BIOMÉRIEUX

PHARMA QUALITY CONTROL SERVICES
QUALIFICATION / VALIDATION OFFER

Expedite implementation of your investment by reducing validation time and expense.

Your Ally in Advancing Quality

PIONEERING DIAGNOSTICS

Service 2

QUALIFICATION/ VALIDATION OFFER

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How long do you take to implement a new technology?

To maximize your return on investment, you need rapid implementation of the new solution, in full accordance with the best practices for laboratory compliance. We are here to assist you, and smooth the path for future achievements.

From qualification / validation guides to turnkey on-site solutions, we offer our customers the best way to implement and use your technology, resulting in **a better return on investment.** All our services are **science-based protocols that are fully compliant with local regulations and execution resource to success.**

Managing validation plans across multiple facilities is nothing less than an artform.

Whether you are implementing in-process testing solutions within your laboratory or on your production floor, you can rest assured that with bioMérieux validation services, **all regulatory standards of local and international pharmacopeias will be fully upheld.**

Our goal is to enable **faster implementation to maximize return on investment,** by providing you with a comprehensive and ready-to-use validation offer. By reallocating lab resources, you'll be able to focus your time and resources on value-added activities in your organization.

On-site validation execution services are performed by bioMérieux experts, or by our partners Worldwide. Our IOPQ protocols follow **international guidelines such as EP/USP, and are fully GxP compliant.** The Validation Life Cycle can be customized based on your system and instrumentation, and can be tailored to meet internal site requirements and user specifications.

If you wish to perform the validation by leveraging your own resources, we will also be happy to provide **the necessary validation templates.**

WHAT WE OFFER:

Validation documentation*

- **URS completion guide :**
  - **User Requirement Specification (URS)**
  - **Functional Design Specification (FDS)**
  - **Requirements Traceability Matrix (RTM)**
- **Qualification Documents (IQ,OQ,PQ)**
- **Customized Validation Documents**
- **Method validation:** Confirm that the method is suitable for the intended application, and can proceed in a reliable manner.
- **Suitability testing:** Demonstrate that the presence of a particular product, material or sample matrix does not impact the performance of the method.

Qualification execution services**

- **Installation Qualification Protocol (IQ)** Verify that the equipment meets the design specifications, and that it is properly and safely installed.
- **Operational Qualification Protocol (OQ)** Verify that relevant equipment parts (including hardware, software and devices) and their functionalities work fully in accordance with your operational procedures.
- **Performance Qualification Protocol (PQ)** (Microbiology test and validation procedures).

* MV, MST and PVR avaibility: depending of the solution.

**All IOPQ qualification execution services are documented and in full accordance with international guidelines such as EP/USP, and are fully GxP compliant.

Not all services are available in all countries. Please contact your local bioMérieux Industrial Microbiology representative for details of local service offering.

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