

Data Integrity for Microbiologists; Understanding the Paradigm Shift *Practical guidance on implementing your own programme of DI Review and Management*

Thursday 7th March 2019 – Cork International Hotel Ireland (HOTEL TBC)

PROGRAMME OUTLINE

Registration: 09.30 - 10.00

Workshop: 10.00 – 16.00 (Lunch will be at approx 12.30 – 13.15)

The format of this meeting is a combination of workshops and interactive discussion sessions and will cover:

Current expectations (FDA/EU/MHRA) and review of recent inspection findings

- Why is it still a hot topic in the industry?
- MHRA, FDA, WHO and EMA data compliance guidelines
- The transition of Data Integrity out of QC and into Microbiology
- Discussion/workshop on some recent audit findings by different regulators

What data do we generate as microbiologists, within and outside the laboratory?

- Case studies on determining what our microbiological data is
- Understanding its generation and control
- How do we control microbiological laboratory data compared to QC Analytical Labs?
- Looking at Hidden Data
- Human Reliability, consistent vs inconsistent data

Data Process Mapping and risk assessing your processes

- Defining Processes
- Understanding the variability within processes
- Data process mapping (workshop exercise)
- Data Life Cycle and review of compliance plans

How should we be controlling and reviewing our data?

- What is critical data and analysing risk from data
- Management culture that propagates good data compliance
- Good data compliance – using new/existing electronic systems and data processes to your advantage
- Case studies – determine the true reason for poor good data compliance

Attend this meeting and you will have the opportunity to deepen your understanding of effective practices, and start to create your data mapping for your own processes

A certificate of attendance will be issued to the delegates for their training records.

Please note: all information addressed by the speaker are of their own/ their company opinions and viewpoints. Pharmig is not responsible for any content presented at the meeting.

Pharmig also has the right to change the programme at any time due to unforeseen circumstances.



Data Integrity for Microbiologists; Understanding the Paradigm shift

Practical guidance on implementing your own programme of DI review and management

Data Integrity (DI) refers to maintaining and assuring the accuracy and consistency of data over its entire life-cycle, and is a critical aspect to the design, implementation and usage of any system which stores, processes, or retrieves data.

Although DI issues are not new, companies are being cited more frequently during inspections for observations related to data integrity, and agencies are even relying on evidence of data integrity issues from other regulatory bodies as the basis for taking enforcement actions against a pharmaceutical manufacturer!

Attend this cost and time effective 1-day workshop for microbiologists and those working alongside the microbiology laboratory, to help achieve a greater understanding of key principles around Data Integrity and its importance in ensuring compliance.

The format of the meeting is a combination of workshops and interactive discussion sessions to inform, explain about and consolidate understanding of Data Integrity for you – the microbiologist.

Your Workshop Leader – Julie Roberts

Quality Director, J Roberts Associates Ltd & Pharmig Committee Member

Julie has over 25 years in the Pharmaceutical industry working for multi-national companies such as AstraZeneca, GSK and Eli Lilly. In recent years she has worked in an international corporate role assessing sites for due diligence and inspection readiness across all dosage forms.

As an experienced microbiologist, Julie has also designed, set up, managed and audited microbiology laboratories and provided remedial support where required. With a strong technical competency in API operations and parenteral manufacture, Julie has practical experience in water system design and qualification, clean room classification, EM programmes. Julie became eligible to work as a Qualified Person in Europe in 2001, is a power user of TrackWise and has lean Six Sigma experience as a Green Belt.

Since becoming an independent Consultant Julie has worked extensively in Asia, Europe and the US conducting on-site gap analyses against EU and US regulations, coaching, training and educating staff to remediate gaps and prepare them for FDA inspections and EMA/MHRA audits.

Julie conducts work under her own company name 'J Roberts Associates' and also as a consultant for the US-based consultancy group 'Jeff Yuen & Associates Inc.', and the Irish-based consultancy group 'McGee Pharma International' and is a current Pharmig committee member.

BOOKING FORM

Please reserve.....place(s) for **Data Integrity for Microbiologists; Understanding the Paradigm shift** being held at **The Cork International Hotel Ireland** on Thursday 7th March 2019

Company: _____

Address: _____

Contact name if different from the delegate: _____

Tel: _____ Email: _____

DELEGATE 1

Surname: _____ First Name: _____

Job Title: _____ Email: _____

Dietary requirements: _____ Please tick to allow Pharmig to contact you

DELEGATE 2

Surname: _____ First Name: _____

Job Title: _____ Email: _____

Dietary requirements: _____ Please tick to allow Pharmig to contact you

Email or fax your completed booking form for a provisional confirmed place

Email: info@pharmig.org.uk

Fax: +44 (0) 1920 871 156

Member Fees *

Day Delegate £395 /€465

NHS RATES £200

(*Euro fee is higher to cover conversion rates)

Non Members*

Day Delegate £595/ €695

NHS RATES £300

Please Note: Fees include attendance to the meeting, an attendance certificate, refreshments and lunch, and links to download presentations in advance of the meeting. Pharmig no longer prints documentation folders. Fees do not include accommodation which has to be booked directly with the hotel.

Payment

- Cheque for £_____ / €_____ euro to cover the fee per delegate(s) enclosed
- Cheque for £_____ / €_____ euro to follow
- Total of £_____ / €_____ euro transferred electronically
- Please supply invoice
- Please quote purchase order number _____
- I wish to pay by credit card (Pharmig will contact you for details)

Hotel Information and Accommodation

- **Hotel Address: Cork International Hotel Ireland – Cork Airport Business Park, Cork, County Cork, Ireland T12 H516**
<https://www.corkinternationalairporthotel.com>
- A reduced rate of €109 B&B has been secured with the hotel
- If you require a room for the night of 6th March 2-19 please call the hotel directly **stating you are booking onto the Pharmig meeting on the 7th March 2019** to ensure you receive the reduced rate.
Reservations: +353 454 9800 / reception@corkinternationalhotel.com
- The Cork International Hotel is a perfectly located at what is affectionately known as the gateway to West Cork. Situated only 20 minutes from Kinsale, 10 minutes from Cork City Centre and has easy access to and from the M8 motorway making this hotel an ideal location for families breaks, couples escape, international tourists and locals. Its close proximity to Cork Airport it is ideal for people travelling on early or late flights

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