

JESSICA VONGOELER, MBA

Program & Portfolio Management Director | Preclinical to Commercial Readiness | Cell & Gene Therapy

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SUMMARY

Program and portfolio leader with deep experience advancing biologics and gene therapy programs from preclinical through late-phase manufacturing readiness and pre-commercial transition. Moves science, operations, and strategy forward in tandem by aligning CMC, Regulatory, Quality, Tech Ops, Clinical, and Supply Chain. Known for making complex workstreams clear, anticipating risk early, and keeping teams aligned on achievable, data-driven decisions.

CORE CAPABILITIES

- ✓ Cross-functional alignment across CMC, Regulatory, Quality, Clinical, Manufacturing, Supply Chain
- ✓ Vendor oversight, CDMO management, and contract alignment
- ✓ Dashboard development, performance metrics, and executive visibility
- ✓ Program Strategy, Governance, & Decision Frameworks
- ✓ Operational readiness, scenario planning, and risk anticipation
- ✓ IND readiness, late-stage planning, and tech transfer execution

KEY ACHIEVEMENTS

- Managed \$20M+ GMP manufacturing site start-up at Ultragenyx, integrating Tech Ops, Quality, and Supply Chain across two gene therapy programs.
- Recovered \$2.7M in overcharges and redirected 20% of spend to stronger vendors, improving delivery and audit outcomes.
- Executed a three-month tech transfer on schedule while adapting to evolving design inputs and maintaining readiness for first GMP run.
- Directed \$13M in CMC programs at Gates MRI, implementing eight readiness metrics, ensuring IND readiness.
- Built site-level schedules reducing material order risk by 60% through alignment of manufacturing and regulatory milestones.
- Improved cross-functional visibility and decision-making through program governance and milestone tracking.

PROFESSIONAL EXPERIENCE

Gates Medical Research Institute

Remote

Operations Consultant, Chemistry, Manufacturing & Controls (CMC)

04/2023 - 12/2024

- Drove execution across five CMC functions to maintain scope, cost, and schedule integrity.
- Created readiness and risk dashboards that strengthened executive visibility and decision-making.
- Partnered with Regulatory and Quality to advance IND readiness – translating technical data into clear, actionable narratives for leadership.

Ultragenyx Pharmaceuticals

Remote

Associate Director, Manufacturing Program & Operations

03/2021 - 01/2023

- Orchestrated cross-functional readiness for \$20 M + GMP site start-up, integrating Tech Ops, MSAT, Quality, and Engineering.
- Partnered with six business unit leads to develop long-range site budgets aligned to portfolio growth.
- Enhanced visibility and decision agility across teams by introducing program governance and milestone tracking.

Ultragenyx Pharmaceuticals

Cambridge, MA

Senior Manager, CDMO Management & Tech Transfer

04/2019 - 03/2021

- Collaborated on 2 gene-therapy programs to increase efficiency by 15% and deliver tech transfers on schedule.
- Transformed manufacturing execution through daily stand-ups and performance metrics, enabling earlier issue identification and faster resolution.

Brammer Bio (now ThermoFisher)

Cambridge, MA

Program Management

11/2017 - 04/2019

- Coordinated Brammer's first GMP manufacturing run, ensuring seamless cross-site coordination and client communication. Identified and recovered \$500 K in unbilled revenue, improving contract integrity and customer satisfaction.

PROFESSIONAL EXPERIENCE

PAREXEL International

Billerica, MA

Technical Project Manager, Randomization Trial & Supply Management (RTSM)

08/2015 - 06/2017

- Facilitated eight global projects from initiation through delivery with 100% UAT success, ensuring compliance and system readiness.

TECHNICAL SKILLS

Project Management & Financial Management: MS Project · Jira · Smartsheets · Adaptive · Coupa · PMP Equivalent

Data Management & Documentation: Veeva · SharePoint · Dropbox · Excel Reporting Systems · PowerBi (foundational)

Collaboration & Effective Communication: Teams · Zoom · Slack · Mural · Microsoft Office Suite (including PowerPoint)

EDUCATION

Worcester Polytechnic Institute

Master of Business Administration (MBA)

- Coursework: Strategic Management, Global Operations, Project Management, Innovation

Massachusetts Maritime Academy

Bachelor of Science, Marine Engineering

- Relevant Training: Leadership, Self-Discipline, Problem-solving, Resilience, Teamwork

LEADERSHIP, IMPACT, & PUBLIC ENGAGEMENT

Mary Tyler Moore Vision Initiative

02/2026

Externally Led Patient-Focused Drug Development Panelist

<https://www.marytylermoore.org/el-pfdd/>

GrownUp T1Ds

04/2025 - Present

Board Member | Chapter Lead

Provide governance, strategic direction, and advocacy

Diabetes Patient Advocacy Coalition

03/2021 - Present

Champion Advocate providing testimony to the Massachusetts Legislature

<https://jessicavongoeler.com/health-equity>

Association of Diabetes Care & Education Specialists

10/2025

State Policy Forum Panelist

https://youtu.be/_b4ZY70-sVo?si=t5oxO8In9DYXlikb

GetT1DtheCovidVax.org

02/2021 - 03/2021

NYT Front Page Article: How America's Vaccine System Makes People With Health Problems Fight for a Place in Line

<https://www.nytimes.com/2021/03/09/us/covid-vaccine-eligible-preexisting-conditions.html>

RECOGNITIONS

 **Innovation & Excellence**
Program Achievement Award – Gates
Medical Research Institute

Client Solution of the Year - Harvard
Business Publishing

 **Collaboration & Leadership**
Best in Manufacturing Readiness -
Brammer Bio

Honorary Paul Harris Fellow - Arlington
Rotary Club

 **Advocacy & Community Impact**
Patient Advocacy Champion - Diabetes
Patient Advocacy Coalition

Community Service Person of the Year -
Cambridge Salvation Army