Scott Jendrek

Eldersburg, MD 21784
ScottJendrek@gmail.com
410-259-3677

SUMMARY

Accomplished biopharmaceutical manufacturing and program director with 30 years of experience spanning the US Government and CDMO spaces. Technical expertise centers on project management, overseeing all phases of cGMP biologics manufacturing, process development for viral vectors and gene therapy products, as well as coordinating fill-finish operations. Recognized for ensuring the successful transfer, scale-up, and optimization of biopharmaceutical manufacturing processes. Demonstrated leadership, innovation, revenue growth, and meticulous attention to detail within the biopharmaceutical industry.

EDUCATION

Towson University | Towson, MD
BS Biology

University of Maryland, Baltimore County | Baltimore, MD
Good Manufacturing Practices for Bioprocess
Quality Control and Quality Assurance of Biotechnology Products, Biotechnology
GMP Facility Design, Construction, and Validation
Regulatory Issues in Biotechnology

SKILLS

• GMP Manufacturing (Clinical and Commercial) • Project Management • CMC Writing • Process Development (Biologics and Viral Vectors) • Technology Transfer • Fill Finish • Risk Management and Mitigation •

WORK EXPERIENCE

AMERICAN TYPE CULTURE COLLECTION
MANASSAS, VA
Director of Manufacturing Operations (08/2024 – 06/2025)

- Launched and structured a new Manufacturing Operations Team, driving enhancements in in-house manufacturing processes.
- Created Leadership Training to guide in-house talent into leadership roles and increase employee retention.
- Engineered AI-driven protocols to extract consumable data from batch production records, streamlining 'Bill of Materials' creation for thousands of products and reducing processing time.
- Coordinated the transition of the manufacturing groups into D365 ERP.
- Work performed resulted in a cost savings exceeding $700,000 realized immediately.

IDT BIOLOGIKA
ROCKVILLE, MD
Associate Director of Operational & Project Management (10/2022 – 05/2024)

- Managed a team of 3 full-time project managers, while also leading cross-functional teams to support the strategic goals of the organization.
- Was responsible for P&L tracking and reporting, ensuring work package completion and client invoicing.
- Led multiple internal capital project teams and budgets ($5 million) from supply chain to CQV activities, including budgetary and planning activities for numerous external clients, subcontractors, and consultants.
- Directed the upgrade of the automated fill line, including the RABs/Isolator installation and all CQV activities for the suite and equipment.
- Provided strategic leadership, utilizing strong project management skills, for successful project execution and work package delivery within established timelines and budget constraints.

CATALENT
HARMANS, MD
Director of Manufacturing Technical Operations (10/2019 – 06/2022)

- Managed a cross-functional team of 30 people (15 contractors and 15 FTEs) in 4 time zones, ranging from entry-level analysts to senior managers.
- Worked closely with MSAT team to document multiple process changes during scale-up and transfer to the cGMP manufacturing teams.
- Supported commercial manufacturing of cell and gene therapy products with deviation investigations, root cause analyses, CAPAs, Change Controls, batch record modifications, and SOP updates.
- Created metrics to monitor deviation backlog and successfully reduced it by more than 45% (from over 900) in under six months.
- Led and managed the completion of two fill-finish suites, overseeing the installation and commissioning of both fill lines, and ensured successful operator qualification.
- Provided technical expertise and support for process and facility validation for the large-scale commercial production of COVID-19 vaccine.
- Developed procedures and processes used by Quality Management to release the first commercially produced genetic therapy product at the Catalent Harmans location.

PARAGON
HARMANS, MD
Business Development, Independent Contractor (11/2017 – 06/2018)

- Represented the company at multiple industry trade shows and conferences to promote products and services.
- Engaged with prospective clients to discuss company capabilities, project timelines, and potential collaboration opportunities.

PATAPSCO DISTILLING COMPANY
SYKESVILLE, MD
Owner / Director of Manufacturing (04/2017 – 08/2024)

- Developed and executed comprehensive business plans and sales strategies to launch a successful, award-winning distillery.
- Manage the financial performance of operations, including Opex/Capex spending and cash flow improvements through inventory optimization.
- Tracked and reported on sales performance metrics, including P&L tracking, identifying areas for improvement, and implementing actionable strategies to achieve sales targets.
- Ensured compliance with government regulations and standards, CFR 27 Parts 19, 5, and 16.

