Laura Sherlock

Senior CMC Associate

Education

- M.Sc. – Science Communication – **Dublin City University**
- B.Sc. – Biotechnology – **Dublin City University**
- Professional Diploma – Project Management – **University College Dublin**

contactus@greyrigge.com

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+44(0) 118 979 1169

About

Laura is an analytical CMC consultant with over 18 years' experience in the biopharmaceutical sector, spanning contract research, biotech, and large pharma environments. She specialises in guiding programmes through analytical development toward IND, BLA, and MAA readiness, with particular strength in resolving complex technical and assay issues, de-risking tech transfers, and setting robust specifications. Laura has extensive experience managing CDMO and CRO oversight across a broad range of modalities. She provides expert technical leadership to ensure GMP compliance and the delivery of high-quality analytical data packages that support successful global regulatory submissions.

Skills & Impact

Analytical Method Lifecycle: Development, qualification and validation management of analytical methods in line with ICH Q2 and Q14.

CDMO/CRO Oversight: Technical leadership and project management of external testing and manufacturing partners, as well ensuring GMP-compliant and timely delivery of results.

Specifications & Stability: Setting phase-appropriate specifications and designing stability programmes to support development and regulatory milestones.

Regulatory Submissions: Preparation of technical reports and submission documents, including BLA, IND, IMPD, and briefing packages.

Cross-Functional CMC Leadership: Influential leadership within matrixed organisations, coordinating Regulatory, Quality, and Manufacturing teams.

Team Leadership & Mentoring: Building and leading analytical teams, mentoring scientists in core techniques and driving departmental performance.

Programme & Project Management: Managing outsourcing contracts, budgets, and timelines, with formal training in project management methodology.

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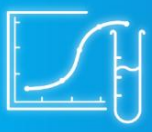
Areas of Expertise

Strategic Planning & Due Diligence

Assay & Quality Control

CMC & Manufacturing

Preclinical, Non-Clinical & Toxicology



CDMO Management

Formulation Development & Stability

QA, Auditing & Regulatory Affairs

Clinical Development & Monitoring

Languages

- English (fluent)

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Experience

GreyRigge Associates
Senior CMC Consultant
2026 - Present

Director External Manufacturing
Prothena
2024 – 2025

Accountable for QC and stability workstreams supporting a Phase 3 monoclonal antibody programme, resolving complex assay issues with external laboratories to protect timelines and ensure analytical readiness for BLA submission. Worked closely with contract testing laboratories and CDMOs to secure GMP-compliant results, drove analytical method improvements aligned with ICH guidance, and partnered with External Manufacturing, Regulatory CMC, QA, and Project Management teams to coordinate BLA-readiness activities.

Director, CMC Analytical Development & QC
bit.bio
2022 – 2024

Defined the analytical strategy for a gene-edited iPSC-derived cell therapy programme, balancing innovation with regulatory rigour to support pre-clinical dossiers and agency interactions. Led analytical strategy across the full production lifecycle, from gene-edited iPSC lines through to Master Cell Bank, Drug Substance, Drug Product, and release testing, and established a scalable Analytical Development and QC infrastructure alongside a robust external laboratory network. Set short- and long-term departmental objectives aligned with Technical Operations strategy and budget.

Associate Director, Bio-Analytical Development
Jazz Pharmaceuticals
2019 – 2021

Established the end-to-end analytical strategy, including method development and validation, specification setting, and stability study design, for an Asparaginase-derived therapeutic protein manufactured at a CDMO entering Phase 1. Evaluated complex data sets to guide development and method-selection decisions, managed outsourcing contracts and stakeholder communications, and led preparation of technical reports and regulatory submission documents, including briefing packages.

Principal Scientist & Manager
Pfizer
2004 – 2019

Managed a team of nine scientists providing analytical support for clinical and commercial products, including proteins, conjugated vaccines, and biosimilars, across Pfizer's global network. Led the technical CMC transfer of a commercial vaccine from an external CDMO to a Pfizer site.