

# DESIGN & TECHNOLOGY

## Facility Qualification Supports Manufacturing Process Validation

■ *Prior to process validation, the qualification of a facility should be completed by an architect/engineer*

■ *Facility qualification verifies that every critical system and building finish that supports or affects the manufacturing process is constructed according to prescribed criteria*

■ *The building designer must document any deviations from the initial design criteria*

**T**o a biotechnology company building a new or renovated production facility for a new drug product, validation of the manufacturing process is an essential step of facility start-up.

Before your company's process engineer or compliance officer can perform the process and equipment validation, the building's architect/engineer (A/E) should complete validation (or qualification) of the facility. Facility qualification relies on documented evidence that every critical system and building finish that supports or affects the manufacturing process is identified and constructed according to prescribed criteria. You should expect your A/E to assist you with this process.

To achieve maximum efficiency, ideally you should provide the A/E with specific plant and utility validation criteria and other facility requirements prior to the design phase of the project. With this information, the A/E can design a plant layout supporting the smooth flow of work and personnel. This also helps to identify adequate space to perform each operation, while separating critical activities to prevent cross-contamination and product flow conflicts. Facility layout has a permanent and dramatic effect on the successful operation of a plant. By organizing space logically, you minimize the potential for inefficiencies and procedural problems.

Another important step of the validation process is the early identification of specific physical and environmental requirements.

*Early identification of validation criteria enables your A/E to design an efficient laboratory.*



Working closely with your A/E, identify each room or space, and establish the qualification criteria that will achieve the purity, quality, safety, or effectiveness of your product. With input from process and environmental engineers, your A/E should prepare a planning document that indicates the specific criteria for each space, such as:

- Clean room - identify minimum acceptable classification, Class 100 through 100,000
- Humidity - select target and acceptable tolerance, i.e.: 50% RH  $\pm$  2%
- Temperature - state the target temperature and acceptable swing, i.e.: 21° C  $\pm$  1°
- Pressurization - determine which rooms need to be positive or negative pressure with respect to their adjacent spaces. Also, what is the acceptable relative difference?
- Air changes - quantify how many air changes per hour are required
- Critical light levels and spectrum or lamp temperature - is specialized lighting required?

- DI or RO water - determine pressure, conductivity and purity levels
- Compressed air, special gases - determine required pressure, capacity and purity
- Unique power systems - identify dedicated circuits, emergency power, uninterruptible power, special voltages or frequencies
- Special finishes - for cleaning, or microbial or chemical resistance
- Laboratory exhaust systems - considerations for radioactive contamination, filtration, dispersion and redundancy
- Waste water collection - floor drains, solvent collection, microbial kill tanks, sampling manholes

After identifying these specific criteria, the A/E can design facility components that enable the space to meet your requirements. The designer will develop construction documents consisting of detailed plans and specifications that identify equipment, systems, finishes, required craftsmanship and testing

procedures that will be used to build and commission (or qualify) the facility.

Due to the complexity of the systems required, and the evolving pharmaceutical industry, laboratory facilities are notorious for revisions during construction. It is imperative to follow protocols that document the inevitable changes to the facility. The A/E must document any deviations from the initial design criteria due to modifications made by the owner or local regulatory agency, or due to equipment redesign, material availability, etc.

Lastly, your A/E also should develop a checklist to ascertain the use and proper installation of specified products, as well as the performance of required tests and equipment verifications. After noting any variances to the specifications, and determining that they are acceptable, your A/E will amend the specifications. This record indicates that an area or system was inspected and meets the design criteria. ■

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