

JESSICA VONGOELER

Program Management Director | Biologics & Gene Therapy | Cross-functional Leadership | GMP Operations

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SUMMARY

Program management leader with 10+ years advancing clinical-stage biopharmaceutical programs through strong cross-functional execution. Experienced building integrated program plans and aligning clinical, CMC, regulatory, quality, and CDMO partners around clear milestones and priorities. Known for bringing structure, risk visibility, and disciplined follow-through that keeps small teams aligned and programs moving forward in fast-paced biotech environments.

PROFESSIONAL EXPERIENCE

Consultant, CMC Operations

Gates Medical Research Institute 04/2023 - 12/2024

- Executed cross-functional leadership across five global teams for viral vector programs, enhancing milestone predictability and clarity in executive decisions.
- Built executive CMC governance dashboards adopted by senior leadership to drive readiness visibility and risk-informed decision-making.
- Chaired structured decision forums and reinforced accountability through disciplined action tracking.
- Drove operational readiness for regulatory submission across distributed teams and external partners.

Associate Director, Manufacturing Program & Operations

Ultragenyx Pharmaceuticals 03/2021 - 01/2023 (Remote)

- Led operational program management for GMP site startup supporting clinical-stage AAV gene therapy manufacturing.
- Managed \$20M+ manufacturing budget planning and multi-year forecasting tied to viral vector production readiness.
- Strengthened cross-functional operating cadence and escalation discipline during startup of regulated AAV manufacturing operations.

Senior Manager, CDMO Management & Tech Transfer

Ultragenyx Pharmaceuticals 04/2019 - 03/2021

- Orchestrated tech transfer and clinical manufacturing initiatives across three CDMOS supporting AAV gene therapy programs.
- Reduced issue resolution cycle time by 20% by strengthening CDMO accountability.
- Recovered \$2.7M in CDMO overcharges through contract reconciliation and stakeholder negotiation.

Program Management, Client Programs

Brammer Bio (now Thermo Fisher Scientific) 11/2017 - 04/2019

- Drove multi-site execution of first clinical manufacturing run for lentiviral and viral vector gene therapy programs.
- Recovered \$500K in unbilled revenue through contract reconciliation tied to CMC delivery.

Technical Project Manager, RTSM

PAREXEL International 08/2015 - 06/2017

- Increased sponsor Net Promoter Score from 40% to 90% through enhanced reporting discipline.
- Ensured system reliability and regulatory alignment through structured stakeholder management.

PROGRAM IMPACT SNAPSHOT

✓ \$20M+ Manufacturing Financial Governance

Developed multi-year budget planning and accrual discipline supporting GMP startup and clinical manufacturing operations across AAV programs.

✓ \$2.7M Cost Recovery from CDMO Overcharges

Identified contract discrepancies, led reconciliation efforts, and secured recovery of \$2.7M in manufacturing overcharges while strengthening financial controls.

✓ 20% Reduction in Clinical Manufacturing Delays

Improved milestone adherence at two external partners through structured governance, escalation discipline, and focused follow-through.

✓ IND CMC Documentation and PAI Readiness

Delivered cross-functional milestone alignment supporting IND Module 3 preparation for drug substance and drug product, and executed PAI-enabling manufacturing readiness through PPQ handoff.

✓ Matrix Leadership Across Distributed CMC Functions

Directed cross-functional execution across Manufacturing, MSAT, Quality, Supply Chain, and Finance to sustain clinical-stage GMP readiness and delivery momentum in the absence of formal authority.

✓ 50-Point NPS Improvement

Increased sponsor Net Promoter Score from 40% to 90% through targeted execution discipline and reporting clarity.

CORE CAPABILITIES

Cell & Gene Therapy Manufacturing

Lentiviral & AAV Program Coordination

CDMO Governance & Tech Transfer

GMP Startup Readiness

Integrated Manufacturing Planning

Risk & Escalation Leadership

Manufacturing Financial Governance

Executive Reporting & Dashboarding

Matrix Team Leadership

Communication

SELECTED STRATEGIC & ADVISORY ENGAGEMENTS (2021-PRESENT)

Independent Health Policy Consultant & Patient Advocate

01/2021 - Present

- Advise organizations on patient engagement, experience integration, and programming. Contributed to national initiatives for advocacy, research visibility, and aligning stakeholders with top diabetes groups.

Volunteer Photographer

11/2024 - Present

Watertown Boys & Girls Club Swim Team

- Design and produce season-long digital and print archives supporting fundraising initiatives, team communication, coach recognition, and community engagement strategy. Lead content curation and visual storytelling efforts matched with organizational outreach goals.

Founding Chapter Lead & Board Member

02/2025 - Present

Grownup T1Ds

- Lead strategic planning initiatives to expand member engagement and strengthen national programming for adults living with Type 1 diabetes. Guide governance discussions, support roadmap development, and shape community growth strategy in collaboration with board leadership.

TOOLS

Microsoft Excel



SmartSheets



SharePoint



Microsoft Power Point



EDUCATION



Master of Business Administration (MBA)

Worcester Polytechnic Institute

Worcester, MA, USA

- Coursework: Strategic Thinking, Global Ops, Project Management, Emotional Intelligence, Presentation Skills, Innovation, Negotiation



Bachelor of Science, Marine Engineering

Massachusetts Maritime Academy

Buzzards Bay, MA, USA

- Relevant Training: Leadership, Self-Discipline, Problem-solving, Resilience, Teamwork, Attention to Detail, Critical Thinking, Risk Management