

# ***Single-Use Technologies Enable Manufacturers to Meet Pivotal Challenges of Viral Vector Manufacturing (VVM)***

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# Overview and Reflections:

- Start date April 2020, Publish(BPSA website) date April 2022
- Web metrics
  - Downloads: 16 total, 10 May, 6 June ( 10 nonmember, 6 member co.)
- Promotion: tbd
- Recommended best practices:
  - Lens of Bioprocess Systems Alliance
    - Single Use / Disposable Components
  - Define scope, boundaries early
  - Interview Subject Matter Experts (SMEs) early in the development of white paper
    - firsthand knowledge, State-of-the-art, define unmet needs and gaps
  - Review by Industry experts



# Learnings from SME's

- Technical, economic, and safety challenges of Viral Vector production include:
  - Ensuring consistency, quality, and performance of the processes
  - In-line analytical capabilities to measure cell densities and metabolites (process analytical technologies (PAT))
  - Rapid scale-up Viral Vector manufacturing capacity
  - Obtaining cGMP-compliant raw materials
  - High cost of goods
  - Lower productivity (low percentage of full capsids)
  - Slower growth rate of cells
  - Achieving high cell densities
  - Changes in cell expression patterns
  - Analytical assays to measure product quality
  - Lack of integrated, automated, and fully closed system
  - Downstream purification challenges
  - Stability of the virus (lentiviruses and retroviruses are fragile)
  - Sterile filtration – losses up to 50%
  - Exposure and effect of impurities and extractables/leachables (E&L) in the process
  - Viral Vector safety concerns – BSL requirements
  - Technology transfer issues when scaling up or out



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# Future Challenges for SUT in VVM

- **Scalability**
- **Standardization**
- **Change management**
- **Robustness and reliability data**
- **Quality**
- **Complete closure of Process**



# Benefits of participation in workstream

- Networking (supply chain, end-users, Academia, consultants)
- Learn about subject matter
- Business collaborations
- Friendships



# Thank You!!

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