

What if you could rigorously manage and efficiently meet regulatory requirements?

STAYING ON TOP OF IT ALL

Rigorous and efficient compliance with regulatory requirements is critical to protecting patients, maintaining the company's reputation and viability, accelerating speed to market, creating a safe working environment, and developing and maintaining a highly skilled workforce.

The biopharmaceutical industry, already highly regulated, is increasingly becoming subject to even tighter regulatory standards and scrutiny. Guidelines are becoming more stringent. Audits are increasing. Validation and documentation requirements are becoming more complex. Operator training is more important than ever. Managing these risk areas can be a full-time job.

The challenge is...

How do you handle time-consuming validation requirements, ensure product excellence and maximize your staff's ability to ensure compliance?

You want to reduce risk by ensuring that your operation meets all relevant regulatory standards, from equipment sterilization to operator training. And you need to do so in an efficient manner that maximizes productivity and controls costs. Mobius® FlexReady Solutions from Millipore can help your company:

- **Handle cumbersome validation requirements** efficiently to accelerate speed to market
- **Ensure product quality** and purity to protect patients
- **Optimize operator skills** to ensure compliance and develop/retain more competent staff



Millipore Access Services validate your equipment onsite, so you don't have to.

Did you know...

28.3% of manufacturers say validation is a significant problem area in their downstream operation.

Source: BioPlan Industry Survey, April 2008

What if you could ensure regulatory compliance with minimum effort?

With their single-use flowpath, Mobius FlexReady Solutions will significantly streamline process validation in your facility. Steaming and cleaning validation steps are completely eliminated.

Our validation protocols will enable you to quickly perform IQ and OQ with ease. We provide complete descriptions of all the activities necessary for proving the suitability of the test methodology, calibration, and maintenance. You also get valuable information on organizing the validation effort.

Access® Services offers on-site validation expertise to laboratories without the personnel and/or time available to perform their own validation. Our scientists can assist in customized validation protocol development and implementation within your laboratory.

What if you could eliminate the risk of contamination due to ineffective sterilization procedures?

The closed design of our systems minimizes the likelihood of operator error, causing contamination, and makes the quality of your processes less dependent on operator skill and reliability.

Our pre-sterilized, single-use products come ready to use with pre-engineered and pre-assembled gamma irradiated flow paths. This helps you avoid cross-contamination and the risk of ineffective sterilization procedures. Our

sterility guarantee virtually eliminates contamination risks and recalls, providing you with maximum peace of mind.

We are an industry leader in Tangential Flow Filtration (TFF) technology for removing impurities from biologic products. Our TFF systems eliminate foaming and particulates and minimize dead legs – helping you ensure consistent product quality.

What if you could train your operators in one day to be competent and compliant on multiple systems?

Through our Access training, we deliver on-site courses that ensure that your staff meets mandatory training requirements and fulfills GMP training best practices. Once an employee is qualified on one Mobius FlexReady system, he or she can easily operate another.

Refine your processes at one of our state-of-the-art training centers, located in the U.S., France and Singapore. Your operators can investigate, explore and optimize your separation, purification and monitoring processes plus get support services from local, regional and international experts.

Studies suggest that the single-use flowpath of the Mobius FlexReady Solutions can streamline process validation and create a time savings as high as **33%**.

TO PLACE AN ORDER OR FOR TECHNICAL ASSISTANCE

For additional information call your nearest Millipore office:

In the U.S. and Canada, call toll-free **1-800-MILLIPORE (1-800-645-5476)**

In the U.S., Canada and Puerto Rico, fax orders to **1-800-MILLIFX (1-800-645-5439)**

Outside of North America contact your local office.



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