159159

DESCRIPTION

PLANT DESIGN SUPPORT SYSTEM AND METHOD THEREFOR

TECHNICAL FIELD

[0001] The present invention relates to a system and method which support the design of a plant used for producing drugs, chemicals, foods and the like.

RELATED ART

[0002] In many countries such as Japan, the U.S.A., European countries, and others, standards for production management and quality control are set forth in GMP (Good Manufacturing Practice) in order to prevent various contaminations from occurring, and produce drugs of good quality. GMP has been employed in the U.S.A. since 1960s, and sets forth management requirements and other requirements to be observed to produce drugs, foods and the like of safe and excellent quality and healthiness. In Japan, GMP for drugs is also adopted in the drug legislation, and drug makers must comply with the standard set forth in GMP.

[0003] Therefore, a factory (plant) producing drugs is required to be designed so as to meet the standard of GMP. Regarding plants for foods and chemicals, validity and safety of the production management and quality control must also be taken into careful

G00002

consideration. Especially in recent years, consciousness for safety has grown all over the world. Hence, even in an industry in which no careful standard has never been set up, a plant design must be carried out in consideration of suitable production management and quality control, and a plant must be constructed in accordance with the design drawing, in order to provide products to the world market.

Patent Document 1:Japanese Patent Laid-Open No. Hei10-269269.

DISCLOSURE OF THE INVENTION

[0004] At present, a plant design that meets the GMP standards requires a relatively long period and high cost depending on its scale. Plant construction companies endeavor to make a design period shorter by holding experiences regarding past plant designs as know-how, and by utilizing fully the know-how; however, a typical plant design still requires a time period of six months or so.

[0005] Constructions of multi-purpose plants that are capable of producing not only one type of drugs but also a plurality of types of drugs, have grown in number of constructions; however, arrangement of the

facilities differs for each drug maker, and an area for a plant construction also differs from each other. For this reason, currently, the effective use of know-how is often limited, and such a situation has sometimes occurred that a plant design substantially has to be carried out from a zero base. In addition to that, such a situation has also occurred that the relevant know-how is lost from a maker or plant construction company in the event of a personnel change, etc., since the know-how is mostly dependant upon the skill of individual persons.

[0006] After a plant design has been completed, an inspection is required to be carried out to see whether it meets the GMP standard or not, as be designed. Conventionally, the inspection has to be carried out after the overall design of a plant has been completed, therefore the design has to be reviewed if there is an inadequacy in a part of the facility design. In some cases, the overall design has to be reviewed, which leads to an increase in a design period and cost.

[0007] The present invention has been made in view of these circumstances and a general purpose of the invention is to provide a technique which can support a plant design effectively.

[0008] To solve the aforementioned problems, an embodiment of the present invention provides a system

which supports a plant design. The plant design support system includes a module storing means for holding equipment installed in a plant, as a module which is designed so as to meet a required standard for a plant design by itself; and an arranging means for arranging a module read out from the module storing means, in a two or three-dimensional virtual space.

[0009] A plant design can be easily achieved by providing a module which meets a design standard by itself in advance, selecting a plurality of modules necessary for constructing a plant, and then connecting the modules together. In the case, since the modules meet the design standard by itself, judgments about whether equipment units, pipes, and ducts in a module meet the design standard or not, are unnecessary, therefore, a great reduction in the design period and a reduction in the design cost can be achieved.

[0010] The module storing means holds groups of modules which are composed of a plurality of modules for each type of equipment. The plant design support system may further include a selecting means for selecting a module from the groups of modules. A highly general purpose of plant design support system can be achieved by providing a plurality of modules for one type of equipment.

[0011] The module storing means preferably holds a

module having a connecting portion at a common position for each type of equipment. A connecting position can be unambiguously identified by standardizing the positions of connecting portions which have functions to be connected to another module, for each type of equipment. A connection between modules can be easily made by simply arranging the modules adjacently to each other, when a connecting portion of a target equipment is placed at the same position when facing each other. Further, the position of a connecting portion is required to be standardized in at least the height from the bottom face of a module. Still further, other connecting components included in a connecting portion, for example, a pipe and duct, are standardized in the arrangement thereof. Due to this, when connecting modules together, the effective plant design support can be achieved since an adjustment of the arranging positions of a pipe and duct in one side or both sides of the modules, is not required.

