BREAKTHROUGHS THAT CHANGE PATIENTS' LIVES

30 September – 4 October 2019

PFIZER EDUCATIONAL PROGRAM

FROM IDEA TO PATIENT

From Idea to Patient: R&D in Pharmaceutical Industry

Drug Safety: Queen of Pre-clinical Development

Clinical Trials through the Phases

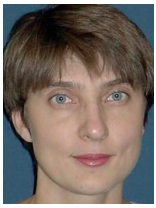
Pharmaceutical Sciences

Drug Delivery Systems

Pfizer Educational program
30 September – 4 October 2019

FROM IDEA TO PATIENT

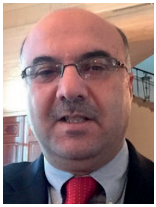
Date	Topic	Delivered by
Monday, Sep 30, 2019		
16:30–19:45 15 min break	**From Idea to Patient:** **R&D in Pharmaceutical Industry**	Ioulia Loubkina Mike Saleh
Tuesday, Oct 1, 2019		
16:30–18:00	**Drug Safety: Queen of Pre-clinical Development** *ONLINE*	Nichole Vansell
18:15–19:45	**Clinical Trials Through the Phases** *Phase 1*	Ioulia Loubkina
Wednesday, Oct 2, 2019		
16:30–18:00	**Clinical Trials through the Phases** *Phases 2,3 and 4*	Ioulia Loubkina
18:15–19:45	**Pharmaceutical Sciences**	Mike Saleh
Thursday, Oct 3, 2019		
16:30–18:00	**Pharmaceutical Sciences** *continued*	Mike Saleh
18:15–19:45	**Drug Delivery System**	Advait Badkar
Friday, Oct 4, 2019		
16:30–18:00	**Drug Delivery System** *continued*	Advait Badkar



Ioulia Loubkina

Director, Project Management, Pfizer

Ioulia joined Pfizer in May 2000 as a Project Analyst in Chemical R&D and worked on many exciting projects that allowed to travel as far away as Australia. She has also been a Supply Chain Coordinator (SCL) and has worked for a wide variety of programs spanning all phases of development in the CVMED, Oncology, Ophthalmology, and Anti-Infective therapeutic areas. Ioulia also worked as a Comparator Strategist within Global Clinical Supplies.
Currently Ioulia is a Project Manager for adalimumab biosimilar program and other programs within Inflammation and Immunology therapeutic area.
Ioulia has an MS in Physical/Analytical Chemistry from Drexel University and outside of work enjoys traveling, entertaining, reading, and spending time with her family and friends.



Mike Saleh

Director, Regional Regulatory Advisor for Africa, Middle East, Eurasian Economic Union, and Turkey, Pfizer

Mike Saleh is a Director at Pfizer Inc., and is currently assigned as a Regional Regulatory Advisor for Africa, Middle East, Eurasian Economic Union, and Turkey.
Mike's role is to ensure the successful alignment, collaboration and strategic planning across the Regional Pfizer Country Offices, Pfizer R&D Teams, Pfizer Manufacturing, and Global Chemistry, Manufacturing, & Controls. Additionally, Mike's role, is to influence the regional regulators by advocating global harmonization and to raise awareness within Pfizer about new regional regulations.
Prior to this assignment, Mike was a team leader in Worldwide Safety and Regulatory/GCMC, responsible for global development, registration, and post approval activities of multiple projects.
Mike & his team led the successful registration & marketing authorisation of Xeljanz in the US, and in over 40 other markets. Additionally, Mike's team was responsible for the marketing authorisations of Xalkori, in over 80 countries. In this role, Mike participated in numerous meetings with the regulators from US FDA, EMA to ensure their full understanding of CMC issues related to the development & control strategies for these products.
Mike has over 30 years of research/development and regulatory experience. Prior to joining Pfizer, Mike worked at a number of global pharmaceutical companies including Bristol-Myers Squibb, Bracco Diagnostics, Daiichi-Sankyo, and Wyeth.
Mike holds Masters degrees in Organic Chemistry from the American University of Beirut and another Masters degree in Analytical Chemistry from the University of Massachusetts.

Nichole R. Vansell

Senior Director, Drug Safety Research and Development, Pfizer

Nichole R. Vansell is currently a Senior Director in the Drug Safety Research and Development organization in Pfizer, where she leads the General Toxicology and Safety Pharmacology disciplines and oversees the design, planning, and reporting of studies and development strategies by staff in these disciplines. Previously, Nichole held the positions of Drug Safety Team Lead in the Pfizer and Wyeth Research organizations, supporting projects across oncology, cardiovascular, musculoskeletal, inflammation, rare disease, and neuroscience therapeutic areas; served as the Discovery-Safety Interface in Wyeth Research for 5 years, and Regulatory Toxicology Study Director for 5 years.
Nichole received her PhD in Toxicology in 2000 from the University of Kansas Medical Center and was certified by the American Board of Toxicology in 2004.

Advait Badkar

Senior Director, Pharmaceutics Research and Development, Pfizer

Advait is Senior Director of Pharmaceutics R&D within Pfizer's Biotherapeutics Pharmaceutical Sciences organization responsible for Novel Delivery Technologies to support Pfizer's entire biotherapeutics portfolio (including, but not limited to- mammalian and microbial fermentation derived candidate molecules, vaccines, gene medicine, targeted delivery strategies, and novel delivery device development). The group supports early-stage Research all the way through Commercial and post-Commercial life-cycle management where the emphasis is on providing risk-based solutions for portfolio enabling drug delivery technologies, with an eye on clinical and commercial development feasibility. Advait has held roles of increasing responsibilities and complexities over his 18-year career at Pfizer. Prior to the current position, Advait was the Director of Bioprocess R&D Technology, Pfizer Inc., where he was accountable for the Technology Strategy and Operations for investment across drug substance, drug product and analytical areas. His responsibilities included: Building and leading cross functional teams in pursuit of technology strategy; Identifying innovations, Planning & Implementing improvements cross-functionally. He was also accountable and responsible for the initiation and management of strategic collaborations and co-development research agreements with external partners amongst other responsibilities. Before this role, he held the position of Group Leader of Drug Product Formulation & Process Development managing a group of scientists and was responsible for: Subject matter expertise in formulation, process and primary packaging development for biological therapeutic entities; Expertise and hands-on experience in aseptic manufacturing, compliance and final dosage form definition; Colleague development, day-to-day personnel management, and deployment of group resources to enable the technical delivery of portfolio project deliverables; Responsible for the strategy, content and review of regulatory filings; Interface with Commercial team and manage launch planning for the product in US, EU and RoW and; Provide scientific expertise and guidance in due diligence exercises for potential in-licensed/acquisition candidates.
Advait received his Ph.D. in Pharmaceutical Sciences from the College of Pharmacy and Health Sciences, Mercer University (Atlanta, GA) and a MS in Pharmaceutics from Auburn University, Auburn, AL. He also has a BS in Pharmacy from Pune University (India). He is a member of AAPS and Controlled Release Society and has authored 3 patents, published over 25 articles in professional scientific journals, and presented more than 40 short papers, posters and talks.

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PP-PFE-RUS-0116
23.09.2019