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## BIOMANUFACTURING USING SINGLE USE SYSTEMS: CASE STUDY OF FLUOROPOLYMER MATERIAL

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### Key Words:

- Cryopreservation
- High Density Cell Banking
- Large Scale Bioreactors
- New Molecular Entities
- FDA approval
- Process Analytical Technology

In this presentation, we will discuss recent biocompatibility data obtained using our gamma stable fluoropolymer platform and its advantage in a modern manufacturing environment for the handling of almost any biological fluids.

Single-use, disposable solutions are now widely accepted as gold standard in the biopharmaceutical industry covering every single steps of the drug manufacture process. From early-stage small scale R&D project, upstream production with several thousand-liters bioreactors, downstream process, API formulation up to critical fill & finish and transport applications, the industry is taking a shift with a significant breakthrough reported in 2021: the largest GMP facility in the world using single-use (from 200L to 4,000 L) bioreactors has been publicly announced this year with a global single-use bioreactor workforce of over 150,000 L (with extension plans for 2024 to expand its use of disposable bioreactors to over 430,000 L).

The presentation will be focusing with recent case studies and analytical technology data obtained in the lab on carefully selected molecular entities / submicron particles in order to support various applications such as large-scale bioprocessing/banking of mammalian cells, cell & gene therapy (adenovirus), critical vaccinology program (mRNA-LNP/liposomes) as well as purified proteins.

Recent trends and challenges in (disposable) materials and technologies used in the decentralized biopharmaceutical industry will be also discussed.

