# BIG PHARMA DAY ONLINE

## Supporting development of R&D projects

How to develop scientific projects in neurology & oncology Overview on requirements for projects to be presented to a commercial partner













European Union European Regional Development Fund



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25th March 2021

| 9:00am  | Presenting scientific results to<br>a non-scientific audience<br>Marcin Kołaczkowski (JU CM)<br>Paweł Żołnierczyk (iQure Pharma) |
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| 9:55am  | Break  |
| 10:00am | Regulatory Dossier - how does it link<br>to research results<br><i>Katrin Rupalla</i>  |
| 10:25am | Break  |
| 10:30am | Indicative experiments for (co-)amorphous<br>drug delivery<br><i>Thomas Rades</i>  |
| 10:55am | Break  |
| 11:00am | CNS - new therapeutics development,<br>a case study<br><i>Joseph Wettstein</i>   |
| 11:30am | 1-2-1 meetings<br>Peter Schiemann<br>Henk de Wilde<br>Beat Widler  |

### BIG PHARMA DAY ONLINE SPEAKERS



#### Marcin Kołaczkowski, Prof. Jagiellonian University Collegium Medicum

Marcin Kołaczkowski graduated from pharmaceutical studies in 2001 at the Jagiellonian University Collegium Medicum (JUCM) and started working at the Department of Pharmaceutical Chemistry JUCM, in the team of Prof. Maciej Pawłowski. In 2007 he obtained his degree of doctor of pharmaceutical sciences at the Faculty of Pharmacy

of the JUCM. In the same year he also started working in Adamed's Research and Development Department, being responsible for innovative projects in the field of the central nervous system. In 2015 he obtained his degree of habilitated doctor, in 2017 the position of associate professor, and in 2019 the title of professor. In the same year he became the head of the Department of Pharmaceutical Chemistry and the Department of Medicinal Chemistry at Faculty of Pharmacy JUCM. Since 2016, he has also been the Vice-Dean of Strategy and Development. He is the originator and one of the main creators of the English-language MA studies Drug Discovery and Development at Faculty of Pharmacy JUCM. He is a scholarship holder of the Foundation for Polish Science, winner of the scientific award of the Minister of Health and decorated with the Gold Cross of Merit for his contribution to cooperation between science and industry. His research interests are focused on the rational design of active biological substances – potential drug candidates, especially in the area of the central nervous system.



#### **Paweł Żołnierczyk, MSc, MEnT (Hons)** CEO of iQure Pharma Inc

Pawel specialises in investments in the Preclinical and Clinical stages. He has worked as an IP and R&D Manager and Chief Operating Officer oncology focused Incanthera Ltd, UK. He managed due diligence processes for many potential therapeutics. He has been responsible for portfolio of over 100 patents and 4 new therapeutics drugs in preclinical

and early clinical stage of development. Pawel is a graduate of the Gdansk University of Technology, Poland - Physics, the University of Salford, UK - Master of Enterprise Technology (Hons).







#### **Katrin Rupalla, Ph.D., MBA** Senior Vice President, Global Head of Regulatory, Lundbeck S/A, Copenhagen, Denmark

Katrin Rupalla has more than 25 years of experience in research & drug development, primarily in the areas of oncology, immunology and neurology. She is currently SVP, Global Head of Regulatory Affairs, Medical Documentation & R&D Quality at Lundbeck,

Copenhagen, Denmark. Prior to joining Lundbeck, Katrin Rupalla worked in several leadership positions at Bristol-Myers Squibb, including as VP, Global Head of Regulatory Oncology based in Princeton, NJ, US and VP, Head of Development China based in Shanghai. Her Regulatory and Drug Development career includes several world-wide approvals of major products, such as REVLIMID®, OPDIVO® and YERVOY®, in the US, Europe and China as well as a multitude of new indication approvals. Katrin Rupalla is a certified pharmacist and obtained her PhD from Philipps University of Marburg, Germany in Pharmacology and Neurobiology and did postgraduate work in CNS Pharmacology at the University of Aachen/Novartis before starting her career in Drug Development at Roche.