[0012] Another embodiment of the present invention provides a method of supporting a plant design, wherein a plant design is performed by in advance providing equipment to be installed in a plant, as a module which is designed so as to meet a required design standard by itself, and then by connecting the modules together in a two or three-dimensional virtual space.

[0013] Note that any combination of the aforementioned components or any manifestation of the present invention realized by modifications of a method, device, system, storing media, computer program, and so forth, is effective as an embodiment of the present invention.

[0014] According to the present invention, a technique which can support a plant design effectively, can be provided.

BRIEF DESCRIPTION OF THE DRAWINGS

[0015] Fig. 1 is a diagram which shows the validation steps in a plant design;

Fig. 2 is a diagram which shows a structure of a plant design support system in accordance with the present invention;

Fig. 3 is an example of a plan view of a facility module;

Fig. 4 is a diagram which shows an example of a selecting screen on which each step in the bulk pharmaceutical production process is displayed;

Fig. 5 is a diagram which shows a selecting screen on which facility modules in the reaction step are displayed;

Fig. 6 shows an example of a front view of a

three-dimensional design drawing;

Fig. 7 shows a right side view of a three-dimensional design drawing; and

Fig. 8 shows a perspective view of a three-dimensional design drawing.

REFERENCE NUMERALS

[0016]

2	input interface
4	display
10	plant design support system
12	receiving unit
20	processing unit
22	arranging unit
24	selecting unit
30	module storing unit
40	design drawing storing unit
50	facility module
52	pipe rack
54	first connecting portion
56	second connecting portion
58	sub pipe portion
60	equipment unit

BEST MODE FOR CARRYING OUT THE INVENTION

[0017] Fig. 1 shows the validation steps in a plant design. While the description below highlights the

design of a plant for manufacturing pharmaceuticals, the description substantially applies to plants for manufacturing food and chemical products. The validation steps include four steps: DQ (Design Qualification), IQ (Installation Qualification), OQ (Operational Qualification), and PQ (Performance Qualification), and PV (Process Validation) which is performed in the last.

[0018] In the DQ, it is determined whether the design is suitable for the required specification or the function specification, etc., or not. Specifically, it is determined whether the plant design will meet not only the requirements from an orderer, i.e., a drug maker, but also the standard of GMP or not. In the IQ, it is verified whether various facilities installed in accordance with the design drawing are qualified. In the OQ, the important functions and performances of the installed facility are tested. The DQ, IQ, and OQ are typically performed by a plant construction company. When the validations up to the OQ have been completed, the plant is transferred to the drug maker. In the PQ, various performances of the plant are confirmed by the drug maker. In case of a multi-purpose plant, for example, it is confirmed whether the plant can produce various types of drugs or not. Lastly, the PV is performed by

making it clear with a written document that it is guaranteed that products which meet the required characteristics and quality are produced consistently.

[0019] The present invention provides a system and method which support a plant design. The plant design support technique can be used in the DQ step of the validation steps, and reduce the DQ step period and the cost.

[0020] Fig. 2 shows a structure of a plant design support system 10 in accordance with the present invention. The plant design support system 10 is used in a plant construction company, and has a function to support a plant design. The plant design support system 10 includes a receiving unit 12 which receives an input instruction from a user, a processing unit 20 which performs the creation of a plant design drawing, a module storing unit 30 which holds a facility module installed in a plant, a design drawing storing unit 40 which stores a design drawing created in the processing unit 20.

[0021] The aforementioned structure is achieved by a CPU, memory, and other LSI of any computer in terms of hardware, and by a program loaded into a memory in terms of software. Herein, a function block which is achieved by a combination thereof will be described. Therefore, it will be understood by those skilled in

the art that such a function block can be achieved in various forms by hardware alone, software alone, or a combination thereof.

[0022] The input interface 2 is composed of a tool which can be operable by a user, such as a mouth, key board. A user makes a design drawing, while watching a screen displayed on the display 4 by operating the input interface 2. The display 4 is composed of a monitor, such as a liquid crystal panel or CRT.

