European Innovation Council

EIC – EMA INFO DAY:

Regulatory support for the development of innovative medicines and technologies

Speaker's biographies

EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH

Emer
COOKE

Executive Director of the European Medicines Agency

[EMA]

Biography

Emer Cooke is as of November 2020 the Executive Director of the European Medicines Agency. She also takes the role of Chair of the International Coalition of Medicines Regulatory Authorities (ICMRA) for a term of 2 years.

She was the Director responsible for all medical product-related regulatory activities at the World Health Organization in Geneva between November 2016 and November 2020. In this role, Ms Cooke was responsible for leading WHO's global work on regulation of health technologies (medicines, vaccines, diagnostics, vector control products and devices), coordinating the regulatory teams (prequalification, regulatory systems strengthening, and safety), and working with member states and international partners to assure the quality, safety and efficacy of appropriate health technologies. Ms. Cooke is a pharmacist with Masters degrees in Science and Business Administration from Trinity College Dublin.

She has over 30 years' experience in international regulatory affairs and spent 14 years (2002 to 2016) in management positions at EMA as Head of Inspections and Head of International Affairs respectively.

From September 1998 to July 2002, she worked in the Pharmaceuticals unit of the European Commission.

Jean-David
MALO

Director of the European Innovation Council and SMEs Agency [EISMEA]

Biography

Jean-David Malo is as of April 2021 the Director of the Agency for EIC and SMEs - EISMEA.

He was Head of Unit in charge of: regional aspects in DG R&I (2006-2010), increasing private finance and closing market gaps by expanding existing EU innovative financial instruments and by developing new ones in the fields of debt (including guarantees) and equity financing (InnovFin) (2011-2013), supporting Horizon 2020 SMEs (EUROSTARS II, SME Instrument and Fast Track to Innovation) and on Financial Instruments and State Aids (2014-2017).

As Director for Open Innovation and Open Science (2017), he designed and expanded initiatives such as the VentureEU Initiative and the RDI dimension under the European Fund for Strategic Investments (EFSI).

In 2019, following the European Council's request to set up the European Innovation Council (EIC), he was appointed Director of the EIC Task Force.

Iordanis
ARZIMANOGLOU

EIC Program Manager for Health and Biotechnology, European Innovation Council and SMEs Agency [EISMEA]

Biography

Iordanis Arzimanoglou has a thirty-year postdoctoral international career at the crossroads of genetics and innovation, having held research and senior management positions at operational and strategic levels.

Since June 2020, he has been Programme Manager for Health and Biotechnology at the European Innovation Council (EIC), where he is responsible for developing visions for technological and innovation breakthroughs.

Dr Arzimanoglou has previously worked as an EIC Coach and Senior advisor to genetic diagnostic, therapeutic and drug discovery start-ups and SMEs in eleven different European countries. In addition, he helped the Research Executive Agency (REA) and European Institute of Innovation & Technology (EIT). He was the Chief Executive Officer of the Thessaloniki Innovation Zone managing company, and prior to that, Chief Executive Officer of the Aarhus Biotech Cluster managing company, Denmark. In both Chief Executive Officer appointments, he managed complex portfolio and shareholder interests and expectations in a cross-functional matrix setting and supervised the drafting of strategy plans. As an academic, he was Adjunct Associate Professor at the Department of Biomedicine, Aarhus University.

Earlier in his career, he was Assistant Professor of Molecular Genetics at Weill Medical College of Cornell University, New York and prior to that, he was Chief of Cancer Genetics Research Program at Lennox Hill Hospital, New York. Before joining Lenox Hill, he was a research scientist in the Division of Medical Genetics at Weill Medical College of Cornell University, New York.

He holds a PhD from the University of Athens in Molecular Genetics and Biochemistry, a Boston University Graduate Certificate in international business management, and performed his postdoctoral work in the Department of Medicine at Weill Medical College of Cornell University, New York.

Enric
CLAVEROL-TINTURÉ

EIC Programme Manager for medical technologies and medical devices, European Innovation Council and SMEs Agency [EISMEA]

Biography

After engineering studies at the Technical University of Catalonia, Enric Claverol-Tinturé obtained a PhD in engineering and neuroscience from the University of Southampton.

