Level 3

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Speaker Bios

GRADUATE BUSINESS SCHOOL

Pharmaceutical REGULATORY SCIENCE Team

DUBLIN TECHNOLOGICAL UNIVERSITY DUBLIN

ACADAMH FIONTRAÍOCHTA ENTERPRISE ACADEMY

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1st June 2023 TU Dublin, Grangegorman

Speaker Bios

Dr Ed Hoffmann

Ed Hoffman is CEO of Knowledge Strategies and is engaged in research, education, and consulting service. His clients include Amazon, Microsoft, BAE, Boeing, Citi, NXP Semiconductor, John Deere, the UK Department of Defense. Dr. Hoffman retired from NASA as a Senior Executive. He was the first NASA Chief Knowledge Officer, and founder of the NASA Project Leadership Academy. Following the Columbia Shuttle failure, he led the team that designed the Strategic Management and Governance Handbook. He received the NASA Outstanding Leadership Medal in 2010. Dr. Hoffman is currently a Senior Lecturer at the Columbia University School of Professional Studies researching and teaching on the future of work. Dr. Hoffman has co-authored *The Smart Mission: NASA's Lessons for Managing Knowledge, People, and Projects* (MIT Press, 2022) which received Axiom award recognition for Business Intelligence and Innovation book. His other books include *Shared Voyage: Learning and Unlearning from Remarkable Projects* (NASA, 2005) and *Project Management Success Stories: Lessons of Project Leaders.*

Dr Emma Ramnarine

Emma Ramnarine is an accomplished senior leader with 23+ years experience of global experience in the pharmaceutical, biotech and medical device industries in Analytical Science & Technology, Product Management, Outsourcing & External Collaborations, Risk Management, QC and Quality Management Systems. Emma recently joined Boehringer Ingelheim as Head of Product Management & Development Operations for US Operations. Prior to this she was at Genentech Roche for 17 years in various global roles in Product Development, Quality, QC and Analytical Sciences. Emma is a purpose-driven leader and a catalyst for change, passionate about making a meaningful difference for patients and public health. She currently co-leads the Industry One-Voice-of-Quality (1VQ) Initiative on Post-Approval Changes, and is a well-recognized industry thought leader and expert on QRM, and Quality Management Systems. Emma is an officer at PDA, and PDA Director for 8 years. She holds a PhD in Pharmaceutical Sciences from TU Dublin, an M.S. in Pharmaceutical Sciences from University of Connecticut, an M. Pharm. and a B. Pharm., both from University of Indore, India, and an Executive Business Education Certificate from Stanford University.

Dr Gregg Claycamp

Gregg Claycamp is an independent risk scientist devoted to scientific development, teaching and application of quantitative risk and decision making in public health. He spent half of his career in academia and half at the US FDA where he held various Senior Biomedical Research Scientist (SBRS) and management positions until his recent retirement. Gregg enjoyed leading or co-developing risk-based decision-making projects at FDA, while never losing his passion for teaching risk analysis and coaching risk-based decision making. He served as regulatory rapporteur for ICH Q9 in addition to serving on other FDA-wide and US interagency advisory committees on risk analysis. Gregg majored in Human Biology at Stanford University followed followed by MS and PhD degrees in Radiological Health Engineering from Northwestern University.

Dr Kevin O'Donnell

Kevin O'Donnell is Market Compliance Manager at the Health Products Regulatory Authority (HPRA) in Ireland. He has been with the HPRA since 2001 and is a Senior GMP Inspector. He is also responsible for a number of compliance programmes, including the Quality Defect and Recall programme, the Sampling and Analysis programme, and Advertising Compliance. Kevin obtained his PhD in the field of Quality Risk Management (QRM) from the Dublin Institute of Technology in 2008. He is currently Rapporteur for the ongoing revision of ICH Q9 and he is also Chair of the PIC/S Expert Circle on QRM.

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Dr Anders Vinther

Anders Vinther is the SVP of Pharmaceutical Development and Manufacturing at Kronos Bio and the owner of QBA, Quality Business Administration and the winery Flying Suitcase, where he is also the winemaker. He has a M.Sc. and a Ph.D. in Chemical Engineering from the Technical University of Denmark and has worked in the Pharmaceutical Industry for more than 30 years. Companies he has worked for in senior level positions are Novo Nordisk, AGC Biologics, Genentech, Roche, Sanofi, Intarcia and Kronos Bio. Anders is actively involved in industry wide activities. He was he Chairman of the PDA Board of Directors, is the author of numerous publications and speaker at conferences, and he is co-leading the one-voice-of-quality for post approval changes initiative.

