Samantha Dowse

Managing Partner & Principal Consultant

Education

B.Sc. (Hons)– Biomedical Sciences, UWE Bristol, UK

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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)

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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.