PARAGON BIOSERVICES
BALTIMORE, MD
cGMP Manufacturing Manager / Senior Project Manager (04/2012 – 06/2017)

- Led and managed a team of 10 operators in Upstream cGMP Manufacturing, improving process efficiency and ensuring compliance with regulatory standards.
- Developed and delivered comprehensive training on 150L cGMP mammalian stirred tank bioreactors, resulting in enhanced team competency and reduced operational errors.
- Provided cross-functional training to the downstream cGMP team on large-scale BPG column packing and purification skid operations, increasing throughput and product quality.
- Obtained PMP certification
- Collaborated with Quality Systems to advance multiple projects from Phase I/II development to commercialization readiness, ensuring adherence to regulatory milestones.
- Served as Project Manager for a $15M US Government-funded Ebola vaccine initiative, overseeing budget and meeting critical development timelines.
- Partnered with Business Development to represent the organization at key industry trade shows, significantly enhancing brand visibility and cultivating new client relationships.

SAIC FREDERICK
FREDERICK, MD
(CMC) Process Development Manager (10/1999 – 12/2011)

- Led a team of 15 scientists and technicians in the Purification Process Development Laboratory, advancing phase I/II clinical development programs and ensuring project success.
- Designed and optimized downstream purification processes for vaccines, therapeutics, antibodies, and viral products using diverse cell lines (E. coli, CHO, HEK293, NSO, A549), enhancing product yield and purity.
- Successfully transferred and scaled up biopharmaceutical manufacturing processes to cGMP teams, consistently meeting project milestones and exceeding quality standards.
- Authored Chemistry, Manufacturing, and Controls (CMC) sections for multiple IND applications, collaborating with Quality Assurance and Regulatory Affairs to expedite regulatory approvals.
- Served as Project Scientist on multiple projects, including a novel antibody-based oncology therapeutic, an antibody drug conjugate (ADC)
- Developed Lyophilization protocols for multiple phase I products

- Appointed member of the National Cancer Institute Biosafety Committee (NCI-FCRF IBC) at Fort Detrick, contributing to biosafety policy development and compliance oversight.

U.S. ARMY MEDICAL RESEARCH INSTITUTE OF INFECTIOUS DISEASES (USAMRIID)
FORT DETRICK, FREDERICK, MD
Research Associate (08/1993 - 10/1999)

- Duties included all aspects of protein production and purification of rPA (*B. anthracis*) and F1-V (*Y. pestis*) for vaccine research through research levels up to 100L fermentations.
- Performed protein biochemistry method development to purify target proteins, configured the computer interface of all fermenters and ancillary production equipment, SOP/Batch Record generation, fermentation optimization, protein recovery, antifoam testing, and filtration testing.
- Developed, optimized, and scaled up multiple vaccine candidate manufacturing processes, ensuring the successful transfer to the selected CDMO.
- Research included working in a Biosafety Level 3 (BSL-3) containment suite, maintaining safety equipment, following strict safety guidelines, and receiving immunizations against *Bacillus anthracis* and *Yersinia pestis*.

PUBLICATIONS
- "Fermentation, Purification, and Characterization of Protective Antigen from a Recombinant, Avirulent Strain of Bacillus anthracis" - Applied and Environmental Microbiology, J. W. Farchaus, S. Jendrek, et al., 03/1998.
- "Evaluation of the compatibility of a second-generation recombinant anthrax vaccine with aluminum-containing adjuvants" - Vaccine, 21 21-22, 3011-8, Jendrek, S et al. 2003.
- "Design and testing for a nontagged F1-V fusion protein as a vaccine antigen against bubonic and pneumonic plague" - Biotechnology Progress 21 5, 1490-510, Powell, B., Jendrek, S., et al., 2005.
- "Development of a Production and Purification Method for Type 5 Adenovirus" - Bioprocessing Journal, Scott Jendrek, et al. 2006.

SPEAKING ENGAGEMENTS
- Workshop Presenter: Viral Vectors and Vaccines Conference, Bioprocessing Journal, Las Vegas, NV, 2003
- Speaker: Development of a Production and Purification Method for Type 5 Adenovirus, Eukaryotic Cell Derived Products Conference, Viral Vectors and Vaccines, Amsterdam, Netherlands, 2004
- Speaker: Development of a Production and Purification Method for Type 5 Adenovirus, Eukaryotic Cell Derived Products Conference, Viral Vectors and Vaccines, Sydney, Australia, 2004
- Speaker: Production and Purification of HSV-1: Process Development and Production Issues, Eukaryotic Cell Derived Products Conference, Viral Vectors and Vaccines, Barcelona, Spain, 2006