Dear Colleagues,

Data Integrity has been and currently is a major global concern of Health Authorities and the pharmaceutical industry. Although not a new issue, numerous recent Health Authority enforcement actions such as Warning Letters, Import Alerts, Product Detentions, and suspension or revocation of Marketing Authorizations has focused attention on Data Integrity. Data Integrity can result from lack of awareness, employee errors, failure to check accuracy of data, software or system malfunction, configuration problems with electronic data handling, or misconduct by employees.

To holistically address Data Integrity, the Parenteral Drug Association (PDA) has developed a set of tools in the form of Data Integrity Workshops, Technical Reports, Training Programs, and Elements of a Code of Conduct for Data Integrity that can be used by industry to address this serious issue.

This two day workshop will include a blend of presentations from Health Authority and Industry experts, Case Studies, and round table discussions. Focus will be on understanding the multiple facets of Data Integrity such as quality culture, human behavior, training needs, and technology requirements. Case studies of data integrity events in manufacturing activities, testing laboratories, and clinical research will help attendees get a broad perspective on common factors, and cause and effect. Through round table discussion attendees will learn about best practices to prevent, detect, mitigate, and remediate Data Integrity issues. There will also be ample opportunity to network with industry peers, regulatory, and solution providers adding to the overall learning experience.

The program is designed for individuals working in Manufacturing, Quality Control Laboratories, Information Technology, Pharmaceutical Development and Technical Services, Regulatory Affairs, Clinical Research, and Audit and Compliance.

It is a privilege to work in an industry that makes a difference in the lives of patients. Every employee has an obligation (duty) to engage in behaviors and practices such that all stakeholders can trust that decisions are based on data and information that are accurate, truthful, and complete.

Welcome to London!

Sincerely,

Workshop Co-Chairs

Madlene Dole, Navartis
Anil Sawant, Merck & Co.
Tuesday, 19 April

9:00 Welcome: Opening Remarks & Introduction
Georg Roessling, PDA Europe
Anil Sawant, Merck & Co.
Madlene Dole, Novartis

Opening Plenary
Moderator: Madlene Dole, Novartis

9:15 Introduction to Data Integrity:
General Overview & PDA Technical Report
Anil Sawant, Merck & Co.

9:45 The Technical Aspects of the MHRA Data Integrity Guideline
David Churchward, MHRA

10:30 Industry Perspective: Auditing / Case Study
Siegfried Schmitt, PAREXEL

11:00 Q&A, Panel Discussion

12:00 Lunch Break & Poster Session

3 Concurrent Breakout Sessions
- Choose 2 out of 3 -

Format:
Short Case Study
Moderated Discussions
Summary of Results

Round 1
Manufacturing
Analytics & Quality Control
Clinical Data

Moderator: Madlene Dole, Novartis
Anil Sawant, Merck & Co.
Larry Puderbach, Pfizer

13:00 Data Integrity Incidents and Root Causes found throughout Industry
This session will cover a case study of a DI incident in a manufacturing setting. The case involves manipulation of computer settings and malfunction of equipment. The participants will use the case as a basis for discussion including root cause analysis, the impact of culture on DI, the role of leadership, impact assessment, and action planning.

Data Integrity Event in Chemistry Laboratory
This session will cover a Case Study of a data integrity incident uncovered in a QC Chemistry Lab. The case will involve electronic data manipulation, actions of fellow chemists and employee dynamics, action and inaction by management, speak-up culture, independent investigation strategy, and identification of true root cause.

Data Integrity Incident at a Clinical Study Investigator Site
This session will cover a case study involving a data integrity incident at a clinical study investigator site. The case involves issues associated with subject eligibility and enrollment, data falsification, vendor performance and oversight and sponsor study management inaction. Discussion topics will include potential implications of the issues, appropriate actions to be taken as well as a discussion of root cause and preventative measures.

14:15 Coffee Break & Poster Session
Presenters and Moderators to Summarize Results
WORKSHOP AGENDA

Round 2

**Manufacturing**

Moderator: [Madlene Dole](#), Novartis

**Analytics & Quality Control**

Moderator: [Anil Sawant](#), Merck & Co.

