely assigned to each of the processing materials is appended to an IC chip of the IC tag. Typically, an operation desk 327 (see FIG. 4) provided with a reader 325 adapted to read the ID number appended to each of the ID tags, a reader antenna 326 and a touch panel-type display unit 328 is disposed adjacent to the insertion opening 316 of the safety cabinet 303. The operation desk 327 is designed to serve as the data terminal (substation) 203 in FIG. 3, and connected to the after-mentioned data processing unit (base station).

Every time each of the processing materials passes through the operation desk 327 when it is carried from the insertion opening 316 into the receiving space 314 of the safety cabinet 303 by the cell-processing operator 318, the ID number appended to the IC tag 324 attached to each of the processing materials is reliably detected by the antenna 326, and read by the reader 325. The reader 325 may be integrated with the data terminal 203 in FIG. 3. As mentioned above, each of the data terminals 201 to 203 is communicatably connected to a data processing unit (base station) 204 in the management room 110. The data processing unit 204 is adapted to be operated by a computer. The data processing unit 204 pre-stores an after-mentioned process-instruction data, such as data about an instruction sheet, which is created in advance of a cell processing process in such a manner as to be associated with a plurality of ID numbers to be cross-checked with the ID numbers read by the reader 325, as will be described in detail later.

The data processing unit 204 in the cell processing center 100 comprises a database server storing data to be used by an application, an application server adapted to execute the application, and a web server having a communication function. The data processing unit 204 is connected to each of the data terminals 201 to 203 via a network. Each of the data terminals 201 to 203 has an input/output function, and may have an input function of writing data into each of the IC tags. The data stored in the database server includes sample (i.e., biological material) data, stage-sequence data having a one-to-one relationship with the sample data, a plurality of

instruction sheet data having a many-to-one relationship with the stage-sequence data, and a plurality of processing material data having a many-to-one relationship with each of the plurality of instruction sheet data. Specifically, a single sample data is associated with a single stage-sequence data, and the single stage-sequence data is associated with a plurality of instruction sheet data. Further, each of the plurality of instruction sheet data is associated with a plurality of processing material data. The data stored in the database server further includes master data to be shared, for example, operator data, such as data about operator's name, department and job type, instruction sheet data as data about an original instruction sheet, stage-sequence data serving as a stage-sequence design rule, processing material data, inspection data, equipment data, and no-business day data required for scheduling.

The application executed by the application server using the data stored in the database server has a sample-data management function, a process management function, an instruction-sheet management function, a processing-material management function, an ID cross-check function and a master management function. The sample-data management function is operable to uniquely assign a sample ID number (serving as biological-material identification data) to each of a plurality of samples (i.e., biological materials) so as to discriminate between respective ones of the samples in the cell processing system, while managing the sample ID number in association with data about a corresponding one of the samples, and make a schedule on what task should be performed for a specific sample when and by whom. Then, the process management function is operable to create stage-sequence data, instruction sheet data and processing material data which are unique to each of the samples. These data are associated with the sample ID number uniquely assigned to a corresponding one of the samples, and therefore the cell processing system can identify each of the processing materials based on the sample ID number assigned to a corresponding one of the processing materials. The process management function is further operable to manage a status of stage of a cell processing process. The instruction-sheet management function is operable to designate a specific content of task to be performed for a specific sample, and record an adequacy of a task result and a quantitative level of the task result. The processing-material management function is operable to manage types and the number of processing materials required for each task for a

specific sample. The ID cross-check function is operable to choose an arbitrary one of a plurality of pre-stored ID numbers uniquely assigned to respective ones of a plurality of processing materials designated by the processing-material management function, and cross-check an ID number input (i.e., read) by the ID number input (i.e., reading) function with the arbitrary ID number. The master management function is operable to store, modify and hold the master data.

The present invention is directed to providing a cell processing process management method capable of managing a processing material quickly and accurately without error, using a processing tool kit as the processing material together with a separate processing tool, such as a chemical agent, wherein the processing tool kit is prepared in such a manner that two or more selected from a large number of unused containers required for a cell processing process to be performed in an aseptic manipulation area are enclosed therein as a set of selectively combined processing tools, and assigned with kit identification data associated with a plurality of tool identification data uniquely assigned to respective ones of the combined processing tools, and providing a processing tool kit for use in the cell processing process management method.

