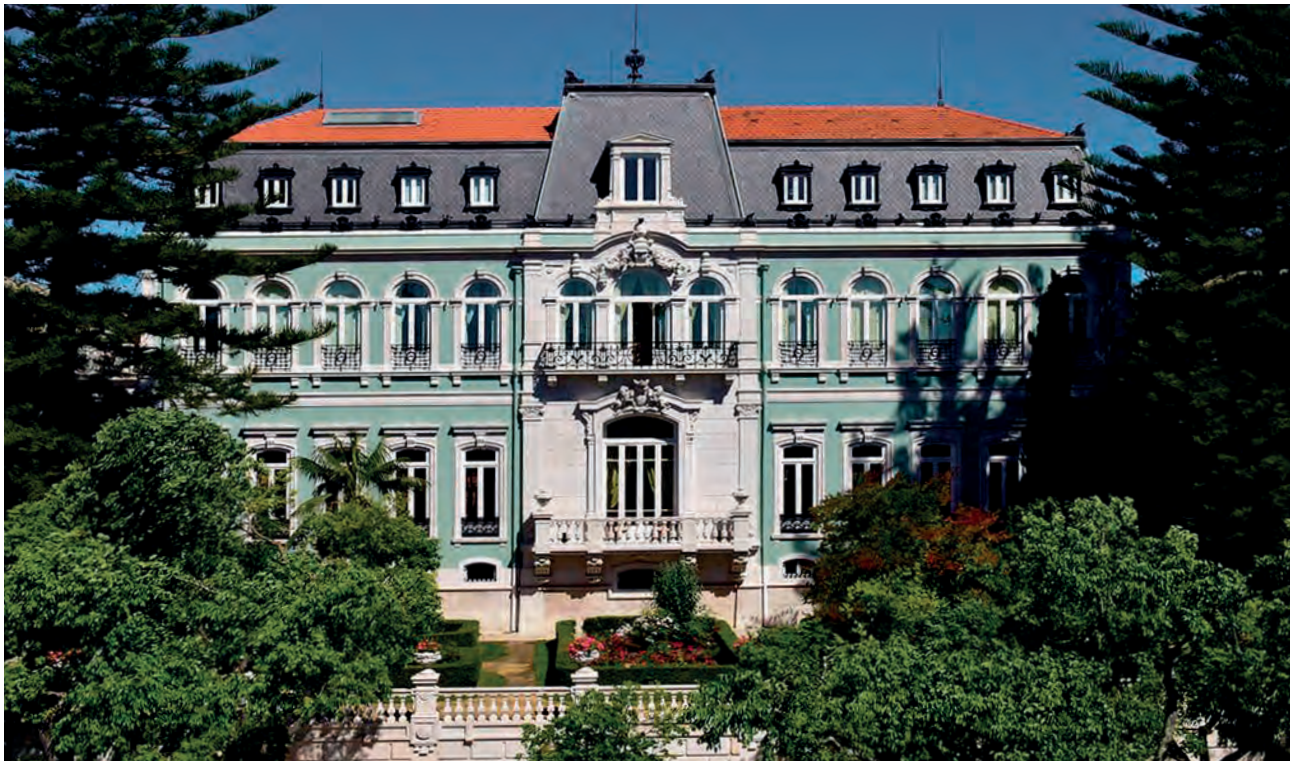
# 2023 IPEC EUROPE ANNUAL EXCIPIENTS FORUM THURSDAY 16 MARCH 2023


the future of excipients is in our hands

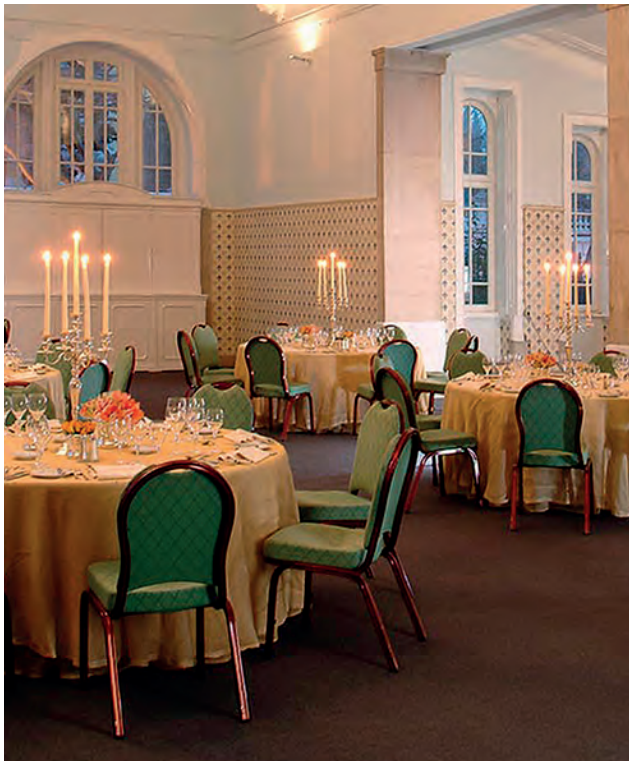
IPEC EUROPE

PROGRAMME
THURSDAY 16 MARCH 2023
PESTANA PALACE
LISBON, PORTUGAL



## FORUM DINNER

After the IPEC Europe Excipient Forum ends, we look forward to welcoming you to the Cocktail Reception and the Forum Dinner, taking place in the old Stables of the Pestana Palace. The old Stables are opposite the entrance of the Pestana Palace Hotel. The meeting point is at the entrance of the hotel at 19:30.



2023
IPEC EUROPE
EXCIPIENTS
FORUM

# FORUM PROGRAMME

## THURSDAY 16 MARCH 2023

**9:00** **Opening Remarks**
*Amina Faham, IFF / Chair, IPEC Europe*

**MORNING SESSION**
*Moderated by Frank Milek, Hedinger*

**9:10** **Updates from the EDQM and the European Pharmacopoeia**
*Petra Doerr, EDQM*

**9:50** **Establishment of standard system for pharmaceutical excipients: from CHP 2020 to further**
*Jiasheng Tu, China Pharmaceutical University*

**10:30** **Coffee Break**

**11:00** **USP's Iterative approach to Excipients Standards Development and its application to novel excipients**
*Catherine Sheehan, USP*

**11:40** **Application of EXCiPACT Certification Scheme to Pharmaceutical Auxiliary Materials (PAMs)**
*Iain Moore, CRODA / Immediate past President, EXCiPACT*

