Indian Pharmaceutical Alliance

ADVANCED GMP WORKSHOPS 2017

06 - 17 November 2017

AGENDA

For

Chandigarh, Ahmedabad, Goa & Hyderabad

IPA
Innovation, Quality and Global Reach

In Collaboration With

FDA U.S. Food and Drug Administration | MHRA | EUROPEAN MEDICINES AGENCY SCIENCE MEDICINES HEALTH | CDSCO

DAY 1 AGENDA*

08:30 Onwards	Registration and Networking
0900 - 0930 hrs	**Welcome and Opening Remarks**
0900 - 0930 hrs	• **IPA:** Representative • **CDSCO:** Drugs Controller General of India (or representative) • **FDA:** Country Director, FDA India Office (or representative) • **MHRA:** Representative • **EMA:** Representative
Session 1 **0930 - 1015 hrs**	**Quality Systems** Dr Patrick Costello, Principal Scientific Administrator, EMA • Quality by Design and Product Development • Quality Risk Management • Describe current concepts of quality systems • Discuss how to use Quality System Indicators and Tools to evaluate GMP compliance
Session 2 **1015 - 1100 hrs**	**Introduction to Data Reliability** Mr Mark Birse, Group Manager Inspectorate, MHRA Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA • What are Data Quality and Data Integrity? • What are the Global Regulatory requirements? • What are the challenges in the Global context? • How to overcome such challenges
1100 - 1115 hrs	**Networking Tea/Coffee**
Session 3 **1115 - 1200 hrs**	**Data Quality in Application Submissions** Dr Krishna Ghosh, Senior Policy Advisor, CDER, Office of Pharmaceutical Quality, USFDA • Risk Assessments and Preapproval Inspections • GMP Issues encountered in Preapproval Inspections • Data Integrity and Data Quality deficiencies in submissions • Quality Risk Management
Session 4 **1200 - 1245 hrs**	**Regulatory Perspective of Data Integrity** Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA • Compliance and data integrity observations in the Industry • Good practices for data collection, validation, storage & archival

DAY 1 AGENDA*

1245 - 1255 hrs	**Instructions for the Afternoon Case Studies Sessions** IPA Representative
1255 - 1355 hrs	**Networking Lunch**
Session 5 **1355 - 1610 hrs**	**Case Studies and Breakout Sessions** • **Case Study: Data Integrity issues in the laboratory** Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA • **Case Study: Data Integrity issues in sterile manufacturing** Mr Thomas Arista, National Expert Investigator (Pharmaceutical/ Biotechnology), Office of Regulatory Affairs and Deputy Director (Incoming), Office of International Programs, India Office, USFDA Dr Ademola Daramola, Assistant Country Director, International Relations Specialist (Drugs), Office of International Programs, India Office, USFDA • **Case Study: Dealing with a broken quality system** Dr Patrick Costello, Principal Scientific Administrator, EMA Mr Mark Birse, Group Manager Inspectorate, MHRA Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA
1610 - 1625 hrs	**Networking Tea/Coffee**
1625 - 1700 Hrs	**General Question and Answer Session** Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA Mr Thomas Arista, National Expert Investigator (Pharmaceutical/ Biotechnology), Office of Regulatory Affairs and Deputy Director (Incoming), Office of International Programs, India Office, USFDA Dr Ademola Daramola, Assistant Country Director, International Relations Specialist (Drugs), Office of International Programs, India Office, USFDA Dr Patrick Costello, Principal Scientific Administrator, EMA Mr Mark Birse, Group Manager Inspectorate, MHRA Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA Dr Krishna Ghosh, Senior Policy Advisor, CDER, Office of Pharmaceutical Quality, USFDA

