The Global Shift Away from PFAS: Challenges and Strategies for the Healthcare Sector

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Abstract

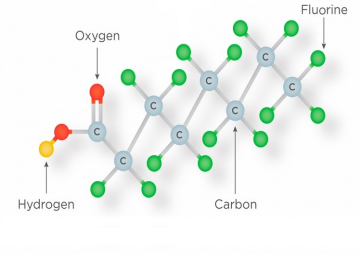
The healthcare industry, being highly regulated, frequently encounters challenges resulting from shifts in global regulatory frameworks. A major regulatory challenge currently facing the industry is the restriction of PFAS chemicals, a largest ever restriction of chemical group in the history. PFAS are widely used across different sectors as they have unique desirable properties. However, the accumulating scientific evidence regarding their persistence, tendency to bioaccumulate, and potential adverse effects on both human health and the environment has resulted in intensified regulatory oversight.

The restriction of these chemicals causes supply chain disruptions, increased production costs, and potential product shortages in the market which may impact patient lives.

This white paper summarizes the significance of PFAS in both the medical device and pharmaceutical sectors, examines the impact of upcoming restrictions on the healthcare industry, and outlines the challenges and opportunities ahead for manufacturer.

Introduction

Per- and polyfluoroalkyl substances (PFAS) are a large class of thousands of synthetic chemicals that are used throughout society. They all contain carbon-fluorine bonds, which are one of the strongest chemical bonds in organic chemistry. The C-F bonds in PFAS lead to very stable substances, a feature that also makes them very persistent in the environment and in the human body, for which reason they are often referred to as “forever chemicals.

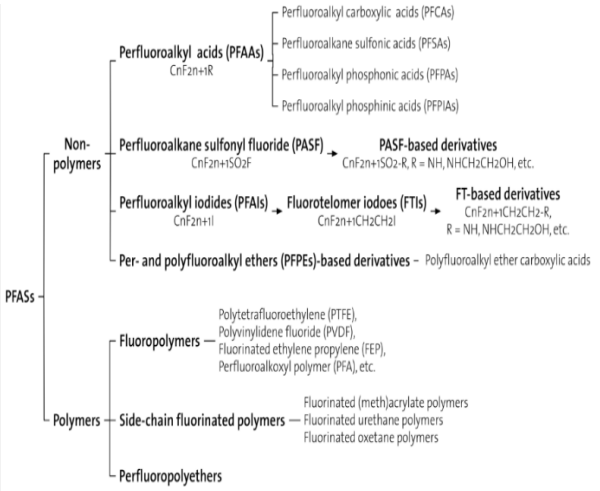


> *“Per- or Poly- Fluoro alkyl substances (PFASs) are defined as fluorinated substances that contain at least one fully fluorinated methyl or methylene carbon atom (without any H/Cl/Br/I atom attached to it), i.e. with a few noted exceptions, any chemical with at least a perfluorinated methyl group (CF3) or a perfluorinated methylene group (–CF2–) is a PFAS.”*

Classification of PFAS substances:

PFAS are broadly classified into Polymeric PFAS and non-polymeric PFAS

Polymeric PFAS: Consists of large molecules made up of repeating units. Due to their size and structure, they are less mobile in the environment and generally considered less likely to pose harm. These substances are primarily used in various industrial applications, including the medical device industry.



Non-polymeric PFAS: These are smaller, individual molecules that are more mobile in the environment and pose greater risks to human health due to their solubility and persistence. Their widespread use has led to broad environmental contamination and associated health concerns. It is also known that non-polymeric PFAS may be used as processing aids in the manufacturing of medical devices throughout the supply chain.

Applications of PFAS:

PFAS chemicals are widely used in the healthcare sector due to their unique and highly desirable physicochemical properties. These include exceptional chemical and thermal stability, corrosion resistance, oil and water repellence, low surface energy, a low dielectric constant, biocompatibility, low friction (lubricity), and excellent electrical insulation.

These characteristics make PFAS compounds nearly indispensable for the manufacturing, performance, and safety of a wide range of medical devices and diagnostic tools.

