



Filtration Process Reviews

An on-site filtration process validation service offered by Millipore

Millipore filtration process reviews are conducted by Validation Specialists at your facility. The review covers all areas associated with your filtration process. Validation Specialists will identify and make recommendations to aid with local and worldwide regulatory standards. All aspects of your purification and filtration processes which could be of interest or concern to regulators will be addressed.

Areas Reviewed

The filtration process review is a comprehensive evaluation of your filtration operations. Below are the specific areas reviewed:

- ▶ Operator Training
- ▶ Filtration Equipment Assembly and Use

- ▶ Control of Filter Devices
- ▶ Documentation
- ▶ Process Control and Environmental Monitoring
- ▶ Sterilization of Filter Devices
- ▶ Water Systems Filtration
- ▶ Validation of Filter Devices

The Review Process

Millipore Validation Specialists conduct the review at your facility. Filtration operating procedures and protocols are examined to ensure they are in compliance with the filter manufacturer's operating specifications and CGMP. The reviewer will also verify that hands-on operating methodologies for integrity testing, equipment set-up, sterilization and filtration comply with internal documentation and recommended industry practices. Filter validation protocols, methodologies and reports are reviewed to ensure they contain the appropriate information, techniques and conclusions.

Immediately after the filtration process review, a Millipore Validation Specialist will meet with your management to discuss the findings. This meeting is a good opportunity for management to ask questions and discuss any problems identified during the review. Recommendations will be made and a summary report will be issued.

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- ▶ Perform comprehensive on-site review of your filtration process
 - ▶ Review filtration process reviewed by qualified Validation Specialists
 - ▶ Conduct inspection of procedures, equipment and documentation
 - ▶ Recommend changes for CGMP compliance
 - ▶ Conclude with on-site wrap-up meeting
 - ▶ Recommend improvements to operating methodologies
 - ▶ Receive documented report of filtration process review
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The Benefit of a Filtration Review

Problems in your filtration process can compromise sterility which results in down-time and lost profits. Millipore knows the importance of complying with CGMP and can help you optimize your operation. Validation Specialists from Millipore have years of experience in pharmaceutical process filtration and they will use their expertise to ensure your filtration process is operating correctly and within appropriate regulatory guidelines.

How to Request a Millipore Filtration Process Review

To request a Millipore Validation Specialist to visit your facility to conduct a Filtration Process Review or to get information on other validation services offered by Millipore, call your Millipore Applications Specialist or the Millipore office nearest you.

The Validation Services program at Millipore is only one of many quality programs in place to ensure Millipore products meet the high standards and regulatory requirements of the pharmaceutical industry.

To Receive More Information on Millipore's Access Services

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)**

Internet: <http://www.millipore.com>

E-mail: tech_service@millipore.com

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