ICH Workshop

Chemistry, Manufacturing and Controls (CMC)

Grand Copthorne Waterfront Hotel

21 - 22 March 2019

Day 1 – 21 March, Thur

	Topic	Speaker/ Organisation
8.30am	Registration	
9.00am	Welcome message for the ICH sub-workshop	**Prof John Lim** Executive Director Centre of Regulatory Excellence (CoRE) Duke-NUS Medical School
Session 2: The New Quality Paradigm in CMC Regulation – Part I		
9.15am	**Pharmaceutical quality supported by concepts developed in ICH** • Background and scientific basis • Linkage between the guidelines	**Dr.-ing Stephan Roenninger** Director External Affairs Europe International Quality Amgen
9.45am	**Understanding quality risk management as a behaviour** • Principles of quality risk management in ICH Q9 • Risk management tools • Potential applications	**Dr.-ing Stephan Roenninger** Amgen
10.45am	**Break**	
11.15am	**Implementation of a pharmaceutical quality system** • Principles and key aspects of ICH Q10 • Potential applications • Differences between a pharmaceutical quality system and a quality (management) system	**Dr.-ing Stephan Roenninger** Amgen
12.15pm	**Lunch and Photograph Taking**	
1.15pm	**Pharmaceutical development of DP *via* the quality-by-design (QbD) approach** • Principles and key aspects of ICH Q8 (annex) • Traditional *versus* enhanced approach in DP development • Real time release testing • Role of multivariate models in regulatory submissions	**Dr Sarah Pope Miksinski** Senior Director Global Regulatory Affairs AstraZeneca
2.15pm	**Panel Discussion** • Challenges in the implementation of ICH Q8/11, 9, and 10	**Moderator:** **Dr Moheb Nasr** Principal Nasr Pharma Regulatory Consulting (NPRC) Former Vice President CMC Strategy GlaxoSmithKline

		Panelist: **Dr Roger Nosal** Vice President Global Head CMC Pfizer **Dr Sarah Pope Miksinski** AstraZeneca **Dr Stephan Roenninger** Amgen **Dr Wassim Nashabeh** Roche
3.15pm	**Break**	
3.45pm	**Case discussion** • Identify the QbD approach in a DP pharmaceutical development process • Discuss the robustness of the data in supporting the proposed design space • Discuss the data required to support real time release testing of a DP	**Dr Moheb Nasr** NPRC **Dr Sarah Pope Miksinski** AstraZeneca
5.30pm	**End**	

Day 2 – 22 March, Fri

	Topic	Speaker/ Organisation
Session 2: The New Quality Paradigm in CMC Regulation – Part II		
9.30am	**Development and manufacture of DS *via* the QbD approach** • Principles and key aspects of ICH Q11 • Traditional *versus* enhanced approach to DS development	**Dr Roger Nosal** Pfizer
10.30am	**Break**	
Session 3: CMC Requirements for Post-market Quality Controls		
11.00am	**Post-approval CMC controls on marketed products** • Current *versus* ICH Q12 approaches • Key aspects of ICH Q12 and current progress • Identification of established conditions (ECs) and categorization of post-approval CMC changes • Management of post-approval changes associated with product or process CMC deviations.	**Dr Moheb Nasr** NPRC
12.30pm	**Lunch**	
1.30pm	Case discussion • Identify CMC changes that require prior approval, notification or no reporting is required	**Dr Moheb Nasr** NPRC
2.30pm	New trends in CMC development and manufacturing • Continuous manufacturing	**Dr Moheb Nasr** NPRC **Dr Wassim Nashabeh** Roche
3.45m	**Break**	
4.15pm	Development of global regulatory submission strategies (focusing on emerging markets) for new drug products: CMC-related considerations. • Common areas of CMC concerns • CMC Regulatory trends – Emerging Markets	**Mr Arun Mishra** Executive Vice President Regulatory Affairs (Indian Sub Continent) GSK Consumer Healthcare Ltd
5.00pm	ICH Sub-workshop conclusion	**Prof John Lim** Executive Director, CoRE Duke-NUS Medical School
5.15pm	Graduate Certificate Programme conclusion	**Prof John Lim** CoRE
5.30pm	**End**	