Medical devices:

Medical devices are critical components of health care delivery, and a large number rely on the unique properties of PFAS. Some of these devices are necessary to save and sustain lives, including cardiovascular stents, pacemakers, vascular grafts, and guidewires.

The applications include

- **Fluorinated meshes and wound treatment:** ePTFE (expanded PTFE) or PVDF are used as mesh material or patches, because they reduce adhesion, one of the possible complications in hernia reinforcement.

- **Medical implants:** PTFE or FEP being the most abundant fluoropolymer used in implants.
- **Coatings:** Fluoropolymers often use as coatings which help lower friction, which helps reduce tissue damage during insertion or removal. These properties are crucial for medical devices like catheters, guidewires, stents, and implants.
- **Processing aids:** Fluoropolymer-based additives are used as extrusion aids. They are for instance used in blown film extrusion of linear low-density polyethylene (LLDPE). Other applications include pipe extrusion of high-density polyethylene (HDPE).
- **Electronic equipment:** In electronics, PFAS is mainly applied in cables and wires, printed circuit boards and in (LCD) screens.
- **Packaging:** PFAS, especially fluoropolymers, are widely used in medical packaging applications
- **Manufacturing equipment:** Non-stick coatings, such as PTFE, line manufacturing equipment, preventing product contamination and ensuring cleanliness.

FDA Says that *"Currently, no other materials exist that can perform the critical roles of fluoropolymers in medical devices. Some of these devices are necessary to save and sustain lives, including cardiovascular stents, pacemakers, vascular grafts, and guidewires".*

Pharmaceutical sector:

The pharmaceutical industry relies heavily on fluoropolymers, a subset of PFAS, for safe manufacturing, distribution and use of medicinal products.

The applications include

- **Active Pharmaceutical Ingredient (API):** More than 300 fluorinated compounds have been launched as medicinal products over the last few decades and over 500 more are in late-stage clinical trials, which indicates the significance of fluorine in pharmaceutical compounds.

- **Excipients:** The only excipients identified as PFAS are F-Gas propellants, used in Metered Dose Inhalers (MDI), which act as safe propellants to aerosolise the API and ensure the delivery of the medicine to the lungs.
- **Solvents and intermediates:** Examples for reagents required in manufacturing, R&D and for analytical purposes in Quality Control (QC) laboratories: e.g. trifluoro acetic acid (TFA), hexafluoro isopropanol and trifluoro ethanol.
- **Drug delivery devices:** Potential PFAS applications included may be seals, lubricants, filters, barriers.
- **Packaging:** Fluoropolymers provide a high barrier against humidity in blister packaging for sensitive pharmaceuticals, and extend the shelf life for dry formulations like pills and powders necessary to patient health.
- **Manufacturing:** PFAS coatings and materials are used in manufacturing equipment and packaging to ensure non-reactivity and durability.
- **Analytical:** PFAS are used in analytical chemistry within pharmaceuticals for various tests and quality control measures.