Peter Twomey

Peter Twomey is currently the Head of Inspections at EMA, with responsibility for the Office tasked with supervising compliance with GMDP, GCP, GLP, GVP and BE practices for human and veterinary medicines, market surveillance, quality defects and recalls and harmonisation and policy development in the inspections area. He is the current Regulatory Chair of the Expert Working Group drafting the revision of ICH GCP E6 (revision 3). He previously worked at the Irish Health Products Regulatory Authority, where he held the position of senior GCP/Pharmacovigilance inspector and GCP/PV Inspection manager, and representative at the GCP/Pharmacovigilance EMA inspector working groups (IWGs) and the CMDh GCP IWG working party. He also held the role of Pharmacovigilance inspector with the UK-MHRA, and positions in various areas of industry, including PV (QPPV and PV manager), medical affairs and wholesaling (responsible person). He holds a BSc and Masters degrees in pharmacy, and two Bachelor of Laws degrees.

Grainne Power

Grainne Power is Director of Compliance in the HPRA. She joined the HPRA in 2018 to lead the Human Products Authorisation and Registration Department. Her responsibilities include the authorisation or registration of human medicines, together with clinical trials authorisation for the Irish market. In January 2022, she was appointed Director of the Compliance Department. Grainne studied Biotechnology at Dublin City University and has worked in a number of Quality leadership roles within the Irish Pharma/Biopharma manufacturing sectors over a period of 25 years before joining the HPRA.

Pedro Ferreira

Pedro Ferreira, is Director, Validation and Quality Risk Management in ValGenesis. He has over ten years of experience in the pharmaceutical and chemical industries. Over the course of his career, he has held positions ranging from quality control and assurance of pharmaceutical products to the quality management of computerized systems and continuous improvement projects under the GMP scope. Pedro is currently leading ValGenesis Consulting's Quality Risk Management division. In this role, he is responsible for delivering world-class validation, quality, risk, and knowledge management consultancy services spanning all phases of drug development and commercialization. Pedro holds a licentiate degree in pharmacy and a master's degree in biotechnology.

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Patrick O'Sullivan

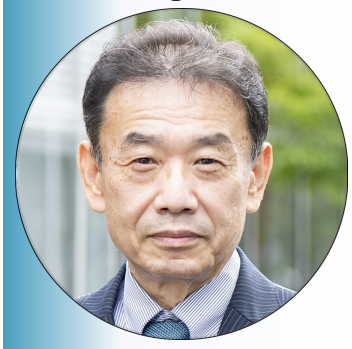
Patrick O'Sullivan is the Director of Life Sciences Data & Analytics at EY where he supports life science clients deliver value through data driven decision making and artificial intelligence. Prior to joining EY Patrick worked at Johnson and Johnson Pharmaceutical company Janssen where he supported, built and lead many of the recent global digital successes in their pharmaceutical business impacting a number of areas such as supply chain, manufacturing and procurement in which supported two sites achieving world economic forum lighthouse status. Patrick was awarded analytics leader of the year in 2022 by the analytics institute of Ireland and is passionate in leveraging analytics to enable the future of medicine.

David Twohig

David Twohig is a Managing Director in Accenture's Life Sciences business with a focus Product Lifecycle Management and digitizing technology transfer. Prior to joining Accenture, he was the Co-lead of the Strategy Consulting Group with Enterprise Systems Partners, supporting clients with the development of their digital transformation strategies. He is a Chemical Engineer by training and has spent a number of years working for Eli Lilly and Gilead Sciences in an array of technical business roles. David was also a member of the European ISPE GAMP Committee in addition to leading the Irish GAMP affiliate. As a part of the International Society of Automation, David was the global winner of the Keith Otto Award in 2012 and won the Project of the Year 2014 within the Irish Branch.

Prof. Shingou Sakurai

Shingou Sakurai is the professor of facility of Pharmaceutical Sciences in Tokyo University of Science. After retiring from PMDA as an operating officer of inspection departments of GMP, QMS and GCTP in 2020, he has opened the laboratory of Pharmaceutical Quality Design and GMP. His research is the international harmonization of Japanese guidelines in these areas. For the human resource development of students and industries, he conducts develop research on the educational materials of GMP and GCTP. He is also a director of PDA Japan chapter and chief director of NPO Drug and Food Quality Assurance Support Center.



