

Matthew Bentley

Senior CMC Consultant

Education

BSc (Hons) – Applied Biochemistry
Liverpool Polytechnic

contactus@greyrigge.com

www.greyrigge.com

+44(0) 118 979 1169

About

Matt has over 25 years' of industry experience, with a strong focus on CMC analytical strategy and execution for cell and gene therapies, biologics and recombinant proteins. He has led stability programs, analytical method validation and QC readiness activities,. He has authored and contributed to regulatory submissions from early development through to BLA approval. His background also includes more than 15 years of experience in the development and validation of PK and ADA assays within GxP environments as well as developing assays to support the assessment of vaccine responses.

Skills & Impact

CMC Analytical Strategy: Extensive expertise across method validation, stability programs, specification setting and reference standard lifecycle management.

Regulatory CMC Authoring: Contribution to IND, IMPD and BLA submissions and preparation of responses to regulatory agency information requests.

Analytical Method Lifecycle & Tech Transfer: Proven track record leading method validation and transfer activities into GMP QC laboratories.

Bioanalytical Assay Development: Broad practical experience across ELISA, SPR (BIAcore), qPCR, flow cytometry and ECL (MSD) platforms, applied to both CMC and clinical bioanalytical settings.

PK and Immunogenicity (ADA) Assays: Strong foundation in the development, validation and regulatory support of PK and ADA assays across clinical development stages.

Global CDMO & CRO Management: Extensive experience managing global contract partnerships and working as an SME for analytical validation.

Team Leadership: Skilled in building and directing cross-functional teams, aligning stakeholders across development, QC and regulatory functions.

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Senior CMC Consultant

Areas of Expertise



Strategic Planning & Due Diligence



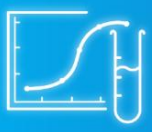
Assay & Quality Control



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

Senior CMC Consultant
GreyRigge Associates Ltd
2025 – Present
Providing CMC analytical strategy support across biologics, biotherapeutics, and cell and gene therapies.

Associate Director of Stability & Method Validation
Adaptimmune
2018 – 2025
Directed the stability program for the company's vector assets and led the transfer and validation of critical analytical methods, including viral titre and potency assays, into GMP-compliant laboratories. Acted as regulatory submission SME for vector QC, covering stability, method validation, and reference standards, and managed responses to regulatory agency information requests.

Scientific Director
Eurofins Pharma Bioanalysis Services UK
2014 – 2018
Oversaw product characterisation services, including biosimilar comparability by SPR and cell-based assays, and provided scientific and regulatory oversight of PK and immunogenicity analytical projects conducted to GCP and GLP standards. Acted as scientific and technical advisor to clients and internal teams on assay development, validation and application.

Development & Validation Services Manager
Merck-Millipore
2010 – 2014
Led a team developing and validating bioanalytical methods, including immunogenicity, PK, biomarker and GMP potency assays, and served as Acting Head of GMP QC supporting batch release and stability testing for biologic drug candidates. Led a division of around twenty staff delivering immunogenicity, pharmacokinetic and biomarker analytical studies to clients.

Analytical Project Manager
BioAnaLab Ltd
2005 – 2010
Managed and reported on over one hundred immunogenicity, pharmacokinetic and biomarker analytical studies, and acted as Study Director/Principal Investigator for GLP studies, leading client requirements for assay transfer, validation and sample analysis across CMC, clinical and non-clinical programmes.

Team Leader, Senior Scientist & Research Assistant
Microscience Ltd
1999 – 2005
Progressed through roles developing, validating and transferring immunoassays and ELISPOT methods to clinical laboratories in support of several candidate vaccine clinical trials, including international technology transfer.