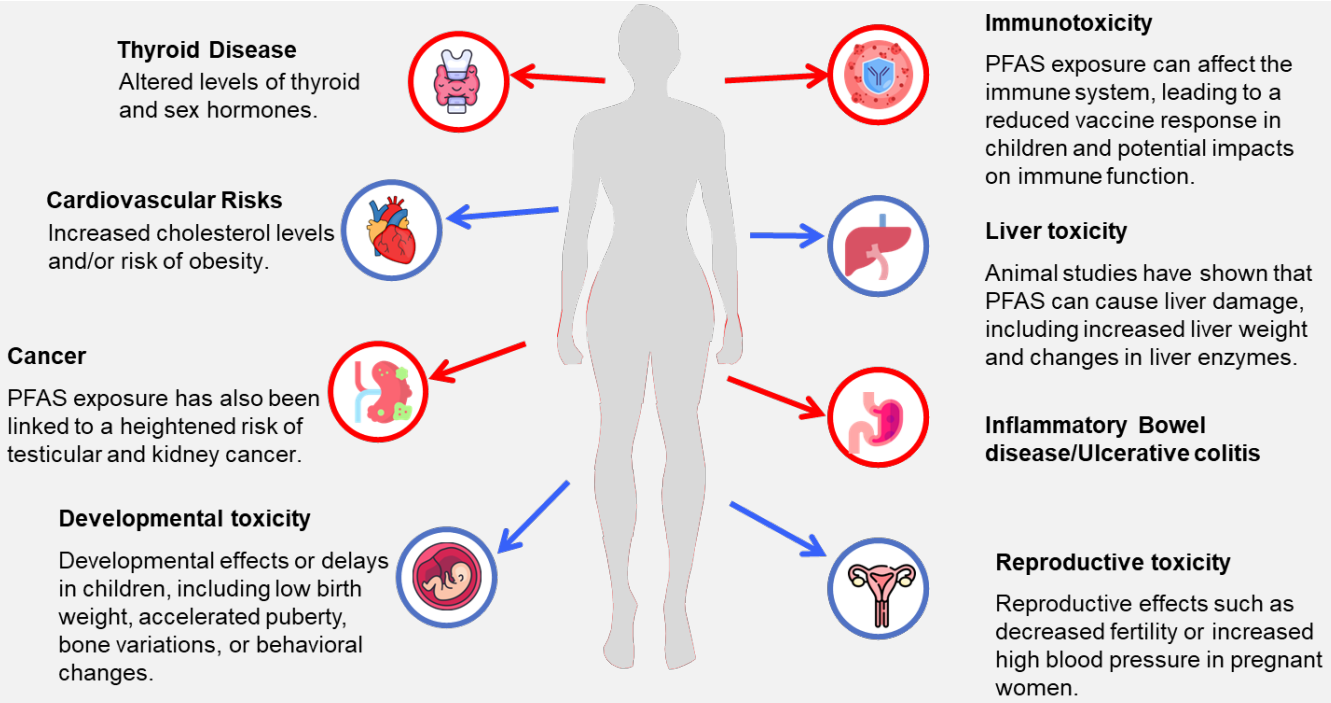
Harmful effects of PFAS

PFAS belong to a class of chemicals known as Persistent, Bioaccumulative, and Toxic (PBT) substances. They are also highly mobile in the environment and have been detected even in some of the most remote regions of the world. Once released, PFAS are extremely difficult, if not impossible to remove, leading to their continued accumulation in ecosystems.

PFAS are easily absorbed and slowly excreted from the human body, the rate at which a chemical is eliminated from the human body is an important feature of its respective hazard profile. Toxicants with long half-lives generally show a greater bioaccumulative potential following repeated/continuous exposure.

The estimated elimination halflives in humans are 2.1–10.1 years for PFOA, 3.3–27 years for PFOS, 4.7– 35 years for PFHxS, 2.5–4.3 years for PFNA, indicating significant accumulation potential of PFAS

PFAS are potentially capable of producing a wide range of adverse health effects such as



