



159159

LAYOUT AND DESIGN OF PRODUCTION FACILITY**FIELD OF THE INVENTION**

The invention relates generally to production facilities. More particularly, the invention relates to improved layouts and design for pharmaceutical production and operation facilities which are compliant with current good manufacturing practices (CGMP).

BACKGROUND OF THE INVENTION

Ideally, the layout of a manufacturing facility should promote efficient flow of work and people. Additionally, the layout should facilitate production, production control, and quality control. For example, the layout should be configured to facilitate quality assurance to minimize defects and operation difficulties, thus ensuring manufacturing and product quality. Quality initiatives also should be built into the facility. This is essential and particularly important for the pharmaceutical manufacturing industry which operates under a strict regulatory environment.

In the United States, the pharmaceutical manufacturing industry must comply with "Current Good Manufacturing Practices" (CGMP) promulgated by the Food and Drug Administration (FDA). See 21 CFR §§ 210-226. Other



G00002

regulations or guidelines which the pharmaceutical industry may be subjected to include, for example, World Health Organization GMP guidelines and Pharmaceutical Inspection Co-operation Scheme (PIC/S).

- 5 CGMP defines requirements with which a drug manufacturing facility and process must comply. This includes for example, having the building and facility suitably designed and constructed to facilitate cleaning, maintenance and proper operations. See 21 CFR § 211.42.
- 10 The flow of components and defined areas should be configured to prevent mix-ups and contaminations. See 21 CFR § 211.42 (b) (c). Premises should be laid out in such a way as to allow the production to take place in areas connected in a logical order corresponding to the sequence
- 15 of the operations and to the requisite cleanliness levels. See PICS 3.7. Also, equipment should be suitably located to facilitate operations for each intended use as well as cleaning and maintenance. See 21 CFR § 211.63. Quality Personnel should have access to production area for
- 20 sampling and investigational as appropriate. See PICS 6.4. There is a need to identify significant steps of operations of equipments, personals and batches. See 21 CFR 211.188-11 & 211.105. These are just some of the myriad of requirements under CGMP.

Non-conformity with CGMP renders a drug "adulterated" under the Food, Drug and Cosmetics Act. See 21 USC § 501(a)(2)(B). A drug is deemed adulterated "if the methods used in, or the facilities or the controls used for its manufacture, process, packing or holding do not conform to or are not operated or administered in conformity with CGMP." The purpose of 21 USC § 501(a)(2)(B) is to protect public interest, by ensuring that the drugs marketed meet its regulated claims specifications. To prevent a drug product from being deemed adulterated, a total quality control, approach and system is necessary. A failure to comply with any regulations may result in the drug being withdrawn from the market, as well as subjecting the manufacturer to sanction. This places a heavy burden on the manufacturer to ensure compliance with CGMP.

However, ambiguity in the language of the statute subjects it to interpretation and imparts uncertainty about the requirements for compliance. For example, compliance is not ensured even though the quality manufacturing process or engineering facility is considered "average" compared to the industry. This is because compliance with the regulations requires that a pharmaceutical product must be manufactured by current good manufacturing practice methods, controls and system in order to protect the public. The absence of a consistent and widely accepted

interpretation of some of regulatory requirements has led to increased cost in engineering new facilities. This has also led to longer lead-times in engineering and, in some cases, delays in bringing new pharmaceutical products to market. In an attempt to clarify the regulatory requirements, the International Society for Pharmaceutical Engineering and the FDA have cooperated to publish a Baseline[®] Pharmaceutical Engineering Guide (Guide).

The Guide includes suggestions from the FDA for compliance with CGMP. The main basic philosophy promoted by the Guide is "Good Engineering Practice" (GEP), which is defined as "established engineering methods and standards that are applied throughout the project life cycle to deliver appropriate and cost effective solutions". It takes into account the design and installation of facilities and equipment and takes "full account of CGMP, safety, health, environmental, ergonomic, operational, maintenance, recognized industry guidance, and statutory requirements". See Guide. In addition to protecting the integrity of the drugs, the safety of the operators and visitors must be considered in the engineering design.

Fig. 1 shows a layout of a conventional pharmaceutical manufacturing facility 101. As shown, the facility comprises a rectangular shaped building with two levels 103a and 103b. Typically, the production area 140 is

located on the ground level 103a while non-production areas are located on the second level 103b. Also located on the ground level are storage area 195, and packing area 197.

Additional areas, such as changing area 194, cafeteria 191, engineering area 193 can also be included on the ground level. The non-production areas on the second level include administration area 108, laboratory area 141, storage area 145, and HVAC plant room 146. In some facilities, all the different areas are provided in a single level.

The various production suites 165 form different stages of a production line for manufacturing pharmaceutical products. Products are tested in their various stages for quality control. The finished products are transferred to the packing area for packaging and then to the storage area.

Although such a layout may comply with CGMP, it is, however, inefficient. For example, quality assurance and quality control cannot be easily carried out in such conventional layouts. The different production stages are not visible from a single point, making it inconvenient to monitor, identify, and verify the manufacturing process. Such deficiencies increase process time in identification and quality monitoring. Therefore, a manufacturer incurs additional costs to ensure that the process can be

monitored adequately for verification and quality control, rendering such layouts not cost effective.

From the foregoing discussion, it is desirable to provide a more efficient and cost effective layout for a manufacturing facility.

SUMMARY OF THE INVENTION

The invention relates to an improved layout for a manufacturing facility. In one embodiment, layout includes a hub surrounded by a production corridor comprising a plurality of production stages. The production stages are visible from the hub, enabling the manufacturing process to be monitored therefrom. In another embodiment, a facility corridor surrounds the production corridor. The facility corridor can be used for servicing and maintaining the production equipment, such as through-the-wall technology type equipment. The facility corridor can also serve to facilitate testing of products from the production stages and/or cleaning and maintenance of production equipment. Additionally, the facility corridor can also serve as a buffer zone to reduce the influence of external building conditions on the production corridor. In another embodiment, the production and non-production areas are separated into two separate buildings. The two buildings can be interconnected by enclosed link-ways or passageways,

forming a satellite configuration. Additional production capacity can be obtained by adding additional production buildings. The additional buildings can be interconnected to either the production or non-production building or a
5 combination of both.

In another embodiment, the layout includes a production area having a hub which is at least partially surrounded by a production corridor comprising a plurality of production stages. The production stages are visible
10 from the hub, enabling the manufacturing process to be monitored therefrom. In another embodiment, a technical corridor surrounds the production corridor. The facility corridor can be used for servicing and maintaining the production equipment, such as through-the-wall technology
15 type equipment. Additionally, the technical corridor can also serve as a buffer zone to reduce the influence of external building conditions on the production corridor.

In yet another embodiment of the invention, the layout includes a production support area. The production support
20 area can be located, for example, on one side of the production area. Functions which support production include, for example, those which facilitate the flow of materials from delivery to production area for processing and processed products from the production area to delivery

to customers. Non-production functions can also be located in the production area.