With reference to FIG. 6 which is a schematic diagram showing a processing material management, and FIGS. 7 and 8 which are flowcharts showing a task-sequence management process utilizing a management method according to one embodiment of the present invention will be described below.

A set of instruction sheets No. 1 (acceptance) to No. 8 (administration) arranged along a horizontal direction in FIG. 6 is one example of stage-sequence data created based on the stage-sequence design rule.

The stage-sequence data is configured by arranging a plurality of instruction sheets along a temporal axis, in terms of when each task is performed. Data about the set of instruction sheets to be combined as stage-sequence data is stored in the database server in such a manner as to allow one of various combinations of the instruction sheets to be selected in conformity to a type of sample, age and gender of a donor of the sample. In each of the instruction sheets, a plurality of data about (1) "processing material to be used" to (5) "waste material" arranged along a vertical direction are specifically created with respect to each donor's sample, and

pre-stored in the database server of the data processing unit 204.

FIG. 9 shows an instruction sheet No. 4 as an example of a specific content of the instruction sheet.

As shown in FIG. 9, the instruction sheet No. 4 includes a description about a safety cabinet No., a task data, an operator's name, cell data (cell type, donor's name, sampling date, etc.), a content of task, a ID list of carrying-in separate processing materials including a chemical agent) and a kit ID of a carrying-in processing tool kit. The instruction sheets are displayed in the touch panel-type display unit 328.

For example, when a task is a processing for subculture, it is necessary to carry a dish containing cultured cells serving as cells to be transferred, from the incubator 306 into the safety cabinet 303. For this purpose, an ID number of a specific dish is described in the instruction sheet. Furthermore, in the processing for subculture, a given culture solution is injected into an empty unused dish to form a new culture medium. Then, for example, a culture solution is removed from a dish of cultured cells, and the cultured cells are transferred to a centrifuge tube using a chemical agent. After the cultured cells are subjected to purification/separation using the centrifuging machine 304, they are transferred to the new culture medium.

In order to perform the above task, an unused disk, a centrifuge tube and a pipette serving as a transfer device are transported from the preservation room 120 to the cell processing/culture room 140 through the preparation room 130. These processing tools may be enclosed in a processing tool kit, particularly when they are unused processing tools, and transported in the form of a package to simplify a carrying-in operation which would otherwise be cumbersome and complicated, so as to strictly manage the processing tools without error. For this purpose, the carrying-in processing material list of the instruction sheet No. 4 includes a description about an ID number uniquely assigned to each of the biological material and the processing tool kit. In addition, the instruction sheet includes a list of processing tools correspondingly associated with a plurality of tool identification data appended to respective IC tags attached to a plurality of processing tools taken out of the carried-in processing tool kit after opening the carried-in processing tool kit. Process-instruction data including data about the set of instruction sheets is created in the above manner, and pre-stored in the data processing unit.

The following description will be made about a column of the instruction sheet No. 4 in FIG. 6 which is a schematic diagram showing a processing material management on the assumption that a cell processing process is performed using a plurality of processing materials having respective ID numbers uniquely assigned thereto.

The (1) "processing material to be used" is a dish which is taken out of the incubator 306 and carried in the safety cabinet 303 while containing cultured cells and having an ID number t uniquely assigned thereto. The (2) "unused processing tool to be used " is a processing tool kit prepared to allow a set of selectively combined processing tools including a plurality of unused dishes and a plurality of unused centrifuge tubes to be enclosed therein, wherein tool identification data uniquely assigned to each of the combined processing tools is appended to an IC tag attached to a corresponding one of the combined processing tools, and associated with after-mentioned kit identification data uniquely assigned to the processing tool kit. The processing tools taken out of the processing tool kit after being carried in the safety cabinet and opened includes an unused dish for receiving therein cultured cells to be transferred thereto. In this stage, the tool identification data is not associated with a biological-material ID number uniquely assigned to each sample. In advance of a cell processing process, the (3) "label to be used" is prepared, for example, using a commercially available sticker-label printer adapted to output a label in such a manner as to be associated with data stored in the database server, and attached to an unused processing tool, whereby the tool identification data uniquely assigned to the unused processing tool is associated with the biological-material ID number to allow the unused processing tool to be the (4) "completed processing tool". Preferably, the label is designed to have an IC tag attached thereto, and an outer surface printed with data corresponding to that written in the IC tag so as to allow an operator to visually check the data. The (5) "waste material" is a used processing tool, such as the dish in the (1) "processing material to be used" to be discarded after the cultured cells are transferred to the unused processing tool.