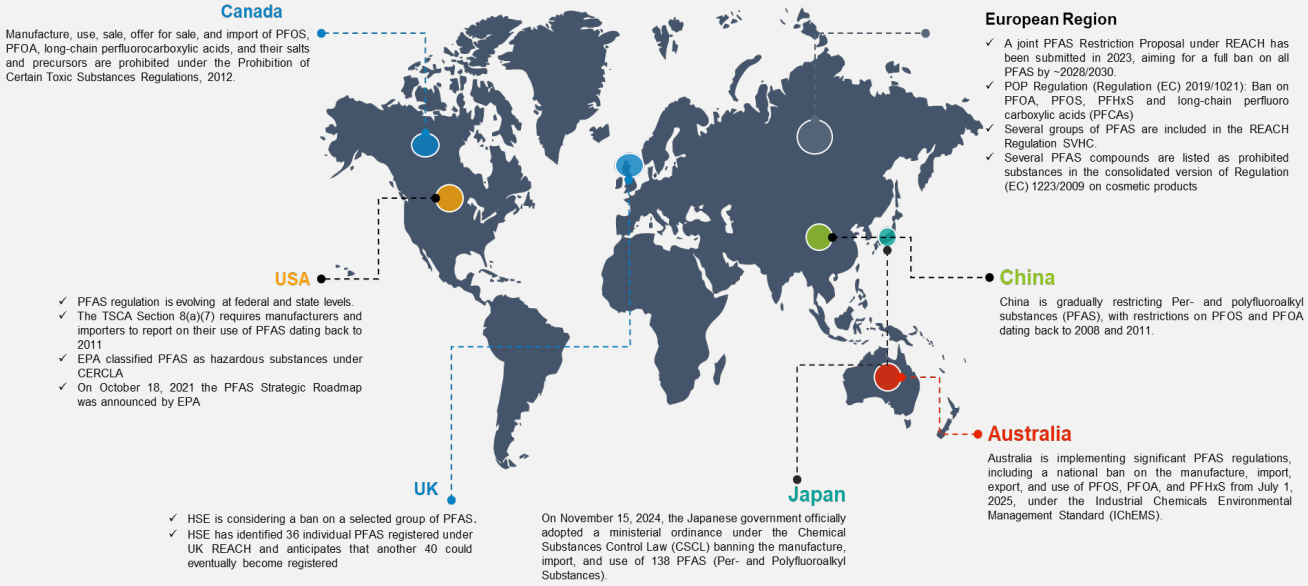
These wide range of potential health effects, combined with the ubiquity of PFAS exposure, poses a significant public health challenge.

Regulatory Landscape:

Regulations surrounding PFAS are evolving rapidly, as countries and regions around the world introduce laws and guidelines to control their use and emissions. For healthcare manufacturers, staying informed about these regulatory developments is essential to ensure compliance, maintain market access, and avoid potential legal or financial penalties.

A variety of legislative approaches are being implemented to address PFAS which includes restrictions on the disposal of PFAS-containing waste; labeling or disclosure requirements for products containing PFAS; prohibitions on the usage of PFAS in products; or financial and legal liability for parties responsible for PFAS contamination through manufacturing, disposal, or other activities.

Global regulatory landscape:



Stockholm convention:

The Stockholm Convention on Persistent Organic Pollutants is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife, and have harmful impacts on human health or on the environment.

The convention prohibits and/or eliminate the production and use, as well as the import and export, of the intentionally produced POPs that are listed in Annex A to the Convention.

- ✓ In 2009: Listed PFOS, its salts and perfluorooctane sulfonyl fluoride (PFOSF) in Annex B to the Stockholm Convention (decision SC-4/17).
- ✓ In 2019: Listed PFOA, its salts and PFOA-related compounds in Annex A to the Stockholm Convention (decision SC-9/12).
- ✓ In 2022: Listed PFHxS, its salts and PFHxS-related compounds in Annex A to the Stockholm Convention (decision SC-10/13)
- ✓ In 2025: At POPRC-20, the Committee adopted decision POPRC-20/3, recommending that the COP consider listing long-chain perfluorocarboxylic acids (PFCAs), their salts, and related compounds in Annex A to the Convention with specific exemptions.

European Union (EU):

The European Chemicals Agency (ECHA) Implemented a mechanism under Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) to protect human health and the environment from risks posed by chemicals.

On 7 February 2023 the European Chemicals Agency (“ECHA”) published a comprehensive dossier concerning a ban on around 10,000 per- and polyfluoroalkyl substances (“PFAS”).

The restriction proposal aims to restrict the manufacture, placing on the market and use of substances harmful to human health and the environment, and to limit their associated risks. The ban is to be implemented under Regulation (EU) No 1907/2006 ("REACH").

The scope of the restriction includes, any substance that contains

- ✓ 25 ppb for any PFAS (except polymeric PFASs) measured with targeted analysis (equals to 25 µg/kg),
- ✓ 250 ppb for the sum of PFAS (equals to 250 µg/kg), optionally with prior degradation of precursors, and
- ✓ 50 ppm for PFASs, including polymeric PFAS (equals to 50 mg/kg).