In accordance with various embodiments of the invention, the layout is designed to comply with CGMP as well as other regulatory and quality requirements. The layout facilitates production and cleaning processes, and movement of people and products. Furthermore, the layout enables the phase of processing to be easily and cost-effectively monitored, identified and verified for greater efficiency in records, quality process control, quality assurance and regulatory compliance with CGMP.

BRIEF DESCRIPTION OF DRAWINGS

Fig. 1 shows a conventional layout of a production facility;

Figs. 2-5 show layouts of production facilities in accordance with various embodiments of the invention.

Fig. 6 shows a cross-section of a production corridor in accordance with one embodiment of the invention;

Fig. 7 shows a layout of a production area in accordance with another embodiment of the invention; and

Figs. 8-9 show a layout of a production facility in accordance with another embodiment of the invention.

DETAILED DESCRIPTION OF THE INVENTION

Fig. 2 shows a building 201 of a production facility in accordance with one embodiment of the invention.

Illustratively, the facility is depicted having a circular shape. Other shapes, such as oval, triangular, square, or
5 other types of polygon, can also be useful. In accordance with the invention, the layout of the production facility includes a production corridor 260 surrounding a hub 240.

The shapes of the production corridor and hub, for example,
10 are consistent with the shape of the building. It is, however, understood that it is not necessary that the building, hub, and production corridor have the same shape. For example, the hub can be rectangular, while the building and production corridor are circular or other polygonal
15 shapes.

The production corridor comprises a plurality of processing stages used in manufacturing one or more products. A processing stage is used to perform one or more steps in the manufacturing process. For example,
20 stages are used to perform front-end and back-end processes. The processing stages can form one or more production lines used to form one or more products. Some stages, for example, can be duplicated. The sequence of the production stages can be arranged to optimize the
25 production process. In one embodiment, the stages are

arranged to facilitate flow of work from stage to stage, to the extent possible, in a clockwise or counter clockwise direction.

In one embodiment, the production stages are used to manufacture pharmaceutical products. Various types of production stages for manufacturing pharmaceutical products include, for example, dispensing, mixing, coating, capsule filling and tableting. Also, the production corridor can include a staging area. The staging area, for example, serves as a temporary or intermediate storage and staging of equipment. A storage area for temporary or intermediate storage of materials and finished products can also be provided.

To reduce or avoid contamination of materials due to servicing or maintenance of equipment used in the manufacturing process, through-the-wall equipment is used. Such types of equipment are designed to be serviced through a wall outside the production stages. For example, the equipment is located, for example, against a wall 269. Servicing of the equipment would then be conducted in a facility corridor 272 through an opening in the wall.

In one embodiment, a test lab is provided in the facility corridor for testing of the products from the different stages. An opening can be provided in the wall through which products from the different stages are passed

from the production stages to the facility corridor. The opening can also serve to pass tested products back to the production stages. The opening can be designed to maintain the controlled environment of the production corridor. For example, the opening can be designed with an air-lock mechanism. The opening can also serve to pass other components of the production stages. For example, equipment which needs to be cleaned can be passed through the opening. Preferably, each production stage is provided with a passageway for convenience. The products are then transferred to the test laboratory for testing.

The production corridor can be enclosed in an environmentally controlled area to maintain, for example, temperature, humidity, and air quality of the production corridor within desired limits. For applications where air quality is important, it is useful to minimize or reduce flow of people or materials in and out of the production corridor. Preferably, the hub is physically separated from the production corridor. An access way 268 is provided to facilitate access to the hub without entering the production corridor. Additionally, the facility corridor can also be outside of the environmentally controlled production corridor.

In one embodiment, the production corridor is segmented into subsegments 267. A subsegment can comprise

one or more production stages. In one embodiment, the subsegments are physically separated by barriers. The barriers can extend the full width of the production corridor, forming separate production stages. In one
5 embodiment, the barriers also extend into the servicing corridor. Providing barriers which do not extend into the servicing corridor is also useful. Accesses, such as doors, can be provided in the barriers to facilitate flow of people, materials, or products from subsegment to
10 subsegment. In an alternative embodiment, the barriers do not extend the full width of the production corridor, leaving an access path between subsegments. In such applications, the production stages can be completely enclosed, (e.g., production suites) having doors for access
15 from the access path. Providing production stages which are not completely enclosed is also useful. Alternatively, the hub can serve as a passageway between the different production stages.

Segmenting the production corridor adds flexibility to
20 the production facility. For example, a subsegment can be upgraded individually without impacting the other segments. Furthermore, a segment can be expanded individually to increase its capacity by extending the barriers and outer wall of the building, as shown by the dotted line 282

In accordance with one embodiment of the invention, the production stages are visible from the hub (i.e., a direct line-of-sight from the hub). If the hub is physically separated from the production corridor, the barriers used to separate the hub from the corridor should be at least partially transparent to allow the production stages to be visible from within the hub. The hub serves as a control area, enabling the manufacturing process to be monitored, identified, and verified easily and efficiently therefrom. In one embodiment, manufacturing data from the processing stages are transferred to the hub. This can be performed in real time or after each process is completed. For example, communication links are provided to one, some, or all the production stages. Manufacturing information is transferred via the communication links to the hub.

In another embodiment, the hub comprises at least first and second levels. In one embodiment, a laboratory is provided for testing of the products at various stages of production. Other functions can also be included. The laboratory may be located on the same level as the production stages. Providing the laboratory at the center allows convenient access from the production stages, increasing manufacturing efficiency. Typically, the laboratory can be part of the same controlled environment as the production facility. Barriers can be provided, if

necessary, to avoid commingling with the production area.

The control area is preferably located above the

laboratory. This allows the control area to have a direct line-of-sight to the production floor below. Additional

5 levels can be provided in the hub to house other areas of the manufacturing facility. For example, dispensing, mixing, cleaning, or engineering activities.

Alternatively, the other areas can be integrated into a single level with the control or monitoring areas.

10 A buffer zone can optionally be located between the outer wall of the building and the production corridor.

The buffer zone is particularly useful for applications in which the changes in the production environment can easily impact yields. The buffer zone serves to provide

15 additional insulation between the internal production environment and external building conditions. Where the facility corridor is outside of the environmental controlled production corridor, it can also serve as the buffer zone. It also serves as an additional barrier

20 against the entry of insets or other contaminants which can adulterate the products.

In accordance with one embodiment of the invention, the non-production area is located in a second building

315, as shown in Fig. 3. Preferably, the second building

25 and the production building are interconnected by enclosed

link-way or passageway 322. Providing non-interconnected buildings is also useful. The non-production area comprises, for example, area for, chemical or supply storage, equipment maintenance, office and administration, 5 meeting rooms, test and/or analysis laboratory, and locker (changing) room. Other non-production functions, such as a cafeteria, can also be included.

