



## Curriculum Vitae

### Personal information **Stephen Fahey**

#### Work experience

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1. Role and Employer: Biologicals Assessor, Health Products Regulatory Authority, Kevin O'Malley House, Earlsfort Terrace, Dublin 2, Ireland.  
Dates: November 2025-present.  
Main activities: Evaluation of quality aspects of applications for human medicinal products of biological origin in the centralised and clinical trial licensing section of the Human Products Authorisation and Registration department.
2. Role and Employer: Senior Scientist, Global Quality Analytical Sciences, Merck Sharpe & Dohme (MSD), Piercetown, Dunboyne, Co. Meath, Ireland.  
Dates: June 2021-October 2025.  
Main activities:  
Technical lead for large molecule method transfer & validation at drug substance commercialisation site.  
Site analytical liaison for new product introductions, method lifecycle management and change control impact assessments.  
Project lead for non-compendial method validations in collaboration with global SMEs to enable raw material identity testing and chromatography column resin reuse.  
Successfully led team efforts to remediate test method performance issues ensuring completion of method transfer in advance of engineering batch, clinical batch and PPQ campaigns.  
Collaborated with stakeholders in managing QC lab readiness and execution of method transfers and validations.  
Primary contact for review of analytical sections of BLA dossier.  
Led and coordinated readiness efforts for Health Authority pre-licencing inspection  
Author of Prior-Approval Supplement sections for marketed biologic.  
Co-authored and presented technical submissions to external auditors.
3. Role and Employer: Analytical Scientist III, Applied Process Company (APC) Ltd., Loughlinstown, Co. Dublin, Ireland.  
Dates: August 2017-May 2021.  
Main activities:  
Lead analytical method transfers and completion of analytical testing in support of large molecule process development, and scale-up.  
Led continuous improvement initiatives for implementation of automated analytical workflows.  
Analytical technical lead on biologic product development studies with responsibilities in preliminary stability studies, development and qualification of test methods, and management of project delivery.  
Authorship of method transfer protocols and reports, deviations & exceptions, SOPs, and risk assessments.  
Test method troubleshooting, optimisation and qualification.
4. Role and Employer: Scientist, PPD Ireland, IDA Business Park, Athlone, Co. Westmeath, Ireland.  
Dates: July 2014-December 2016.  
Main activities:  
mAb DS and final DP analyses for clinical and commercial phase stability and release programs (HPLC, Capillary and Gel Electrophoresis, Isoelectric Focusing, ELISA, Bioassay).  
Troubleshooting of bioassay methods in order to complete method transfer within project timelines.  
Owner of quality notifications and participant in investigation of out-of-specification results, out-of-trend data, deviations and associated CAPAs.  
Author of cumulative stability and release reports for DS/DP development programs, method transfer reports, and certificates of analysis.  
Miscellaneous tasks: qualification, calibration and maintenance of instruments, sample management, training of analysts, technical presentations, cGMP documentation.
5. Role and Employer: Research Assistant, Institute of Molecular Medicine, Trinity College Dublin, Dublin 2, Ireland.  
Dates: July 2013-June 2014, October 2010-August 2011.  
Main activities: Operational support role for academic biomolecular research.
6. Role and Employer: Research Technician (Maternity leave cover), Royal College of Surgeons in Ireland (RCSI), Dublin 2, Ireland.  
Dates: October 2008-April 2009.  
Main activities: Operational support role for academic animal physiology research.
7. Role and Employer: Analytical Scientist, Analytical Development (Contractor) Wyeth Biotech, Grange Castle, Dublin 22, Ireland.  
Dates: October 2007-September 2008.  
Main activities: Analytical test method qualification, provision of technical support for manufacturing and development, Separations (HPLC) and Wet Chemistry analyses of monoclonal antibodies, vaccines and small molecules.
8. Role and Employer: Quality Control Biochemist, Trinity Biotech plc. IDA Business Park, Bray, Ireland.  
Dates: September 2006-September 2007.  
Main activities: Release and Stability testing of in vitro diagnostic kits and reagents (haemostasis products).

#### Education and training

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September 2011-June 2012 Masters of Science in Molecular Medicine, Trinity College Dublin, Dublin 2, Ireland.

Subjects: Molecular Immunology, Molecular Oncology, Mechanisms of Human Disease.

September 2002- June 2006 Bachelor of Science (Biology), National University of Ireland (NUI), Maynooth, Co. Kildare, Ireland.

Subjects: Biology (Physiology, Biochemistry, Molecular Oncology, Immunology, Microbiology), Chemistry, Mathematical Physics, Mathematics.

## Additional information

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### Publications

**Fahey S**, Dempsey E, Long A. The role of chemokines in acute and chronic hepatitis C infection. *Cell Mol Immunol*. Advance online publication, 19 August 2013; doi:10.1038/cmi.2013.37.

### Projects

Oesophageal Cancer, 'towards new therapies' (Institute of Molecular Medicine, Trinity College Dublin), July 2013-June 2014

### Memberships

### Other Relevant Information

## PROFESSIONAL SUMMARY

Analytical Scientist with 12+ years of biopharmaceuticals industry experience.

Experienced in quality control, method development, analytical tech transfer and validation, regulatory inspections and filings. Advanced knowledge of protein analytics, biologics manufacturing and process validation, Working knowledge of Quality Management Systems, Pharmacopoeias, ICH, FDA & EMA regulatory guidance's.

*Analytical Proficiencies:* ELISA, Bioassays, Separations (Chromatography, SDS-PAGE, CE, iCIEF) electrophoresis) qPCR, Glycan analysis, Microbiology, Protein Purification, Solid Phase Extraction, Wet Chemistry, Karl Fisher, compendia.

*Industry Expertise;* Technical project management, cGMPs, QC stability and release testing, EHS & Biosafety, analytical CMC, Change Control, technical investigations & deviations, Quality Risk Assessment, HA inspections and internal compliance audits, leadership, coaching and development of analysts.

## SOFTWARE AND I.T. SKILLS

Microsoft Office, Adobe, KNEAT digital validation software, JMP, 32-Karat, Labware LIMS, Veeva Vault, TrackWise, SAP, Empower CDS, SoftMax Pro GxP, 32-Karat, PLA.

## PROFESSIONAL DEVELOPMENT

**November 2023**  
**Quality Practices**

**Advanced CMC Analytical Studies and Lab**  
(Informa Connect)

**May 2023**

**Practical Statistics, Statistical Process Control and Statistics for Bioassay** (Internal to MSD)

**February 2022**

**Fundamentals of GMO and Biosafety** (NIBRT, Dublin)

**October 2018**

**How to Develop HPLC Methods, How to Troubleshoot HPLC**

(Phenomenex, Dublin)