The restriction proposal analyses various risk management options and concludes that a restriction under REACH is the preferred path. Two options are considered:

Restriction Option 1 (RO1)

- ✓ A full ban of all PFAS with no derogation
- ✓ Ban of manufacture, placing on the market and use
- ✓ Prohibition entering into force after a transition period of 18 months after regulation's enforcement

Restriction Option 2 (RO2)

- ✓ A full ban of all PFAS with time limited, use-specific derogations for either 5 or 12 years, based on analyses of alternatives and socio-economic considerations.
- ✓ Only few permanent derogations (e.g., active substances in medicinal products), NOT for medical devices

The Agency's scientific committees for Risk Assessment (RAC) and Socio-Economic Analysis (SEAC) are currently evaluating the proposed restriction together with the numerous comments (5,600+) received from the public consultation. Following this consultation, alternative restriction options, other than a full ban or a ban with time-limited derogations, are being considered.

Considering the proposal's complexity, the restriction is estimated to come into force no earlier than 2029-2030 (initial timeline: 2026/2027).

Substances of very high concern (SVHC):

Several groups of PFAS are included in the REACH Regulation Candidate List of substances of very high concern (SVHC). As a general rule, listed chemicals should not be present in products or materials in concentrations above 0.1% by weight

PFAS compounds on the SVHC list include the following:

- ✓ PFOA, PFHxS and its salts
- ✓ Perfluoroheptanoic acid (PFHpA) and its salts
- ✓ Perfluorobutane sulfonic acid (PFBS) and its salts
- ✓ Nonadecafluorodecanoic acid (PFDA), also known as perfluorodecanoic acid, and its sodium and ammonium salts
- ✓ Perfluorononan-1-oic-acid and its sodium and ammonium salts
- ✓ Perfluamine
- ✓ Ammonium pentadecafluorooctanoate (APFO), also known as perfluorooctanoic acid, ammonium salt

- ✓ Pentacosafluorotridecanoic acid, also known as perfluorotridecanoic acid (PFTrDA)
- ✓ Tricosafluorododecanoic acid, also known as perfluorododecanoic acid (PFDoDA)
- ✓ Heptacosafluorotetradecanoic acid, also known as perfluorotetradecanoic acid (PFTDA)
- ✓ Henicosafluoroundecanoic acid, also known as perfluoroundecanoic acid (PFUnDA)
- ✓ 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy)propionic acid, its salts, and its acyl halides (HFPO-DA)

USA:

There has been significantly more action taken in the USA than in both the EU and the UK in respect of PFAS and product safety. PFAS regulation is evolving at federal and state levels, with laws restricting unnecessary PFAS use in single states. Key actions included

- ✓ The Toxic Substances Control Act (TSCA) Section 8(a)(7) requires manufacturers and importers to report on their use of PFAS dating back to 2011. This rule is designed to help the U.S. Environmental Protection Agency (EPA) gather the largest-ever database of PFAS data in the country.
- ✓ At the federal level, US Environmental Protection Agency (EPA) proposes to classify seven PFAS and their related salts as hazardous substances. Meaning upon a release a responsibly party is subject to reporting and clean up under the Environmental Response, Compensation & Liability Act (CERCLA, also known as the Superfund law).
- ✓ At the federal level, the United States Environmental Protection Agency (the EPA) has recently finalized a rule requiring all manufacturers and importers of PFAS substances or products containing PFAS substances, dating back to 1 January 2011, to provide a report to EPA by April 2025
- ✓ Established enforceable Maximum Contaminant Levels (MCLs) for six PFAS (PFOA, PFOS, PFHxS, PFNA, HFPO-DA, and PFBS)

Canada:

- ✓ Canada has acted to address PFAS for which early evidence had indicated potential concerns for the environment or human health.
- ✓ The manufacture, use, sale, offer for sale, and import of PFOS, PFOA, long-chain perfluorocarboxylic acids, and their salts and precursors are prohibited under the Prohibition of Certain Toxic Substances Regulations, 2012, with a limited number of exemptions.
- ✓ New PFAS that are manufactured or imported into Canada are assessed and risks are managed as required through the New Substances Notification Regulations.