**12:20** **Success through Excipient QbD Efforts – Your recipe for success**
*Mohammad Qadir, IFF*

**13:00** **Lunch Break**

**PANEL SESSION**
*Moderated by Adrian Bone, IPEC Europe*

**14:00** **Sustainability and Excipients**
*Geertrui Haest, Cargill / Robert Williams, AstraZeneca*
*Petra Doerr, EDQM / Catherine Sheehan, USP*

**AFTERNOON SESSION**
*Moderated by Mahmud Yunis, BIOGRUND*

**15:00** **Developability Classification System (DCS): Enabling an Optimized Approach for Formulation of Poorly Soluble Molecules**
*Markus Lubda, Merck KGaA*

**15:40** **Coffee Break**

**16:00** **Pre-competitive data sharing to support ICH Q3D risk assessments**
*Grace Kocks, LHASA Limited*

**16:40** **Nitrite & Nitrate and Nitrosamines in excipients and mitigation strategies – an excipient suppliers' view**
*Rodrigo Arias, DFE Pharma*

**17:20** **Q&A – Afternoon Session**
*Moderated by Mahmud Yunis, BIOGRUND and Frank Milek, Hedinger*

**17:40** **Closing Remarks**
*Amina Faham, IFF / Chair, IPEC Europe*

*Programme subject to change.*

# SPEAKERS & MODERATORS

IN ORDER OF APPEARANCE:

## Amina Faham

**Vice-President, Global Research & Development Pharma Solutions for International Flavors & Fragrances (IFF) and Chair, IPEC Europe**

