3M Purification Inc.
Technical and Scientific Services
Global Support for the Life Science Industry

Global Expertise… delivered locally

3M

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As a global leader in measuring, characterizing, and understanding materials, products and processes, 3M recognizes that our commitment to our customers does not end with the supply of a world class product; in fact that is just the beginning.

3M has a global network of world-class scientists and facilities that are available to support our globally connected Life Science customers. Whether you are an emerging start-up or a global life sciences powerhouse, the expertise of our global team is committed to providing a high level of support. 3M is founded in a cross-functional collaborative culture committed to providing customer support with a diverse team having technical expertise in disciplines ranging from microbiology, chemistry, biochemistry, engineering, polymer science, chemical engineering, physics, and material science.

3M's global team is dedicated to investigating and solving our customers' purification challenges from research, through product and process development, to large scale manufacturing. We provide our customers with full product, application, and technical support through our globally distributed network of testing and research laboratories, or through 3M's team of on-site technical specialists.

Our Support…

Commitment…

- Responsiveness
- Technical Depth
- Quality

Global Capabilities…

- Extractables and leachables testing
- Micro-organism challenge testing
- Compatibility testing
- Integrity testing
- Viability testing
- Process design
- Process optimization

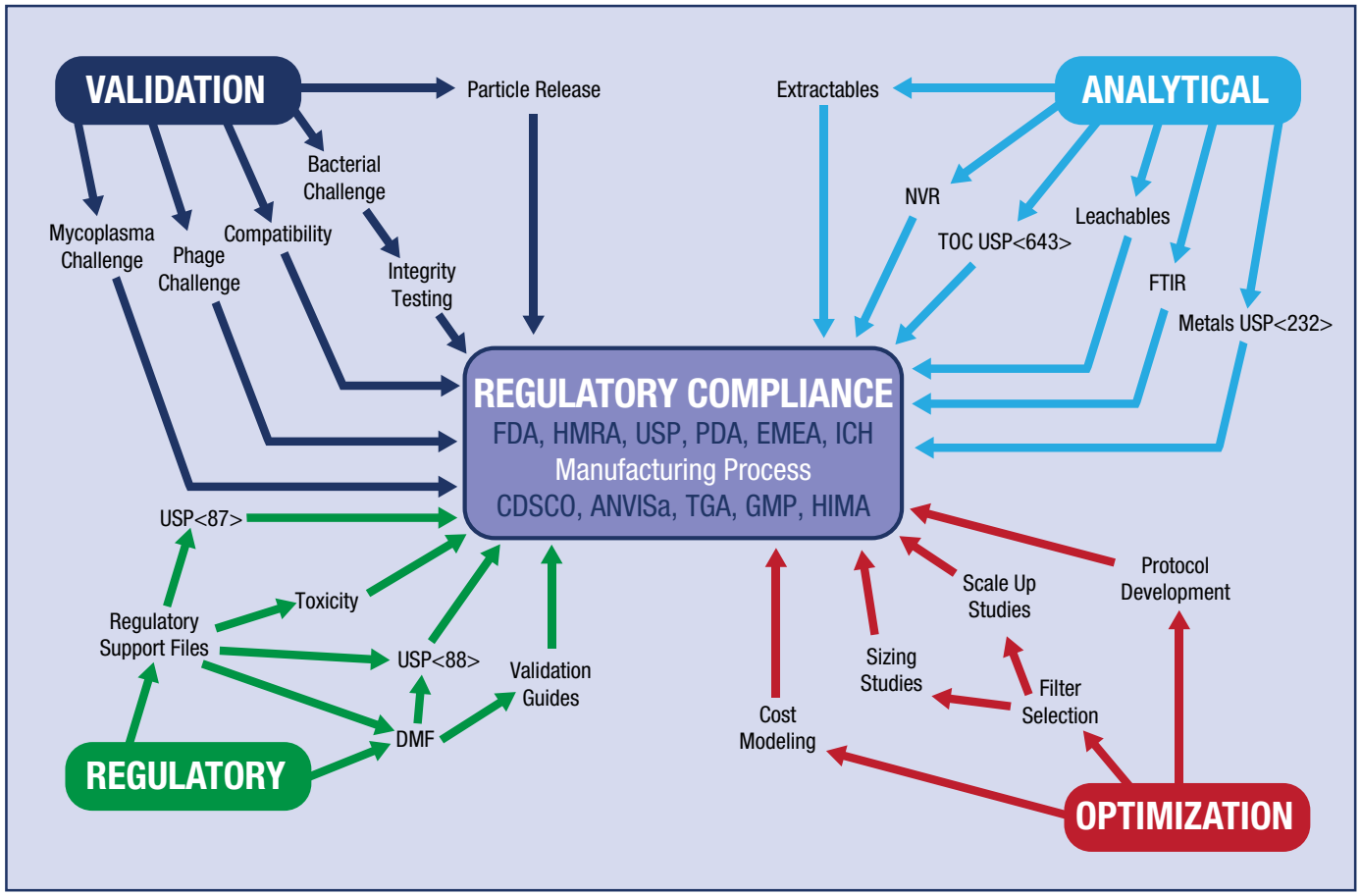
Validated…

- Scientific processes
- Material handling
- Reporting and documentation

Enabling Technical and Regulatory Success …

3M's goal is to enable the technical and regulatory success of our customers. Meeting this goal requires a comprehensive and detailed understanding of how all aspects of design, materials, structure and manufacturing processes.

To understand how each of these elements interact and impact the performance of the final product, 3M uses model solutions and extensive statistical experimentation throughout the design and qualification of each product. Much of extensive data package is provided in the appropriate validation guides and regulatory support files.



- To support the use of 3M technologies 3M can perform extensive product and process development testing using our customers' process solutions.
- 3M's scientists and engineers will work with our customers to identify a single or set of filtration and/or purification products to optimize multiple process operations, and simultaneously maximize throughputs and improve our customers return-on-investment (ROI) from their process.