In one embodiment, the non-production building 315 comprises at least first and second levels. The first 10 level comprises, for example, maintenance, storage, delivery and reception areas. The storage area can include first and second areas, one for storing raw materials and other for finished products. The second level can include, for example, cafeteria, administration, office, and 15 training areas. Providing the storage area in the first level (e.g., same level as production floor) facilitate flow of materials or products to and from the production corridor, as shown by the arrows. Such a design also gives flexibility for expansion. For example, production 20 capacity can be increased by adding additional production facilities (e.g., similar to building 201) via, for example, link-way 392, as needed. The additional production facilities can be interconnected to the non-production building 315, creating a satellite production 25 arrangement. Alternatively, the additional production

facilities can be interconnected to other production facilities or a combination thereof. The buildings can be configured (e.g., sizes, interconnections, etc.), can be designed to optimize the use of available land area.

5 The layout, as described, provides an efficient process flow. For example, work flows along the production corridor while product testing and flow of information are toward the center to the hub area 240. Furthermore, since the hub has a direct line-of-sight and access to
10 manufacturing data, the layout enables easy monitoring of the manufacturing process, effectively assuring that the flow of materials, people, products are efficient, correct, and verified. The layout also minimizes the number people going through the production corridor (e.g., people can
15 view the production area from the hub without having to enter the production area), facilitating control of the production environment (e.g., temperature, dust, and humidity) and to prevent contamination. This facilitates control of the production environment. Such advantages
20 reduce manufacturing costs by increasing efficiency and reducing errors while being compliant with CGMP.

In an alternative embodiment, the non-production area can be located in the same building as the production area. The non-production area can be provided as a concentric
25 area outside the production corridor. Alternatively, the

non-production area is provided in an area adjacent to only a part of the production corridor.

Fig. 4 shows another embodiment of the invention. As shown, a building 401 is provided which encloses the production area. In one embodiment, the shape of the building is a polygonal. Preferably, the shape of the building is an octagon. A production corridor 260 surrounds a hub 240. The production corridor and hub preferably are octagons. Providing a production corridor and a hub which have different shapes are also useful. The production corridor comprises a plurality of production stages 265. The production corridor is enclosed in an environmentally controlled space to maintain, for example, air quality, temperature, and humidity within desired limits.

The production corridor can be segmented into subsegments 267. In one embodiment, a subsegment is equal to one side of the polygon. In the case of an octagon, the production corridor comprises 8 subsegments. A subsegment can include one or more production stages. Also, a production stage can overlap into an adjacent subsegment. A segment can be separated by a barrier. The barrier can extend the full width of the production corridor. Accesses can be provided to facilitate flow of materials, products, and people for segment to segment. Alternatively, the

barrier extends partially the width of the production corridor. In another alternative embodiment, barriers which separate different production stages extend the full width of the production corridor.

5 In one embodiment, the production stages are used to manufacture pharmaceutical products, such as drugs. The production stages include, for example, dispensing, granulator mixing, drying, tableting, tablet coating, IBC blending, and packaging stages. Other stages, such as
10 utility, or storage, can also be included in the production corridor. Preferably, the stages are arranged to optimize the efficiency of the manufacturing process (e.g., flow of materials, products, and people). In one embodiment, the front-end stages are located toward a first end of the
15 production corridor while the back end stages are located in the other end. Preferably, the first end begins near the entrance of the production corridor.

In one embodiment, the first stage 265₁ of the production located by an entrance 487 serves as a utility
20 area. A dispensing and sieving stage 265₂, large granulator mixing stage 265₃, fluidised-bed drying stage 265₄, small granulator mixing stage 265₅, tableting stage 265₆, table-coating stage, IBC blending stage 265₇, capsule filling stage 265₈, and packaging stage 265₉ are
25 sequentially providing in the production corridor.

Providing other type of stages or in other sequences is also useful. Preferably, the various types of equipment used are serviced from behind a wall 269 outside the production stage. A service corridor 272 is provided to
5 service the equipment. The service corridor preferably is not part of the controlled environment of the production corridor, enabling it to also serve as a buffer zone.

In one embodiment, the hub comprises first and second levels. The first level comprises, for example, a
10 laboratory for testing products at various stages of production. The first level may be on the same level as the production stages. Providing the laboratory at the center of the production stages enables efficient testing of products at different stages of production.

15 The second level of the hub comprises a control center for monitoring the production process. In a preferred embodiment, the second level is above the production stages. Manufacturing data from the processing stages are transferred to the hub via, for example, communication
20 links. Administration or non-production functions are located in a second building (not shown).

As described, the present invention provides an efficient layout for manufacturing facility which complies with CGMP. Internally, the manufacturing facility includes
25 a hub surrounding by a production corridor having a

plurality of production stages used in the manufacturing process. The hub serves as a control, assurance and management area for production. Due to the fact that the production phases are directly visible from the hub, the manufacturing process can easily be monitored, identified and verified therefrom. The Hub functions like a "cockpit" of the process information data control center, which has the ability to directly view the process at will. A facility corridor can be provided around the production corridor. Activities such as quality testing, maintenance and cleaning can be conducted in the facility corridor. Additionally, non-production areas can be provided in the facility corridor or surrounding the facility corridor.

In accordance with the invention, the layout allows fast access of quality control and cleaning activities to the production process and enabling a highly integrated operational environment for compliance and effectiveness. The facility corridor efficiently utilizes space and provides flexibility to implement "behind-the-wall" or "through-the-wall" equipment arrangement for better control of environment. In addition, the facility corridor could also act as a buffer to better control external weather and climatic changes.

Externally, the production and the non-production sections are separated into separate buildings in

accordance with one embodiment of the invention.

Additional production buildings can also be provided.

Preferably, the production and non-production buildings are joined by one or more link-ways. The functional use, size
5 proportions, dimension, floor levels and the location of the two buildings and the link-way can be modified for particular applications. The separation of the non-production and the production areas into separate buildings facilitates better management and control of environmental
10 parameters, people and product flow. The separate buildings, for example, form a satellite configuration to provide the complete operations of a company. A series of link-ways can join various buildings in different configurations.

15 By providing independent buildings (e.g., satellites), each can have their own management and control of environmental parameters, and work and people flow, according to their individual needs and priority.

Furthermore, increased flexibility results through the use
20 of satellite configuration, enabling modular or segmental retrofitting, upgrading and renovation of each building or sections of each building.

Fig. 5 shows a building 201 of a production facility in accordance with another embodiment of the invention.

25 Illustratively, the building is depicted as having a

rectangular shape. Other geometric shapes are also useful. In one embodiment, the building comprises production and production support areas 240 and 245. As shown, the production area is located on one side of the building while the production support area is located on the other side. Other configurations of production and production support areas are also useful. For example, the production support area can be located on opposite sides of the production area. One or more pathways or corridors can be provided to interconnect sections of the production support areas, if desired. Alternatively, the production support area can be located on different sides, partially or fully surrounding the production area. For example, the production support area can surround two adjacent, three, or all sides of the production area.

