



## CURRICULUM VITAE

# Scott R. Thatcher

**BSc (Molecular Biology)  
Senior Consultant**



### Recognised Areas of Expertise:

- Executive and Scientist with over 25 years of end-to-end pharmaceutical and biopharmaceutical experience, spanning development, manufacturing, regulatory, and quality leadership.
- Record of 9 NDA approvals from 52 total submissions, demonstrating strong regulatory execution and asset progression.
- Leadership of 10 successful development-to-commercial technology transfers and participation in 5 FDA in-room audits (routine and PAI).
- Strong record in CMC development, including creation of TPPs, QTPPs, CQAs, control strategies, risk assessments, solid-state characterisation, formulation development, QbD studies, PAT assessments, CTM release, stability programme management, and PAR studies.
- Extensive analytical and process expertise, including 200+ analytical method validations (ICH Q2/Q14) and 10+ process validations supporting product commercialization.
- Broad technical coverage across tablets, capsules, injectables, creams, syrups, inhalers, and drug-device systems.
- Contributor to 50+ corporate project teams, influencing CMC strategy, control strategies, risk management, and lifecycle planning for diverse small- and large-molecule assets.
- Budget ownership and programme oversight exceeding £2M, ensuring resource efficiency, delivery performance, and regulatory compliance.
- Significant contributions to approved or marketed assets including Gemzar®, Seromycin®, TobroDex®, Xigris®, Cialis®, Humulin®, Klor-Con®, Qudexy™ XR, LoteMax®, Morphine Sulfate ER, among others.
- Regulatory author and reviewer for eCTD Modules 2 and 3, SUPAC, PAS, CBE; contributor to deficiency responses and FDA-facing documentation.



- Achieved 20+ successful technology transfers, and oversight of primary reference standard programmes.
- Developer of two full GxP-compliant Quality Management Systems, comprising 400+ SOPs and policies, implemented and validated at CDMOs.
- Extensive Quality and QMS leadership, including OOS/OOT management, deviation/CAPA systems, test method governance, specification management (ICH Q6), batch record design, change control, and 21 CFR Part 11 system qualification (CSA).
- Experienced CDMO and vendor management professional, leading 30+ RFI/RFP processes, contract evaluations, governance models, KPIs, SME documentation reviews, and multi-site oversight for API, DP manufacturing, packaging, analytical services, and solid-state analysis.
- Programme and supply-chain oversight covering APIs, raw materials, excipients, intermediates, container-closure systems, and clinical supply logistics.
- Skilled GxP auditor for CDMOs/CROs (onsite and paper-based), including Quality Agreements and vendor qualification.
- Recognised and respected industry SME, speaker for compliance training (e.g., Analytical Method Validation, ICH Q1B Photostability, Technology Transfer, Dissolution), and USP Review Panel Expert.

### **Current Employment:**

- Independent Consultant working on behalf of GxPassure Limited
- President / Principal CMC Consultant on behalf of Precision Pharma Consulting, llc

### **Career History:**

- **September 2025 – Present: Precision Parma Consulting, W Lafayette, Indiana, US – President / Principal CMC Consultant**
  - Deliver on all CMC and GxP needs of client assets
  - Meet or exceed client timeline requirements for asset progression
  - eCTD submissions, FDA meeting interactions
  - CDMO/vendor technical oversight and relationship governance
- **October 2023 – September 2025: Humanetics Corporation, Minneapolis, Minnesota, US – Director CMC**
  - Report directly to CEO and COO
  - Oversight of all CMC and GxP requirements for multiple assets
  - QMS from inception, CSA, SOPs, Policies, Quality Manual, Training
  - eCTD submissions and FDA correspondence/interactions

- Asset budget oversight and management
- Corporate board interaction
- CDMO Identification, Selection, Governance, Technical oversight
- **February 2023 – July 2023: Fulcrum Therapeutics, Cambridge, Massachusetts, US – CMC Consultant**
  - Deliver on all CMC requirements for multiple assets
  - GxP compliance for multiple assets
  - SOP and Policy authorship and review
- **November 2022 – January 2023: Compliance Insights, Cincinnati, Ohio, US – GxP Consultant**
  - Deliver on all GxP requirements for multiple clients
  - SOP and Policy authorship and review
  - Establish client QMS requirements to meet regulatory rigor
- **January 2022 – January 2023: Third Bridge Group, New York, US – CDMO Consulting**
  - Consult on CDMO Identification, Selection, and Governance processes for multiple clients
- **February 2017 – January 2020: RECRO (now Bend Biosciences), Gainesville, Georgia, US – Project Manager**
  - Program and Budget Management of multiple client assets
  - Internal technical consultant on CMC regulatory
  - FDA Consent decree remediation and subsequent approval
  - Life-cycle management practices for multiple corporate assets
- **January 2016 – January 2017: Tapemark, W. St Paul, Minnesota, US – CMC / GXP Consultant**
  - QMS remediation, CSA, SOP and Policy authorship and review
  - Warning letter remediation and subsequent approval
  - Oversight of Quality Control release review and internal GxP compliance

**Education:**

- 1990: Purdue University – Assoc. Pharmacy, Bachelor of Science, Molecular Biology, Chemistry minor