

# JESSICA VONGOELER

## Associate Director | CMC Program Leadership

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### SUMMARY

Non-technical CMC program leader with 10+ years driving execution across clinical-stage biologics manufacturing, including lentiviral and AAV gene therapy programs. Proven record of leading multi-program CDMO governance, directing \$20M+ manufacturing financial oversight, improving GMP milestone predictability, and building scalable execution frameworks that strengthen accountability across distributed teams.

### 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.
- Aligned multi-site CMC timelines with global health funding constraints to protect GMP readiness and clinical study delivery.

#### 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.
- Directed \$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

Directed 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.

#### ✓ 20% Reduction in Issue Resolution Cycle Time

Strengthened operating cadence and accountability standards to accelerate cross-functional decision-making.

#### ✓ 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 strengthened 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

SELECTED STRATEGIC & ADVISORY ENGAGEMENTS (2021-PRESENT)

## 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.

## 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, coach recognition, and community engagement strategy. Lead content curation and visual storytelling efforts aligned with organizational outreach goals.

EDUCATION



## Master of Business Administration (MBA)

Worcester Polytechnic Institute

Worcester, MA, USA

- Coursework: Strategic Thinking, Global Ops, Project Mgmt, 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