



Ronan O'Kennedy

Senior CMC Consultant

Education

- Ph.D. – Plasmid Stability in Recombinant *Saccharomyces cerevisiae* and its improvement
National University of Ireland
- B.Sc. – Microbiology
University of Galway

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About

Dr. Ronan O'Kennedy is a senior upstream process development (USP) scientist with over 25 years' experience in biopharmaceutical development and technology transfer. He specialises in mammalian and microbial cell upstream process development, statistical-based process modelling, Quality by Design (QbD) and research data management. His career spans academia, industry and consultancy, including senior technical leadership roles at GlaxoSmithKline and Fujifilm Diosynth Biotechnologies. He has extensive experience in bioreactor design, scale-up and technology transfer for GMP manufacture of biologics, providing applied technical expertise and strategic consultancy across the biopharmaceutical sector.

Skills & Impact

Biologics Process Development: Design and optimisation of upstream processes for mammalian and microbial biologics manufacture, from lab scale, through to pilot and commercial manufacturing scale.

Mammalian and Microbial Fermentation: Expertise across single-use and stainless-steel bioreactor systems, including Ambr micro-bioreactor platforms for cell line development (CLD) and process characterisation.

Statistical Process Modelling and DoE: Application of Design of Experiment (DoE) methodologies and multivariate analysis to support data-driven bioprocess modelling.

cGMP Manufacturing and Technical Transfer: Leading technical transfer of upstream processes into GMP manufacturing facilities for clinical and commercial supply.

Quality by Design (QbD): Embedding QbD principles throughout process development to build quality and robustness into biologics manufacturing.

Bioreactor and Facility Design: Specification, design and commissioning of R&D and GMP-scale cell culture laboratories, bioreactor controllers and SCADA systems.

Validation and Regulatory Support: Supporting process validation and technical transfer activities for biologics including monoclonal antibodies, DNA vaccines and peptide therapeutics.



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Areas of Expertise



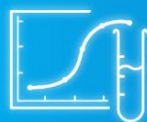
Strategic
Planning &
Due Diligence



Assay &
Quality
Control



CMC &
Manufacturing



CDMO
Management



QA, Auditing
& Regulatory
Affairs



Preclinical,
Non-Clinical
& Toxicology



Formulation
Development
& Stability



Clinical
Development
& Monitoring

Languages

- English (native)

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Experience

Senior CMC Consultant

GreyRigge Associates

2018 – Present

Provides specialist consultancy in upstream process development and manufacture of biological pharmaceutical products, covering fermentation at bench, pilot and manufacturing scale, single-use and Ambr bioreactor systems, and statistically based process characterisation.

Principal Consultant

ROK Bioconsulting

2015 – Present

Delivers technical and strategic consultancy across biopharmaceutical process development, including experimental design, data analysis, media optimisation and laboratory equipment configuration.

Head of Mammalian USP

Fujifilm Diosynth Biotechnologies

2011 – 2014

Led the Bioprocess Development group, responsible for technical transfer of client processes into upstream development and the design and equipping of R&D and GMP upstream manufacturing facilities.

Lecturer in BioPharm Development, Newcastle University, Chemical Engineering

2009 – 2010

Established a biotechnology laboratory with upstream and downstream unit operations and organised industrial collaborative research for Engineering Doctoral and PhD students.

USP Scientist

GlaxoSmithKline (GSK), Biopharmaceutical Dev.

2000 – 2008

Developed robust cell culture and microbial fermentation processes and led technical transfer for GMP manufacture of monoclonal antibodies, DNA vaccines and peptide therapeutics for clinical trials.