- 3M will also work to develop customer specific protocols and SOP's to support the use of 3M products.

Scope of Services …

Analytical Services:

Extractables and Leachables

Extractables are compounds that can be extracted from a material when in the presence of solvents of varying polarity under extreme conditions. Leachables are compounds that leach off the product in contact with the customers' solution during the normal operation of the process. The Code of Federal Regulations (CFR), Title 21, Part 21.65 states: "Equipment shall be constructed so that surfaces that contact components, in-process materials, or drug products shall not be reactive, additive, or adsorptive so as to alter the safety, identity, strength, quality, or purity of the drug product." To this end, 3M recognizes the critical importance of characterization, control, and minimization of extractables and leachables from our products and uses state-of-the-art tools instrumentation and industry leading methods to support our customers' deployment of 3M products in their application.

3M Purification leverages the analytical power of 3M's Global Corporate Research Analytical Laboratory. 3M brings customers an unrivaled ability to identify, quantify, and profile individual compounds of interest and to develop strategies for minimization of their leaching into our customers' process stream.3M has characterized the extractables from its products using standard solutions and report this information in the corresponding validation guide.

3M characterizes the extractables and leachables using a combination of the following protocols and instrumentation:

- USP <643> Total organic content (TOC)
- Organic material identification and quantification (LC-MS, GC-MS, NMR)
- Gravimetric non-volatile residue (GNVR)
- Infrared Spectroscopy (FTIR)
- USP <233> Metals content and identification (ICP-MS, ICP-AES)

As noted, leachables are compounds that migrate from a material in the presence of an actual formulation under normal process operating conditions. Testing is undertaken as per extractables testing. Because it is possible for a drug formulation to chemically alter known extractable compounds, the possibility exists for leachables to be detected that were not detected in a corresponding extractables study. 3M has a long history of experience with polymer and elastomer extractables and leachables in both drug formulations and medical devices.

USP <232> and <233> Elemental Impurities Analysis

In May 2014 USP chapters <232> Limits and <233> Procedures became mandatory for the testing of elemental impurities on drug substances using ICP-AES or ICP-MS, following USP <730>. While these tests are only mandatory on drug substances, 3M can offer analytical support to identify the targeted elements in process solutions before and/or after passage through a 3M Purification product.