#### **Thomas Rades, Prof.** Head of Research at the Department of Pharmacy, University of Copenhagen

Prof. Thomas Rades has vast experience in technical development and drug delivery gained over more than 25 years in industry and academic research. He is currently holding the position of Research Chair in Pharmaceutical Design and Drug Delivery

at the University of Copenhagen in Denmark Prof. Rades graduated with a Master's in Pharmacy from the University of Hamburg, Germany, and obtained his PhD at the Technical University of Braunschweig, Germany. Prof. Rades has spent time in the industry at F. Hoffmann – La Roche in Switzerland and in academic research mostly in New Zealand and Denmark, where he collaborated successfully with colleagues across the globe. In 2014, he received an honorary doctorate from Åbo Academi University, Turku, Finland. Prof. Rades has developed an international reputation for his research in the physical characterization of drugs in solid dosage forms as well as in vaccine delivery using nanoparticulate systems (both polymeric and lipid-based). Prof. Rades has published more than 400 papers in international peer-review journals as well as several book chapters, one book and applied for more than 14 patents. His key research interests are in the formulation and drug delivery and the physical characterizations in both solid and liquid crystalline matter. His research in both areas aims to improve drug therapy through the appropriate formulation of medicines and to increase the understanding of the physico-chemical properties of drugs and medicines, which combines physical, chemical, and biological sciences and technology to optimally formulate drugs for use in humans as well as animals.





#### **Joseph Wettstein, Ph.D.** ex Head of Functional Neuroscience at Roche

Joseph Wettstein began his career in academic science, first as a student in biology at the University of California. In the mid-1980s, Joseph Wettstein had an appointment in the Department of Psychiatry at Harvard Medical School. From 1996 to 2003 Joe worked for Hoechst Marion Roussel through two mergers, concluding with Aventis

Pharmaceuticals in New Jersey where he was Department Head of Systems Biology. Along with other accomplishments there, he and his team played a critical role in the discovery of teriflunomide, a drug that is now prescribed for patients with multiple sclerosis under the trade name Aubagio with annual sales in 2018 at US\$ 1.6 billion. Joe Wettstein's most recent position in Pharma was with Roche in Basel where he was Vice President and Head of Functional Neuroscience through 2014 having oversight on preclinical research activities associated with programs designed to discover new drugs for patients with neuropsychiatric disorders.



#### Peter Schiemann, Ph.D.

#### ex Roche

Peter Schiemann has over 27 years of professional experience in the industry working as Managing Partner at Wilder & Schiemann AG, a boutique drug development consultancy, with Roche in Switzerland and in the US (Manufacturing, Clinical Supplies, Clinical Audit Planning, Quality Risk Management), with PricewaterhouseCoopers (PwC)

in management consulting in Europe and the US and, in academic research in Germany (Cell Biology & Molecular Biology). Peter is a graduate of the Philipps University of Marburg - Pharmacy and Human Biology.



#### Henk de Wilde ex Roche

Over 20 years of industry experience with Roche in Switzerland (Clinical Operations, Oncology, Project Management, Quality Management, Vendor management), 7 years with Pharma Bio-research in the Netherlands (Clinical Pharmacology, CRO, ISO, GCP and GLP Certification) and 2 years in academic research in the Netherlands (Microsurgery,

Pain Management).



#### **Beat Widler, Ph.D.** ex Roche

Beat is an expert in the field of Quality Management and Assurance. He has 10 years experience as Managing Partner at Widler & Schiemann AG, a boutique drug development consultancy, over 25 years of professional experience with Roche in Switzerland and the UK in the areas of regulatory affairs, clinical research and Quality

Assurance & Risk Management. He has been the Global Head of Roche Clinical Quality for 15 years and the Head of Roche Clinical Development UK for 5 years. He has been the representative of IFPMA, EFPIA, Interpharma working groups for more than 15 years and a delegate to the Health Authorities. Beat is a graduate of the Swiss Federal Institute of Technology (ETH-Zurich) in Natural Sciences.