HPRA
An tÚdarás Rialála Táirgí Sláinte
Health Products Regulatory Authority

Agenda for GMP CONFERENCE

7 February 2017, Crowne Plaza Hotel, Northwood, Dublin 9

Registration will begin at 07.45

Session Content	Speaker	TIME
Welcome and Opening Address	John Lynch, Director of Compliance	09:00
Session 1: • Risk Based Inspections & Recent Developments	Anne Hayes, Inspection Manager	09:15
Session 2: • Regulatory Update	Greg McGurk, GMP Manager (acting)	10:00
Tea & Coffee Break		10:45
Session 3: • Data Integrity ➢ Developments/Updates ➢ Common Deficiencies	Paul Moody, GMP Inspector	11:15
Session 4: • Qualification • Process Validation : Life Cycle Approach	Ciara Turley, GMP Inspector Catherine Neary, GMP Inspector	12:00
Lunch		12:45
Parallel Session 1A: Sterile Manufacture	Paul Moody, GMP Inspector	14:00
• Common Deficiencies • Annex 1 Revision • EU Guidance / Q&A ➢ TPN Manufacture ➢ Production of WFI through RO & Biofilm Q&A ➢ Sterilisation of Primary Packaging ➢ Disinfectant Efficacy ➢ Aseptic Process Risk Assessment	Dearbhla Cullen, GMP Inspector Greg McGurk, GMP Manager (acting) Greg McGurk, GMP Manager (acting)	
Parallel Session 1B: Non-Sterile & API Manufacture	Anne Hayes, Inspection Manager	14:00
• Inspection of API manufacturers & Update on Registration Process • Excipient Risk Assessment - Update • Common Deficiencies/ Hot Topics	Catherine Neary, GMP Inspector Richard O'Sullivan, GMP Inspector Oisin Daly, GMP Inspector	

15 minute break – changeover between parallel sessions		15.15
Parallel Session 2A: Market Compliance	Amy Kelly, Quality Defects & Recalls Manager	15:30
• Case Study: Risk Assessing a Simple Quality Defect Case and a Brief Review of CH.8	Kevin O'Donnell, Market Compliance Manager Martina Wong, Scientific Officer	
• Quality Defect Investigation and Reporting	Rob Smyth, Scientific Officer	
• Recall Process – Key Parameters	Breda Gleeson, Market Compliance Inspector	
Parallel Session 2B	Anne Hayes, Inspection Manager	15:30
• Safety Features : Update on National Implementation including Set Up of the National Medicines Verification Organisation's repository	Leonie Clarke, Irish Medicines Verification Organisation Representative	
Questions & Answers Discussion Plenary Sessions Fora	Questions can be submitted via e-mail/text. Further details will be provided on the day.	16:45
End of Conference		17:30