Dr Osamu Hiruta

Osamu Hiruta is a research professor of quality assurance / quality control laboratory at Kumamoto Health Science University since October 2020. He graduated from the University of Tsukuba in March 1980 and joined Meiji Seika Co. Ltd., where he was engaged in the development of fermentation process for APIs. 1997 PhD. Head of Quality Assurance Department, Quality Assurance Manager, Meiji Seika Pharma Co. Ltd., in 2012. He was a chairman of the quality committee of the Tokyo Pharmaceutical Manufacturers Association in 2014, and Chairman of the Quality Committee of the Federation of Pharmaceutical Manufacturers' Associations of Japan in 2018.

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Prof. Ryoko Naruse

Ryoko Naruse is a visiting professor in the "Laboratory of Pharmaceutical Quality Assurance and Assessment" established in the Faculty of Pharmaceutical Sciences at the University of Toyama in April 2022. She is on sabbatical from PMDA for 3 years and she is developing building GMP education for students and the pharmaceutical industry. She joined PMDA as a GMP inspector in 2005 after 11 years of QA experience at a pharmaceutical company. During her tenure as a manager of GMP division, she participated in the development of guidelines for GMP and GCTP in MHLW Science Research, and considered various guidance based on regulatory science.

Dr Jean Louis Robert

Jean-Louis Robert has a PhD in Chemistry from the University of Basle, followed by a PostDoc in Pharmaceutical Institute of the "Eidgenössische Technische Hochschule" (ETH) in Zurich. He joined the National Health Laboratory (LNS) in Luxembourg as he was head of the Unit Pharmaceutical Chemistry, an Official Medicines Control Laboratory (OMCL) at the LNS. He retired in March 2015. He was a member of the Committee for Human Medicinal Products (CHMP) since 1995 (co-opted member since 2004 till December 2017) at the European Medicines Agency (EMA). He was a chairman of the CHMP/CVMP Quality Working Party from 1995 to June 2017. Within the International Council on Harmonization (ICH), he was involved since 1992 in different topics as expert of the European Commission (EC) and as EC topic leader in ICH Q12. He was a chair of the European Pharmacopoeia Commission (2013-2016).

Valerie Mulholland

Valerie Mulholland is the Senior Consultant with GMP Services based in Ireland. For over 20 years she has provided Regulatory and Compliance Intelligence, including training & auditing services to the biopharmaceutical, pharmaceutical, ATMP, medical device, and blood transfusion industries. She is a researcher with the PRST with an interest in decision making within QRM and the PQS. She is the current secretary of the Irish Chapter of the PDA and is committed to the organization and moderation of PDA events for many years. She regularly networks with regulators and industry experts in emerging or topical areas of interest across the biomanufacturing industry.

Prof. Baruch Fischhoff

Baruch Fischhoff is Howard Heinz University Professor, Department of Engineering and Public Policy and Institute for Politics and Strategy, Carnegie Mellon University. A graduate of the Detroit Public Schools, he holds a BS (mathematics, psychology) from Wayne State University and a PhD (psychology) from the Hebrew University of Jerusalem. He is a member of the US National Academy of Sciences and National Academy of Medicine, and past President of the Society for Judgment and Decision Making the Society for Risk Analysis. He has served on many advisory bodies, including recent ones on science communication, intelligence analysis, cybersecurity, global change, and pandemic disease.

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Dr Emily Grayek

Emily Grayek is a postdoctoral researcher in the Department of Engineering and Public Policy, Carnegie Mellon University. Her research focuses on the nexus of technology and human behavior. Currently, she is part of the National Network for Critical Technology Assessment, supporting the (US) National Science Foundation's new Technology, Innovation, and Partnership Directorate, working with Baruch Fischhoff on public acceptance of critical and emerging technologies, with an initial focus on manufacturing technologies for generic pharmaceuticals. Emily received her PhD from Carnegie Mellon University in 2022. She received a BS in Bioengineering from the University of Missouri-Columbia in 2016. Her dissertation work focused on how to account for imperfect adherence in trials of digital health devices.

Stephanie Friedrichsen

Stephanie Friedrichsen is Director, Competitive Continuous Improvement Coach at Eli Lilly. Steph joined Lilly in 2008 as part of PR&D's Clinical Trial QA group. In 2015, she joined the Global Serialization Program where she owned the strategic plan for knowledge management, training strategy, and lean six sigma projects. Steph joined Lilly's Indianapolis Parenteral Manufacturing team in March of 2022, as a Lean Coach. Both an industry author and speaker on KM, she is a core team member on the ISPE KM Good Practice Guide and has spoken at events such as APQC's KM Conference on Lilly's use of KM, at IFPAC on behalf of the BPOG KM workstream, and at the US Federal KM exchange. She co-chaired the IFPAC KM session 2021-2022 and continues to explore the relationship between KM and OpEx.