Amina is a highly effective senior leader with several years of experience in leadership, generating business growth through technology expertise and creating value for customers utilizing business acumen. Amina earned a PhD degree in Pharmaceutical Sciences from the school of Pharmacy, University de la Mediterranean France. She has over 15 years of Healthcare industry experience and has worked for several pharmaceutical and chemical companies. Amina offers an array of skills in customer-centric cultures, logical problem solving, and cross-functional collaboration, team leadership, strengthening competitive position, business development and talent acquisition. Since 2022, Amina is Vice-President, Global Research & Development Pharma Solutions for International Flavors & Fragrances (IFF).

## Frank Milek

**Head of GMP and SHEQ Operations, Aug. Hedinger**

Dr. Frank Milek is an industrial pharmacist and has been working in pharmaceutical excipients industry for more than 20 years, specialised in the field of supply chain and distribution. He is registered QP according to EU regulation and responsible at Aug. Hedinger GmbH & Co. KG for Quality, Regulatory Affairs and GMP.

## Petra Doerr

**Director, European Directorate for the Quality of Medicines & HealthCare (EDQM)**

Dr. Petra Doerr (pharm. D; PhD) is the Director of the European Directorate for the Quality of Medicines and HealthCare (EDQM), since October 2021. Following the first ten years in the medical products industry, working in international regulatory affairs, she joined Swissmedic, Swiss Agency for Therapeutic Products, in October 2004 as the Head of International Affairs. In 2007, she became a member of the management board and from 2014 to 2019, she served as Head of Communication & Networking and Deputy Executive Director. From July 2019 to October 2020, she provided consultancy services to the WHO, and then joined the WHO as the Head of Unit Regulation and Safety in November 2020.

## Jiasheng Tu

**Professor, China Pharmaceutical University**

Jiasheng Tu is the professor of pharmaceutics of China Pharmaceutical University, a supervisor of doctorate students. Dr. Tu has also served as the chair of CHP pharmaceutical excipient committee, an expert committee member of CHP, an expert committee member of pharmaceutical excipient of USP. Dr. Tu graduated from Beijing Medical University. He was awarded PhD of pharmaceutics in China Pharmaceutical University at 1992 and did postdoctoral researches in University of the Pacific, CA, during 2001 – 2003.

## Catherine Sheehan

### Senior Director, Foods and Excipients – Global Science and Standards, US Pharmacopeia

Dr. Sheehan is currently the Senior Director of Growth Programs, Foods and Excipients under the Global Science and Standards Division at the United States Pharmacopeia (USP), Rockville, MD. In her current role, she supports USP's mission and priority initiatives for strengthening the global supply of quality medicines and foods. Her responsibilities also include partnering through USP's Stakeholder Engagement Model to improve awareness and advocating for adoption of new and up-to-date quality standards and related programs around the globe.

## Iain Moore

### Global Head of Quality Assurance, Croda International and immediate Past President, EXCiPACT

Dr. Iain Moore is the Global Head of Quality Assurance at Croda International. He has contributed to the publication of European and US National Standards, many IPEC Guides and papers, and the EFfCI GMP Guide for Cosmetic Ingredients. He is the current chair of the EFFCI GMP Committee and is the immediate past President of the Board of EXCIPACT asbl.

## Mohammad Qadir

### Application development and Innovation Scientist, IFF

Mohammad Qadir holds a degree in Pharmacy, a Master's in Pharmaceutical Analysis and a PhD in Drug Delivery and Formulation Design. Dr. Qadir has over 14 years of experience in the pharmaceutical industry and academia, particularly in formulation design and delivery of various dosage forms. His focused areas and expertise are in controlled, sustained, delayed and pulsatile delivery. He mostly worked in R&D and possesses extensive experience in drug product and combined device development from proof of concept to clinical trials. He previously worked with multinational companies within the UK and abroad. In his current role he is actively involved in new product development, application development work and multivariate analysis.

