EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Academia Info Day

10 November 2023
European Medicines Agency, Amsterdam

The European Medicines Agency is holding the Academia Info Day as hybrid informative event with the vision to acquaint the Academic Sector, particularly students and young professionals, with regulatory standards and practices as well as the relevance of regulatory science for medicines innovation and public health. The event contributes to the Agency's transparency about how it works and how it comes to its decisions, to the priorities of the Regulatory Science Strategy to 2025 (RSS 2025) and to the Framework of collaboration between the European Medicines Agency and academia.

Academia Info Day – updated agenda

08:30 Welcome and registration

Badge collection and possibility to interact with EMA staff at poster stations on:

- *Career opportunities*
- *Paediatric medicines*
- *EMA Public engagement*
- *Future-proofing the EMA with Academia*

09:30 Opening and welcome address

Presentation **5'**
Tony Humphreys, Regulatory Science Adviser (EMA)

09:35 Session 1: Organisation and functioning of the EMA and the EU regulatory Network

Moderator: Ralf Herold, *Ad interim Head of Regulatory Science and Academia (EMA)*

Presentation **25'**
Kristina Larsson, Head of Orphan Medicines Office (EMA)
Q&A **10'**

10:15 Session 2: Veterinary medicinal products specificities and challenges

Moderator: Maribel Rico-Salas, Academia liaison, Regulatory Science and Academia (EMA)

Presentation **15'**
Ana Vidal, Veterinary Strategic Support (EMA)
Q&A **5'**

10:35 Session 3: Engagement with Stakeholders

Moderator: Pierpaolo Moscariello, Regulatory Science and Academia (EMA)

Presentation **15'**
Ivana Silva, Healthcare professionals and learned societies liaison (EMA)
Q&A **5'**

10:50 Coffee break

11:20 Session 4. Fostering innovation in medicines

Moderator: Emmanuel Cormier, Head of Regulatory Science and Innovation Taskforce (EMA)

Engagement with Academia **20'**

Maribel Rico-Salas, Academia Liaison, Regulatory Science and Academia (EMA)

Programmes catered to academic developers: PRIME, Orphan drugs, Paediatric drugs, Advanced Therapies, Repurposing **20'**

Ralf Herold, Ad interim Head of Regulatory Science and Academia (EMA)

Innovation in medicines **20'**

Valentina Cordò, Innovation and Development Accelerator (EMA)

Q&A **20'**

12:40 Session 5. Opportunities at EMA

Moderator: Ralf Herold *Ad interim* Head of Regulatory Science and Academia (EMA)

Traineeship **15'**

IJsbrand den Rooijen, Clinical Trials Systems (EMA)

Career

Monika Hankiewicz, Head of Talent Acquisition (EMA)

Q&A **20'**

13:30 Farewell

List of speakers

Kristina Larsson Head of Orphan Medicines Office (EMA)

Ana Vidal Veterinary Strategic Support (EMA)

Ivana Silva Healthcare professionals and learned societies liaison (EMA)

Maribel Rico-Salas, Academia liaison, Regulatory Science and Academia (EMA)

Ralf Herold Ad interim Head of Regulatory Science and Academia (EMA)

Valentina Cordò Innovation and Development Accelerator (EMA)

IJsbrand den Rooijen Clinical Trials Systems (EMA)

Monika Hankiewicz Head of Talent Acquisition (EMA)

About the speakers

Kristina Larsson

Head of Orphan Medicines Office (EMA)

Kristina Larsson is the Head of the Orphan Medicines Office at EMA and the scientific lead of the Committee of Orphan Medicinal Products (COMP), a position she has held since July 2014. Prior to this she spent 8 years as a scientific officer in the scientific advice team of the EMA, mostly focusing on oncology, inborn errors of metabolism and biosimilar monoclonal antibodies. Before joining the agency, she worked three years in clinical research for AstraZeneca in Mölndal, Sweden. Kristina has a Master of Medicine in Pharmaceutical Bioscience from the University of Gothenburg.