The operator 318 can perform a plurality of tasks of the cell processing process one by one while checking whether the ID number of the IC tag attached to each of the processing materials corresponds to an arbitrary one of the plurality of ID numbers associated with the process-identification data, by the touch panel-type display unit 328.

With reference to the flowcharts in FIGS. 7 and 8, a cell processing process, for example, in the safety cabinet 302, will be described below, together with respective stages of production, preparation and use of a processing tool kit.

While this embodiment will be described on the assumption that a processing tool kit is produced by the processing-tool manufacturer different from the cell processing center, as shown in FIG. 1, the present invention is not limited to such a scheme.

In a processing-tool-kit production stage 400, plural types and a plural number of processing tools are firstly produced in Step 410. In Step 420, tool identification data is uniquely assigned to each of the processing tools, and appended to an IC tag attached to a corresponding one of the processing tools. Then, two or more of the processing tools required for a cell processing process are selectively combined as a single set in Step 430, and a processing tool kit is prepared to allow the set of selectively combined processing tools to be enclosed therein, in Step 460. In Steps 440 and 450 preceding Step 460, all the tool IDs of the combined processing tools to be encloses are recognized, and all the recognized tool IDs are associated with the after-mentioned kit ID. In Step 470 as a final step in the processing-tool-kit production stage, a kit ID (kit identification data) uniquely assigned to the processing tool kit having the combined processing tools enclosed therein is appended to an ID tag attached thereto. Instead of the ID tag, a recording medium recording thereon the association data may be attached to the processing tool kit according to need.

Thus, a shipping of the processing tool kit to the cell processing center 100 in Step 480 is performed in a state after the respective tool IDs of the combined processing tools enclosed in the processing tool kit are associated with the kit ID of the processing tool kit.

Then, in a processing-tool-kit storage stage 500 in the cell processing center, the processing tool kit is procured together with a separate unused processing tool in Step 510. Each of the processing tool kit and the separate unused processing tool is subjected to an acceptance test, such as inspection for a validity date and breakage of an outer package. Then, in Step 530, the kit ID of the processing tool kit is read, for example, using the data terminal 201 in the preservation room 120 in FIG. 3, so that all the tool IDs of the combined processing tools associated with the kit ID are pre-stored in the data processing unit in the management room 110

via the data terminal 201 in Step 540. As shown in FIG. 2, it is understood that data about a stock of the separate processing tools and data about a stock of the processing tool kits are registered to the master data of the database server of the data processing unit to allow a stock state to be figured out on a constant basis. Through the above process, the procured processing tool kits are stored, for example, on a shelf in the preservation room 120 of the cell processing center.

Then, referring to FIG. 8, in a processing-tool-kit preparation stage in the preservation room 120 of the cell processing center, an operator of the preservation room operates the data terminal 201 to calls up an ID of a cell to be subjected to a cell processing process, and a pre-stored stage-sequence data from the data processing unit 204 pre-storing process-instruction data including data about instruction sheets in FIG. 6, and cause display means or the like to display the cell ID and the stage-sequence thereon, in Step 600. Then, in Step 620, the operator of the preservation room takes out a processing tool kit from the shelf in the preservation room 120, based on the displayed process-instruction data, and reads a kit ID of the processing tool kit, for example, using a reader provided to the data terminal 201. Furthermore, in advance of the use of combined processing tools enclosed in the processing tool kit, the operator of the preservation room operates the data terminal 201 to call up all tool IDs associated with the read kit ID, from data processing unit 204, and associate the respective tool IDs with the cell ID and the stage-sequence called up from the data processing unit 204, in Step 630. After completion of the association, in Step 640, the processing tool kit is transported from the preservation room 120 to the cell processing/culture room 140 through the preparation room 130.