Dr Nuala Calnan

Nuala Calnan has over 20 years experience in the bio-pharmaceutical industry across operations, new product introduction and facility start-up and manufacturing. Nuala's current focus is on the integration of Knowledge Excellence**,** Operational Excellence, & Cultural Excellence **i**n delivering enhanced quality outcomes for the patient. Nuala works across the BioPharma and Medtech industries, as well as service providers to these industries, delivering research, consultancy and training that drives innovation. She is currently an Adjunct Research Fellow with the PRST, where she teaches and leads a number of patient-focused regulatory science research projects at Masters and PhD level

Prof. Thomas Friedli

Thomas Friedli is a Professor for Production Management at the University of St. Gallen (Switzerland) and Director at the Institute of Technology Management (ITEM-HSG), where he leads a team of 15 PhD students. His main research interests are in the fields of operational excellence, global production management and management of industrial services. He studied business administration at the University of St. Gallen from 1992 to 1996. Afterwards, he was involved in numerous national and international industrial projects as a research assistant at ITEM-HSG, later as a project manager. After receiving his PhD in 2000, with highest honors, he was appointed Assistant Professor of Management and permanent lecturer in 2004 and in 2011 Associate Professor of Management, in particular Production Management.

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Michael Schousboe

Michael Schousboe is Process Manager for Quality Risk Management in Novo Nordisk, and has the overall responsibility for maintaining a well performing and compliant process of Quality Risk Management across the quality management system. Prior to this Michael has successfully managed a wide range of projects providing benefits across the organization. Currently Michael serves as Industry Expert and Deputy Topic lead for EFPIA in the ICH Working Group for revision of ICH Q9. Michael holds a master's degree in pharmaceutical science (M.Sc. Pharm.) from the Royal Danish School of Pharmacy, he is a Design For Six Sigma Black Belt and has many years of experience within the pharmaceutical industry. Michael has worked with qualification and validation within the areas of computerized systems, laboratories, as well as production of drug products and API in different Danish pharmaceutical companies. Furthermore, Michael is an experienced auditor and has served as a qualified person.

Rick Friedman

Richard L. Friedman is the Deputy Director, Manufacturing Quality, in the Office of Manufacturing Quality, which is part of the compliance office in FDA's Center for Drug Evaluation and Research (CDER). This position includes oversight of regulatory action recommendations relating to inspections and manufacturing site acceptability, and promoting sound regulatory policy development. Mr. Friedman has authored several publications on topics including sterile drugs and quality systems. Mr. Friedman has been a faculty member in Temple University School of Pharmacy's QA/RA graduate program since 2003. Prior to joining FDA in 1990, Mr. Friedman worked in the toxicology research division of Parke-Davis. Mr. Friedman received his B.S. in Biology with honors from Montclair State University in 1989, and his M.S. in Microbiology from Georgetown University School of Medicine in May 2001.

Dr Martin Lipa

Martin (Marty) Lipa has over 25 years of biopharmaceutical industry experience with 12 years in Knowledge Management (KM), as Executive Director of the KM CoE for the Manufacturing Division of Merck & Co. His prior experience includes various roles in technology, engineering, operations, software validation and IT. Marty has a PhD from TU Dublin in pharmaceutical sciences with a focus on improving KM and its interdependency with risk management, and is a Lean Six Sigma Black Belt. Marty is an active member of the global KM community as a regular speaker and author and has been recognized for his industry contributions by ISPE as the 2022 *Max Seals Yonker Member of the Year*.

Prof. Anne Greene

Anne Greene is head of Part-Time Education in the School of Chemical and BioPharmaceutical Science in TU Dublin. She leads the Pharmaceutical Regulatory Science Team (PRST) and has spearheaded the development of several MSc and BSc Pharmaceutical Programmes. She has supervised industry based executive students to PhD awards in areas of Quality Risk Management, Knowledge Management, Operational Excellence, and PQS. Prior to embarking on an academic career, Anne worked at a senior level for several years in the pharmaceutical sector in Validation and Technical Management roles. Anne has a BSc and PhD in Chemistry from University College Dublin.