In another embodiment, the production and production support areas can be located on different levels of the building. For example, the building can comprise first and second levels, with the production area in the first level and the production support area on the second level. Providing a building with more than two levels is also useful. The first level is, for example, the lower level. The first level can also be the top level. Providing a layout in which the production and production support areas are located on different levels advantageously reduces the

building's footprint (e.g., size of building). Expansion can be achieved by adding additional levels, as needed. Alternatively, expansion can be achieved by enlarging the building's footprint. In another embodiment, the

5 production and production support areas can be located in different buildings. The different buildings can be interconnected by pathways or linkways. Such configurations are described in co-pending patent application USSN 10/172,327, titled "Layout of Production

10 Facility", which is herein incorporated by reference for all purposes. The production area, as shown, is rectangular in shape. Providing the production area with other shapes are also useful. Hub 250 and production corridor 260 are provided in the production area. As

15 shown, the hub comprises a rectangular shape. Providing a hub with other geometric shapes is also useful. For example, the hub can comprise a circular, semicircular, octagonal, semioctagonal, or a combination of different geometric shapes. In one embodiment, a portion of the hub

20 abuts the boundary of the production area. Preferably, the portion of the hub abuts the boundary of the production area which is contiguous or adjacent to the production support area. Providing a hub which does not abut the boundary of the production area is also useful.

In one embodiment, the production corridor partially surrounds the hub. Preferably, the production corridor surrounds the hub except the portion abutting the boundary of the production area 240. Providing a production corridor surrounding the hub completely is also useful. Alternatively, the production corridor can be separated into distinct sub-production corridors that partially or fully surround the hub. It is understood that the production subcorridors need not be continuous. The production corridor comprises a plurality of processing stages used in the manufacturing of one or more products. A processing stage can be used to perform one or more steps in the manufacturing process. For example, stages are used to perform front-end and back-end processes. Providing stages to perform back-end or back-end and front end processes is also useful. The processing stages can form one or more production lines used to form one or more products. Some stages, for example, can be duplicated as desired.

The sequence of the production stages are preferably arranged to optimize the production process. In one embodiment, the stages are arranged to facilitate flow of work from stage to stage, to the extent possible, in sequence. For example, the sequence of production stages are arranged to facilitate process flow in a counter-clock

wise direction, as shown by arrow 248. Arranging the production stages to facilitate process flow in a clockwise direction is also useful. Other flow arrangements for the production stages are also useful.

5 In accordance with one embodiment of the invention, the production stages are visible from the hub (i.e., a direct line-of-sight from the hub). If the hub is physically separated from the production corridor, the barriers used to separate the hub from the corridor should
10 be at least partially transparent to allow the production stages to be visible from within the hub.

Manufacturing data from the processing stages, in one embodiment, are transferred to the hub. This can be performed in real time or after each process is completed.
15 For example, communication links are provided to one, some, or all the production stages. Manufacturing information is transferred via the communication links to the hub. Thus the hub serves as a control area or center, enabling the manufacturing process to be monitored, identified, and
20 verified easily and efficiently therefrom.

In another embodiment, the hub comprises at least first and second levels. One of the levels serves as the control center or control hub while the other level can serve as a workflow hub or circle corridor. The workflow
25 hub facilitates flow of products and/or people in the

production corridor. Additionally, the workflow hub can serve as a staging area, work in process storage area and/or support utility area. The workflow hub, for example, can be physically a part of the production
5 corridor.

In one embodiment, a laboratory can be provided in the workflow hub for testing of the products at various stages of production. Providing the laboratory at the center allows convenient access from the production stages,
10 increasing manufacturing efficiency. Barriers can be provided, if necessary, to avoid commingling with the production area. The control area is preferably located above the workflow hub. Locating the control area below the workflow hub is also useful. Additional levels can be
15 provided in the hub as desired.

The production corridor can be enclosed in an environmentally controlled area (e.g., clean room) to maintain, for example, temperature, humidity, and air quality within desired limits. A controlled environment is
20 particularly useful for manufacturing, for example, pharmaceutical products. The clean room environment is also useful for manufacturing other types of products, for example, semiconductors, chemical products, food processing, biotechnical products. Various types of
25 production stages for manufacturing pharmaceutical products

include, for example, dispensing, mixing, capsule filling, tableting and coating.

To minimize or reduce flow of people or materials in and out of the clean room, the control hub is preferably physically separated from the production corridor. Alternatively, the production corridor can be a non-clean room environment for manufacturing products which do not require a controlled environment. For example, non-clean room environment can be useful for manufacturing paper or food products.

The production corridor can be separated into segments, each comprising one or more production stages. The segment can be in different shapes and sizes, even comprises of other corridors and segments. In one embodiment, the segments are physically separated by barriers. Preferably, the segments are completely separated by barriers to create production rooms. The rooms may be in different sizes and shapes. Doors, interlocking rooms, and/or openings are used to provide access to the production rooms. Preferably, at least the portion of the barrier facing the hub is transparent. More preferably, the barriers are transparent, enabling visible communication between the segments as well between the hub and segments. An access path can be provided between the hub and the production corridor to facilitate flow of

people and materials, or products from segment to segment. For an environmentally controlled production facility, the access path is preferably part of the clean room or controlled environment. Where a workflow hub is provided, it is preferably part of the controlled environment. Providing a workflow hub which is not part of the controlled environment is also useful.

Segmenting the production corridor adds flexibility to the production facility. For example, a segment can be upgraded individually without impacting the other segments. Furthermore, a segment can be expanded individually to increase its capacity by extending the outer barrier without affecting the other segments.

In another embodiment, the production corridor is arranged in first and second levels. The additional levels increase capacity without increasing area (e.g., footprint). Providing a production corridor with more than two levels is also useful. In accordance with one embodiment of the invention, the production corridor comprises a first and a pseudo second level. The levels, for example, are not physically or completely physically separated. Providing levels which are physically separated is also useful. Bins (e.g., intermediate bulk containers (IBCs) or other types of containers) can be located in the upper level. A bin, for example, contains raw materials or

partially processed products (generally referred to as processing material) which will be charged or fed to an equipment or a process operation in a production stage for processing. Other techniques for charging, such as vacuum techniques, are also useful. After processing is completed, the processed material is discharged to a bin for transport to either another stage for further processing, testing or packaging. In one embodiment, the charging and discharging are performed outside of the production corridor. Performing charging and/or discharging inside or a combination of inside and outside of the production corridor is also useful.

In one embodiment, a technical corridor 230 surrounds the production corridor in the production area. In one embodiment, the technical corridor is between the production corridor and the boundary of the production area. The technical corridor can be in any shape and size. Preferably, the technical corridor comprises first and second levels. The first and second levels, for example, correspond to the first and second or pseudo second levels of the production corridor. Providing the technical corridor with additional levels or other sections within the technical corridor is also useful.

