



# BIOMÉRIEUX SERVICES



PIONEERING DIAGNOSTICS

# YOUR MICROBIOLOGY PARTNER FOR PRODUCTIVITY AND PRODUCT QUALITY

Our mission is to provide the pharmaceutical and healthcare industries with **rapid, accurate and cost-effective** solutions, ensuring patient safety while enhancing both workflow and productivity. Our technical team and scientific experts are on hand to help **you get the most out of your equipment** and **to ensure the continuity of your operations**.

Our entire range of services can be customized, allowing you **to focus on your core business** and **optimise your resources**.

bioMérieux can also assist you in meeting **your regulatory requirements**. Through **our extensive network of local subsidiaries and distributors**, we are able to dispatch highly-skilled and trained system engineers or application specialists to your lab. No matter where you are, we're able to assist 24 hours per day and seven days per week.

Our complete range of services are tailored to your unique needs, and are ready to assist you throughout **the entire life cycle of your equipment**.





## FEASIBILITY STUDY

# Quickly confirm your product compatibility and method

**You're looking to improve or change the method of your application and product. Are you confident that the solution you want is fully compatible?**



Proving compatibility requires resources and expertise. We are here to help you undertake the necessary feasibility studies, giving you the time to focus on your priorities.

**We can develop the feasibility study you need. In doing so, we'll prove the compatibility of your matrices with a validated bioMérieux platform regarding your microbiological specification(s).**



A feasibility study is probably the single most important consideration when it comes to changing your method of application. Saving you time, resources, and energy, it's a vital aspect of **ensuring compatibility.**

That's why we propose a feasibility study to assist you through the whole process.

bioMérieux is known for providing high-quality products, and we apply these same exacting standards to our feasibility studies, thus ensuring the same meticulous attention to **regulatory compliance and quality of results.**

These experimental studies are performed in our application laboratory using your samples and microbial strain(s). Depending on the scope of your project, we will assemble **a team of experienced scientists** with the right expertise (e.g. expertise in Mycoplasma detection, Endotoxin detection, Sterility testing, etc).

We can also offer an **on-demand study** for any specific needs or requirements you may have. Our experts can design, perform and provide you with all the necessary documentation for your peace of mind.



### WHAT WE OFFER:



**Product compatibility assessment.**



**Service includes 1 product and up to 2 strains.**



**Additional products &/or strains can be quoted as an option.**



**Duration: 4 to 6 weeks.**



**Deliverable: customized presentation &/or study report.**



## VALIDATION PROTOCOLS

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

### How long do you take to implement a new technology?



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

The on-site solution is the fastest way to implement and begin using your technology, resulting in a better return on investment. From validation guides to turnkey on-site solutions, we offer our customers the best way to implement for **a better return on investment**. All our services are **science-based protocols that are fully compliant with local regulations**.



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 WW i.e. Sequence Inc. (US market). 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 systems and instrumentation, and can be tailored to meet internal site requirements and user specifications.

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**.

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 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)  
**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.



#### Validation documentation

- **URS completion guide :**
  - User Requirement Specification (URS)
  - Functional Design Specification (FDS)
  - Requirements Traceability Matrix (RTM)
- **Validation Documents (IQ,OQ,PQ)**
- **Customized Validation Documents**

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



## SUPPLY SERVICE

# Optimize your supply operations. Focus on what matters to your business

How much time do you spend managing your supply chain operations? Is there room for improvement or cost reductions to be found?



As we're all aware, managing supplies can be very time-consuming for laboratory staff. An effective way to save time is by optimizing your supply management, replenishment and delivery processes by improving your logistics knowledge, alongside other organization processes.

By minimizing administrative operations, you will be free to refocus on your core business activities. Let us help enhance **your process reliability** and help you achieve peace of mind knowing that bioMérieux offers a solution to not only **save time**, but also **reduce logistics costs and related expenses**.

**We can help optimize your logistics to increase operational efficiency, allowing you to refocus on your core expertise in testing and product safety.**

Introduction

1. Feasibility studies

2. Validation protocols

**3. Supply service**

4. Instrument service plans and support

We know how to **optimize supply operations**, prevent shortage and waste, and monitor your supply performance for optimal results. We will work alongside you to **simplify your supplies** and guarantee the availability of key products, ensuring **the efficient continuity of your activities**.

We serve customers in **more than 160 countries**, and process **1 million orders per year**. Our experts prepare and ship your order in full compliance with **the strictest regulatory and quality standards**.

