2022 IPEC EUROPE EXCIPIENTS FORUM

30th ANNIVERSARY

23 June 2022 – Brussels

IPEC EUROPE 30 YRS

PROGRAMME
THURSDAY 23 JUNE 2022
LE LOUISE M GALLERY HOTEL
BRUSSELS, BELGIUM

COCKTAIL RECEPTION AND FORUM DINNER

A special place for a special event… we look forward to welcoming you at the BELvue Museum, a Brussels gem, all about Belgian history and its democracy.

A visit of the Coudenberg Palace will be organised just for you. The Coudenberg Palace towered over the city of Brussels and hosted the most powerful rulers of Europe for many centuries, until it was consumed by a terrible fire in 1731. Today, these ruins constitute a fascinating archaeological site incorporating a network of underground passages and chambers.

Don't forget to bring something warm to wear and comfortable shoes for the visit: the temperature is around 15 degrees year round!

Throughout the evening, we will celebrate with you not only 30 years of existence but also 10 years of EXCiPACT operations. Rendez-vous at 18:00 in the hall of the MGallery!

18:30 Cocktail Reception
19:00 Visit of Coudenberg Palace
20:00 Forum Dinner

2022
IPEC EUROPE
EXCIPIENTS
FORUM

FORUM PROGRAMME

THURSDAY 23 JUNE 2022

9:00 **Opening Remarks**
Frithjof Holtz, Merck / Chair, IPEC Europe

MORNING SESSION

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

9:50 **Novel Excipients – the need, regulatory challenge and FDA Pilot Review programme**
Nigel Langley, BASF USA

10:30 **Coffee Break**

11:00 **Comparison of Pharmaceutical Excipients and Food Ingredient Requirements**
Matthias Rheinheimer, Merck

11:40 **Co-Processed excipients: securing their future in Europe**
Christian Becker, BASF and Darek Lewin, JRS Pharma

12:20 **Q&A – Morning Session**

12:35 **Lunch Break**

AFTERNOON SESSION

13:30 **How to ensure Pharmaceutical Product Success through Excipient QbD Efforts**
Mohammad Qadir, IFF

14:10 **Lipid Excipients in mRNA delivery**
Lars Albermann, Merck

15:00 **COFFEE BREAK**

15:30 **Stability understanding of excipients for solid-based biopharmaceutical products**
Wouter Hinrichs, University of Groningen

16:10 **A regulatory update on Titanium Dioxide**
Kevin Hughes, Colorcon

16:40 **Q&A – Afternoon Session**

16:55 **Closing Remarks**
Frithjof Holtz, Merck / Chair, IPEC Europe

Programme subject to change.

SPEAKERS

Frithjof Holtz

Senior Expert Regulatory Intelligence Life Science, Regulatory Management, Merck KGaA and Chair, IPEC Europe

Frithjof Holtz is a biologist and has been working for almost 30 years with Merck KGaA, Darmstadt, Germany, having many years of experience in quality assurance and regulatory affairs. Besides experience in chemical manufacturing (excipients/APIs) he has also working experience in quality assurance for drug products (sterile/non-sterile). Furthermore, he is now working for almost 15 years in Regulatory Affairs (CMC) for pharmaceutical starting materials. Currently he is responsible for the coordination of the advocacy & surveillance activities of Merck Life Science.

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 that WHO as the Head of Unit Regulation and Safety in November 2020.

Nigel Langley

Global Technology Director, BASF USA and Chair, IPEC-Americas

Nigel Langley is the current Chair of IPEC-Americas (2022-2024) and Global Technology Director, BASF Pharma Solutions. Dr. Langley has contributed to more than 100 scientific publications and received the IPEC Foundation Award for Industry Research Achievements in Excipient Technology in 2018. He has been included on the Medicine Maker Power List for small molecules in 2020, 2021 and 2022.

Matthias Rheinheimer

Senior Consultant – Food Quality & Regulatory Compliance, Merck KGaA

Dr. Matthias Rheinheimer works as Senior Consultant – Food Quality & Regulatory Compliance at the Life Science business of Merck KGaA, Darmstadt, in the Regulatory Management team. As an expert for pharma and food materials, he is working on various projects in product development and maintenance, marketing initiatives, customer service, quality, and supplier qualification.

Christian Becker

Pharmacist / Apotheker, Global Regulatory and External Affairs Pharma, BASF

Christian Becker studied pharmacy at the Ruprecht-Karls-University in Heidelberg, Germany. He joined BASF in 2004 and gained a global expert function in Regulatory Affairs with a focus on Novel Excipients and co-processed excipients.

Darek Lewin

Head of Quality, J. Rettenmaier & Söhne GmbH + Co. KG (JRS Pharma)

Darek Lewin graduated in “Technology of Renewable Raw Materials” in 2001 at the University of Applied Sciences Hannover. In 2003, he was employed as the Project Manager for “Microencapsulation of Probiotic Bacteria” at J. Rettenmaier & Söhne GmbH & Co. KG, Rosenberg, Germany, a world-wide, dynamic leader in the fiber industry. JRS provides with their fiber products solutions for various applications and chemical processes for almost every field of daily life, i.e. for pharmaceutical and food applications, or for technical and industrial use. From 2004 to 2006, he was responsible as the Food and Feed Safety Manager and then as Corporate Quality Manager for JRS Pharma GmbH & Co. KG. JRS Pharma is currently the biggest producer of Microcrystalline Cellulose world-wide. Additionally, JRS Pharma serves the pharmaceutical industry with a family of high functional solid excipients. Since 2007, Darek Lewin is the Head of Quality for the JRS Group with production plants in Europe, USA, India, China and Mexico.

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. Mohammad 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.