Japan:

On November 15, 2024, the Japanese government officially adopted a ministerial ordinance under the Chemical Substances Control Law (CSCL) banning the manufacture, import, and use of 138 PFAS (Per- and Polyfluoroalkyl Substances). These substances have now been classified as Class I Specified Chemical Substances, meaning their use is prohibited in nearly all circumstances The ban takes effect on January 10, 2025. There is no grace period

The ban applies to 138 individual PFAS, including:

- PFOA-related substances and salts
- Perfluorinated carboxylic acids
- PFAS derivatives used in coatings, fluoropolymers, electronics, batteries, and textiles

China:

China is gradually restricting Per- and polyfluoroalkyl substances (PFAS), with restrictions on PFOS and PFOA dating back to 2008 and 2011, culminating in their inclusion on the 2023 List of New Pollutants for Priority Management. While not yet enacting broad bans beyond the Stockholm Convention-listed substances.

Australia:

Australia is implementing significant PFAS regulations, including a national ban on the manufacture, import, export, and use of PFOS, PFOA, and PFHxS from July 1, 2025, under the Industrial Chemicals Environmental Management Standard (IChEMS).

The NHMRC has reviewed and updated health-based guideline values for PFAS in drinking water. New, lower values have been set to reduce health risks.

Impact of PFAS ban

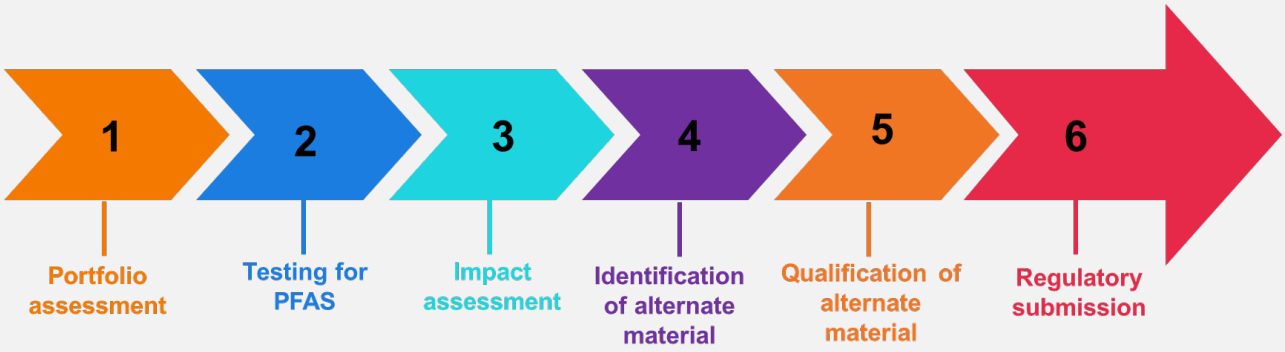
The increasing global restrictions on PFAS use—along with the anticipated complete ban in the European Union—are expected to have a significant impact on the medical device and pharmaceutical sector.

Impact on essential medicines & Medical technologies	Over 600 medicines on the WHO Essential Medicines List and 78% of Norway's critical medicines could be affected
Supply chain disruption	• Restriction on PFAS could lead to supply chain disruptions with manufacturers facing critical component or raw material shortages. For instance, 3M, a leading supplier of PFAS, announced in 2022 it will exit PFAS manufacturing across its product portfolio by the end of 2025
Delays in product launch	• These restrictions could delay product development and delivery, affecting healthcare providers and patients
Transition time & Cost	• Navigating evolving regulatory landscape requires significant effort and resources, which increases the cost of product
Competitive Disadvantages	Companies may face higher production costs compared to other global competitors
Regulatory Compliance	Manufacturers must ensure that their devices do not contain restricted PFAS substances and that they meet all regulatory requirements related to chemical safety and material composition
Losing market share	Global manufacturers, importers and distributors will need to comply with the most restrictive requirements in order to avoid restricting the market to which they are able to supply

PFAS Transition Strategy

Organizations in the healthcare sector particularly those involved in medical devices and pharmaceuticals must proactively monitor evolving PFAS-related legislation and regulations across global markets. This involves assessing how these changes apply to their product portfolios and implementing appropriate compliance strategies.

