



Samantha Dowse

Managing Partner & Principal Consultant

Education

B.Sc. (Hons)– Biomedical Sciences, UWE
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About

Samantha is a Managing Partner and Principal Consultant at GreyRigge Associates with over 25 years' biopharma experience at GSK, Ipsen, Lonza and Emergent BioSolutions. She is an expert in CMC strategy and project management. Analytical development including assay design, delivering statistically robust, regulatory-ready analytical programmes and overseeing method validation, stability studies and technology transfers globally.

Skills & Impact

CMC Project Management: Experienced in managing joint-venture projects, negotiating and managing contracts and supply agreements. Managed CMOs and CDMOs on behalf of clients, led compliant technology transfers across external and internal sites and resolved complex CMC issues through effective troubleshooting to maintain smooth, on-time project delivery.

Analytical Leadership: Drove redevelopment initiatives across analytical, stability, and manufacturing functions. Optimised product and process strategies to enable cost-efficient site closures, and conducted technically focused due-diligence assessments covering analytical methods, stability data, CMC packages, and manufacturing readiness.

Stability: Designed and led regulatorily compliant stability programmes for complex biologics and vaccines, providing expert oversight across diverse modalities. Provided expert oversight of advanced statistical analyses within ICH guidelines, set robust quality controls, and managed investigations, data trending, and global regulatory submissions to ensure high quality study execution.

Strategy Development: Strategic bridge between scientific and commercial teams, leading internal redevelopment initiatives. Optimised product and manufacturing strategies to enable cost-efficient site closures. Led investor and client due-diligence on technical and commercial data.

Technical Support: Provided technical oversight to CMO's and internal facilities for process, analytical development and validation projects with statistical design and evaluation tools. Development, validation and transfer of test methods for control of the manufacturing of numerous complex biological products including commercial products or up to late phase clinical.



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Areas of Expertise



Strategic
Planning &
Due Diligence



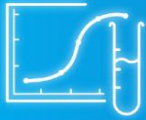
Assay &
Quality
Control



CMC &
Manufacturing



Preclinical,
Non-clinical, &
Toxicology



CDMO
Management



Formulation
Development
& Stability



QA, Auditing
& Regulatory
Affairs



Clinical
Development
& Monitoring

Languages

English (Fluent)

Experience

GreyRigge Associates Group **Managing Partner & Principal Consultant** **Jan 2023 - Current**

Merged Nathan Consulting, creating GreyRigge Associates Group whilst establishing resilient business practices, growing global clients, and delivering consulting engagements.

UK Vaccine Taskforce **Technical Specialist and Industry Consultant** **Apr 2021 - Feb 2023**

Provided advice on development of the COVID-19 vaccines with focus on analytical development, validation, stability and shelf-life management. Facilitated the capability to develop early-stage vaccines, as part of the pandemic preparedness of the UK.

Nathan Consulting Ltd **Owner and Principal Consultant** **Apr 2011 - Current**

Clients included: Fresenius Kabi, F-Star, VHSquared, Lonza Biologics, Ipsen Biopharma, Jazz Pharmaceuticals, Chiesi, Allergan Biologics, Merck Serono (Consumer Health), Takeda, Circassia, RSSL, Laleham, Oxford University, Synairgen, Themis, FluGen, and Brunel Healthcare.

Ernst & Young Management Consulting GmbH **Senior Consultant and Associate Partner** **Jan 2013 - Dec 2014**

Focus areas included: method transfer and validation, as well as consumer health product stability.

Emergent Product Development UK Ltd **UK Manager, Manufacturing Assay Development** **Sep 2002 - Apr 2011**

CMC PM selecting CDMO and leading tech transfer and scale-up of a Phase II viral vector vaccine, enabling global regulatory submissions. Led analytical, and QC capabilities through cGMP release. Contributed to due diligence and grant applications.

GSK **Scientist, Biopharma Analytical Development** **Sep 1998 – Sep 1999 then Jul 2000 – Sep 2002**

Analytical scientist with focus development and validation of methods including confocal microscopy, ELISAs, enzymatic assays and cleaning validation.

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