**Clinical Data**

Moderator: [Larry Puderbach](#), Pfizer

15:00  
**Data Integrity Incidents and Root Causes found throughout Industry**
- Case Study Presentation
- Moderated Discussion
- Collection of Results for Presentation

**Data Integrity Event in Chemistry Laboratory**
- Moderated Discussion
- Collection of Results for Presentation

**Data Integrity Incident at a Clinical Study Investigator Site**
- Moderated Discussion
- Collection of Results for Presentation

16:15  
Presenters and Moderators to Summarize Results

16:30  
Summary and Discussion of Case Studies

17:30  
Networking Reception

**Wednesday, 20 April**

**Opening Plenary Day 2**  
*Moderator: [Anil Sawant](#), Merck & Co.*

9:00  
General Concept of Data Integrity / Holistic Approach  
[Madlene Dole](#), Novartis

9:30  
Data Integrity: Local Implementation Considering Societal & Cultural Aspects  
[Steven Brown](#), Novartis

10:00  
Coffee Break, Poster Session & Exhibition

10:30  
Regulatory Inspection Observations: Implementation of Guidelines and Adherence  
MHRA Inspector

11:00  
Addressing Behavioural Practices in a Mature Quality Environment  
[Cormac Dalton](#), AbbVie

11:30  
Q&A, Panel Discussion

12:00  
Lunch Break & Poster Session

**3 CONCURRENT BREAKOUT SESSIONS**

- **Format:** Short Case Study, Moderated Discussions, Summary of Results

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7 Apr 2016
Round 1 Diagnosis & Detection Remediation Prevention

Moderator:  
Crystal Mersh, QxP  
Cormac Dalton, AbbVie  
Siegfried Schmitt, PAREXEL

13:00 Data Integrity Issues in a QC Chemistry Laboratory

The session will focus on methods for detecting and diagnosing data integrity issues in a QC lab. This will include setting the scope and targeting high risk data, assessing controls, discovering the cultural and organizational impact, and conducting the forensic audit. Forensic auditing is a methodology utilized in this space and others that allows for the use of existing data to facilitate “where to look”. The session will include practical scenarios that will utilize the learned techniques.

MHRA presenting two Data Integrity Scenarios from a GCP and a GMP Perspective

This session will enable delegates to respond to a simulated serious data integrity failure in a safe environment. Participants can choose between two scenarios that will present real-life data integrity deficiencies identified during inspections by MHRA. Delegates will be given the opportunity to discuss the findings, and propose an approach to investigation and remediation actions. MHRA inspectors will be available to act as facilitators, providing further information in response to delegates’ investigation questions, and giving advice and feedback on the groups proposed corrective actions.

Data Integrity Events in Clinical Trial Study Sites and Laboratories

This session will cover a Case Study of data integrity incidents uncovered in Clinical Study sites and Laboratories conducted on sites located in two continents (Europe and Asia). The case will involve electronic data manipulation, paper documentation management, sponsor and CRO oversight, competence and availability of study site personnel, independent investigation strategy, and cultural aspects.

14:15 Coffee Break & Poster Session

Round 2 Diagnosis & Detection Remediation Prevention

Moderator:  
Crystal Mersh, QxP  
Cormac Dalton, AbbVie  
Siegfried Schmitt, PAREXEL

15:00 Data Integrity Issues in a QC Chemistry Laboratory

- Case Study Presentation
- Moderated Discussion
- Collection of Results for Presentation

MHRA presenting two Data Integrity Scenarios from a GCP and a GMP Perspective

- Case Study Presentation
- Moderated Discussion
- Collection of Results for Presentation

Data Integrity Events in Clinical Trial Study Sites and Laboratories

- Case Study Presentation
- Moderated Discussion
- Collection of Results for Presentation

16:15 Presenters and Moderators to Summarize Results

16:30 Summary and Discussion of Case Studies

17:30 Closing Remarks & End of Workshop
The Parenteral Drug Association presents:

2016 1st PDA Europe Annual Meeting

THE FUTURE IN INJECTABLES

30 June - 1 July
Root Cause Investigation

30 June - 1 July
Development of a Pre-Filled Syringe

30 June
Test Methods for Pre-Filled Syringes

30 June
Cleaning and Disinfection

30 June
How to Find the Right GMP for APIs

28-29 June 2016
Estrel Hotel Berlin
Berlin | Germany

europe.pda.org/AnnualMeeting2016
Contacts
For additional conference information please contact:

Scientific Program Planning Committee
1. Madlene Dole, Conference Co-Chair, Novartis
2. Anil Sawant, Conference Co-Chair, Merck & Co.
3. Cormac Dalton, AbbVie Manufacturing Management
4. Zena Kaufman, ZGK Quality Consulting
5. Crystal Mersh, Quality Executive Partners
6. Siegfried Schmitt, PAREXEL Consulting
7. Ronald Tetzlaff, PAREXEL Consulting
8. Georg Roessling, PDA Europe
9. Richard Johnson, PDA