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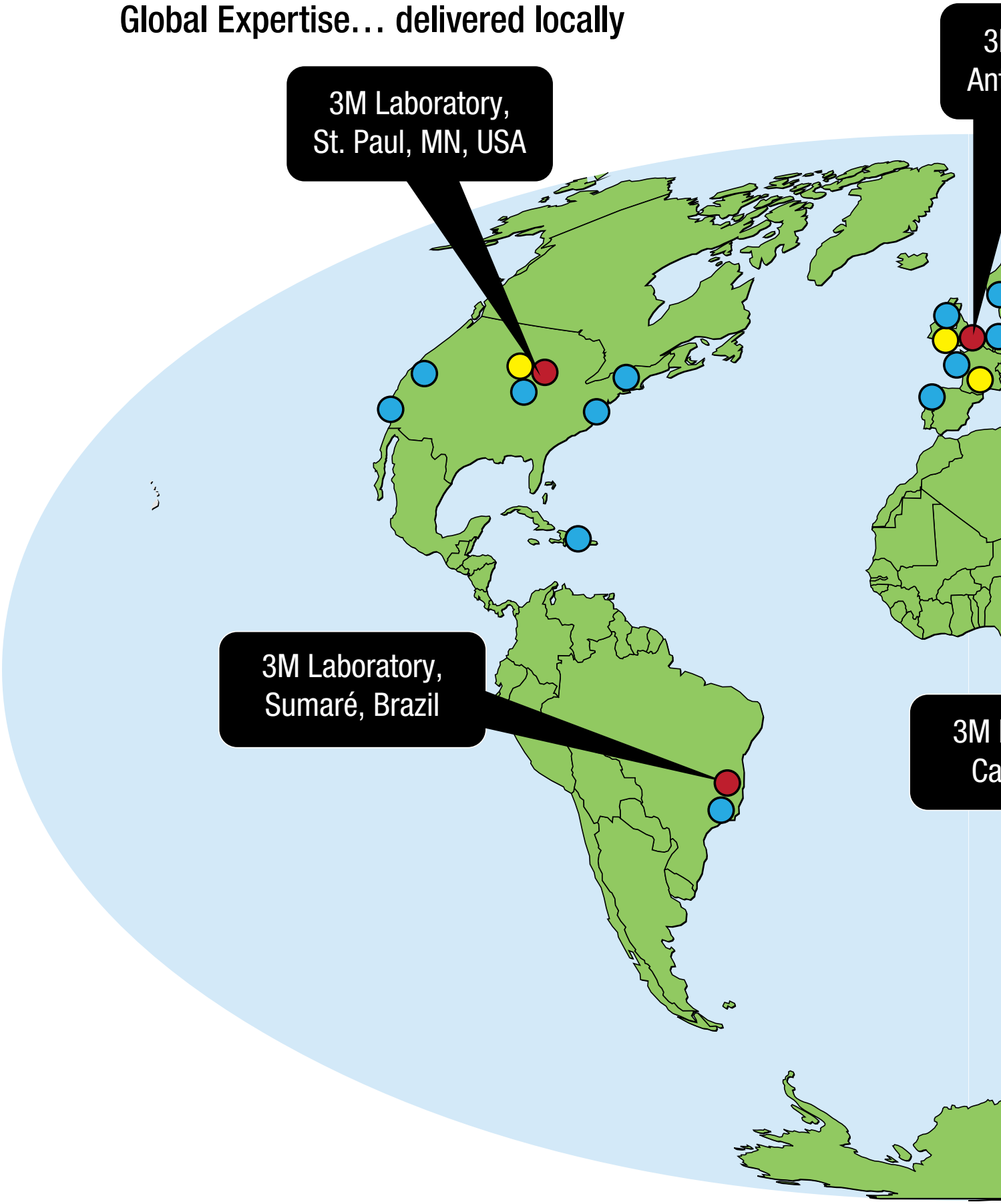