The technical corridor includes, for example, staging areas or other areas to support production. To reduce or

avoid contamination of materials due to servicing or maintenance of equipment used in the manufacturing process, through-the-wall equipment is used. Such types of equipment are designed to be serviced through a wall outside the production corridor. In one embodiment, equipments in some or all the production stages are located against the outer wall of the production corridor. The technical corridor can include cleaning areas for cleaning such through-the-wall type of equipment. Additional areas for maintaining the equipment can also be included in the technical corridor. Also, the technical corridor can include one or more cleaning areas for cleaning bins or other equipment. Generally, the technical corridor is non-environmentally controlled area. If necessary, a portion or the whole technical corridor can be part of the environmentally controlled area.

The technical corridor can also facilitate movement of container, bins, and/or carrier devices from stage to stage as well as level to level. In one embodiment, the technical corridor includes a transport area or subcorridor for facilitating the movement of the containers or other carrier devices between the stages and/or levels. The transport area is preferably adjacent to the production corridor. It is understood that the transport area need not be physically separated in the technical corridor.

The production support area 245 comprises, for example, sections for storage, packing, quality testing, inspection, receiving materials, material preparation, and dispatching products or material. Additional sections for non-production functions, such as for changing, eating, engineering, administration, security, meeting and offices can also be included in the production support area. Sections for other types of production or production support functions can also be included in the production support area. Preferably, the areas are arranged to optimize flow of material to and processed products from the production area.

In one embodiment, the production area comprises inflow and outflow corridors 270 and 280. The inflow corridor comprises preprocessing sections (e.g., receiving, testing, storing, and preparing materials for processing in the production corridor). The outflow corridor comprises postprocessing sections (e.g., receiving, testing, packaging, and storing finished products). Additional sections that serve other functions can also be provided in the inflow and outflow corridors as needed. The various sections of the inflow and outflow corridors are arranged to optimize flow of material into and processed products out of the production corridor.

An inflow and outflow support corridors 271 and 281, in one embodiment, can be provided. The inflow support corridor includes sections that support the flow of material from the point of delivery to processing in the production area. Such sections include, for example, support storage. Other sections, such as waste storage and collection, rejected material storage, can also be included. The outflow support corridor comprises sections that support the flow of processed material from the production corridor for delivery to customers or distributors. For example, sections for storage of packaging supplies, support for packaging, packaging office, and packaging inspection. Other sections which serve other functions can also be included.

In one embodiment, the inflow and inflow support corridors are contiguous. Likewise the outflow and outflow support corridors are contiguous. Preferably the support corridors are located between the main corridors and the boundary of the production support area. Providing support corridors which are not contiguous to main corridors are also useful. In another embodiment, the main corridors include sections which serve the functions of support corridors.

Preferably, the inflow and outflow corridors serve as an extension of the production corridor in the production

area. The inflow and outflow support corridors serve as an extension of the technical corridor of the production area. The inflow corridor, for example, abuts the portion of the production corridor at the beginning of the process flow and the outflow corridor abuts the portion of the production corridor at the end of the process flow. The inflow and outflow support corridors abuts the technical corridor. In one embodiment, the inflow, inflow support production, outflow and outflow support corridors create a U shaped flow. Arranging the various corridors, areas, and sections therein to have other flow shapes, such as straight line, is also useful. Additionally, security areas can be provided at the beginning and end of the process flow (e.g., beginning of the inflow and outflow corridors).

A support corridor 290 can also be provided in the production support area. The support corridor can be of any shape and size. In one embodiment, the support corridor is adjacent to the inflow and outflow corridors. Preferably, the support corridor is located between the inflow and outflow corridors, creating a spine in the production support area. The inflow and outflow corridor can be connected at the end opposite the production area, creating a u-shaped inflow/outflow corridor which surrounds the spine. Alternatively, or additionally, passageways

that connect the inflow and outflow corridors can be provided along the spine. Likewise, the inflow and outflow support corridors can be coupled. Alternatively, only one of either the support or main corridor sets is connected.

5 The spine, for example, is an extension of the hub in the production area. An entrance to the building can be located on an end of the spine opposite the end abutting the production area. The entrance preferably is a secured entrance to prevent unauthorized entrance to the building.

10 Locating the entrance in other parts of the spine can also be useful. The spine, for example, serves as a point of entry to the building. Flow of material and people to other sections of the facility are facilitated by the spine.

15 In one embodiment, the spine can include areas for critical control and monitoring processes which preferably are closely located to the production processes, such as quality control or test laboratory, to enhance quality control and assurance. Preferably, one or more view sub-

20 corridors can be provided in the support corridor, providing a direct line of view to, for example, the packaging, finished product, and/or other areas which require to or should be monitored. Other supporting functions can also be located in the spine. For example,

25 changing area or other areas can be provided. Sections

which facilitate access to the production corridor as well as the inflow and outflow corridors are also useful.

In one embodiment, the spine comprises first and second levels. The first or lower level comprises, for example, an entrance to the building as well as areas for critical control and monitoring processes, such as quality control or test laboratory, to enhance quality control and assurance. The second level preferably includes a view sub-corridor, providing a direct line of view to, for example, the packaging, finished product, and/or other areas which require to or should be monitored. In one embodiment, first and second sub-view corridors are provided, with support sections therebetween. Other supporting functions can also be located in the second level of the spine. For example, a changing area or other areas can be provided. Areas which facilitate access to the production corridor as well as the inflow and outflow corridors are also useful.

Preferably, the production support area comprises first and second levels. This enables more efficient use of space to house the various sections of the production support area. The first level comprises inflow and outflow corridors separated by a first level of the spine. Inflow and outflow support corridors can also be provided. The second level can include support functions, such as

changing room, meeting rooms, offices, research and development offices, one or more stairwells and/or elevator to enable or facilitate movement between the levels.

Although the production and production support areas are described as separate areas physically separated by a boundary, providing production and production support areas which are partially or fully integrated together is also useful. For example, a boundary between the production and production support areas can be provided for none, one, some, or all of the levels of the production facility.

Fig. 6 shows a cross-sectional view of a production corridor 360 in accordance with one embodiment of the invention. The production corridor is part of the environmentally controlled area. In one embodiment, the production corridor comprises a first level 361 and a second pseudo level 362, delineated by the dotted line 366. A technical corridor 330 surrounds the production corridor. The technical corridor, in one embodiment, comprises first and second levels corresponding to the levels in the production corridor. Unlike the production corridor, a floor 336 physically separates the levels of the technical corridor. Providing technical corridor with one level or additional levels is also useful. In one embodiment, transport areas 339a-b are provided in the technical area, located adjacent to the production corridor.

In accordance with one embodiment of the invention, the wall of the second pseudo level adjacent to the technical corridor is inset with respect to the first level. This creates a step 364 in the cross-section. The equipment 369 in a production stage is located below the inset. Preferably, the equipment is located against the wall of the production corridor adjacent to the technical corridor, facilitating maintenance of the equipment in the technical corridor. It is understood that not all stages of the production corridor need to have the wall in the second level adjacent to technical corridor inset with respect to the first level.