SPEAKERS

Lars Albermann

Head of Pharma Registration and Regulatory Projects, Merck KGaA

Originally a molecular biologist, for the last 14 years Lars Albermann has been working in several regulatory positions in the pharmaceutical industry as well as contributing to a number of industry associations. Currently, he is responsible for a team of regulatory experts in Merck Life Science Regulatory Management working on regulatory topics mainly related to APIs and excipients.

Wouter Hinrichs

Lecturer/researcher, Department of Pharmaceutical Technology and Biopharmacy, University of Groningen, The Netherlands

After a PhD at the University of Twente (The Netherlands), Dr. Hinrichs obtained a post-doc at the University of Twente and the Utrecht University. Dr. Hinrichs is a Senior researcher/lecturer at the Department of Pharmaceutical Technology and Biopharmacy at the University of Groningen. His research interests include: stabilization of biopharmaceuticals by spray drying and (spray) freeze drying, alternative dosage forms for dry/stabilized biopharmaceuticals and strategies to improve dissolution behaviour of lipophilic drugs.

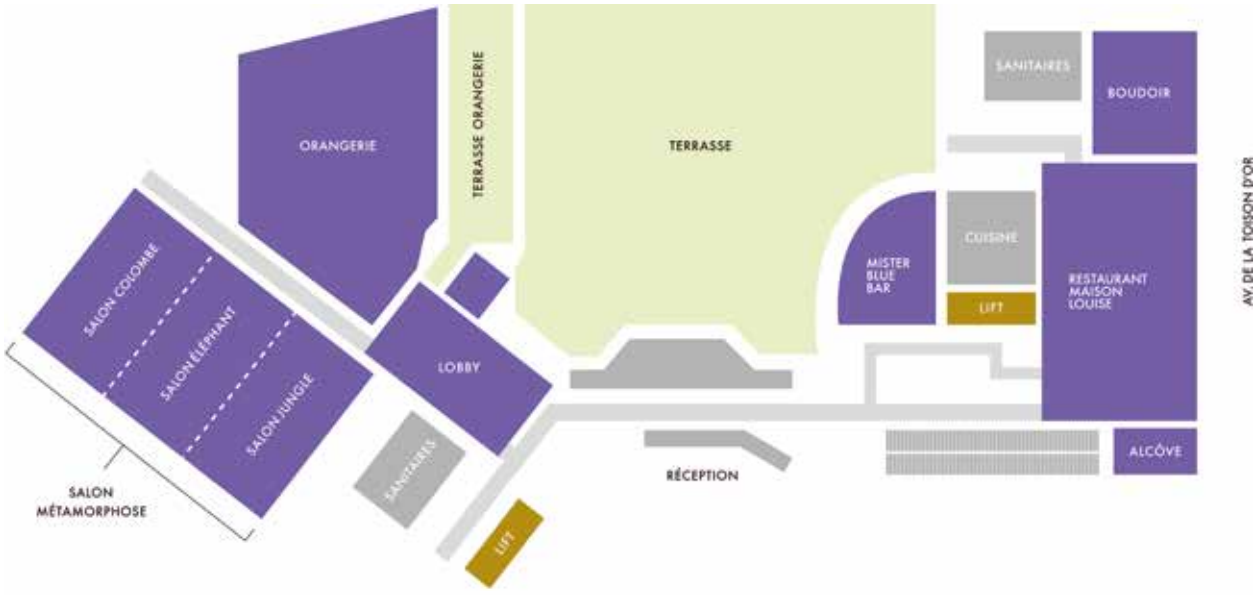
Kevin Hughes

Regulatory Affairs and QA Manager, Colorcon

Kevin Hughes has been with Colorcon for over 15 years where he has been the Technical Expert in film coating, immediate release excipients and extended release excipients. Now Regulatory Affairs and Quality Assurance Manager for Colorcon, he is responsible for the EMEA region, providing regulatory support to customers in both the pharmaceutical and food industries, monitoring any regulatory changes, industry initiatives and is closely involved with the IPEC Quality and Regulatory Affairs Committee. Mr. Hughes is also responsible for Quality at the Dartford site, and hosting of all customer and certification audits as well as conducting supplier audits as an IRCA qualified Lead Auditor. Prior to Colorcon, Kevin Hughes spent 5 years at Boots Healthcare Development, where he was Team Leader developing solid oral dosage forms for Boots Pharmacies. He has been involved in the pharmaceutical industry for 20 years.

GENERAL INFORMATION

FLOORPLAN



USEFUL INFORMATION

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

Wi-Fi name: **Le Louise WiFi**

ORGANISATION

For all queries, please contact:

Ms Carole Capitaine
+32 (0)4 83 44 00 75

Mr Stefano Luppino
+32 (0)4 94 46 22 57

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, the BIOGRUND Group 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 coatings, sugar-coatings, colourings and tabletting enable optimum results in a short time. Easy, fast and reliable!

THE 2022 IPEC EUROPE ANNUAL EXCIPIENTS FORUM IS SPONSORED BY

BIOGRUND IPSEN Innovation for patient care JRS PHARMA JRS

IPEC Europe asbl
Rue Marie de Bourgogne 52, B-1000 Brussels
+32 2 213 74 40
info@ipec-europe.org
www.ipec-europe.org

IPEC EUROPE

IPEC Europe: Rue Marie de Bourgogne 52, 1000 Brussels, Brussels Capital Region, Belgium - RPM Brussels Capital Region - Telephone: +32 2 213 74 40 - E-mail: info@ipec-europe.org - Website: www.ipec-europe.org - VAT number: BE 0501816137 - IBAN: BE50 3631 1388 1818 - Transparency Register: 341962119314-36