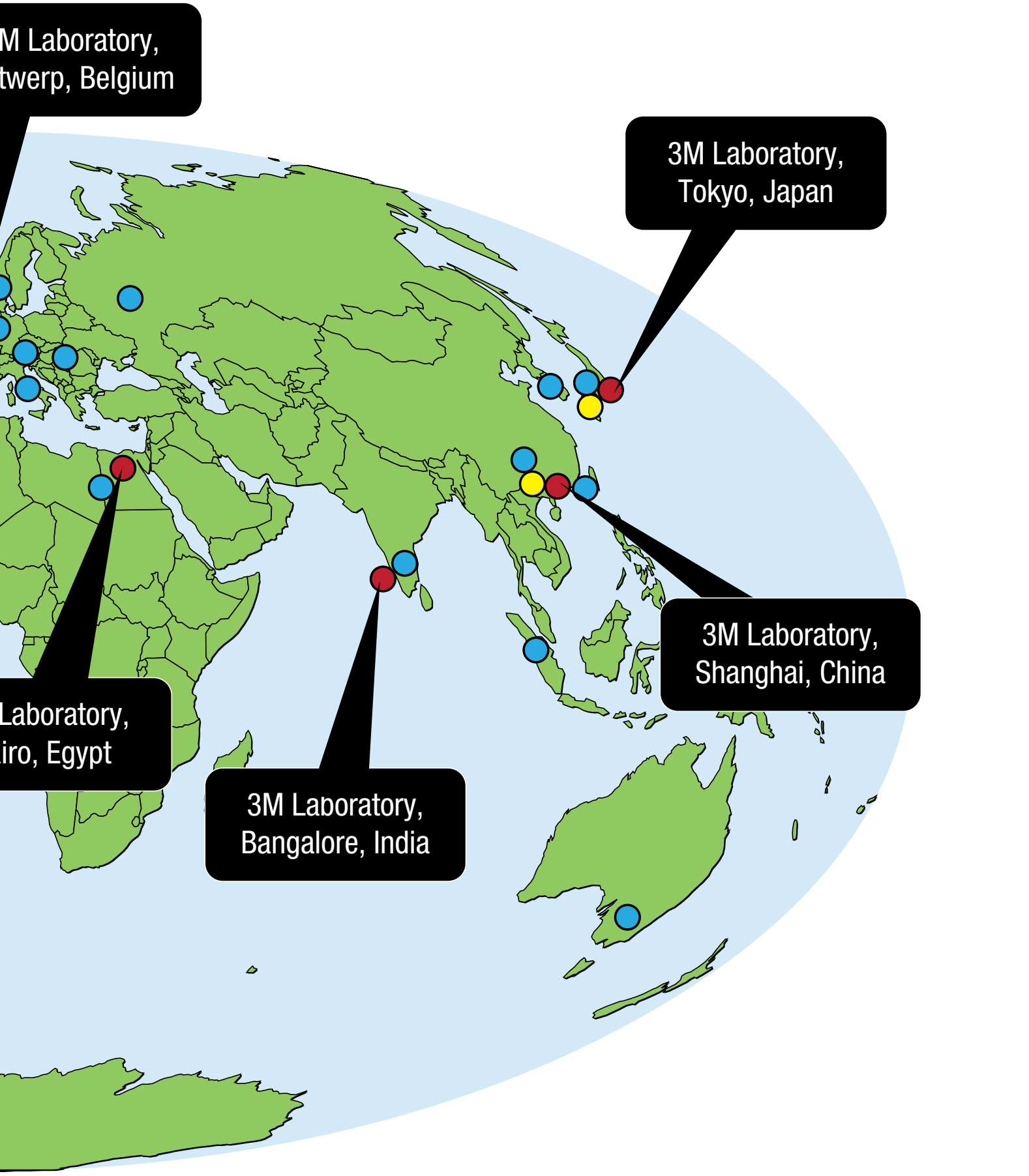

3M Validation Laboratory 3M Technical Specialist 3M Corporate Research Laboratory

Scope of Services …

Regulatory Support Documentation:

Filter Validation Guides and Regulatory Support Files

3M Purification provides extensive regulatory information in each published LifeASSURE™ series filters Validation Guide. 3M also pioneered the industry in providing this service and support documentation for all other products marketed to our Life Science customers.

Drug Master File Documentation

The 3M Purification Drug Master File, on record with the United States Food and Drug Administration (FDA), outlines critical aspects of our product design, manufacturing and control. 3M may grant access to regulatory authorities to this proprietary information in support our customers' regulatory filings.

USP <88> Class VI and USP <87> Biological Reactivity

Independent, 3rd party test reports are available for all 3M Purification filters documenting that component materials meet the requirements of the USP Class VI Biological Reactivity tests.

Process and Performance Optimization Services:

Filter Selection Support

3M can assist in many ways in recommending an optimum combination of membrane products and overall purification process configuration.

Application Engineering

3M technical experts are trained in developing new applications with customers, and in the optimization of pharmaceutical, biopharmaceutical and biologics manufacturing processes utilizing 3M's matched component product lines. They will work with your team to identify, research, develop, and deploy 3M products in the most innovative, efficient, and cost effective way possible.

