

JESSICA VONGOELER, MBA

Program & Portfolio Management | Biologics & Gene Therapy Leadership | Strategic Execution

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SUMMARY

Strategic program and portfolio leader with 15+ years of experience advancing complex biologics and gene therapy programs from early development through late-phase manufacturing readiness and pre-commercial transition. Known for asking where help is needed most and aligning science, operations, and strategy to deliver results, bringing deep experience connecting CMC, Regulatory, Quality, Tech Ops, Clinical, and Supply Chain teams to ensure decisions are data-driven, timelines are achievable, and execution is cohesive.

STRENGTHS

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| ✓ Program Strategy & Governance
Partner with team leads to define clear decision frameworks, align stakeholders, and drive accountability. | ✓ Cross-Functional Integration
Connect CMC, clinical, and commercial plans into cohesive execution paths that keep milestones visible and realistic. | ✓ Operational Excellence
Build dashboards, readiness metrics, and scenario plans that translate complexity into clarity for leadership teams. |
| ✓ Launch Readiness
Ensure late-stage programs have the right operational scaffolding to move seamlessly from submission to commercialization. | ✓ Portfolio Integration & Resource Strategy
Align portfolio priorities with operational resources – asking where cross-program dependencies or capacity limits could threaten timelines, and developing actionable solutions that protect delivery and value. | ✓ Risk Anticipation & Decision Agility
Surface emerging risks early and turn uncertainty into structured decision points, ensuring leadership has clear options before issues escalate. |

KEY ACHIEVEMENTS

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| 📈 Recovered \$2.7M in overcharges and redirected 20% of spend to higher-performing vendors, improving delivery and audit outcomes. | 📈 Managed \$20M+ GMP manufacturing site start-up at Ultragenyx, integrating Tech Ops, Quality, and Supply Chain to achieve operational readiness across two gene therapy programs. | 📈 Executed a three-month tech transfer on schedule, adapting to evolving design inputs and maintaining readiness for first GMP run. |
| 📈 Directed \$13M in CMC programs at Gates MRI, implementing 8 readiness metrics that increased transparency and ensured Phase 1 IND readiness. | 📈 Built site-level schedules reducing material order risk by 60%, aligning manufacturing and regulatory milestones. | 📈 Anticipated and mitigated a late-phase manufacturing risk through coordinated cross-functional decision-making, preserving IND submission and credibility. |

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 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 6 business unit lead to develop long-range site budget aligned to portfolio growth.
- Enhanced visibility and decision agility across teams by introducing program governance and milestone tracking.

PROFESSIONAL EXPERIENCE

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 15% 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.

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 TOOLKIT

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

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

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

ADDITIONAL LEADERSHIP & IMPACT

GrownUp T1Ds

Board Member | Chapter Lead |

08/2025 - Present

Provide governance, strategic direction, and community advocacy for a national nonprofit serving midlife adults with Type 1 diabetes. Established the first Boston chapter and model for national expansion, leading organizational filing, program design, and community engagement efforts.

Diabetes Patient Advocacy Coalition

Champion Advocate

03/2021 - Present

Promoting equitable access and coverage for diabetes care.

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 – Rotary Club of Arlington, MA



Advocacy & Community Impact

Patient Advocacy Champion – Diabetes Patient Advocacy Coalition

Community Service Award – Salvation Army, Cambridge Corps