[0023] In the present embodiment, the module storing unit 30 holds facility modules of equipment installed in a plant, which are designed so as to meet a required standard for plant design by itself. The design standard may be a statutory standard such as GMP, or a standard derived from the know-how to meet the statutory standard of GMP. The module storing unit 30 holds groups of modules which are composed of a plurality of facility modules for each type of equipment. A facility module unit is structured as a three-dimensional drawing in which equipment unit, surrounding pipes and ducts are shown three-dimensionally. For example, a facility module unit can be formed with the use of CAD data.

[0024] A facility module includes types of equipment which is foreseen to be necessary for a multiple-purpose plant. A plurality of facility modules may

preferably be provided in advance with respect to all the steps necessary for producing various types of drugs, in order to enhance the versatility of the plant design support system 10. For example, in the case a drug is produced by performing the following steps: the reaction step, solid-liquid separation step, drying step, crystallization step, solid-liquid separation step, and drying step, the module storing unit 30 is required to store the facility modules in each step in advance.

[0025] For example, with respect to the reaction step, a group of facility modules having a plurality of types of reaction apparatuses is provided, and in each facility module, a pharmaceutical material supply port of the reaction apparatus, and pipes, ducts and the like which extend from the reaction apparatus, are formed in a manner that they meet GMP standard. In this way, a facility module is set so as to meet a required design standard by itself, and it becomes a module of a closed system which meets a certain design standard by itself except for an inlet and outlet for communicating with another facility module. Alternatively, a plurality of steps may be put together in one facility module, for example, a facility module may be provided for the solid-liquid separation/drying step in which the solid-liquid separation step and the

drying step are performed collectively.

[0026] Examples of an operation performed in the reaction step (hereinafter referred to as a "unit operation") include supply of raw materials, receiving operation, operation of supplying purified water, temperature increase/decrease operation, pressure reduction/increase operation, plant nitrogen purge operation, stirring operation, and transfer operation, etc. A design standard is defined for each unit operation and the standard is derived from GMP or the accumulation of experiences of the past, as described before.

[0027] A typical design standard requires the following: 1) To prevent contamination by extraneous substance generated by corrosion of or elution from a process line or reaction apparatus unit;

2) To prevent survival of a raw material or generation of a by-product due to an error in the volume of raw material added;

3) To provide a function to appropriately control the temperature adjustment;

4) To provide a function to appropriately control the pressure adjustment;

5) To prevent a contamination of the inside of the equipment by nitrogen purging;

6) To provide a function to appropriately stir;

7) To provide a function to appropriately clean the system by CIP (Cleaning in Place) or disassembling.

[0028] A facility module is provided with a block structured with steel frames in a manner that the module meets these design standards. The pipes and ducts which are installed in the block, and equipment unit, etc., are arranged in appropriate positions of the block according to the design. For example, dusts tend to accumulate on the pipes and ducts, which would hinder an appropriate step from being performed, if the dust enters the equipment unit. For this reason, pipes and ducts are installed at such positions that the dust thereon will not enter the equipment unit, even if dusts accumulate on the pipes and ducts, thereby preventing contamination by extraneous substance. Furthermore, a facility module is preferably defined not only in respect of the structures of block, pipes, and ducts or the like but also the materials thereof.

[0029] Fig. 3 is a concept view of a top surface of a facility module. The facility module 50 includes the equipment unit 60, a first connecting portion 54 which receives a product from another facility module arranged in the stage preceding the facility module 50, a second connecting portion 56 which transfers a product to still another facility module arranged in the stage subsequent to the facility module 50, a pipe

rack 52 with a plurality of pipes, and a sub pipe portion 58 which connects a pipe in the pipe rack 52 with the equipment unit 60. The pipe rack 52 is installed apart from the equipment unit 60 so that the dust thereon will not enter the equipment unit 60. In Fig. 3, the direction of an arrow of each sub pipe in the sub pipe portion 58 shows whether the sub pipe is for supply to the equipment unit 60 or for retrieval from the equipment unit 60. In the example of the Figure, the equipment unit 60 represents a reaction apparatus.

