Jim Mills

Principal CMC Consultant

Education

- Ph.D. – Biochemistry – **University of Leicester**
- B.Sc. (Hons) – Biotechnology – **University of Wolverhampton**

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+44(0) 118 979 1169

About

Dr James (Jim) Mills is a bioprocess and biopharmaceutical executive with over 27 years' experience across senior technical operations and senior leadership roles in the biopharma sector. He has extensive experience developing a wide range of product types in prokaryotic and eukaryotic systems, including proteins, fusions, antibodies, vaccines, live-viruses (including ATMPs), live-bacteria and conjugated products such as Antibody Drug Conjugates. His technical expertise spans upstream process, downstream process and analytical development, from early research phase through to market approval, with practical leadership of Design of Experiments (DoE) and Quality by Design (QbD) approaches.

Skills & Impact

Senior Technical & Leadership: Extensive experience in senior technical operations and senior leadership roles across the biopharma sector.

Bioprocess Development: Upstream, downstream and analytical development expertise across a wide range of product types and expression systems.

Product Range: Proteins, fusion proteins, antibodies, vaccines, live-viruses (including ATMPs), live-bacteria and Antibody Drug Conjugates.

CMC Strategy & Planning: CMC product development planning and manufacturing strategy development from pre-clinical through to clinical phases.

Quality by Design: Practical leadership on Design of Experiments (DoE) and QbD approaches within bioprocess development.

Facility & Manufacturing Design: Design of R&D laboratories and GMP manufacturing facilities, including basis of design for new sites.

Due Diligence & Technology Assessment: Manufacturing technical due diligence, technology assessment and company acquisition due diligence.

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Principal CMC Consultant

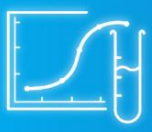
Areas of Expertise

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

Principal CMC Consultant
GreyRigge Associates
2019 to present

Providing bioprocess and biopharmaceutical technical and strategic consulting to biopharma companies, including CMC strategy development, manufacturing technical due diligence and advisory board contributions.

Senior Vice President Product Supply
Freeline Therapeutics,
2019-2020

Responsible for all internal and external GMP operations supporting the company's AAV-based gene therapy portfolio, overseeing manufacturing, supply, procurement and QC functions, and developing long-term product supply strategy.

Senior Vice President Technical Operations
Abzena PLC
2015-2019

Held P&L responsibility for a biologics development and manufacturing site in San Diego, led its restructuring, oversaw modernisation to single-use manufacturing platforms, and developed a cross-site ADC manufacturing strategy. Responsible for group GMP Quality, programme management and supporting functions, and served as a company director of UK and US subsidiaries. Part of the executive team which delivered two US acquisitions which expanded the company's service offering.

Chief Executive Officer
Cantab Biopharmaceuticals
2009-2015

Led a private equity-funded biopharmaceutical development company, refocusing the business from contract services toward in-house development of biosuperior products.

Director of Operations
Xenova Research Ltd / Xenova Biomanufacturing
2001-2009

Progressed from Senior Scientist to Director of Operations, leading departments responsible for fermentation and cell culture process development, and for optimisation, scale-up and technology transfer of upstream production processes for internal projects and external contracts, before taking responsibility for a contract process development and GMP manufacturing business unit.

Senior Scientist & Post-doctoral Research Associate
Cantab Pharmaceuticals & University of Leicester
1995-2001

Led a group responsible for fermentation process development and clinical trials material production for protein-based vaccine products, following post-doctoral research in the Department of Biochemistry at the University of Leicester.