3M Purification Inc.

Validation Support Services
For the Pharmaceutical and Bioprocess Industries

Innovative
Filtration
Performance. Quality. Service.

Validation:

"Establishing documented evidence that provides a high degree of assurance that a specific process will consistently produce a product meeting its predetermined specifications and quality attributes."

-FDA Guideline on Sterile Drug Products Produced by Aseptic Processing – Sept. 2004

A Service of 3M Purification Inc. Scientific Applications Support Services (SASS)

3M Purification understands the exacting nature of regulatory demands on today's pharmaceutical and bioprocess industries and has designed our Validation Support Services program to meet these needs. 3M Purification Validation Support Services streamlines filter regulatory compliance, saving you money, and more critically, time. 3M Purification services extend beyond the validation of sterilizing grade membrane filters to the validation of prefilters. 3M Purification helped pioneer prefilter validation, an emerging industry trend, with our Zeta Plus™ line of cellulosic depth filters.

Goal

The goal of 3M Purification Validation Support Services is to ease regulatory compliance for our customers by providing well designed, properly executed, and completely documented test protocols on 3M Purification filter products in their intended application.

Scientific Applications Support Services

SASS is a global organization of market-focused scientists and engineers who serve as vital links in effective, collaborative efforts between our customers and 3M Purification's R&D efforts. Members of the Global SASS group are skilled in performing on-site bench-scale tests and relating their results to full scale manufacturing filter operations. When unique processing problems are encountered, SASS is expertly equipped to identify filter solutions using either 3M Purification very broad array of existing filter products or working with 3M Purification R&D to design a custom solution for the job.

Scope Of Services Offered

Core Services

Integrity Testing

Water-wet integrity test values are supplied with all sterilizing grade 3M Purification membrane filters. However, many filtration applications are in solutions other than water. The properties of these solutions (surface tension, wetting angle, etc.) may alter the integrity test value of the filter under consideration. 3M Purification can execute the required tests to provide product-specific integrity test parameters to answer this critical question.

Bacterial Retention

This evaluation supports the ability of a given filter to quantitatively retain a test organism when maximally challenged. The appropriate test organism is typically suspended in the drug product or solvent of choice, at a concentration that will yield a complete "challenge" to all areas of the membrane surface.

Chemical Compatibility

This evaluation provides evidence that the 3M Purification filters selected for a particular application are chemically and physically compatible with the fluids used in the application, as well as the operating conditions in which the filters are expected to function.

Extractables

This evaluation provides information regarding the amount and identity of material extracted from a filter when exposed to a particular solvent system. Combined with appropriate flushing protocols, this information can be used to minimize extractables.

Additionally, 3M Purification can recommend filter combinations that reduce the number of extractable components present, minimizing regulatory complexity. For instance, selecting prefilters and final filters composed of the same support and membrane materials consolidates the number of materials exposed to a process, simplifying validation issues.

Additional Services

Sterilizing Grade Filter Validation Guides

3M Purification provides extensive regulatory information in our Validation Guides for sterilizing grade filters including the LifeASSURE™ SA, SP, ST, PSA and PFS filter families.

Prefilter Regulatory Support Files

3M Purification leads the industry in supplying validation support for upstream filter products. Our Regulatory Support Files cover upstream filters such as Betapure™ NT-P, LifeASSURE™ PLA, Betafine™ PEG and Zeta Plus™ filters.

USP Biological Reactivity - Class VI Plastics Test Results

Third-party testing reports are available for 3M Purification filters documenting that their component materials meet the requirements of the USP Class VI Biological Test for Plastics.

On-site Filtration Audits

3M Purification SASS specialists are skilled in conducting on-site audits of filtration processes and recommending ways to improve filtration performance, reduce filter costs and minimize process downtime.

3M™ Series 200 Automated Integrity Testing Device

3M Purification supplies on-site validation of automated integrity test devices, such as the 3M™ series 200 Automated Integrity Testing Device, tailored to meet the specific needs of the customer. IQ/OQ/PQ documentation are also available to speed regulatory compliance.

SOP & Test Protocol Development

3M Purification is skilled in helping customers develop standard operating procedures and test protocols for a variety of filter applications.

Pre-inspection Audit Support

3M Purification SASS specialists can provide assistance in preparing customers for internal and external audits of filtration processes. Operator training courses, report consultation, and compliance trouble-shooting, are just some of the services 3M Purification Validation Support Services can provide.

Regulatory Document Preparation Assistance

3M Purification specialists bring their familiarity with regulatory documentation to assist customers in preparation of the necessary materials required by regulatory authorities.

Audits of 3M Purification Manufacturing Sites

3M Purification welcomes audits of our manufacturing facilities and has assembled a team of specialists to provide this service to our customers.

Contaminant Analysis

3M Purification laboratories have decades of experience in analysis of contaminants and can supply technical advice on improved filter selection and usage based on the findings. This service often results in significant cost savings in optimized filtration.

How To Contact 3M Purification Validation Support Services

To engage Validation Support Services, contact your local 3M Purification office, or visit us at www.3Mpurification.com. A SASS specialist will contact you and begin the validation process by conducting a survey of your requirements. The SASS specialist will then provide you with a recommended set of test protocols designed to meet these requirements. Validation processes such as these are meant to address the regulatory aspects of filtration, and 3M Purification's recommended protocols will be consistent with prevailing regulatory guidelines. Once a test plan has been agreed to, validation testing can begin either on-site or in a 3M Purification laboratory. Upon completion of the testing regimen, Validation Support Services will completely document the test results for you.

Your Local Distributor:

3M Purification Inc.
400 Research Parkway
Meriden, CT 06450
U.S.A.
Phone (800) 243-6894
(203) 237-5541
Fax (203) 630-4530
www.3Mpurification.com

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