He became a postdoctoral fellow at the California Institute of technology, returning to Europe as a Ramon y Cajal fellow, becoming a tenured academic at the Barcelona-based Bioengineering Research Centre.

He then left academic life to run his spin-off company, Aleria Biodevices, after which he became the director general of the Catalonia Foundation for R&I (FCRi), coordinating funding to support ground-breaking technologies.

He also founded Afferent Technologies, a medical technology start-up.

Leonor
ENES

Scientific Officer, SME Office, Regulatory Science and Innovation Task Force, European Medicines Agency [EMA]

Biography

Leonor Enes is a senior scientific officer in the European Medicines Agency (EMA) SME Office. She joined the EMA in 2004 as an experienced manager leading regulatory, quality control and production teams in the pharmaceutical industry.

From 2004 to 2013, she was a Product Team Leader (PTL) in the Anti-infectives Office focusing on HIV therapeutics. In 2014, she moved to the Procedure Management Department where she handled innovative marketing authorisation applications. In 2016, she joined the SME Office where she is a senior member supporting early interactions on product development, actively involved in stakeholder engagement and training activities.

In the first half of 2021 she temporarily returned to the Anti-infectives Office to help support its COVID efforts. Leonor Enes studied Pharmaceutical Sciences at Lisbon University, Portugal and has a Master in Drug Regulatory Affairs (University of Bonn, Germany).

Falk
EHMANN

Scientific Officer, Regulatory Science and Innovation Task Force, European Medicines Agency [EMA]

Biography

Falk Ehmann is a medical doctor with a degree in European and International Law. He is currently working at the European Medicines Agency (EMA) in the Regulatory Science and Innovation Task Force.

His main responsibilities include co-chairing the EU Innovation Network and managing and chairing the EMA's Innovation Task Force promoting research and development of innovative substances, methodologies and technologies.

Falk Ehmann wrote his PhD thesis on Molecular Intra Cellular Cell Signalling at the Institute of Biochemistry and Molecular Biology at the University Hospital Hamburg-Eppendorf.

His Master Thesis discusses coping mechanisms and responses of European Health Care Systems to the 2009 H1N1v Influenza Pandemic.

Igor
BALAZ

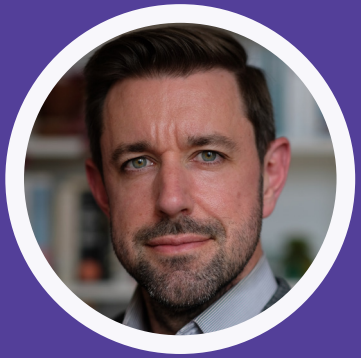
Professor of Biophysics at the University of Novi Sad

Biography

Igor Balaz is a professor of Biophysics at the University of Novi Sad, Serbia.

His main research interests are machine learning and modelling biological systems. He is the author of more than thirty peer-reviewed papers, book chapters, monographs and editorials.

He has been the leader of three EU-funded Horizon projects, including the EIC Pathfinder project EVO-NANO, focused on nanomedicine–based drug delivery systems, tumor modelling, and bio-hybrid machines.



Kevin
CUNNINGHAM

PRIME Scientific Coordinator, Human Medicines Diuision , European Medicines Agency [EMA]

Biography

Dr. Kevin Cunningham is the PRIME Scientific Coordinator at the European Medicines Agency.

He previously worked as a non-clinical assessor at the Health Products Regulatory Authority (HPRA), Ireland, before joining EMA in 2015, most recently as a scientific officer in the EMA Scientific Advice Office.

He holds a degree in pharmacology and a PhD in biomolecular and biomedical science from University College Dublin.

Spiros
VAMVAKAS

Scientific Adviser on Human Medicines, Human Medicines Division [EMA]

Biography

Spiros Vamvakas is a medical Doctor (University of Würzburg, Germany), a board-certified specialist in pharmacology and toxicology (Bavarian Chamber of Physicians) and associate Professor for pharmacology and toxicology (University of Würzburg, Germany).