** Subject to change without prior notice.*

DAY 2 AGENDA

Session 6 **0900 - 0910 hrs**	**Opening Remarks (to include summary of Day 1)**
0910 - 0930 hrs	**Assessment on Sessions 1, 2, 3, and 4** • Dr Patrick Costello, Principal Scientific Administrator, EMA • Mr Mark Birse, Group Manager Inspectorate, MHRA • Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division International Drug Quality, USFDA
Session 7 **0930 - 1015 hrs**	**Aseptic Processing and Quality Issues** Mr Thomas Arista, National Expert Investigator (Pharmaceutical/ Biotechnology), Office of Regulatory Affairs and Deputy Director (Incoming), Office of International Programs, India Office, USFDA • Discuss common quality observations in sterile production • Examine regulatory expectations for sterile products
Session 8 **1015 - 1100 hrs**	**Data Quality and Integrity Investigation in Laboratories (Analytical)** Dr Ademola Daramola, Assistant Country Director, International Relations Specialist (Drugs), Office of International Programs, India Office, USFDA • Discuss basics of data quality and integrity in laboratory • Discuss common data integrity issues with a case study
1100 - 1115 hrs	**Networking Tea/Coffee**
Session 9 **1115 - 1200 hrs**	**Data Quality and Integrity Investigations in Manufacturing and Documentation Practices** Dr Patrick Costello, Principal Scientific Administrator, EMA • Discuss basics of data quality and integrity in Manufacturing • Discuss Good Documentation Practices • Discuss common data integrity issues with a case study
Session 10 **1200 - 1230 hrs**	**Laboratory OOS Investigations and the Missing Link** Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA • Discuss regulatory expectations • Explore industry understanding of OOS process and CAPA

DAY 2 AGENDA*

1230 - 1330 hrs	**Networking Lunch**
Session 11 **1330 - 1415 hrs**	**Current Trends in Data Quality and Integrity Issues in Inspections and Risk Based Approach to Investigations** Mr Mark Birse, Group Manager Inspectorate, MHRA Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA • Discuss current trends in data quality and integrity with worldwide inspectional metrics • Demonstrate the current integrity issues using risk based approach with a case study
Session 12 **1415 - 1445 hrs**	**Current Trends in Data Quality and Integrity Issues in Inspections and Risk Based Approach to Investigations; US perspective** Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA • Data reliability and data integrity, what are we seeing?
Session 13 **1445 - 1500 hrs**	**Open Panel Discussion on Root Causes of Data Integrity/ Serious GMP Issues** Dr Krishna Ghosh, Senior Policy Advisor, CDER, Office of Pharmaceutical Quality, USFDA Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA Dr Patrick Costello, Principal Scientific Administrator, EMA Mr Mark Birse, Group Manager Inspectorate, MHRA Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA
1500 - 1515 hrs	**Networking Tea/Coffee**
Session 14 **1515 - 1545 hrs**	**Performing a Quality Risk Assessment** Mr Thomas Arista, National Expert Investigator (Pharmaceutical/ Biotechnology), Office of Regulatory Affairs and Deputy Director (Incoming), Office of International Programs, India Office, USFDA

DAY 2 AGENDA*

Session 15
1545 - 1645 hrs

Remediation, Resolution, and Outcomes

Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA

Mr Thomas Arista, National Expert Investigator (Pharmaceutical/ Biotechnology), Office of Regulatory Affairs and Deputy Director (Incoming), Office of International Programs, India Office, USFDA

Dr Krishna Ghosh, Senior Policy Advisor, Centre for Drug Evaluation and Research, Office of Pharmaceutical Quality, USFDA

Dr Ademola Daramola, Assistant Country Director, International Relations Specialist (Drugs), Office of International Programs, India Office, USFDA

- What to do after deficiencies are found
- How to respond to observations and regulatory actions

Session 16
1645 - 1705 hrs

General Question and Answer Session

Dr Krishna Ghosh, Senior Policy Advisor, Centre for Drug Evaluation and Research, Office of Pharmaceutical Quality, USFDA

Dr Carmelo Rosa, Division Director, CDER, Office of Compliance; Office of Manufacturing and Product Quality; Division of International Drug Quality, USFDA

Dr Patrick Costello, Principal Scientific Administrator, EMA

Mr Mark Birse, Group Manager Inspectorate, MHRA

Mr Richard Andrews, Unit Manager Inspectorate Operations Inspection, Enforcement & Standards Division, MHRA

Wrap Up – Evaluation – IPA Representative

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NOTES

INSTRUCTIONS

- **If you have not registered and obtained your Registration Badge, please do so now at the Registration Desk.**

- **Please carry your Registration Badge for entry in the Conference Hall and for Lunch.**