

Filter Validation Services

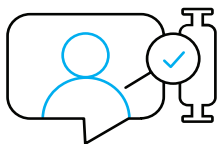
MTS - Meissner Technical Services



Meissner Technical Services

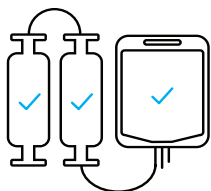
At Meissner, we are more than a filter manufacturer; we are your trusted compliance partner. With four decades of industry expertise, we simplify the filter validation process for drug products, freeing you to concentrate on your core work.

Our Sterile Filter Validation Process



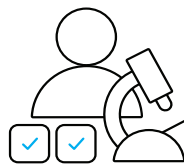
Consultation

Our team is available to discuss your needs and guide you through the necessary information for designing your study.



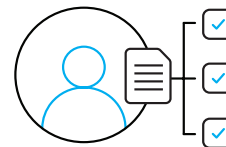
Custom Study Design

Our team of subject matter experts will design a study that aligns with your validation needs.



Laboratory Testing

Our skilled laboratory team will conduct the testing according to the study protocol.



Deliverable

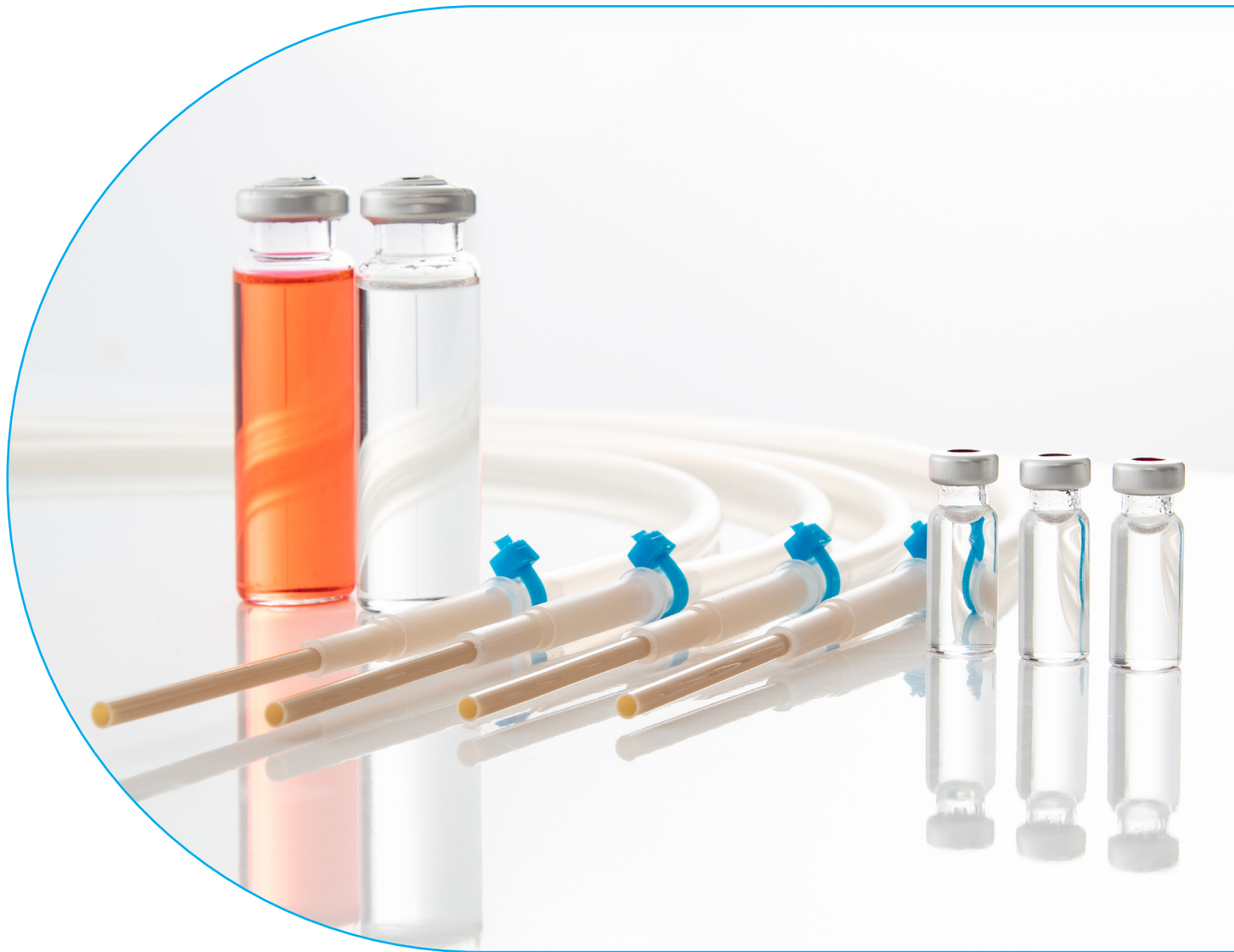
Our technical team will create a comprehensive study report suitable for supporting submissions and regulatory filings.



Services

We offer a comprehensive portfolio of microbial and analytical testing to ensure compliance with the FDA and EC regulatory guidelines. Available testing includes:

- **Bacterial Challenge:** Confirms the filter's ability to sterilize the product, correlated to filter integrity test.
- **Compatibility:** Confirms the product does not degrade the filter media.
- **Basic Extractables:** Determines maximum level of extractables that may be introduced into a product batch from the filter based on model solvent testing data.
- **Filterability:** Confirms appropriate filter size for batch.
- **Product Wet Bubble Point:** Determines minimum bubble point integrity test values for product wet filter.
- **Product Wet Diffusive:** Determines maximum diffusive flow integrity test values for product wet filter.
- **Adsorption:** Determines whether product ingredients bind to filter membrane.



Industry Leadership in Validation Guidance

As co-authors of several of the industry's leading validation guidance documents, including PDA TR 26, Sterilization Filtration of Liquids, we've contributed to shaping best practices. Our commitment to excellence extends beyond supporting our clients, as we actively participate in defining compliance standards.

Why Choose Meissner?

- **Expertise:** Our team of seasoned professionals understands the nuances of biopharmaceutical processes.
- **Compliance Assurance:** We help keep you compliant with regulatory standards.
- **Tailored Solutions:** We provide customized validation study protocols to meet your unique requirements.
- **Reliable Results:** We perform rigorous testing in accordance with PDA TR 26 guidance.
- **Responsive Support:** We are here to assist you.

Contact Us

For inquiries or to discuss your specific needs, reach out to our team at mts.validations@meissner.com.



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