In this embodiment, Steps 610 to 640 in the processing-tool-kit preparation stage 600 are performed using the data terminal 201 by the operator of the preservation room 120. Alternatively, this operation may be performed using the reader 325 of the operation desk 327 by the cell-processing operator 318 in the cell processing/culture room.

In a processing-tool-kit use stage 700, the processing tool kit transported to the cell processing/culture room 140 is received by the cell-processing operator 318. The processing tool kit having the combined unused processing tools enclosed therein is carried in an aseptic manipulation area, such as the safety cabinet 303 illustrated in FIG. 4, and opened to use the

unused processing tools. In advance of this operation, the processing tool kit is placed on the operation desk 327 corresponding to a data terminal in the cell processing/culture room. In Step 710, the reader 325 reads the kit ID appended to the IC tag attached to the placed processing tool kit. In Step 720, the data processing unit 204 communicatably connected to the reader 325 chooses an arbitrary one of a plurality of the kit IDs associated with the process-instruction data which is associated with identification data pre-stored in the data processing unit, comprising a plurality of sample IDs uniquely assigned to respective ones of a plurality of samples, a plurality of stage ID uniquely assigned to respective ones of a plurality of stages of the cell processing process, and a plurality of tool IDs uniquely assigned to respective one of a plurality of separate and combined processing tools, and cross-checks the read kit ID with the arbitrary kit ID to output cross-check data indicative of whether the two cross-checked IDs are coincident with each other. Then, when it is confirmed that the output cross-check data indicates coincidence between the two cross-checked data, the cell-processing operator will carry the processing tool kit into the safety cabinet 303, and open the processing tool kit to take out the combined processing tools therefrom and use the combined processing tools as unused processing tools so as to perform the cell processing process, in Step 730.

Although not illustrated in the flowcharts of FIGS. 7 and 8, when the output cross-check data indicates non-coincidence between the two cross-checked data, the operator 318 will perform an error handling. That is, the output cross-check data indicating non-coincidence between the two cross-checked data clearly shows that the carried-in processing material does not exist in the process-instruction data. Thus, the error handling may include carrying in a proper processing material while stopping the task, or, restarting the task itself from the beginning in a serious situation where the two cross-checked data are associated with different sample IDs. After completion of the error handling, the operator 318 will restart the task of carrying the processing material into the safety cabinet 303 in Step 700.

After completion of the cell processing process, the tool ID associated with a sample, i.e., biological material, is appended to the IC tag attached to each of the unused processing tools. Thus, subsequent stages will be managed based on this IC tag.

In a processing-tool discarding stage 800, a container, such as a dish or a centrifuge tube, to

be discarded after being used for subinoculation/replacement of a sampler (i.e., biological material) or a culture medium, is confirmed based on the process-instruction data displayed on the touch panel-type display unit 328, during an operation of charring it into the safety cabinet 303. Based on the process-instruction data, in Step 810, the operator 318 carried such a used waste material from the safety cabinet 303, into the waste chamber 305. In this operation, according to need, the tool ID appended to the IC tag attached to the used waste material may be re-read using a second reader provided in the waste chamber 305, in Step 820. Then, the data processing unit 204 chooses an arbitrary one of the plurality of tool ID associated with the process-instruction data, and cross-check the arbitrary tool ID with the read ID to output a cross-check result as a second cross-check data, in Step 830. In Step S318, the operator 318 checks the second cross-check data to determine whether the processing tool is a used waste material or a biological material-containing useful material. If it is determined that the processing tool is a used waste material, the processing tool will be discarded in Step 840. This makes it possible to reliably avoid misplacement of the waste material in the safety cabinet 303.

In order to check whether processing materials are entirely carried out of the safety cabinet after completion of the cell processing process, a processing material may be carried out of the safety cabinet 303 via the operation desk 327 to re-read a tool ID so as to cause the data processing unit 204 to output third check-out data.

