

# William OConnell PMP

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☁️ Senior Business Analyst | TPM | GxP Life Sciences Implementation | Enterprise System Delivery

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## SUMMARY

Senior Business Analyst and Technical Program Manager with 20+ years delivering enterprise systems in GxP-regulated life sciences and global enterprise environments. Deep expertise in 21 CFR Part 11 platforms including TrackWise, QMS, CAPA, and Change Control. Proven leader of requirements, UAT, validation, and stakeholder workshops for large-scale regulated migrations. Built and led BA teams supporting \$25M+ portfolios. AWS Certified with hands-on validated cloud architecture experience.

### CORE COMPETENCIES

GxP / 21 CFR Part 11 Compliance | TrackWise / QMS / CAPA / Change Control | Business Requirements & BRD / FRD | UAT Design & Validation Lifecycle | Stakeholder Workshops & Facilitation | Agile, Waterfall & Hybrid SDLC | Data Analysis & Systems Integration | User Training & Adoption | People Management | Digital Asset Management (DAM) | Cloud Migration & Validated Systems

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## EXPERIENCE

### Implementation Consultant / Senior BA – GxP Cloud

O'Connell Cloud & Program Advisory LLC

January 2025 - Present, Seattle, WA

- Designed and built a production GxP-aligned AWS serverless Validated Document Control (VDC) platform end-to-end — Cognito, Lambda/API Gateway, DynamoDB, S3 — owning all requirements, validation strategy, and full IQ/OQ/PQ documentation.
- Developed UAT test scenarios, rollback criteria, and validation traceability matrix; integrated Amazon Bedrock/Claude AI with structured RBAC, MFA, and audit logging for regulated AI workflows.

### Program Lead – Portfolio Operations

OCO Investments LLC

August 2019 - December 2024, San Francisco & Remote

- Managed structured program governance across a \$3M+ diversified portfolio — vendor management, risk tracking, and capital planning — while maintaining active engagement with life sciences technology market and GxP regulatory trends.

### Delivery Head & Senior BA Manager – IT Infrastructure

Roche (based at Genentech)

March 2013 - August 2019, South San Francisco

- Served as BA and TPM for the Enhanced Data & Insights Sharing (EDIS) initiative — a corporate data-sharing program across Research, Early Development, Clinical Trials, Manufacturing, and Personalized Healthcare divisions under HIPAA and GDPR.
- Built and led a 10 person TPM team and 4-person BA team supporting 25+ infrastructure programs annually across \$20M portfolio.
- Served as BA Lead/TPM for enterprise data-sharing and resource management platforms (800+ users).
- Oversaw \$100M global data center modernization — zero unplanned downtime, zero compliance findings.
- Improved delivery velocity 30% and reduced resource over-allocation 80% through structured requirements governance

### Technical Program Manager / Senior Program Analyst

Genentech / Roche

March 2009 - March 2013, South San Francisco

- Led change management workstream for Roche's migration of 100,000+ users from Microsoft Office to Google Cloud — coordinating across engineering, security, change management, and operations globally with zero unplanned downtime.
- Re-engineered 17 Global IT PMO processes across a 3,000-person IT organization: facilitated requirements workshops, documented current-state processes, defined future-state solutions, and implemented algorithm-driven RAG portfolio reporting that shifted executive visibility from subjective to objective, data-driven signals.
- Delivered Windows OS upgrade program (20,000 users across 7 sites) — managing application compatibility analysis, remediation requirements, and deployment planning across 100+ resources and 7 sub-teams.

### Senior Business Analyst – Digital Asset Management

EMI Music

September 2005 - August 2008, London, UK

- Led a team of BAs in delivering EMI Music's web-based 'Global Repertoire' Digital Asset Management (DAM) platform — a global rollout enabling metadata capture from users across 43 countries and 17 languages, connecting the firm's central repository to its worldwide digital supply chain.
- Acted as both Business Analyst and Business Systems Analyst on EMI's Digital Supply Chain platform: performed in-depth system integration analysis, data flow mapping, and requirements documentation for repertoire metadata flowing from central London systems through global distribution infrastructure.
- Facilitated stakeholder workshops with international business units, defined data governance requirements, and led UAT across multiple geographies — delivering a complex multi-country platform on schedule.

### Senior IT Business Analyst (Consultant)

Genentech

February 2002 - March 2005, South San Francisco

- Led BA team for Genentech's Manufacturing Change Control transformation that consolidated 7 disparate validated Change Control systems into a single centralized GMP-validated enterprise platform, eliminating transcription errors and improving audit compliance.
- Led analysis, testing, and training for multiple GxP-regulated TrackWise platforms under 21 CFR Part 11, including QMS, CAPA, ELN, and LIMS integrations — contributing directly to a 100% FDA inspection pass record.
- Delivered requirements, business process mapping, UAT test design, and end-user training programs for validated system implementations across regulated manufacturing and quality environments.

### EARLIER CAREER

Robertson Stephens & Bank of America

San Francisco

- Owned enterprise Major Incident and Change Control programs in a regulated high-stakes financial services environment, acting as Incident Commander for Sev-1 events and building structured RCA and remediation frameworks.
- Systems engineering roles supporting trading floor infrastructure in regulated, high-availability financial environments.

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## EDUCATION & COMMUNITY ENGAGEMENT

- **B.S. Health Sciences** (San Francisco State University)
- AWS Certified Solutions Architect – Associate • PMP (PMI ID: 563082) • Google Data Analytics Professional Certificate - Leading SAFe 6.0
  - Certified SAFe PO/PM • Certified Change Practitioner (Prosci) • MCSE (Microsoft Certified Systems Engineer)
- **In Progress:** *Microsoft Azure Fundamentals (AZ-900)* • *Google Cloud Digital Leader*
- **Community Engagement:** SF AIDS Foundation | SF AIDS Department Community Advisory Board | Founder, Vaccine Advocates (VACT UP)