TYPICAL PFAS USAGE THROUGHOUT THE VACCINES MANUFACTURE, RELEASE AND SUPPLY CHAIN

VACCINES MANUFACTURE (STERILE PRODUCTION)

Equipment:
- fluoropolymers in production equipment (e.g., reactor lining, seals, gaskets, piping, anti-stick coating, surfaces, filtration units)
- fluoropolymers with product contact and quality impact, including spare or replacement parts.

Consumables (including fluoropolymers with product contact and quality impact):
- fluoropolymers in filters
- bioreactors
- bags
- tubes, etc.

General production equipment: fluoropolymers in complex equipment, such as:
- insulation material
- mechanical parts, including spare or replacement parts

VACCINES PACKAGING

Fluoropolymers: stoppers, syringes etc with product contact.

QUALITY CONTROL (QC) RELEASE

Independent OMCL release in the EU (see QC release)

Independent NCL release on import for non-EU countries (see QC Release).

Laboratory equipment/consumables:
- PFAS fluoropolymers (e.g., Teflon tubing, valves, gaskets, filters) including product contact and quality impact
- electrical components
- diagnostic laboratory testing
- refrigerants in laboratory equipment (temperature-controlled centrifuges)

Laboratory reagents: PFAS materials and reagents used in quality control activities are mandated by product licenses or regulations such as European Pharmacopoeia monographs. Examples:
- trifluoro acetic acid (TFA) in the mobile phase of high-performance liquid chromatography (HPLC)
- perfluoro butanoic acid (PFBA) as ion pair reagent in chromatography
- N-methyl-bis(trifluoroacetamide) (MB-TFA), N,O-bis-trimethylsilyl-trifluoroacetamide (BS-TFA), and N-methyl-N-trimethylsilyl-trifluoroacetamide (MS-TFA) to derive silyl derivatives in gas chromatography or other methods.

Local QC release on import by manufacturer (see QC Release)

COLD CHAIN MAINTENANCE

Manufacturing, storage and transport: polymeric (e.g., filters, seals) and non-polymeric PFAS in equipment, such as electrical components, refrigerants in HVACR equipment and low temperature refrigeration, refrigerants in storage and transport, including spare or replacement parts.