Since 1984 he held positions in the department of pharmacology and toxicology in the university clinic of Würzburg and in the department of pharmacology at the medical centre of the university of Rochester (NY, USA). He joined EMA in 1999 and his activities over the years included the establishment of orphan drug designation, scientific advice/ protocol assistance including the qualification of novel methodologies and parallel scientific advice with health technology assessment bodies and payers. Between 2003 and 2016 he had various roles representing EMA in ICH.

In 2020 he was appointed CHMP scientific lead and adviser on human medicines including COVID-19 products and guidelines. He has an active teaching appointment in clinical pharmacology at the university clinic of Würzburg.

Since 2019 he is associate editor of the Clinical Pharmacology and Therapeutics journal.

Iordanis
GRAVANIS

Head of the Scientific Advice Office, Human Medicines Division , European Medicines Agency [EMA]

Biography

Iordanis Gravanis holds a medical degree from the University of Ioannina, Greece and a PhD in Molecular and Cellular Pharmacology from Stony Brook University, NY, USA. His thesis research revolved around neurodegenerative models of excitotoxicity in mice.

He joined the EMA in 2008 and worked initially in the Oncology, Haematology and Diagnostics Section as EMA Product Team Leader for centralised marketing authorization applications and post-authorisation lifecycle applications.

In 2014, he moved to the Procedure Management Department supporting the improvement of the medicines authorisation and post-authorisation processes and the EMA IT tools which support such processes.

Since 2020, he has been heading the Scientific Advice Office which supports scientific advice/protocol assistance including the qualification of novel methodologies, parallel scientific advice with health technology assessment bodies and scientific advice for public health emergencies.

Gemma
FIERRO

Clinical & Regulatory Affairs VP, Ability Pharma

Biography

Gemma obtained a BSc degree in Pharmacy from the University of Barcelona and a Master degree in European Regulatory Affairs from the Autonomous University of Barcelona.

Gemma has a broad experience in the regulatory area acquired in several pharmaceutical companies. She started at Lacer, S.A., from 1990 to 1993, as Regulatory Affairs manager.

From 1993 to 1997, she worked at Merck Farma y Química as Senior Regulatory Affairs manager.

From 1998 to 2004, she was Head of Regulatory Affairs at Laboratorios Vita, S.A.

Then, with the acquisition of Grupo Vita by Procter & Gamble in 2004, she became Regulatory Affairs Director for Spain and Portugal, assuming additional responsibilities in pharmacovigilance until 2009.

After the acquisition from Warner Chilcott, Gemma assumed the regulatory responsibilities for all European countries from 2009 to 2012.

After that, Gemma was appointed as Head of Regulatory Affairs in Bayer Hispania, SL, from 2012 to 2014, assuming responsibilities in clinical trials submissions as well.

Gemma joined Ability Pharma in 2015 as Clinical & Regulatory Affairs VP.

Carles
DOMÈNECH

Cofounder and CEO of Ability Pharma

Biography

Carles obtained a BSs/MSc degree in biology (first class honours) from the Autonomous University of Barcelona and also a PhD degree in cellular biology from the same University, working at the Council of Science Research (CSIC).

He has additional business training at ESADE business school and other business programs. After his career in CSIC in Barcelona (1985-89) and at Memorial Sloan-Kettering Cancer Center in New York (1990-1992), he held senior positions at Almirall, SA (1992-2003) as Manager and Head of Business Development and Licensing and Lacer, SA (2005-2007) as Director, Business Development and Licensing.

Carles has also 4 years experience in biotech venture capital and business angels associations and has also been collaborating with government innovation agencies. Between 2004 and 2005 he was Director, Biotech Investments at the seed venture capital firm Barcelona Emprèn, SCRSA.

During 2008-2009 he collaborated with agencies of the Government of Catalonia as Director, Technology Transfer and Valorization and as Managing Director, Investment and Enterprise Growth. He had under his responsibility the seed venture capital company Invertec, SA and the entrepreneurship finance programs Genesis Capital and Concept Capital.

Since July 2009 he also advises Keiretsu Forum Barcelona in biotech investments. In 2009 Carles cofounded Ability Pharmaceuticals, SL to become its Chief Executive Officer in September 2009.

Piotr
TRZONKOWSKI

CEO of PolTREG S.A.

