Application Summary Table

The table below highlights initial assessments of biopharmaceutical applications and likelihood that existing alternatives could replace the current application. The table does not represent an in depth through analysis and is not intended to represent a conservative worst-case analysis. It is intended to provide some assessment and industry perspective within the relative short consultation period. Please note that where alternatives may be available, there is often a high economic trade-off, risk of product loss, or incurrent revalidation time and cost.

Application	PFAS Material	Potential Alternatives	Feasibility/Likelihood of Replacement*	Replacement cost/Process development/ Revalidation	Typical Replacement where available Timeline (yrs.)**	Patient Safety /Drug Quality Impact Risk	Market Fraction / Impact
Liquid Filtration – Sterile	PVDF	PES membranes, Nylon Membranes	<50%	Very High	9+ **per case**	High	Very High
	PTFE	""	<10%	Very High	9+ **per case**	High	Low
Liquid Filtration - particulate	PVDF	PES, Nylon	75%	Moderate	5+ **per case**	Moderate	High
	PTFE	PES, Nylon	30%	Moderate/High	5+ **per case**	Moderate	Low
Liquid Filtration - Virus	PVDF	PES	80%	Very, Very High	8+ **per case**	Moderate	Moderate
Gas filtration	PVDF	TBD	<10%	Moderate	4+ **per case**	Moderate	Very, Very High
	PTFE	TBD, PE	<10%	High	7+ **per case**	Moderate	Moderate
Gaskets & Seals	PVDF	TBD	50%	Moderate	TBD	High	Moderate
	PTFE	TBD	<20%	Moderate	TBD	High	Moderate
Components, Fittings, Tubing, Mixers, etc	PVDF, FEP, PTFE	PES, PP, Silicone, TPE	90%	High	3+ **per case**	Moderate	High
Pharmaceutical cryostorage Bags	PTFE, FEP, Custom Fluoropolymer	ULDPE bags, EVA	<50%	High	TBD	High	Growing
Cell culture cryostorage bags for cell therapy applications	FEP	EVA or EVA blends	75% (with significant trade-offs)	Very High	10+ **per case**	High	Growing
Non-Fluid Contact Materials (tubing clamps)	PVDF	Nylon, PP	High	Low	<1	Low	Moderate
Oleophobic/hydrophobic vent membranes	PFAS-coated PES	(Must redevelop)	>90% with redevelopment	High	11+ **per case**	High	High

*Table 1. Non-exhaustive overview of common bioprocess materials, including likelihood of identifying alternatives for each drug manufacturing use, estimated replacement resource cost and timelines when suitable alternatives are available, the risk to drug product quality and patients, and overall prevalence of use in the bioprocess market. For additional applications, please see text. *Feasibility/Likelihood of Replacement represents best estimates of the number of drug manufacturing use cases where a suitable alternative may exist and replaced with an alternative. **Typical Replacement Timeline represents the estimated time per drug application use case, when testing and qualification resources are available.*