[0030] The facility module 50 has a connecting portion at a common position for each type of equipment. That is, in the same group of facility modules, the connecting portions of all of the facility modules 50 are standardized. When viewing the second connecting portion 56 two-dimensionally, a distance d1 between one side of the facility module 50 (the top side in Fig. 3) and the one edge part of the second connecting portion 56, and the length d2 from one edge to the other edge of the second connection portion 56 are the same for all the facility modules 50 in the same group of the facility modules. In addition, the height of the second connecting portion 56 from the bottom of the facility module 50 is the same. The number and the arrangement of the pipes and ducts in

the second connecting portion 56 are the same. So are those in the first connecting portion 54. Standardization is not required to be performed between the first connecting portion 54 and the second connection portion 56. Standardization is only required in the positions and the inner arrangements of the first connecting portions 54 in the same group of facility modules. Also, standardization is required in the positions and the inner arrangements of the second connecting portions 56 in the same group of facility modules. According to the plant design support system 10 of the present embodiment, a facility module 50 can be easily connected with another facility module.

[0031] What must be standardized are the height of the connecting portion from the bottom face of the facility module 50 and the inner structure (inner arrangement) of the connecting portion. The distance d1 between one side of the facility module 50 and the edge part of the connecting portion is not necessarily standardized; however, if the distance d1 is standardized, it allows connections between facility modules to be easily performed, since the one side of a facility module can be arranged at a predetermined position in designing a plant.

[0032] In another group of facility modules, connecting positions are standardized. In the bulk

pharmaceutical production process, the steps proceed in a predetermined order in most cases. Therefore, connections between facility modules can be easily performed by simply arranging the facility modules adjacent to each other, thanks to an arrangement in which the positions of the connecting portions for each group of the facility modules are defined so that the first connecting portion 54 is connected to another facility module arranged in the preceding stage, and the second connection portion 56 to still another facility module arranged in the subsequent stage. In addition, the meaning of "positions of the connecting portions" includes positions of pipes and ducts which are connected, therefore pipes included in each of two facility modules will be connected together by arranging the connecting portions of the two facility modules in contact together. In this way, according to the plant design support system 10 of the present embodiment, connections between facility modules can be made by simply arranging facility modules adjacent to each other, therefore the system is available as a highly convenient design support tool.

[0033] Referring back to Fig. 2, the selection unit 24 displays a selection screen for selecting the facility module 50 on the display 4. The selection screen may be displayed on the display 4 when a user

conducts a plant design. The screen may be displayed upon start-up of the plant design support system 10. Fig. 4 shows an example of a selection screen in which each steps in the bulk pharmaceutical production process is displayed. Check boxes are provided on the left of the step names. When a user checks any box using the input interface 2, a specification of a facility module used in the step is displayed. In addition, Fig. 4 shows only five steps for convenience of explanation, other groups of facility modules in each step necessary for the bulk pharmaceutical production process, such as the measuring step, filling step, are provided in the module storing unit 30.

[0034] Fig. 5 shows a selection screen for selecting a facility module in the reaction step which is displayed when the reaction step is selected in the selection screen in the Fig. 4. The selection screen displays a specification which defines a capacity of the reaction apparatus, maker, price of a facility module, etc. Checkboxes are provided on the left of each specification. When a user checks any one of the checkboxes using the input interface 2, the facility module is selected. A user selects a facility module using the input interface 2, in accordance with a demand and budget or the like which are presented by a drug maker (client). In this way, the selection unit

24 has a function by which a user is allowed to select any facility module from a group of facility modules including a plurality of facility modules. The selection unit 24 reads out the facility module selected by a user from the module storing unit 30, and provides it to the arranging unit 22.

[0035] The arranging unit 22 arranges the facility module read out from the module storing unit 30 in a two or three-dimensional virtual space. When a plant is structured three-dimensionally, namely, equipment units are stacked vertically, the arranging unit 22 forms a three-dimensional virtual space on the display 4, and arranges facility modules in the space. In this case, the facility module 50 is provided with connecting portions on top and bottom faces thereof. As mentioned above, the facility module 50 is structured three-dimensionally, therefore, a CAD design drawing which is easy to visually understand, can be created by arranging the facility module in a three-dimensional virtual space.

[0036] Further, this processing may be performed as an inner processing of the arranging unit 22, hence a screen provided to a user on the display 4 may simply be a selection screen shown in Figs. 4 and 5, etc. For example, in the case where five steps: the reaction step, solid-liquid separation step, drying step,

crystallization step, solid-liquid separation step, and drying step, are performed in succession, a user selects a facility module of each step, with the use of the function of the selection unit 24. When all facility modules are selected, the arranging unit 22 may automatically arrange each facility module in a limited plant space. In the case, a highly convenient plant design support system 10 can be achieved since a user can save the labor of having to arrange each facility module by his hand.