In this context, we explore six key approaches to achieving PFAS compliance, including.



Step 1: Portfolio assessment:

PFAS are commonly used throughout the manufacturing process, not only in core components but also as processing aids and surface treatments. To effectively phase out these materials,

manufacturers must first gain a comprehensive understanding of where and how PFAS are utilized across their entire product portfolio. This foundational step is critical for developing targeted, effective substitution and compliance strategies.

Identifying PFAS requires a comprehensive audit of the entire supply chain, carefully examining every stage of production and every material source. This process includes:

- **Engaging with suppliers** to gather detailed information on material composition and manufacturing processes of the components they provide
- **Material Review:** Conduct a detailed review of all materials used in your devices. This includes active ingredients, ancillary substances, and even the materials used in packaging and shipping.
- **Analysing manufacturing processes:** Includes review of cleaning agents, processing aids, coatings, and lubricants that may contain PFAS.
- **Testing materials and components**, where necessary, to detect the presence of PFAS;
- **Documentation and Record Keeping:** maintain detailed records of your findings. This documentation will aid in compliance and serve as a reference point for future product development and supply chain management.
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Step 2: Testing for PFAS

If supplier data may be incomplete or uncertain, it is necessary to employ advanced analytical techniques to test for the presence of PFAS

Targeted analysis:

Targeted PFAS analysis is used to quantify individual specific PFAS, for example for the comparison with a concentration limit value for PFAS in a product. Most often liquid chromatography coupled with triple quadrupole mass spectrometry (LC-MS/MS) according to standards EN 17681 Part 1 & 2 and ISO 23702 Part 1.

Non-targeted analysis:

The current analytical methods are capable of quantitatively measuring a number of specific PFASs, they do not provide a complete picture of the thousands of PFASs. These unmeasured PFASs include many PFAS precursors, which may be converted into related PFAS chemicals through oxidation. The total oxidizable precursor (TOP) assay offers a means of bridging this gap by oxidizing unknown PFAS.

Total Fluorine Content:

Total fluorine' methods measure the overall amount of (organic) fluorine in a sample: total fluorine (TF), extractable organic fluorine (EOF) and adsorbable organic fluorine (AOF). In such an analysis all fluorine in the sample will be measured, both inorganic and organic fluorine.

An additional advantage of total fluorine methods is that they are significantly faster and cheaper than targeted analyses. Hence, the use of total fluorine methods to quantify PFASs, e.g. for compliance and enforcement purposes, is practical as they are more compatible with the scope of the restriction proposal (which encompasses all PFASs).

Step 3: Impact assessment:

Once PFAS usage has been identified across your product portfolio, the next critical step is to conduct a comprehensive impact assessment. This assessment helps you understand how phasing out PFAS will affect your products, operations, and compliance scenario.

An effective PFAS impact assessment should evaluate the following key areas:

- Supplier feasibility: Assessing the ability of current or new suppliers to deliver PFAS-free alternatives
- Strengthening Supply: Enhancing supply chain controls to ensure consistent quality, compliance, and traceability of PFAS-free components
- Product design requirements: Determining whether material changes require redesigns and evaluating their impact on device functionality and regulatory status
- Cross-Functional collaboration: Engaging R&D, Quality, Regulatory, and Procurement teams for a comprehensive and aligned transition strategy

Step 4: Identification of PFAS-free material

Finding suitable alternatives to PFAS is a complex process, as it is difficult to replicate the unique combination of properties that these chemicals offer. In other words, there is no single “magic” material that can replace PFAS in every use case.