A bin containing material or product to be processed (e.g., processing material) can be moved to the step area in the transport area in the second level of the technical corridor above the equipment. The processing material can be charged (e.g., delivered) into the production stage below. The processing material, for example, fills the equipment of the processing stage for processing, as indicated by arrow 393. Alternatively, the processing material is used in a process operation. After processing is completed, the processed material is dispensed (e.g., sent) to a bin, for example, in the transport area 339a outside of the production corridor.

To facilitate charging and dispensing material into and out from the production stages, inflow and outflow docks can be used. The docks are appropriated located, for example, in the step area and on the walls of the production corridor adjacent to the technical corridor. The bins or containers used for transport of materials can also mated to the docks, with valves with enable the transfer of material. The valves, for example, are hydraulically or pneumatically controlled. The valves and docks sever to maintain the integrity of the controlled environment of the production corridor.

The bin can be moved to another production stage for further processing, testing or packaging (if processing of the product is completed). Lifts or elevators can be employed for moving the bins between the levels. For example, bins are moved from the second to the first level after charging. In one embodiment, prior to having materials dispensed into it, the bin is cleaned. Cleaning can be performed at either level. On the other hand, bins containing processing materials are moved from the first to the second level for charging. The movement of the bin or bins can be achieved by automated transport systems, reducing the likelihood of mix-ups. Automated transport systems can be facilitated by, for example, rails or tracks. Other techniques that can facilitate movement or

flow of the bins are also useful. Thus, a bin can be easily moved from one stage to another as well as from one level to another.

As described, the charging of material is facilitated by gravity, thus avoiding the need to use vacuum techniques which increase the likelihood of contamination. Additionally, by providing an inset 364, the filling process can be performed outside the clean room environment. This reduces the traffic movement of products, materials and people within the production corridor, thus minimizing cross contamination. Also, the overall area of the clean room environment can be smaller, which in turn reduces costs. For example, conventional gravity techniques use multi-level production stages for charging equipment in a lower level stage from a higher level stage. Such configuration significantly increases the clean room area needed compared to the present invention.

A buffer zone can optionally be located between the outer wall of the building and the production corridor. The buffer zone is particularly useful for applications in which the changes in the production environment can easily impact yields. The buffer zone serves to provide additional insulation between the internal production environment and external building conditions. It also

serves as an additional barrier against the entry of insects or other contaminants which can adulterate the products. It can also serve as a security buffer to guard against intrusion and also a safety buffer in the management of products with high toxicity. Where a technical corridor is provided, it can also serve as the buffer zone.

In another embodiment, the production area can comprise one or more additional hubs and production corridors. This can be advantageous since the technical corridor can be shared, enabling more efficient use of space. The different hubs and production corridors can also share production support area as well. Alternatively, a production support area can be associated with each hub and production corridor.

Fig. 7 shows another embodiment of a production area 440. As shown, the production area comprises first and second production corridors 460a-b, each partially surrounding a common hub 450. Providing other numbers of production corridors which partially surrounds a common hub is also useful. The hub and production corridor can have various geometric shapes. The shape or shapes are preferably selected to optimize the layout of hub and production corridors. The various production corridors can be connected or partially connected to partially or

completely surround the hub. Providing one production corridor which partially or completely surrounds the hub is also useful.

A production corridor comprises a plurality of
5 production stages for manufacturing one or more products. Preferably, each production corridor manufactures its respective product or products. Providing production corridors which manufacture the same or some of the same products is also useful. The stages are preferably
10 arranged to optimize production flow, to the extent possible. For example, the production flows in from the left sides of the production area to the production corridors out to the right side of the production area. Other flow arrangements are also useful. In one
15 embodiment, a technical corridor 430 surrounds the production corridors. The technical corridor is shared between the production corridors.

Production support areas can be located on left and right sides of the production area. Other arrangement of
20 the production support area is also useful. For example, the production support area partially or fully surrounds the production area. Alternatively, providing a production support area on one side of the production area is also useful. In yet another embodiment of the invention, the
25 production support area can be located in another building.

Figs. 8-9 show a manufacturing facility 501 in accordance with one embodiment of the invention. The facility is designed with a layout for efficient and effective manufacturing of products. Preferably, the facility facilitates efficient and effective manufacturing of pharmaceutical products which is compliant with CGMP and other regulations to which the manufacturing of pharmaceutical products are subjected.

Fig. 8 shows the first level 502 and Fig. 9 shows the second level 602 of the facility. Referring both to Figs 8-9, the building comprises a rectangular shape and includes production and production support areas 540 and 545. Lined-filled areas in the second level represent the same areas in the first level (e.g., such areas in the first level have ceilings extending to the top or other levels of the building). Providing a building with other shapes is also useful. In one embodiment, the production support area is on the left side of the building while the production area is on the right side. Each area is also rectangular in shape. Other configurations and/or shapes of the production and production support areas are also useful.

The production area comprises a hub 550. In one embodiment, the hub abuts a boundary 543 of the production and production support areas. In one embodiment, a

production corridor partially surrounds the hub and also abuts the boundary of the production and production support areas. The production corridor 560 and hub comprises a semi-octagonal shape. Providing the production corridor and hub with other shapes is also useful. It is also understood that it is not necessary that both the hub and production corridor have the same shape. A technical corridor surrounds the production corridor 530. In one embodiment, the technical corridor is located between the production corridor and boundary of the production area.

The production corridor is separated into a plurality of production stages 567a-567g for manufacturing one or more products. A processing stage can be used to perform one or more steps in the manufacturing process. For example, stages are used to perform front-end and back-end processes. Some stages, for example, can be duplicated. The sequence of the production stages are preferably arranged to optimize the production process. In one embodiment, the stages are arranged to facilitate flow of work from stage to stage, to the extent possible, in sequence. For example, the sequence of production stages are arranged to facilitate process flow in a counter-clockwise direction, as shown by arrow 548. Arranging the production stages to facilitate process flow in a clockwise direction is also useful.

Preferably, the production stages are used to form one or more pharmaceutical products. In one embodiment, the production corridor is located in a controlled environment. The production stages are physically separated by barriers.

5 The production corridor includes stages 567a-e for dispensing processing material, granulation, tableting, tablet coating, and capsule filling. Storage and interlevel stages 567f-g are also included in production corridor. The storing stage, for example, temporarily

10 stores processed product for removal for testing and packaging. The interlevel stage, in one embodiment, includes elevator for facilitating movement between first and second levels. An air lock is also included in the interlevel stage to facilitate maintaining the integrity of

15 the controlled environment. Additional or other stages as well as other stage sequence can also be useful.

In a preferred embodiment, the production corridor comprises first and second pseudo levels, as described in Fig. 6. The outer wall of the production corridor on the

20 second level is inset with respect to the outer wall in the first level (indicated by the dotted line 668), creating a step above the first level in the cross-sectional profile of the production corridor. Providing a production corridor with such first and second pseudo levels takes

25 advantage of gravity to charge the production stage

equipment from outside the controlled environment of the production corridor. Other techniques or arrangements for charging the production stages are also useful.