## Adrian Bone

### Senior Advisor, IPEC Europe

Adrian Bone is the Executive Secretary of the IPEC Federation. He graduated in Pharmacy from the University of London in 1979. Thereafter, he pursued a career of 35 years in the pharmaceutical industry working primarily in Quality assurance in several international roles. He also served as Chair of IPEC Europe for two terms and is currently the Senior Advisor for IPEC Europe.

## Geertrui Haest

### Scientific & Regulatory Affairs Manager EMEA, Cargill

Geertrui Haest is Scientific & Regulatory Affairs Manager EMEA at Cargill. Cargill has a broad range of products supplied to the pharmaceutical industry, both as excipients or active pharmaceutical ingredients. She has more than three decades of experience in product development, application support to customers and regulatory support for EMEA markets. Geertrui is an expert member of the carbohydrate working party of the EDQM and as such she is involved in the development of carbohydrate product monographs in the Ph. Eur. As a member of IPEC Europe's Quality and Regulatory Affairs working group, she is part of the team compiling IPEC's new Sustainability chapter for the IPEC Excipient Information Package Guide.

# SPEAKERS

## Robert Williams

### Director, Sustainable Procurement, AstraZeneca

Robert Williams is Director of Sustainability in AstraZeneca's ONEProcurement team, working with the global supply chain to deliver AZ Sustainability goals. Lead on reducing Scope 3 emissions towards Net Zero, driving Responsible Supply Chain and supporting the Power of Diversity to inspire innovation. Focus on developing high performing supply chains to deliver truly sustainable business growth. Co-lead for PSCI Decarbonization Topic Team; lecturer in energy procurement for the Energy Institute; member of Durham University's Energy & Industry Board (DEI).

## Mahmud Yunis

### Technical Director, BIOGRUND

Dr. Mahmud Yunis has been working for over 15 years at BIOGRUND in several positions. In his current function as Technical Director, he is responsible for preparing and implementing global strategic regulatory plan for BIOGRUND products and the strategic development of the Quality, Production and R&D department. He has a PhD degree in Analytical Chemistry from University of Muenster, Germany. Before joining BIOGRUND he worked for a consulting company on the area of GxP procedures and processes for five years.

## Markus Lubda

### Strategic Marketing Manager – Excipients Solid Application, Merck KGaA

Markus Lubda holds a PhD in Bio/Chemistry from the Technical University of Darmstadt, Germany and is by academical education a Biomolecular Engineer. He is responsible for the strategic development and positioning of an excipient portfolio for oral solid dosage form applications. Thereby the focus is to enhance solubility and bioavailability of the most challenging APIs with specifically engineered excipients.

## Grace Kocks

### Principal Application Scientist, LHASA Limited

Grace Kocks is a Principal Application Scientist in Lhasa Limited's Applied Sciences Team. She joined Lhasa in 2013 as a Scientist, after achieving her BSc at the University of Leeds in Biomedical Science. She has continued to build on Lhasa's strong reputation for facilitating data sharing and is proud to co-chair two industry data sharing consortiums. The first aims to aid ICH Q3D elemental impurities excipient risk assessments, and the most recent focuses on sharing excipient nitrites levels to aid compiling nitrosamine risk assessments.

