Millipore®
Expert Pharm/BioPharm
Products & CTDMO Services

Tech Brief

PFAS Considerations for Pharma and Biopharma Manufacturers

Understanding PFAS use in Pharmaceutical Manufacturing

Per- and poly-fluoroalkyl substances (PFAS) are a broad group of synthetic chemicals which, due to their chemical and physical properties, have been used by manufacturers to fulfill requirements in high quality applications for research, development, and manufacturing of biopharmaceutical products. Amidst an evolving regulatory environment, the scientific community is deepening its understanding of persistency and related challenges, and manufacturers are increasingly evaluating materials in their processes as well as longer-term planning options.

The regulatory landscape is complex, with multiple regulatory agencies advancing policies and guidance to oversee PFAS use and monitoring across manufacturing processes. There is, for example, no single unified definition of PFAS, and regulatory approaches differ by region.

To navigate this complexity, manufacturers can benefit from working with experienced partners like Merck KGaA Darmstadt, Germany who understand both current PFAS-based materials and emerging non-PFAS alternatives.

Planning and Considerations for Pharma/Biopharma Manufacturers

As a dependable supplier with considerable materials science expertise, we support pharma/biopharma manufacturers operating in highly regulated environments. Our products and services are designed to support stable, resilient, and predictable supply chains and enable pharma/biopharma manufacturers to comply with global regulatory expectations.

We actively monitor scientific and regulatory developments pertaining to PFAS in Europe, the United States, and other global markets. We innovate across our differentiated portfolio to address evolving customer needs. This includes research and development to explore alternative materials where appropriate, while prioritizing performance, quality, and product standards that meet pharma/biopharma manufacturer needs. Development and qualification of alternative solutions require careful evaluation and time to ensure supply chain continuity, reliability, and sustainability.

Through continued collaboration, we aim to support long-term planning by focusing on:

- Proactively monitoring and engaging on evolving global PFAS regulations
- Assessing potential impact on products, manufacturing processes, and infrastructure
- Developing a diverse portfolio of products
- Enabling continued access to essential products for regulated manufacturing environments

Non-PFAS Options for Pharma/ Biopharma Manufacturers

We offer non-PFAS options for pharma/biopharma manufacturers who are evaluating alternative materials based on their specific application or regulatory considerations. These include solutions within selected product families for aseptic filtration used in pharmaceutical manufacturing workflows.

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The selection of alternative materials is application-specific and should consider performance, quality, validation, and regulatory expectations.

Examples from the Millipore Express® product families with non-PFAS options for sterile filtration include:

- Millipore Express® Sterile High Retention (SHR) filters
- Millipore Express® Ace 0.2 µm filters
- Millipore Express® Sterile High Capacity (SHC) filters
- Millipore Express® Sterile High Flux (SHF) filters
- Millipore Express® Process Protection High Flux (PHF) filters

Please refer to the **Millipore Express® Sterilizing-Grade Membrane Filters Selection Guide** for additional technical details.

Support

We continue to expand our non-PFAS options by developing new material solutions to meet application-specific performance requirements, quality standards, and regulatory guidance. In parallel, we support the scientific community through technical and validation services for current and future manufacturing processes, helping pharma/biopharma manufacturers assess material options and address PFAS-related questions in a structured, application-specific manner.

We are working closely with pharma/biopharma manufacturers to help navigate this complexity with a focus on product quality, supply resilience, and innovation. By combining scientific leadership, regulatory expertise, and collaborative innovation, we aim to help shape the next generation of pharmaceutical manufacturing solutions.

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