Technical corridors 530 are located outside the
5 production corridor in first and second levels of the production area. The technical corridors are preferably between the production corridor and boundary of the production area. Transport areas 536 and 636 are located in technical corridors adjacent the production corridor.
10 Bins, for example, are moved from stage to stage and level to level for charging and discharging of processing or processed materials in the transport areas. Preferably, the bins are transported using an automated transport system.

15 In one embodiment, washrooms (not shown), if appropriate, are located in the first level access area to facilitate washing of equipment through the wall of the production corridor. The washroom should physically be separated from the clean room environment of the production
20 corridor to reduce contamination. Preferably, airlocks can be provided to enable access between the washroom and production stage. It is understood that not all stages need to be provided with its respective washroom.

The technical corridor can also include, for example,
25 a wash area to clean the bins after use. Stairwells and/or

elevators can be included in the technical corridor to facilitate movement between the levels. Additionally, the technical corridor can include technical area between the production area boundary and transport area. The technical
5 area can serve various functions that, for example, support production. For example, the technical area in the second level includes a blending area 637, various plant rooms 634a-c, and a wash area 632 for bins. Other types of functions in lieu of and/or in addition to those mentioned
10 which support production can also be included in the technical corridors of either and/or both levels, as desired. Preferably, the various support functions are located to optimize process flow.

In one embodiment, a hub 550 abuts the boundary
15 between the production and production support areas and is partially surrounded by the production corridor. Providing a hub which does not abut the boundary between the production and production support areas is also useful. In such case, the production corridor can completely surround
20 the hub. The hub preferably comprises first and second levels corresponding to the first and second levels of the facility. In one embodiment, the first level serves as a workflow hub while the second level serves as a control hub.

The workflow hub preferably is part of the controlled environment of the production corridor. The workflow hub facilitates the flow of products and/or people in the production corridor. In one embodiment, an access corridor
5 558 is provided in the workflow hub to facilitate flow of people and materials for processing. Preferably, a laboratory 556 is located in the workflow hub to test of the products at various stages of production. Providing the laboratory at the center allows convenient access from
10 the production stages, increasing manufacturing efficiency. A support area 554 can also be provided to serve, for example, as a staging area, work in process storage area and/or support utility area.

The control hub, in one embodiment, is separate from
15 the controlled environment. The control serves as a control area, enabling the manufacturing process to be monitored, identified, and verified easily and efficiently there from. In particular, the control hub has a direct line-of-sight to the production stages. Preferably, a
20 viewing corridor 658 can be provided, enabling the production stages to be visible from the hub. A data center 657 can also be provided to receive manufacturing data from the processing stages. This can be performed in real time or after each process is completed, for example,
25 communication links.

In one embodiment, the production support area comprises inflow and outflow corridors 570 and 580. The inflow corridor comprises various sections for receiving, storing, and preparing materials for production. The various sections are preferably arranged to optimize process flow. For example, the flow of materials can be arranged to flow from one end of the inflow corridor to the other end adjacent to the production area. The outflow corridor comprises sections which receiving, testing, packaging, and storing processed products from the production corridor. Like the inflow corridor, the flow of material can be arranged to flow from one end of the outflow corridor adjacent to the production area to the other end.

In one embodiment, an unloading dock (not shown) is located at a first end of inflow corridor opposite the end adjacent to the production area. Raw materials are delivered and unloaded onto the unloading dock and moved to the receiving section 571. A material sampling section 572a can be provided to test the delivered materials to determine whether they are of acceptable quality or not. Accepted materials are moved to raw material storage section 574. Rejected materials are moved to rejected material storage section 572b for return to supplier. In a preferred embodiment, the material sampling and rejected

material storage sections are located between the receiving and raw material storage sections. A pre-dispensing section 576 is located adjacent the raw material storage section and the production area. Raw materials are moved
5 to the pre-dispensing section in preparation for processing. The sections are preferably arranged from the receiving end of inflow corridor to the end adjacent the production area.

Additional sections, such as inflow support storage,
10 waste collection and waste storage sections 575 and 577a-b, can be included in the inflow corridor. The waste storage section should be located adjacent or in close proximity to the production area for receiving waste produced there from. Preferably, the waste collection section should be
15 adjacent to the waste storage section. The inflow support storage is located adjacent or in close proximity to the raw material storage section. Providing the corridor with other sections to facilitate movement of raw material to the production area is also useful. The various sections
20 can be arranged in other configurations. Preferably, the various sections are arranged to facilitate or optimize the flow of raw material to the production area.

In one embodiment, the outflow corridor comprises a loading dock (not shown) located at a first end opposite
25 the end adjacent to the production area. Packaging and

finished products storage sections 586 and 582 are also included. The sections are preferably arranged to optimize flow of processed material from the production corridor to shipping of the finished products to customers. For example, processed materials are discharged from the production corridor to a packaging section 586 located adjacent thereto. After the processed materials are packaged, they are stored in a finished product storage section 582. When ready for shipping to customers, the finished products are removed from storage and placed in the dispatched section 581 and loaded into transports (e.g., trucks) for delivery in the loading docks.

Additional sections can be included in the outflow corridor. In one embodiment, packaging and finished product support sections 587-588 are provided. For example, packaging support sections include packaging inspection, packaging supplies, and packaging office sections 587a-c to facilitate product packaging.

Preferably, the packaging support sections are located adjacent to the packaging section. The finished product support section [purpose] and is preferably located adjacent to the finished product storage section. Other sections can also be included in the outflow corridor, as desired.

In one embodiment, the various sections of the inflow and outflow corridors are arranged to form a U-shaped process flow. Arranging the various section of the corridors or the corridors to produce other process flows, such as straight or L-shaped, are also useful. Preferably, the various sections are arranged to optimize the process flow.

The production support area preferably comprises a second level. The second level of the production support area comprises, for example, support section such as administration and office, cafeteria, and research and development, charge to packing, and training sections 671, 681, 687, 688, and 676. As shown, packaging, finished product storage, and raw material storage sections have their ceilings extending to the top of the second level. Stairwells and/or elevators can be provided to facilitate movement between the levels. Other support sections can also be provided, as desired. The various support sections can be arranged to optimize flow or people and material.

A support corridor 590 can also be provided in the production support area. The support corridor, in one embodiment, is located between the inflow and outflow corridors, forming a spine. The spine can serve as an extension to the hub, performing quality, monitoring functions in the production support area. In a preferred

embodiment, the support corridor comprises first and second levels.

In one embodiment, the first level includes an entrance section 592 to the building located at an end of the spine opposite the end abutting the production area. The entrance preferably is a secured entrance to prevent unauthorized entrance to the building. A locker section 593 can be provided adjacent the entrance section, enabling employees to prepare for work. Quality and quality support sections 594 and 596, such as quality test lab and retained samples, are located in the first level. Additional sections 597-598, such as those to support quality or other functions can be included in the support corridor.

