

6th Advanced GMP Workshop

Tentative Agenda (20 – 22 October 2021)

Day 1: 20 October 2021

Session 1 1600 – 1700 hrs	Welcome and Setting the Context Sudarshan Jain - Secretary General, Indian Pharmaceutical Alliance Inaugural Address Samir Mehta – President, Indian Pharmaceutical Alliance Video Message Sarah McMullen – Country Director, India Office, Office of Global Operations, USFDA Keynote Address and inauguration of IPA Best Practices Document V G Somani - DCG(I)
Session 2 1700 – 1830 hrs	Remote Interactive Evaluations – Expectations and Way Forward Rachel Harrington - CSO/Office of Medical Products and Tobacco Operations Remote Inspections – Observations and Experience Sharing Ewan Norton - Lead Senior GMDP Inspector, MHRA Ian Jackson - Unit Manager Inspectorate Risk, Control & Governance, IE&S, MHRA
1830 – 1845 hrs	Tea / Coffee Break
Session 3 1845 – 1930 hrs	Interactive Session - RCA and Investigations Case Studies McKinsey Speaker
Session 4 1930 – 2030 hrs	Nitrosamine Impurities – Current Regulatory Status B M Rao - Head - QA for Emerging Markets, CQC & ASAT, Dr Reddy's Laboratories Analytical Techniques to Evaluate Nitrosamine impurities Mrunal Jaywant – Senior Director, R&D, USP (India)

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Session 5 1600 – 1645 hrs	Lyophilisation – Recent Advancements Prasenjit Dange - Sales Director India, TruKing Technology Limited
Session 6 1645 – 1745 hrs	Advancements in Continuous Manufacturing Technology Sanjay Gorana – Senior Vice President, Manufacturing, Cipla James Holman - Senior Director Technology Management - Pharma Solids, GEA
1745 – 1800 hrs	Tea / Coffee Break
Session 7 1800 – 1900 hrs	Advancements in Cold Chain Logistics Ravi Mathur - Vice President Supply Chain Management, Dr Reddy's Laboratories Speaker Role of blockchain in next generation pharmaceutical supply chain Anubha Dixit – Founder, Tongadive Ltd
Session 8 1900 – 1930 hrs	Recent Developments in Vaccines Technology / Evaluation of Vaccines Deus Mubangizi - Group Lead, Inspection Services, PREQUAL Team, WHO
Session 9 1930 – 2030 hrs	Panel Discussion: Use of digitization for Quality and efficiency improvement in pharmaceutical operations Moderator: McKinsey Speaker Panellists: Vimal Manchanda – Digital Transformation Officer, Sun Pharmaceutical Industries Ltd Geena Malhotra - Global Chief Technology Officer, Cipla Ltd Rajendra Chunodkar – President, Manufacturing Operations, Lupin Ltd Prashant Sharma – Chief Technical Officer, Zydus Cadila

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Day 3: 22 October 2021

Session 10 1600 – 1800 hrs	IPA Quality Forum Subgroups 2020-21 Industry Best Practices Sharing: <ul style="list-style-type: none"> • Sterile operations covering aseptic practices, smoke studies and media fill – Pradipta Swain – Vice President, Operations, Sun Pharma • Cleaning methodology and validation – S V Gopalakrishnan – Sr Vice President, Corporate Quality, Zydus Cadila • Engineering and facility maintenance – Sanjeev Sharma – Engineering Projects and Maintenance, Syngene • Visual inspections of parenteral products – Mustak Sherasia – Sr General Manager, Sun Pharma
1800 – 1815 hrs	Tea / Coffee Break
Session 11 1815 – 1945 hrs	Panel Discussion: Global Best Practices and Future of GMP Moderator: McKinsey Speaker Panellists: Vipul Doshi – President Corporate Quality, Zydus Cadila Ranjana Pathak – President Global Quality, Cipla Indrajit Bose - Global Head of Quality, Dr Reddy's Laboratories Rajiv Desai - Global Head of Quality, Lupin Jila Breeze - Global Head Quality & Compliance, Sun Pharma Dilkesh Shah – Vice President Quality, Torrent
Session 12 1945 – 2000 hrs	Closing Remarks Nilesh Gupta – Chair Quality Forum, Indian Pharmaceutical Alliance Vote of Thanks Shirish Belapure – Senior Technical Advisor, Indian Pharmaceutical Alliance