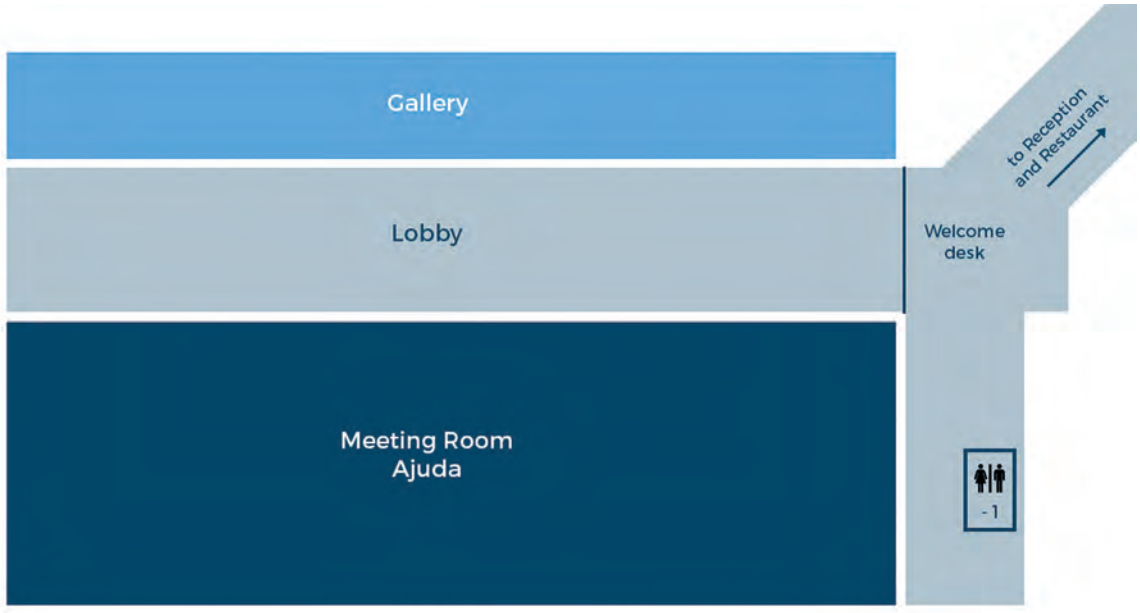
## Rodrigo Arias

### Technical Sales Manager Direct Business EMEA, DFE Pharma

Rodrigo Arias holds a degree on industrial and process engineering, a master's in international business and diplomas on pharmaceutical production processes, high speed tableting, and international logistics. He worked at Novartis manufacturing site in the engineering projects and maintenance department. At DFE Pharma, since 2010, he has had several responsibilities in Latin America and EMEA regions, always with focus on tech support and quality-based sales. He has joined key tasks such as QbD training for global distribution network and business development for 3D printing and Dry Powder Inhalation. Since 2020 a permanent member of the GDP committee at IPEC Europe.

# GENERAL INFORMATION

## FLOORPLAN




## USEFUL INFORMATION

### WI-FI

High-speed Wi-Fi is available to all attendees.

WLAN: **Pestana Guest**

### ORGANISATION

For all queries, please contact:

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26-27 September 2023 - Rotterdam, The Netherlands

the future of excipients is in our hands

IPEC EUROPE

IPEC Europe Excipient Conference 2023

– An update on regulatory developments and excipient applications in Drug Delivery –

## ABOUT IPEC EUROPE

IPEC Europe, the International Pharmaceutical Excipients Council, has been a powerful voice in Europe's excipients industry since 1992. We bring together producers, distributors and users of pharmaceutical excipients to share best practices and develop harmonised standards.

Since 2010, together with its sister associations, IPEC Americas, IPEC Japan, IPEC China and IPEC India, IPEC Europe is a member of IPEC Federation whose global membership extends to more than 250 companies. In 2008, IPEC Europe initiated with other industry experts the development of a certification scheme for excipients suppliers that has become in January 2014 the free-standing association EXCiPACT.

Our goal is that the joint expertise of our members is voiced and heard. IPEC Europe is a progressive organisation, focused on sharing knowledge. We encourage learning through networks and experience, offering an informal and welcoming space to exchange ideas, science-based insights and information, with a strong emphasis on cooperation.

## THIS PROGRAMME IS SPONSORED BY

BIOGRUND

Since 1999, BIOGRUND has been the specialist for the homogeneous mixing of excipients and carriers. With locations in Germany, Switzerland, America and Russia, we support the food supplement and pharmaceutical industry in the development, formulation and production of solid oral dosage forms. The tailor-made and ready-to-use special powder mixtures for film coating, sugar-coating, coloring and tableting enable optimum results in a short time. Easy, fast and reliable!

## THE 2023 IPEC EUROPE ANNUAL EXCIPIENTS FORUM IS SPONSORED BY

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