Our goal is to build a solid partnership, allowing us to customize our service offer to suit your needs and exacting requirements. We have developed a **complete catalog of Supply Chain services** that can be fully personalized to your specific needs, enabling us to support you in your daily missions and key responsibilities. Here you will find a few examples of key services we can offer. However, a full catalog is available on demand.



bioMérieux cares about providing you with an **eco-friendly supply chain**. Over the past few years, we have committed to reducing CO<sub>2</sub> emissions through various projects and initiatives. Sustainable development remains a key organizational priority today, tomorrow, and for the years to come.



### WHAT WE OFFER:



#### Stock management optimization : Efficiency & Time saving

- **VMI** : Vendor Managed Inventory – We manage and oversee replenishment on your behalf
- **Express delivery** : Get priority delivery on critical products (i.e – overnight)
- **Order consolidation** : Place multiple orders and receive them in one single shipment
- **Time slot** : Agree on a delivery date and time that suits your schedule
- **Monolot** : One single batch delivered for several product ranges



#### Adaptation to your needs : Partnership and Customization

- **Order tracking** : Track & trace your orders at any time and on any device
- **Extended expiry date** : Receive a fresher shelf life to ease your product rotation
- **Customized Packaging** : Select materials and dimensions that fit your business processes
- **KPI & Dashboard** : Control and steer your replenishment activities to improve ROI
- **Temperature Loggers** : Efficiently manage your cold chain and compliance process
- **Dedicated contact** : Proactive support and specific care with your needs in mind

NB: a feasibility study will be conducted according to the country, region or sector in which the client operates



## INSTRUMENT SERVICE PLANS AND SUPPORT:

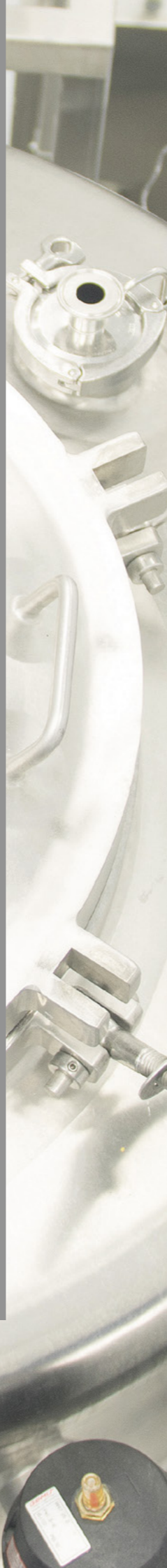
# Maximize the uptime of your instruments and ensure continuous operations

To maximize your uptime, you need to keep continuous operations. Who do you trust to support you in this task?



Instrument uptime is critical in ensuring uninterrupted testing and operations workflow. Our experts ensure that your instruments are continuously available, and performing at their optimal capabilities. bioMérieux provides effective, personalized solutions that both respond to and anticipate your instrument support needs, avoiding issues and providing peace of mind.

We support you with service maintenance and repairs, ensuring the reliable continuity of your operations.



Introduction

1. Feasibility studies

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Regular maintenance means more reliable and stable systems that **reduce downtime, increase efficiency, and improve the performance of your equipment.** At bioMérieux, our goal is to provide the service you need, when you need it. In order to achieve this, we've developed a range of service packages tailored to labs of all sizes. What's more, our services go beyond merely fixing the instrument when it's down; they're designed to **deliver more instrument uptime.**

The VILINK® remote support tool saves you valuable time and resources by allowing faster troubleshooting and turnaround time, performed with minimal lab disruption. VILINK® provides on-demand system updates, predicting maintenance requirements with high security and data protection standards.

Moreover, we can rapidly send highly-skilled and trained system engineers and application specialists to your lab, anywhere in the world. bioMérieux offers a suite of service solutions that ensures maintenance in accordance with manufacturers' specifications and recommended frequency.

24 hours a day, 365 days a year, we're ready to help **ensure the continuity of your operations,** allowing you to ensure timely and accurate results. With >200,000 successful field activities, you can count on us to **increase the reliability of your equipment performance, and maximize your instrument uptime.**



### WHAT WE OFFER:



**Hotline support with bioMérieux specialists:** Service engineers and application specialists are available for questions and immediate assistance.



**Preventative maintenance program** to improve equipment life and avoid any unplanned maintenance activity.



**Technical training :** expert technical training curriculum for your staff, allowing you to proactively ensure you always have the right skills and are prepared for any and all technological evolutions.



**Top Tier interventions / Fast interventions** Proximity to our customers, premises, efficient interventions with Technical Expert Engineers, and swift efficiency in spare parts procurement are the levers to better and faster repairs.



**Remote access solution (VILINK®) :** bioMérieux is able to fix most of your issues remotely and assist your lab specialists in achieving full autonomy.



**Priority for all updates and upgrades :** ensuring the latest and most comprehensively secured version of your instrument.



**Industry leading Customer Service** with our best Experts.



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