



## 2020 PDA Data Integrity Workshop

*Data Governance Programs: Fit for Innovation*

### Wednesday, September 2 – Part 1

10:30 a.m. – 11:45 a.m.

#### **P1: Data Governance: Journey to Enhanced Processes and Products**

**Moderator:** Kir Henrici, CEO, *The Henrici Group*

*Join this session to hear from MHRA and industry on the topic of data governance and gain valuable insights for a pragmatic, integrated approach to data governance across the product lifecycle in support of process verification and process improvement.*

10:30 a.m. – 10:55 a.m.

#### **Now and the Future**

**Tracy Moore**, Expert GMP Inspector, *MHRA*

10:55 a.m. – 11:20 a.m.

#### **Development of Product and Process Knowledge throughout the Product Lifecycle using Data Collection and Analysis for Continuous Process Verification and Improvement**

**Patrick D. Blacha**, Senior Advisor, Technical Services/Manufacturing Sciences, *Eli Lilly and Company* and **Anne V. Renton, MBA**, Research Scientist, *Eli Lilly and Company*

11:20 a.m. – 11:45 a.m.

#### **Q&A Panel**

11:45 a.m. – 12:00 p.m.

#### **Break**

12:00 p.m. – 1:00 p.m.

#### **Interactive Session 1: Knowledge Management - Data Insights, Decisions, and Continuous Improvement Actions**

**Moderator:** Monica J. Cahilly, MS, President/Consultant, *Green Mountain Quality Assurance*

**Speaker:** Travis A. Frick, MSc, Head Data Integrity & Analytics, *GlaxoSmithKline*

*In this session, attendees will execute a practical case study within manufacturing operations demonstrating targeted improvements to increase knowledge management. Attendees will improve process outputs to deliver meaningful information and insights and increase control strategy by applying data integrity by design through the pharmaceutical quality management system.*

### Thursday, September 3 – Part 2

10:30 a.m. – 11:45 a.m.

#### **Interactive Session 2: Quality Data: The Secret Sauce of a Robust Pharma Manufacturing Process**

**Moderator:** Kir Henrici, CEO, *The Henrici Group*

**Speaker:** Toni Manzano, PhD, Co-founder and CSO, *Bigfinite*

*How do you design a robust manufacturing process in Pharma and Biotech? A theoretical answer would need to consider all the involved variables and constants that determine the system to establish the dynamic state equations that characterize the process. However, the laws of physics, chemistry and engineering force us to make approximations because the available data does not always explain the entire context. Obtaining real-time data of all the variables that must be taken into account to apply the theoretical model is an arduous, if not impossible task as the multitude of information sources are usually not integrated or not available. The application of Artificial Intelligence in industrial environments has drastically changed this scenario.*

*Join this session for a case-study of the granulation process where the application of multiple Artificial Intelligence algorithms informs improving the manufacturing process utilizing good quality data.*

11:45 a.m. – 12:00 p.m.

#### **Break**

12:00 p.m. – 1:00 p.m.

#### **Interactive Session 3: Data Integrity: From Details Revealed via Data Forensics to Big Picture**

**Moderator: Monica J. Cahilly, MS**, President/Consultant, *Green Mountain Quality Assurance*

**Speaker: Mark E. Newton**, Owner, *Heartland QA*

*We have blind spots in our thinking and our Quality Systems. These come from our approach, backgrounds and experiences, organizational structure, project plans, governance, and culture. In the ideal world, we note these spots in each other and collectively remove them. This session will view a manufacturing facility with data integrity issues (but doesn't know it) from QC data forensics outward to the bigger picture. We will start with simple tools and techniques for data forensic analysis of QC analytical data and metadata to see a data integrity issue, then through the small bits of information provided by people in different areas of the company, we will work outward to the environment that created the data issues. The goal is to demonstrate how decisions that seem completely unrelated to data integrity can create an environment where integrity lapses live and discuss how the data samples and metrics provided in the workshop can help us see the bigger picture.*

## Wednesday, September 9 – Part 3

10:30 a.m. – 11:45 a.m.

### **P2: Current Regulatory and Compliance Perspectives on Data Integrity in Changing Times**

**Moderator: Monica J. Cahilly, MS**, President/Consultant, *Green Mountain Quality Assurance*

*Join us to hear from FDA and former FDA regulators on current regulatory and compliance perspectives on data integrity, including discussions of emerging U.S. FDA inspectional approaches for data integrity during the global pandemic, new tools and techniques, perspectives on data materiality and quality risk management approaches to remediation, and examples of recent data integrity observations.*

10:30 a.m. – 10:55 a.m.

**Brooke K. Higgins, MS**, Senior Policy Advisor, CDER, *U.S. FDA*

**Carmelo Rosa, PsyD**, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

10:55 a.m. – 11:20 a.m.

### **Data Materiality and Risk-Based Data Governance, a Practical Approach**

**Tom Cosgrove, JD**, Partner, *Covington & Burling LLP* and formerly with the *FDA*

11:20 a.m. – 11:45 a.m.

**Q&A Panel**

11:45 a.m. – 12:00 p.m.

**Break**

12:00 p.m. – 1:00 p.m.

### **Interactive Session 4: Agile Development and Computer Software Assurance**

**Moderator: Mark A. DiMartino, MS**, Director, Quality Data Sciences, *Amgen Inc.*

**Speaker: Carrie Babcock**, Senior Specialist Quality Assurance, *Amgen Inc.*, **Brian T. McBreen, Jr.**, Director, Knowledge Analytics, *Amgen Inc.*, and **Sebastian R. Hanet**, Senior Associate Data Scientist, *Amgen Inc.*

*This session will be a panel discussion on the initiation, development, suitability for use demonstration and lifecycle management of advanced analytics/AI based tools that are used to support GMP operations. The business processes and procedures used will be discussed, along with discussion of a practical use case. Key considerations on how to demonstrate software assurance will be discussed. The audience will be invited to ask questions throughout the session and the moderator will pose questions to the panel.*

## Thursday, September 10 – Part 4

10:30 a.m. – 11:45 a.m.

### **Interactive Session 5: Critical Thinking Applied to Data Maps and Audit Trail Reviews**

**Moderator: Els Poff**, Executive Director, Data Integrity Center of Excellence, *Merck & Co., Inc.*

**Speaker: Michael Maltman**, Director, Data Integrity Center of Excellence, *Merck & Co., Inc.*

*During this session we will utilize critical thinking in reviewing the process map and data management controls to apply a risk-based approach to the Quality review, of audit trails associated with manufacturing systems.*

11:45 a.m. – 12:00 p.m.

**Break**

12:00 p.m. – 1:00 p.m.

### **Interactive Session 6: Submissions to the FDA: Keeping it Real**

**Moderator: Aditi S. Thakur, MS**, Acting Quality Assessment Lead, CDER, *U.S. FDA*

**Speaker: Karen K. Takahashi, MS**, Senior Policy Advisor, CDER, U.S. FDA and **Amy B. Muhlberg, PhD**, Staff Fellow, CDER, U.S. FDA

*This session will explore the FDA's perspective on the reliability of data submitted in or omitted from drug applications. Participants will come away with a better understanding of the agency's thinking about the reliability of data submitted in or omitted from drug applications and about how they may think more critically about data that they maintain, submit to the agency, and the importance that this data plays throughout the product lifecycle.*