[0037] In the case where all equipment are installed on a plane, namely, on a floor of a plant, the arranging unit 22 may arrange the facility modules 50 after forming a two-dimensional virtual space. The facility module unit is structured as a three-dimensional object; however, when only an arrangement relation of equipment is presented to a user, the three-dimensional structure of each equipment is not required to be displayed on the display 4. A plurality of facility modules arranged two-dimensionally in an appropriate order may be displayed on the display 4.

[0038] The case where the arranging unit 22 has a function which automatically arranges the facility modules, is described above. The unit may arrange the facility modules in a two or three-dimensional virtual space based on inputs from the input interface 2 by a

user. For example, if the facility modules can not be arranged appropriately with the use of the automatic arranging function, then a user may adjust relation of each position therebetween. In addition, when the arranging unit 22 does not have the automatic arranging function in the first place, a facility module may be arranged at any position with the use of user's operation of the interface 2. In this way, the arranging unit 22 may have the automatic arranging function, or have the function which arranges a facility module with the use of user's operations. The arranging unit 22 preferably has both functions, thereby the plant design support system 10 which is highly convenient to users can be achieved.

[0039] When the arranging unit 22 arranges all facility modules in a virtual space, a design drawing is completed. A completed design drawing is stored in the design drawing storing unit 40. According to the plant design support system 10 of the embodiment, the facility module 50 is structured so as to meet GMP by itself, and the modules 50 can be easily connected together, therefore it is possible to easily ensure that the overall design complies with GMP.

[0040] Fig. 6 shows an example of a front view of a three-dimensional design drawing. In the Figure, the reaction apparatus module 50a, solid-liquid

separation/drying apparatus module 50b, crystallization apparatus module 50c, solid-liquid separation apparatus module 50d, and drying apparatus module 50e are illustrated as the facility module 50. The bulk pharmaceutical production process proceeds in the order of the reaction step in the reaction apparatus module 50a, solid-liquid separation/drying step in the solid-liquid separation/drying apparatus module 50b, crystallization step in the crystallization apparatus module 50c, solid-liquid separation step in the solid-liquid separation apparatus module 50d, and drying step in the drying apparatus module 50e. Advantageously, the products generated in the steps are easily transferred by arranging the apparatus modules from the top to the bottom in the order of the steps. As shown in Fig. 6, when facility modules 50 arranged in a plurality of tiers vertically, the connecting portions are provided in the direction in which the facility module 50 is connected vertically, while the connecting portions are provided horizontally in the Fig. 3. Transfer of the products from the solid-liquid separation/drying apparatus module 50b to the crystallization apparatus module 50c is performed with the use of an elevator.

[0041] Fig. 7 shows a right side view of a three-dimensional design drawing, and Fig. 8 a perspective

view of the same. Connections between facility modules 50 are easily made since the connecting portions of all facility modules 50 are provided at the common position, and the connecting portion of a facility module is formed so as to fit the position of the connecting portion of the adjacent counterpart, in each group of facility modules.

[0042] The present invention has been described above in conjunction with the embodiments thereof. The embodiment has been given solely by way of illustration, and it will be understood by a person skilled in the art that various modifications may be made to combinations of the foregoing components and processes, and all such modifications are also intended to fall within the scope of the present invention.

INDUSTRIAL APPLICABILITY

[0043] The present invention can be used in a system which supports a plant design.

CLAIMS

1. A plant design support system comprising:

a module storing means for holding modules of equipment installed in a plant, each of which is designed so as to meet a required standard for a plant design by itself; and

an arranging means for arranging a module read out from the module storing means, in a two or three-dimensional virtual space.

2. The plant design support system according to claim 1, wherein the module storing means holds groups of modules which are composed of a plurality of modules for each type of equipment, and the plant design support system further comprises a selecting means for selecting a module from the groups of modules.

3. The plant design support system according to claims 1 or 2, wherein the module storing means holds a module having a connecting portion at a common position for each type of equipment.

4. A method of supporting a plant design, wherein a plant design is performed by in advance providing modules of equipment to be installed in a plant, each of which is

designed so as to meet a required design standard by itself, and by connecting the modules together in a two or three-dimensional virtual space.