General Address
PDA Europe gGmbH
Am Borsigturm 60
13507 Berlin, Germany
Tel: +49 30 4365508-0
Fax: +49 30 4365508-66
info-europe@pda.org

Venue
Millennium Gloucester Hotel Kensington
4-18 Harrington Gardens
SW7 4LH,
London, UK
Tel: +44 (0) 073736030

2016 PDA Europe
Outsourcing & Contract Manufacturing

14 November
Risk-based Approach for Prevention and Management of Drug Shortages
15-16 November
Conference, Exhibition
17 November
Quality by Design for Biopharmaceuticals
17-18 November
Root Cause Investigation

15-16 November 2016
Olivia Balmes Hotel
Barcelona | Spain
## 2016 PDA Europe Activities & Events

<table>
<thead>
<tr>
<th>Date Range</th>
<th>Activity Description</th>
<th>Type</th>
<th>Location</th>
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</thead>
<tbody>
<tr>
<td>25-29 April</td>
<td>Praxis der Pharmazeutischen Gefriertrocknung</td>
<td>TC</td>
<td>Osterode, Germany</td>
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<td>2-3 May</td>
<td>Critical Demands on Modern Pharmaceutical Packaging</td>
<td>WS</td>
<td>Bern, Switzerland</td>
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<td>9 May - 10 May</td>
<td>DoE Basics for Validation by Design®</td>
<td>TC</td>
<td>Berlin, Germany</td>
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<td>31 May - 1 June</td>
<td>Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision</td>
<td>WS</td>
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<td>6 June</td>
<td>Viral Safety of ATMPs</td>
<td>Conference</td>
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<td>7-8 June</td>
<td>Advanced Therapy Medicinal Products</td>
<td>Conference</td>
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<td>9 June</td>
<td>Practical Application of GMP for Development of ATMPs</td>
<td>TC</td>
<td>Berlin, Germany</td>
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<td>28-29 June</td>
<td>1st PDA Europe Annual Meeting</td>
<td>TC</td>
<td>Berlin, Germany</td>
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<td>30 June</td>
<td>Test Methods for Pre-filled Syringe Systems</td>
<td>TC</td>
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<td>20-21 September</td>
<td>9th Workshop on Monoclonal Antibodies</td>
<td>TC</td>
<td>Rome, Italy</td>
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<td>22 September</td>
<td>Elastomers</td>
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<td>22-23 September</td>
<td>CMC Regulatory Compliance for Biopharmaceuticals</td>
<td>TC</td>
<td>Strasbourg, France</td>
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<td>22-23 September</td>
<td>Extractables and Leachables</td>
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<td>22-23 September</td>
<td>Introduction to Aseptic Processes Principles</td>
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<td>Statistics of Production Monitoring and Capability</td>
<td>TC</td>
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<td>27-28 September</td>
<td>Pharmaceutical Freeze Drying Technology</td>
<td>Conference</td>
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<td>29 September</td>
<td>Application of a Risk-Based Approach to Freeze-Drying Processes</td>
<td>TC</td>
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<td>29-30 September</td>
<td>Development of a Freeze Drying Process</td>
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<td>5-6 October</td>
<td>Current Challenges in Aseptic Processing, Potential Changes in EMA/PIC/S Annex 1 Revision</td>
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<td>Dublin, Ireland</td>
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<td>10 October</td>
<td>Interest Group Meeting Pharmaceutical Cold Chain</td>
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<td>Amsterdam, The Netherlands</td>
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<td>11-12 October</td>
<td>Pharmaceutical Cold &amp; Supply Chain Logistics</td>
<td>WS</td>
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<td>13-14 October</td>
<td>Good Cold Chain Practices</td>
<td>WS</td>
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<td>24 October</td>
<td>Particle Identification in Parenterals</td>
<td>TC</td>
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<td>25-26 October</td>
<td>Visual Inspection Forum</td>
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<td>27-28 October</td>
<td>An Introduction to Visual Inspection: A Hands-on Course</td>
<td>TC</td>
<td>Berlin, Germany</td>
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<td>8-9 November</td>
<td>Data Integrity</td>
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Subject to change
For latest info: europe.pda.org
Shortlist 7 Apr 2016