Ana Vidal

Veterinary Strategic Support (EMA)

Ana Vidal graduated as a veterinarian in 1999, holds a PhD on Infectious diseases and a master's in Epidemiology. Her area of expertise includes food safety, zoonotic diseases and other public health issues such as AMR. Ana has held different research and policy positions both in academia and government organisations. She joined the Veterinary Division at the EMA in 2020 as an AMR Scientific Senior Specialist. Currently, she is part of the Veterinary Strategy and Support Office where she coordinates the veterinary regulatory research activities, providing support and strategic advice on One Health issues.

Ivana Silva

Healthcare professionals and learned societies liaison (EMA)

Ivana Silva joined the European Medicines Agency (EMA) in 2010. She is part of the Stakeholders and Public engagement team. Ivana was an Adviser for Pharmaceuticals and Professional Affairs (2006-2010) in the Pharmaceutical Group of the European Union (PGEU) in Brussels before moving to London. Previously, she was employed by the Portuguese Pharmaceutical Society from 1999 to 2006, where she was responsible for the development and implementation of an accreditation system for the Portuguese Pharmaceutical Sciences degrees and a system of revalidation of the professional license based on continuous professional development in Portugal. Ivana holds a master in Pharmaceutical Sciences by the Faculty of Pharmacy of the Lisbon University and a master in Business and Administration by the Portuguese Catholic University.

Maribel Rico-Salas

Academia liaison, Regulatory Science and Academia (EMA)

Maribel Rico is doctor in biomedicine and holds over 10 years of experience in translational research in the USA, where she studied the pathophysiology of renal diseases and France, where she worked on genetic instability in cancer. She is a qualified patent information professional, over the last 15 years she has worked as patent advisor, Intellectual property manager, technology transfer professional and lately as translational medicine advisor as head of the scientific information and results analysis unit in Fundación Progreso y Salud, which is the managing organization for healthcare research from the Andalucian health council. She is currently a seconded national expert in the role of Academia Liaison at the European Medicines Agency.

Ralf Herold

Ad interim Head of Regulatory Science and Academia (EMA)

Dr Ralf Herold is the ad interim Head of the Regulatory Science and Academia Workstream of the EMA's Regulatory Science & Innovation Taskforce, covering Regulatory science research and external involvement as well as Academia liaison and Not-for-profit developers support. Previously, he worked as senior scientific officer with stakeholders on oncology, haematology & diagnostic as well as paediatric medicines, starting 2007 at the Agency. Ralf was the Pediatric development leader of Bayer AG, Regulatory affairs from 2017 to 2018, involved for BIO in ICH E11A. At Humboldt University Berlin (1994-2007), he obtained an experimental research PhD, board-certified in Paediatric and adolescent medicine, trained in Paediatric oncology and haematology, and managed a national clinical research network.

Valentina Cordò

Innovation and Development Accelerator (EMA)

Valentina Cordò is a biomedical scientist by training. She holds a master's degree in biomedical sciences from Leiden University (the Netherlands) and a PhD in cancer biology from Utrecht university (The Netherlands). After working at the Princess Máxima Center for Pediatric Oncology in Utrecht, Valentina joined the EMA in 2022. She is currently working as scientific specialist in the Regulatory Science and Innovation task force of the agency where she coordinates the early support activities offered by the EMA to developers of innovative medicinal products and emerging technologies for drug development.

IJsbrand den Rooijen

Clinical Trials Systems (EMA)

IJsbrand den Rooijen is a health data scientist in the Data Analytics and Methods Task Force at EMA. He has a BSc in Medicine from Maastricht University and MSc in biomedical science from Leiden university. He has experience building machine learning solutions in clinical and lab settings and was a trainee at EMA within the Healthcare Data workstream. He is currently the clinical trial analytics lead within the Clinical Trials Systems team and is trying to identify how data on clinical trials can better support the EMA and EU research needs.

Monika Hankiewicz

Head of Talent Acquisition (EMA)

Monika Hankiewicz-Klopotek is a Head of Talent Acquisition at the EMA, leading a service responsible for selection and recruitment of statutory staff (temporary/contract agents), Seconded National Experts, and Collaborating Experts. Her service also manages two programmes – Interim Support and Traineeship programme. Prior to this for over 15 years she worked for various international organisations (e.g. North Atlantic Treaty Organization), and has lived not only in Belgium and the Netherlands, but also in Iran and Afghanistan where she gained appreciation for working for a purpose and with people from various cultures.