

JESSICA VONGOELER, MBA

Project Management Technical Operations & External Manufacturing

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SUMMARY

Experienced biotech program leader with expertise in cell and gene therapy, regulatory submissions, and CDMO oversight. Skilled in managing CMC execution, risk mitigation, and cross-functional planning to advance therapies through development while supporting regulatory and manufacturing readiness.

SELECTED ACHIEVEMENTS

- Led CMC strategy and execution for advanced therapy programs, delivering on-time IND Module 3 submissions and driving programs into Phase I–III trials.
- Managed \$20M+ in CDMO contracts, optimizing cost, quality, and compliance—recovering \$3.2M via financial governance and vendor renegotiations.
- Built cross-functional risk frameworks that identified business bottlenecks early and improved manufacturing readiness for first-in-human milestones.
- Strengthened budget discipline, delivering a 15% supply chain cost reduction while maintaining 100% financial compliance.

PROFESSIONAL EXPERIENCE

Consultant, CMC Operations, Large Molecule Drug Development

Bill and Melinda Gates Medical Research Institute, Remote

Apr 2023 - Jan 2025

- Identified and resolved 3 CMC operational gaps, designing cross-functional processes to accelerate regulatory readiness and manufacturing timelines.
- Oversaw cGMP manufacturing activities at 2 CDMOs, ensuring compliance with evolving CMC requirements and maintaining critical program timelines.
- Led cross-functional TechOps teams in CMC submissions, managing timelines, dependencies, and scenario-based risk planning.

Associate Director, Master Scheduler, Cell & Gene Therapy

Ultragenyx Pharmaceuticals, Remote

Mar 2021 - Jan 2023

- Developed and implemented a capacity planning system aligned with clinical supply demands.
- Delivered a 15% reduction in supply chain budget and improved production planning responsiveness.
- Improved operational agility by reducing response times to demand changes from 3 months to 2 weeks through the deployment of robust business systems.

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Senior Manager, CDMO Project Management, Cell & Gene Therapy

Ultragenyx Pharmaceuticals, Cambridge, MA

Apr 2019 - Mar 2021

- Led a successful tech transfer of clinical manufacturing process to CDMO within 3 months.
- Recovered \$2.7M in overcharges through contract audits and financial tracking.
- Strengthened financial operations by ensuring accuracy and compliance across accruals, invoices, and purchase orders, improving fiscal transparency and vendor accountability.

Client Program Manager, Program Management Office, Cell & Gene Therapy

Brammer Bio; Cambridge, MA

Oct 2017 - Apr 2019

- Drove 50% increase in project transparency through integrated reporting and dashboards.
- Recovered \$500K in unbilled revenue via contract audits and client negotiation.
- Identified and mitigated CMC and material readiness risks across multiple programs.

Technical Project Manager, Clinical Trials Informatics

PAREXEL International; Billerica, MA

Aug 2015 - Jun 2017

- Increased client satisfaction scores by 15% through strong project delivery and cross-functional collaboration.
- Supported oncology programs with secure clinical data systems tailored to trial needs.

ADDITIONAL EXPERIENCE

- Patient Advocate Champion Corp, DPAC Remote, MA
- Project Coordinator, Harvard Business Publishing Watertown, MA
- Supervisor, Community Outreach, ACCC Newton, MA
- Past President, Rotary Club of Arlington, MA Arlington, MA

TECHNICAL COMPETENCIES

Large Molecule Drug Substance | CDMO Oversight | Process Development | Technical Transfer | CMC Lifecycle Management | Regulatory Submissions | Supplier Technical Management | Risk Mitigation | Microsoft Project | GMP Compliance

EDUCATION

Master Business Administration

Worcester Polytechnic Institute (WPI) — Worcester, MA

Coursework: Strategic Management, Global Operations, Program Management, Innovation, remote collaboration.

Bachelor of Science, Marine Engineering

Massachusetts Maritime Academy — Buzzards Bay, MA

Technical Experience: Problem Solving, Utilizing Data, Systems Design, and Operational Readiness.