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Design Considerations for cGMP Facilities

A Biotech and Pharmaceutical company's success is often attributed to its ability to design a scalable and productive process that can eventually be manufactured as quickly and cheaply as possible. Most of these companies have to approach the topic of how to manufacture their drug or technology to be commercially available to the public which likely means going down the path of cGMP. This eventually steers into discussions on how to design a facility that will suit the needs of the technology. The design of all labs are driven by the requirements of process and equipment, and it's no different for cGMP facilities.

What is cGMP?

Before digging into design considerations, it will be helpful to understand what cGMP is. Since patients and consumers have no point of reference that the products they are using as treatments, are safe, it is critical that products be manufactured under compliance and regulations to ensure that quality is built into the manufacturing process. Current Good Manufacturing Processes (cGMP) are the regulations that are governed by the FDA. It provides guidelines around the design, monitoring, and control of manufacturing processes and facilities.

This ensures that products are produced uniformly with the correct strength, purity, and quality. According to the FDA, "this formal system of controls at a pharmaceutical company, if adequately put into practice, helps to prevent instances of contamination, mix-ups, deviations, failures, and errors. This assures that drug products meet their quality standards."

cGMP Guidelines

Due to the array of different types of products manufactured under cGMP, these guidelines aren't specific instructions rather a set of principles that should be applied to the design of the facility. Some of these guidelines specifically address the facility design, but looking at the other guidelines offer insight on the additional details needed to support cGMP compliance. For example, having dedicated areas specifically for record management or QC labs for testing in-process products to ensure sterility. **See guidelines here from NNE.**

cGMP Products

As mentioned, there are many different types of products that can be manufactured under cGMP, each having their own set of process and functional requirements. Let's examine some of the different types of products and their impact on design:

- **Active Pharmaceutical Ingredients (API):** While APIs can be biologically produced material, it has traditionally been considered as a chemical or chemistry derived product. Many of the large pharma companies, like Merck, Pfizer, Novartis, have become giants in the industry due to their robust pipeline of small molecule products.
- **Biopharmaceuticals:** This includes monoclonal antibodies, recombinant protein therapies, vaccines, blood components, and enzymes.
- **Cell and Gene Therapy:** This includes viral vectors, other types of delivery mechanisms (exosomes, vesicles), gene edited cells, and stem cell therapy/replacement.
- **Medical device:** Actual devices are likely to not fall under cGMP, but any of their accompanying accessories that are "invasive" to an individual, will be. This includes catheters, needles, and cameras/scopes

cGMP Operational Perspectives

Regardless of the product, there are general considerations focused on the planning and selection of the facility that will contribute to the design.

Equipment: Having a matrix that details the instrumentation required at each stage of the manufacturing will be critical to plan for adequately sized rooms and required infrastructure. How much power is going into the building, and is it enough to support your equipment? Are the floor loads and ceiling heights adequate once large-scale reactors are assembled and at full capacity? How much emergency power is needed to ensure processes continue without disruption and loss of in-process material? What types of gases and volumes are needed for specialized equipment?

Material, product, and people flow: In any type of manufacturing (cGMP or otherwise) materials, products, and people coming in and going out need to be planned for accordingly. Is there a uni/bi-directional flow being considered? Is there a plan to control for any increasing levels of HVAC or ISO-class controls for "dirty" to "clean" materials? Are quarantine areas required for incoming materials? How will finished product be handled or stored? How will material be passed between processes? Will warehousing be needed? How will employees interact in the space?

Process mapping: Interdependencies between the actual process and any support functions are important for efficiency and effectiveness. Will materials need to be stored at intermittent stages and do they need to be temperature controlled? Is there any type of testing needed for in-process materials? How will waste be handled or removed from the spaces?

Quality Control: cGMP spaces are maintained by a set of controls that ensure that the product produced is safe and the facility itself is able to sustain those controls. How will inventory be managed? Will air particle and microbial testing be managed on-site? Will in-process testing of material be done on-site? How will the integrity of in process material and finished products be maintained?

Facility build-out/modifications: Because GMP spaces are very specific to the technology, undoubtably there will be some sort of modification, if not a full build out, that will need to occur. How much power is going into the building? Is there a need for power/back-up power redundancy? What are the ceiling heights and floor loads? Will a service mezzanine be required?

There are many factors contributing to the design of a cGMP facility. Compliance and cGMP guidelines set the basis of design while scientific modality, products being manufactured, and operational needs steer the design requirements. Comprehensive planning and collective gathering of these requirements from stake-holders, end-users, and subject matter experts will ensure a successful build.

Interested in learning more on how we can help? Send us a note to:
RJ Panzo
Corporate Managing Director
RJ@t3advisors.com