For example, **HIGUARD NF-184**, an acrylic-based resin developed by Hi-Chem, can provide oil and water repellency on textile fibers. However, this material cannot be used in firefighting foams or cosmetic products like mascara, where PFAS compounds such as PFOA impart very specific performance characteristics. This highlights the limitation of one-size-fits-all solutions.

Given this complexity, the industry has shifted its focus from finding a direct substitute for each PFAS compound to developing industry-specific alternatives. Instead of trying to replace PFOA or PFOS with a single material, efforts are now directed toward understanding the specific properties that PFAS provide in a given application (e.g., chemical resistance, thermal stability, surface tension reduction) and identifying other chemicals that can deliver comparable performance while meeting technical, safety, and regulatory requirements.

This targeted approach allows for more practical and effective substitution strategies tailored to each application rather than relying on a universal replacement.

Step 5: Qualification of PFAS free material

The search for PFAS alternatives is not solely a technical challenge—it is equally a regulatory and clinical one. In the context of medical products, success hinges not only on materials science expertise but also on a deep understanding of regulatory frameworks and market dynamics.

Any new material or process must undergo rigorous testing to ensure it meets all relevant performance, safety, and regulatory requirements. This includes a comprehensive suite of evaluations such as chemical analysis, mechanical testing, and biocompatibility assessments, to confirm that the alternative materials can match the safety and efficacy profiles of PFAS-containing components.

Even when suppliers provide biocompatibility data, it is essential to **validate** those claims independently.

Collaborations with research organizations, or industry partners—can play a critical role in accelerating the development of viable PFAS alternatives. Such partnerships provide access to cutting-edge research, testing capabilities, and emerging technologies that are essential for navigating this complex transition.

Step 6: Regulatory Submission

The final stage in the PFAS phase-out journey is the meticulous preparation and submission of technical documentation to global regulatory authorities. The effectiveness of this step heavily depends on how well the preceding stages—such as material selection, testing, and validation—have been executed. The submitted documentation must clearly demonstrate compliance with all relevant regulatory standards and guidelines.

The documentation and submission strategy must be tailored to the specific requirements of each regulatory body. In general, your submission should include the following elements:

- A clear and detailed explanation of all changes made as a result of PFAS replacement.
- A comprehensive description of the qualification strategy used for evaluating new materials or chemicals, particularly regarding device safety and efficacy.
- Thorough presentation of testing and verification results, including chemical, mechanical, and biocompatibility assessments.
- In cases where partial testing or test waivers are pursued, the submission must include robust scientific justification that supports the rationale for reduced testing.

Given the rapidly evolving regulatory landscape surrounding PFAS, it is critical for stakeholders in the medical device industry to remain proactive. This includes continuously monitoring updates to regulatory guidelines, engaging with industry associations, and participating in collaborative discussions on best practices for PFAS substitution and compliance.

How Auxochromofours Can Help

At Auxochromofours, we are a trusted partner in navigating the complex journey of PFAS substitution in medical devices. Our team of seasoned professionals brings decades of experience in product safety, regulatory compliance, and market authorization.

We understand the unique challenges involved in identifying, testing, and validating alternative materials without compromising on product safety, performance, or regulatory compliance. Our comprehensive support is designed to streamline your PFAS transition and minimize risk at every stage.

Our Services Include:

- **Product portfolio assessment:** We analyze your materials and manufacturing processes to identify PFAS usage and assess potential risks and regulatory implications.
- **Material Selection:** Our consultants provide expert guidance in selecting suitable alternative materials that meet both performance and compliance requirements
- **Qualification of alternate materials:** We support the development of testing strategies, monitor testing execution, and review results to ensure new materials meet safety and efficacy standards.
- **Regulatory submission Support:** We support in the preparation of necessary documentation for global regulatory submissions.
- **Regulatory Monitoring and Guidance:** We continuously track evolving PFAS regulations worldwide and offer proactive advice to ensure your products remain compliant with the latest international standards

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Speak with our experts to learn how Auxochromofours can support your efforts to phase out PFAS safely, efficiently, and in full regulatory alignment.

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