



CURRICULUM VITAE

Rebecca Rutter

Senior Consultant



Recognised Areas of Expertise:

An experienced pharmaceutical quality, manufacturing and supply chain consultant with senior leadership experience across advanced therapy medicinal products, biologics, sterile and aseptic manufacturing, clinical trials, consumer healthcare and SME environments. Eligible Qualified Person under the permanent provisions of Directives EC 2001/82 and EC 2001/83, an IRCA Lead Auditor and trainer, and holds a BSc (Hons) in Biochemistry, Diploma in Pharmaceutical Project Management. With expertise combining strategic quality system assessment, operational leadership, regulatory readiness, validation, technical transfer, remediation and quality risk management, supported by decades of experience in organisational change, crisis response, auditing, QP mentoring and leadership development.

With key areas of experience:

- Advanced therapy medicinal products, biologics, sterile and aseptic manufacturing.
- IMP and clinical trial set up execution and management
- GMP facility set-up, site initiation, decommissioning and supply chain development.
- Pharmaceutical quality systems, ICH Q10, quality risk management and strategic system assessment.
- Inspection readiness, regulatory readiness, remediation gap assessment and remediation plan execution.
- CAPA, root cause analysis, deviation management, complaints assessment and resolution.
- Validation and qualification strategy, including development of IQ, OQ and PQ plans.
- Technical transfer from R&D to GMP manufacturing and operational efficiency improvement.
- Business strategy, organisational change management and quality system transformation.



- Auditing, Qualified Person tutoring, mentoring, coaching and leadership development.
- Crisis management and supply continuity support within regulated pharmaceutical operations.

Current Employment:

- Independent Consultant working on behalf of GxPassure Limited
- Independent Consultant and Director of Totilas QP Services Limited

Career History:

- **2023 to date: Totilas QP Services Ltd. - Director**
 - QMS consultancy and build-out for controlled drug medicines start-ups; gap assessments and remediation for MS(IMP), MS (Specials) and cosmetic manufacturers.
 - Interim management for remediation projects within licensed pharmaceutical manufacturers.
 - Designed and delivered mentoring/training solutions for eligible Qualified Persons; industry speaker (ATMP AAV LVV production, biotechnology production, law and admin, Clinical trials, API production, Roles and Duties, Analysis and Testing, Maths & stats etc).
 - Provided internal training and mentoring for blue-chip pharma, government and international training orgs
- **2015 – 2023: GSK – Director of Manufacturing Cell and Gene Therapy; Global Quality Lead, Consumer Health; Category Quality Manager / R&D Site Quality Manager**
 - Delivered new ATMP AAV LVV manufacturing infrastructure from greenfield to validated, MHRA inspection-ready in 22 months.
 - Recruited/managed 6 direct, 21 indirect and 14 matrix reports across Manufacturing Operations, Data/Tech (SAP, LIMS, eCellITS, ERP), Validation, Supply Chain and Tech Transfer.
 - Designed/implemented systems to reduce COGS versus CMO and improve efficiency from tech transfer to GMP production.
 - Developed release-by-exception drivers and lead indicators; transferred processes and analytical methods from CMO to internal GMP site.
 - Decommissioned GMP facility while managing team redundancy.

- Delivered three FDA-approved expedited API supplier changes in six months for USA; managed pandemic supply disruptions.
 - Delivered £1.5m dual-sourcing projects across ~£10bn revenue, 15 sites and 21 product lines.
 - Led quality crisis response relating to global paracetamol supply during COVID-19 and supported complaint assessment and resolution.
 - Developed COVID-appropriate strategy to onboard new API/excipient suppliers ensuring global paracetamol supply.
 - QA release of batches for global clinical trials; qualified vendors and new raw materials; led deviation/CAPA investigations.
 - Quality lead for Sensodyne Rapid brand subsequently exceeded £1bn revenue;
 - CMO quality relationship lead in India.
 - Accountable for post-launch quality lifecycle (COGs and compliance) and NPI due diligence/oversight for global launches.
 - Led global Community of Practice and Digital Quality Task Force SME for devices; updated QMS for Medical Device Directive.
- **2005 – 2015: Cells4Life LLP – Site Quality Lead**
 - Held responsibility for site quality leadership, quality management systems and regulatory readiness.
 - Supported inspection readiness, risk management, remediation and change management activities.
 - Led agile team increasing sales by 50% and productivity by 40%; accountable for Finance, Supply Chain, Manufacturing Ops and Customer functions (21 direct reports).
 - Legal Designated Individual under Human Tissue Act / Q&S Regulations (licence #11083).
 - Designed/implemented EU GMP-aligned QMS; deployed real-time business intelligence for quality issue identification.
 - Project-managed new premises and manufacturing facility build (from shell); SME to EU 7th Framework SoHo V&S (2012).
 - **2003 – 2004: Fisher Clinical Services – Clinical Trials Project Manager**
 - Managed clinical trials projects within a regulated pharmaceutical services environment.
 - Applied project management, quality and supply chain experience to support delivery of clinical trial services.

- **1999 – 2003: UK and USA-based SMEs – Project Management and Business Development Roles**
 - Held multiple project management and business development roles across small and medium-sized enterprises.
 - Built early experience in commercial operations, project delivery and cross-functional stakeholder engagement.

Education:

- 1999: University of Sussex – BSc (Hons) Biochemistry
- 2003: University of Cardiff – Pharmaceuticals Project Management Lead

Continuing Education & Job Related Training:

- 2019: European Qualified Person status under permanent provisions
- 2014: Human Tissue Authority – Designated Individual training
- 2025: IRCA Lead Auditor Pharma and trainer

Professional Memberships:

- Eligible Qualified Person under permanent provisions of Directives EC 2001/82 and EC 2001/83