Biography

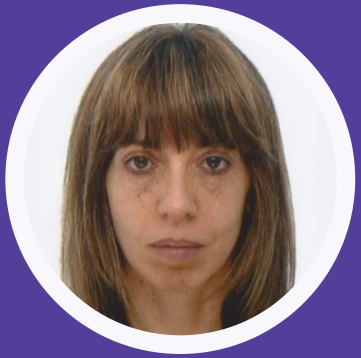
Piotr Trzonkowski isprofessor of Immunology, actively involved in clinical research with T regulatory cells and mechanisms of immunosuppression for over 20 years.

His group developed and applied first-in-man protocols of the treatment with expanded T regulatory cells. In 2003 Dr. Trzonkowski defended his Ph.D. thesis on the suppressive mechanisms in human immunosenescence, which included his first works on T regulatory cells. From 2004 at the Oxford University, he worked on the immune background of the depleting therapy with alemtuzumab in kidney transplant recipients. He was also involved in the work on T regulatory cells biology.

These studies were continued in Poland as PI in the Department of Medical Immunology, Medical University of Gdańsk and also as a visiting professor in the Department of Surgery, University of Chicago. The trials on clinical application of T regulatory cells supervised by prof. Trzonkowski covered graft versus host disease, type 1 diabetes, multiple sclerosis and pancreatic islets allotransplantation.

In 2015, he set up a spin-off PolTREG in order to commercialize the therapy. His group conducts research in novel approaches to cellular therapy in autoimmune and malignant diseases in man, synthesis of immunosuppressive small-particle drug candidates and posttransplant laboratory diagnostics in allograft recipients.

In 2017, he has been awarded with the highest scientific award in Poland, the Foundation for Polish Science Prize in the life and earth sciences in 2017.



Barbara
GERRATANA

Programme coordination manager at the European Innovation Council and SMEs Agency [EISMEA]

Biography

Barbara Gerratana is a programme coordination manager at the European Innovation Council and SMEs Agency (EISMEA)in the European Innovation Council (EIC) Pathfinder Unit handling a portfolio of projects in synthetic biology, regenerative medicine, and engineered living materials for which she developed the 2021 EIC Call.

After graduating in chemistry from the University of Pavia, Barbara received her PhD in biochemistry from the University of Wisconsin, Madison working in mechanistic enzymology for drug development.

In 2004, after a post-doc in natural products biosynthesis at The Johns Hopkins University, she became assistant professor and then associate tenured professor at the University of Maryland- College Park. Her research group funded by National Institute of Health (NIH) worked on drug target characterization for infectious diseases and bioengineering for cancer drug development.

In 2010 Barbara joined NIH as a programme manager managing portfolios of projects in biotechnology and biocatalysis; and developing programmes and policy in biotechnology with focus in microbiome and synthetic biology representing NIH and cooperating with other US funding agencies and departments as well as the Office of Science and Technology Policy of the White House.

Before coming back to Europe in 2017, Barbara was a programme leader in the Office of the NIH Director managing and implementing Common Funds programmes in Metabolomics, the Druggable Genome, and Molecular Transducers of Physical Activity.

Tony
HUMPHREYS

Head of the Regulatory Science and Innovation Taskforce, European Medicines Agency [EMA]

Biography

Tony Humphreys is the Head of the Regulatory Science and Innovation Task Force (TRS). He is responsible for providing leadership in the Task Force and the Agency to enable its continuous future proofing through operation of a regulatory science observatory, addressing key scientific and technological trends and their translation through the development of regulatory science strategy, planning and governance.

Tony started work in 1983 in the area of development pharmaceutics for a national branded generics manufacturer and an international research and development company before moving into international regulatory affairs in 1991.

He joined the EMA in May 1996 and fulfilled a variety of managerial positions including Head of Sector Regulatory Affairs and Organisational Support (2000-2009) and Head of Sector for Regulatory, Procedural and Committee Support (2009-2013), Head of Scientific Committee Support Department (2013-2016), Head of Procedure Management and Committees Support Division (ad interim) (2015-2016) and Head of Scientific Committees Regulatory Science Strategy (2016-2020).

In the context of the most recent organisation at the Agency from 1st March 2020, he was appointed Head of the Regulatory Science and Innovation Taskforce.