As mentioned above, the present invention provides a cell processing process management method using a processing tool kit prepared to allow a set of selectively combined processing tools to be enclosed therein, wherein tool ID is appended to an IC tag attached to each of the combined processing tools, and kit ID is appended to an IC tag attached to the processing tool kit in such a manner as to be associated with all the tool IDs. The toll IDs and the kit ID in a plurality of the processing tool kits required for a cell processing process are pre-stored in data processing unit in such a manner as to be associated with process-instruction data pre-stored therein. Then, when the kit ID is read using a reader communicatably connected to the data processing unit, the data processing unit is operable to choose an arbitrary one of the plurality of kit IDs associated with the process-instruction data, and cross-check the read kit ID with the arbitrary kit ID, whereby, if the two cross-checked data are coincident with each other, the

processing tool kit will be allowed to be used. The management method of the present invention makes it possible to automatically associate the tool ID appended to each of the IC tags of the processing tools, with data about a sample to be subjected to a cell processing process defined in the process-instruction data, such as donor's name, cell type and sampling date.

This eliminates a need for an operator involved in a cell processing process to write new tool ID in each processing tool every time it is newly used, as in conventional techniques, so as to reduce a risk of registration error.

Additionally, as might be expected, as compared with an operation of carrying a large number of separate processing materials into a safety cabinet or the like, the present invention is can further facilitate process management, and significantly contribute to improvement in operating efficiency.

What is claimed is:

1. A method of managing a cell processing process to be performed in an aseptic manipulation area by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample and a culture medium; a processing tool kit prepared in advance of said cell processing process in such a manner as to allow a set of selectively combined processing tools including an unused dish and/or an unused centrifuge tube to be enclosed therein; and a separate processing tool including a chemical agent, said method comprising:

pre-appending, to a wireless communication device attached to said processing tool kit, kit identification data assigned to said processing tool kit and associated with tool identification data which is uniquely assigned to each of said combined processing tools enclosed in said processing tool kit, and appended to a wireless communication device attached to a corresponding one of said combined processing tools;

pre-storing, in a computer-operated data processing unit, process-instruction data configured to indicate an instruction for said cell processing process and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of a plurality of said biological materials, a plurality of stage identification data uniquely assigned to respective ones of a plurality of stages of said cell processing process, a plurality of said tool identification data uniquely assigned to respective ones of said combined and separate processing tools, and a plurality of said kit identification data uniquely assigned to respective ones of a plurality of said processing tool kits;

causing a wireless reading unit communicatably connected to said data processing unit, to read said kit identification data pre-appended to said kit tool; and

causing said data processing unit to choose an arbitrary one of said plurality of kit identification data associated with said process-instruction data, , and cross-check said read kit identification data with said arbitrary kit identification data so as to output cross-check data indicative of whether said two cross-checked data are coincident with each other, whereby, when it is confirmed that said output cross-check data indicates coincidence between said two

cross-checked data, an operator involved in said cell processing process is permitted to carry said processing tool kit into said aseptic processing area.

2. A method of managing a cell processing process to be performed in an aseptic manipulation area by use of a processing material which comprises: a biological material consisting of a cell associated with a specific sample and a culture medium; a processing tool kit prepared in advance of said cell processing process in such a manner as to allow a set of selectively combined processing tools including an unused dish and/or an unused centrifuge tube to be enclosed therein; and a separate processing tool including a chemical agent, wherein said processing material is carried into said aseptic manipulation area by an operator involved in said cell processing process, said method comprising the steps of:

pre-appending, to a wireless communication device attached to each of said combined processing tools to be enclosed in said processing tool kit, a plurality of tool identification data uniquely assigned to respective ones of said combined processing tools;

pre-appending, to a wireless communication device attached to said processing tool kit, kit identification data assigned to said processing tool kit and associated with said respective tool identification data of said combined processing tools;

pre-storing, in a computer-operated data processing unit, process-instruction data configured to indicate an instruction for said cell processing and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of a plurality of said biological materials, a plurality of stage identification data uniquely assigned to respective ones of a plurality of stages of said cell processing process, a plurality of said tool identification data uniquely assigned to respective ones of said combined and separate processing tools, and a plurality of said kit identification data uniquely assigned to respective ones of a plurality of said processing tool kits;