Scale Up Studies

3M can assist in on-site testing to recommend the configuration and sizing of products for your process at all scales of operation.

Contaminant Analysis

3M's laboratories have many decades of experience in analyzing contaminants and can supply technical advice on improved filter selection and operation based on expertise. This service often results in significant cost savings by optimizing the filtration process.

SOP and Protocol Development

3M Purification technical specialists are skilled in assisting customers in the development of Standard Operating Procedures (SOP's) for using 3M Purification.

Validation Services:

Bacterial Challenge Testing

Bacterial (*Brevundimonas diminuta*) retention testing using customer process fluids is often a critical step in filter validation and is mandated by regulatory agencies in validated processes. The US Food and Drug Administration (FDA) recommends that microbial retention testing is conducted using the candidate pharmaceutical product under simulated processing conditions to validate the sterilizing grade filter performance.

Product Integrity Testing

Water wet integrity test values are supplied with all 3M Purification sterilizing grade membrane filters and are documented in the instructions for use, and in the appropriate corresponding validation guides. Some applications are in solvents other than water. The properties of these solutions, such as surface tension, solubility and diffusion, will alter the integrity test values of the filter. 3M can undertake the required testing to provide specific integrity values in alternative solvents.

Mycoplasma Challenge Testing

In addition to bacterial challenge testing, 0.1µm rated sterilizing grade filters are commonly challenged with solutions of mycoplasma (e.g., *Acholeplasma laidlawii*) to provide supplemental mycoplasma clearance data. Although there is currently no published, industry recommended standard method for a Mycoplasma Challenge Test (MCT), 3M can undertake mycoplasma challenge testing using *A. laidlawii* at a concentration of 10^7 CFU per cm^2 filter in customer solutions to provide this data. 3M also offers *Mycoplasma orale* retention testing as this organism now accounts for more than 40% of cell culture mycoplasma contamination events.

Chemical Compatibility

Correct selection and qualification of process components, including filters should always include assessment of the chemical compatibility of the filter with the product.

3M can undertake testing to assess the chemical compatibility, based on a range of performance and physical attributes, of 3M Purification products with customer fluids at operating conditions under which the filters are expected to be used. The scope of the recommended chemical compatibility service offered is based on the following risk factors:

- Drug product or intermediate composition
- 3M product materials of construction
- Duration of product contact
- Temperature of product contact
- Critical product performance factors reported in the Regulatory Support Documents
- Worst case process parameters.

Particle Release Testing

Particle and fiber release testing is undertaken on all 3M Purification filters as part of the filter validation. However, during operation particles may be released into the fluid stream from a number of sources such as the filter, or other disposable components in a system, or may be caused by crystallization or aggregation of the drug product or process material. 3M can provide a detailed test program to capture and identify particles from the process stream under operational conditions.

How to Contact Us …

Global Technical and Scientific Support for the Life Science Industry

To speak with a 3M technical specialist contact your local:

3M Purification office
3M Purification Sales Representative
3M Purification Distributor

or

Or visit us at www.3Mpurification.com
Click on “Contact Us” (top right corner
Enter your information, click send
And we will respond within 24 hours

NOTES

Warranty, Limited Remedy, and Disclaimer:

Many factors beyond 3M Purification Inc.'s (3M's) control and uniquely within user's knowledge and control can affect the use and performance of a 3M product in a particular application. User is solely responsible for evaluating the 3M product and determining whether it is fit for a particular purpose and suitable for user's method of application. Unless an additional warranty is specifically stated on the applicable 3M product packaging or product literature, 3M warrants that each 3M product meets the applicable 3M product specification at the time 3M ships the product. **3M MAKES NO OTHER WARRANTIES OR CONDITIONS, EXPRESS OR IMPLIED, INCLUDING, BUT NOT LIMITED TO, ANY IMPLIED WARRANTY OR CONDITION OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE OR ANY IMPLIED WARRANTY OR CONDITION ARISING OUT OF A COURSE OF DEALING, CUSTOM OR USAGE OF TRADE.**

If the 3M product does not conform to this warranty, then the sole and exclusive remedy is, at 3M's option, replacement of the 3M product or refund of the purchase price.

Limitation of Liability:

Except where prohibited by law, 3M will not be liable for any loss or damage arising from the 3M product, whether direct, indirect, special, incidental or consequential, regardless of the legal theory asserted, including warranty, contract, negligence or strict liability.

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