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Understanding validation and commissioning

Mistakenly used interchangeably, the terms have crucial differences

In the pharmaceutical, biotech, and life sciences industries, the terms validation and commissioning are frequently — and mistakenly — used interchangeably. These two essential processes often occur side-by-side during equipment startup, leading some to view them as interchangeable. They are not.

Commissioning: Setting the stage

Commissioning ensures that facilities, utilities, and equipment are installed correctly, and function as intended. It includes initial checks, inspections, installation verification, functional and safety testing, calibration, and preliminary troubleshooting and tests such as Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT). The focus is on operational readiness not regulatory compliance or quality assurance documentation.

Key aspects of commissioning include installation verification, utilities verification, calibration, operational readiness, functional testing, equipment calibration and initial troubleshooting.

Commissioning verifies the “as-built” state, ensuring that all components of a system or piece of equipment work correctly under defined operational conditions.

Validation: Ensuring compliance and quality

Validation, on the other hand, is a documented, systematic process

that demonstrates with a high degree of assurance that a system, equipment, process, or method consistently produces results meeting predetermined specifications. It also requires adherence to standards such as ISO 17025 (for calibration traceability) and 21 CFR Part 11 (for data integrity and electronic records compliance).

Validation directly impacts regulatory compliance and product quality and is mandated by regulatory authorities such as the FDA, EMA, and others. Validation consists of three core phases:

- Installation qualification (IQ): Making sure that equipment is installed per the manufacturer’s and clients specifications and regulatory requirements.
- Operational qualification (OQ): Testing that equipment consistently operates within the established parameters.
- Performance qualification (PQ): Demonstrating that the equipment or system consistently performs reliably under real-world conditions.

Common pitfalls to avoid

Common errors in validation that should be diligently avoided include:

- Deviations: Even minor deviations can snowball into compliance risks if not properly documented, investigated, and justified.
- Typographical Errors: Minor typos in protocols can lead to significant

misunderstandings, misinterpretation, or regulatory citations. Ensure rigorous proofreading and technical reviews.

- Protocol generation errors: Every protocol must be an accurate reflection of actual procedures. Using generic or outdated templates without sufficient adaptation to the current system or equipment can cause compliance and execution issues.
- Improper training: Personnel executing validation activities must be properly trained and qualified. Documentation of this training is essential.
- Ignoring traceability: Validation must demonstrate traceability to User Requirements Specifications (URS), Functional Design Specifications (FDS), and other design and requirement documents.

Best practices

Define the handoff early: Establish the transition point from commissioning to validation at the beginning of the project to avoid confusion later.

Involve QA early: Engage validation and quality teams during commissioning planning to align expectations and deliverables.

Run Mock Qualifications: Conduct dry runs or mock qualifications to identify gaps before execution. Commissioning gets systems ready to run. Validation ensures those systems are compliant and capable of consistently producing quality results. The distinction matters. ●