causing a wireless reading unit communicatably connected to said data processing unit, to read said kit identification data pre-appended to said wireless communication device attached to said processing tool kit to be carried in said aseptic manipulation area; and

causing said data processing unit to choose an arbitrary one of said plurality of kit

identification data associated with said process-instruction data, and cross-check said read kit identification data with said arbitrary kit identification data so as to output a result of a determination on whether said two cross-checked data are coincident with each other, in the form of cross-check data, whereby:

when said output cross-check data indicates coincidence between said two cross-checked data, said operator is permitted to carry said processing tool kit into said aseptic processing area, after causing said data processing unit to associate a specific one of said plurality of biological-material identification data with said respective tool identification data of said combined processing tools enclosed in said processing tool kit; and

when said output cross-check data indicates non-coincidence between said two cross-checked data, said operator is instructed to perform an error handling while stopping the task of carrying said processing tool kit into said aseptic processing area.

3. The method as defined in claim 2, which further includes the step of, when said output cross-check data indicates coincidence between said two cross-checked data, allowing said operator to confirm said output cross-check data indicative of said coincidence, and then causing said data processing unit to associate a specific one of said plurality of biological-material identification data with said respective tool identification data of said combined processing tools enclosed in said processing tool kit,

whereafter said operator is permitted to carry said processing tool kit into said aseptic processing area and open said processing tool kit so as to take out said combined processing tools from said opened processing tool kit.

4. The method as defined in claim 2 or 3, wherein, after said error handling is performed while stopping the task of carrying said processing tool kit into said aseptic processing area, said operator is permitted to restart said task of carrying said processing tool kit into said aseptic processing area.

5. The method as defined in any one of claims 2 to 4, which further includes the step of

causing said data processing unit to instruct display means provided in said aseptic processing area to display said output cross-check data.

6. A processing tool kit comprising:

a set of selectively combined unused processing tools including an unused dish and/or an unused centrifuge tube, said combined unused processing tools being enclosed therein in advance of a cell processing process to be performed in an aseptic processing area, and used in said cell processing process together with a biological material consisting of a cell associated with a specific sample and a culture medium, and a separate processing tool including a chemical agent; and

a wireless communication device attached thereto while having kit identification data assigned to said processing tool kit and appended thereto, said kit identification data being associated with tool identification data which is uniquely assigned to each of said combined unused processing tools and appended to a wireless communication device attached to a corresponding one of said combined unused processing tools.

7. A processing tool kit for use in a cell processing system, said cell processing system including: a computer-operated data processing unit pre-storing therein process-instruction data configured to indicate an instruction for a cell processing process and associated with at least a plurality of biological-material identification data uniquely assigned to respective ones of a plurality of biological materials to be subjected to said cell processing process, and a plurality of kit identification data uniquely assigned to respective ones of a plurality of said processing tool kits required for said cell processing process; and a wireless reading unit communicatably connected to said data processing unit, said processing tool kit comprising:

a set of selectively combined unused processing tools enclosed therein; and

a wireless communication device attached to each of said combined unused processing tools while having a plurality of tool identification data uniquely assigned to respective ones of said combined unused processing tools and appended thereto,

wherein said wireless reading unit is adapted to read said kit identification data

pre-appended to said processing tool kit, and said data processing unit is adapted to choose an arbitrary one of said plurality of kit identification data associated with said process-instruction data, and cross-check said read kit identification data with said arbitrary kit identification data, to output a result of a determination on whether said two cross-checked data are coincident with each other, in the form of cross-check data,

wherein, when it is conformed that said output cross-check data indicates coincidence between said two cross-checked data, an operator involved in said cell processing process is permitted to carry said processing tool kit having said combined unused processing tools enclosed therein, into an aseptic processing area, and open said processing tool kit so as to take out said combined unused processing tools from said opened processing tool kit, after causing said data processing unit to associate a specific one of said plurality of biological-material identification data with said respective tool identification data appended to said wireless communication devices attached to said combined unused processing tools.