The second level can comprises various support sections. In one embodiment, the second level comprises boardroom, training, documentation reproduction and storage, meeting room, miscellaneous storage, clothing storage, and changing sections 692-698. A viewing corridor 699 is also included to enable visual monitoring of the packaging and finished product storage sections of the outflow corridor. Another viewing corridor can also be provided to enable visual monitoring of the inflow corridor. Other support sections can also be provided, as desired in the support corridor.

As described, the various sections of the production support area are arranged to facilitate flow of material and people in sequence. Other arrangements are also useful. Other sections can also be included in addition to
5 or in lieu of sections described. Preferably, the sections are arranged to optimize the flow of people and material in the manufacturing process.

The layout, as described, provides an efficient process flow. For example, work flows along the production
10 corridor while product testing and flow of information are toward the center to the hub area. Furthermore, since the hub has a direct line-of-sight and access to manufacturing data, the layout enables easy monitoring of the manufacturing process, effectively assuring that the flow
15 of materials, people, products are efficient, correct, and verified. The layout also minimizes the number people going through the production corridor (e.g., people can view the production area from the hub without having to enter the production area), facilitating control of the
20 production environment (e.g., temperature, dust, and humidity) and to prevent contamination. This facilitates control of the production environment. Such advantages reduce manufacturing costs by increasing efficiency and reducing errors while being compliant with CGMP.

While the invention has been particularly shown and described with reference to various embodiments, it will be recognized by those skilled in the art that modifications and changes may be made to the present invention without departing from the spirit and scope thereof. The scope of the invention should therefore be determined not with reference to the above description but with reference to the appended claims along with their full scope of equivalents.

What is claimed is:

1. A layout for a production facility comprising:
 - a hub for monitoring a manufacturing process; and
 - a production corridor surrounding the hub, the
- 5 production corridor includes a plurality of production stages of the manufacturing process, wherein the production stages are visible from the hub to enable monitoring of the production process therefrom.
- 10 2. The layout of claim 1 wherein the hub serves as a control hub for monitoring the manufacturing process.
3. The layout of claim 2 wherein the control hub comprises communication links to the production corridor
- 15 for collecting manufacturing data.
4. The layout of claim 1 wherein the hub comprises first and second levels, the first level facilitate production and the second level serves to as a control hub for
- 20 monitoring the manufacturing process.
5. The layout of claim 4 wherein the first level and the second level is above the first level.

6. The layout of claim 5 wherein the first level serves as a control hub for monitoring the manufacturing process and collects manufacturing data through communication links to the production corridor.

5

7. The layout of claim 6 wherein the second level which facilitates production comprises a test lab.

8. The layout of claim 4 wherein the second level which
10 facilitates production comprises a test lab.

9. The layout of claim 4 wherein the first level serves as a control hub for monitoring the manufacturing process and collects manufacturing data through communication links
15 to the production corridor.

10. The layout of claim 9 wherein the second level which facilitates production comprises a test lab.

20 11. The layout of claim 1 wherein the production facility is CGMP compliant.

12. The layout of claim 11 wherein the hub comprises first and second levels, the first level facilitate production

and the second level serves to as a control hub for monitoring the manufacturing process.

13. The layout of claim 12 wherein the first level and the
5 second level is above the first level.

14. The layout of claim 13 wherein the first level serves
as a control hub for monitoring the manufacturing process
and collects manufacturing data through communication links
10 to the production corridor.

15. The layout of claim 14 wherein the second level which
facilitates production comprises a test lab.

15 16. The layout of claim 13 wherein the second level which
facilitates production comprises a test lab.

17. The layout of claim 12 wherein the first level serves
as a control hub for monitoring the manufacturing process
20 and collects manufacturing data through communication links
to the production corridor.

18. The layout of claim 17 wherein the second level which
facilitates production comprises a test lab.

19. The layout of claim 11 wherein the hub serves as a control hub for monitoring the manufacturing process.

20. The layout of claim 19 wherein the control hub
5 comprises communication links to the production corridor for collecting manufacturing data.

21. The layout of claim 1 wherein the production stages
comprise production stages for manufacturing pharmaceutical
10 products.

22. The layout of claim 21 further comprises a facility corridor surrounding the production corridor.

15 23. The layout of claim 22 wherein the production corridor comprises an environmentally controlled production corridor.

24. The layout of claim 23 wherein some of the production
20 stages comprise equipment maintained from the facility corridor.

25. The layout of claim 21 wherein the production corridor
comprises an environmentally controlled production
25 corridor.

26. The layout of claim 25 wherein some of the production stages comprise equipment maintained from a facility corridor surrounding the production corridor.

5 27. The layout of claim 1 further comprises a facility corridor surrounding the production corridor.

28. The layout of claim 27 wherein the production corridor comprises an environmentally controlled production
10 corridor.

29. The layout of claim 28 wherein some of the production stages comprise equipment maintained from the facility
15 corridor.

30. The layout of claim 1 wherein the production corridor comprises an environmentally controlled production
corridor.

20 31. The layout of claim 30 wherein some of the production stages comprise equipment maintained from the facility
corridor.

32. A method of efficient manufacturing comprising:

providing a hub surrounded by a production corridor,
the production corridor comprising production stages for
manufacturing a process for a product; and

5 monitoring the manufacturing process from the hub,
wherein the hub can view the production stages.

33. A production layout comprising:

a production area, the production area includes
10 a hub;

a production corridor at least partially surrounding
the hub, the production corridor comprising production
stages for manufacturing; and

wherein the hub has a direct line of sight to the
15 production stages and serves as a control area for
monitoring the production stages.

34. A method of efficient manufacturing comprising:

providing a hub and a production corridor surrounding
20 at least a portion of the hub, the production corridor
comprising production stages for a manufacturing process;
and

monitoring the manufacturing process from the hub,
wherein the hub can view the production stages.

35. A production corridor comprising:

a first outerwall separating the production corridor
from a facility corridor;

a first level

- 5 a second pseudo-level, wherein the first outerwall of
the second pseudo is inset from the first outerwall of the
first level, the inset creating a first section of a
ceiling for the production corridor, the first section of
the ceiling lower than a second section of the ceiling; and
- 10 a material transport system for removing material from
the production corridor via the first outerwall and moving
material into the production corridor via the first section
of the ceiling.

15 36. A production layout comprising a production area, the
production area includes:

a hub, the hub serving as a control area for
processing, and

a production corridor for processing, the production
20 corridor at least partially surrounds the hub.

37. A production layout comprising:

a production area, the production area includes a hub;

at least first and second production corridors at

25 least partially surrounding the hub, wherein a production

corridor comprises production stages used in manufacturing;
and

wherein the hub has a direct line of sight to the
production stages and serves as a control area for
5 monitoring the production stages.