pda.org/2019DIWorkshop

2019 PDA Data Integrity Workshop

Navigating the Data Integrity Journey

FINAL PROGRAM

CONNECTING PEOPLE SCIENCE AND REGULATION®

SEPTEMBER 18-19 | WASHINGTON, DC

EXHIBITION: SEPT. 18-19
TRAINING COURSES: SEPT. 20
#PDADIWorkshop

GENERAL INFORMATION

REGISTRATION
Wednesday, September 18: 11:30 a.m. – 6:30 p.m.
Thursday, September 19: 7:00 a.m. – 5:30 p.m.

EXHIBIT AREA
Wednesday, September 18: 3:15 p.m. – 6:30 p.m.
Thursday, September 19: 9:45 a.m. – 4:00 p.m.

WIFI INFORMATION
Network Name/SSID: PDAFDA19
Password: Veeva (not case sensitive)

RECOMMENDED ATTIRE
Business casual attire is recommended for all events. The temperature in the meeting rooms tends to be cool, so a jacket or sweater is advised for your comfort.

BADGES
Attendees are required to wear their Workshop badge as proof of their registration and permits admission to Sessions, the Exhibit Area, and the Networking Reception.

VENUE
PDA will conduct all of the sessions and events at the Renaissance Washington, DC Downtown Hotel.

NETWORKING RECEPTION
All attendees are welcome to attend Wednesday evening's Networking Reception.

SPECIAL REQUIREMENTS
For information regarding special needs accommodations, please inquire at the Registration Desk. PDA is committed to make all events accessible to all individuals.

PROGRAM PLANNING COMMITTEE

Program Co-Chairs
Jackie Veivia-Panter, *Legend Biotech*
Carmelo Rosa, PsyD, *U.S. FDA*

Peter E. Baker, MS, *Green Mountain Quality Assurance*
Monica Cahilly, *Green Mountain Quality Assurance LLC*
Amanda M. McFarland, MS, *ValSource LLC*
Kir Henrici, *The Henrici Group*
Ronald F. Tetzlaff, PhD, *PAREXEL International*

PDA Staff
Tina S. Morris, PhD
Brooke Schneider, CMP

SCHEDULE-AT-A-GLANCE

WEDNESDAY, SEPTEMBER 18

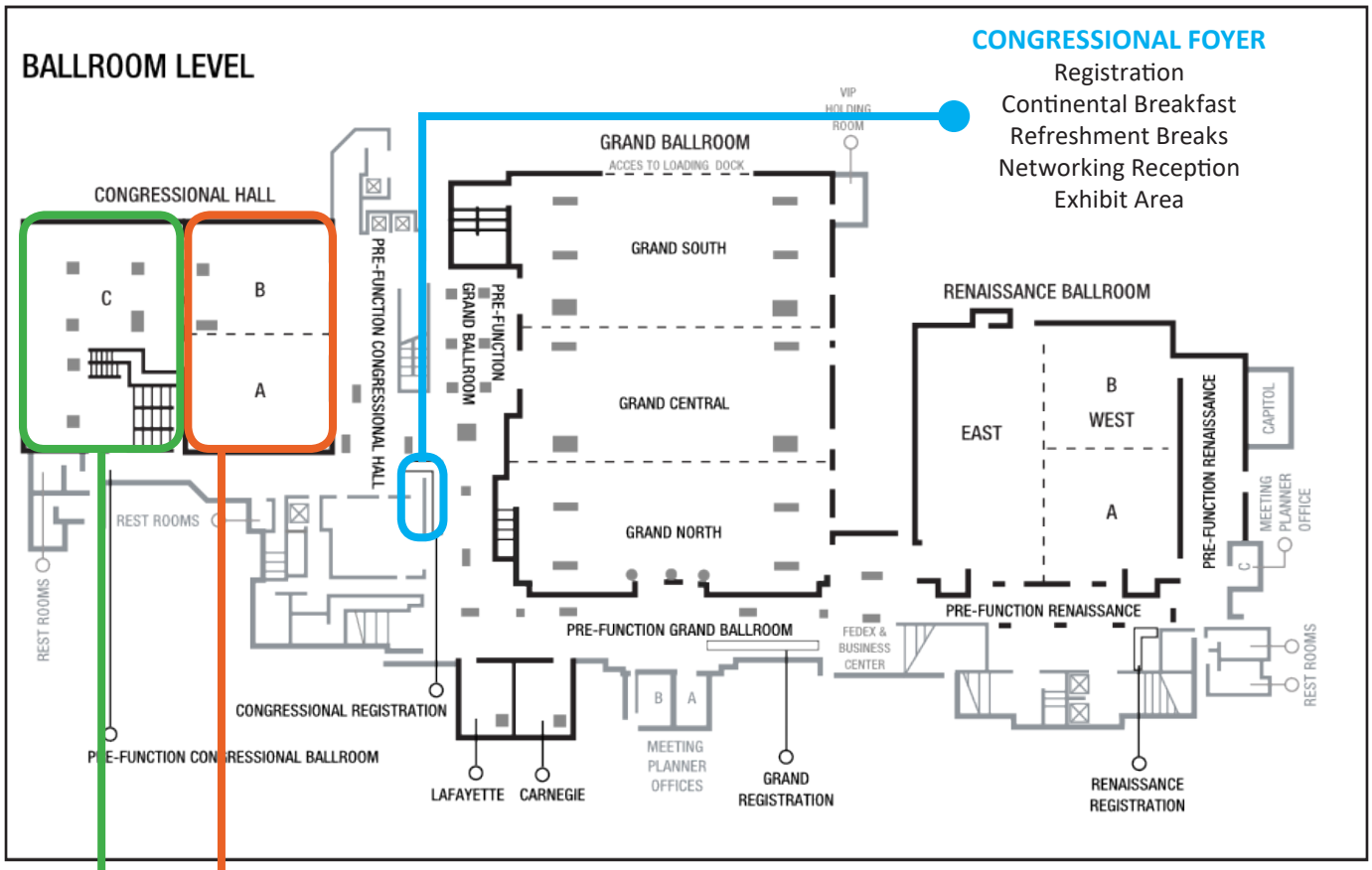
1:45 p.m. – 3:30 p.m. ..... **P1: Overcoming the Data Integrity Challenges**
3:30 p.m. – 4:00 p.m. ..... **Refreshment Break**
4:00 p.m. – 5:30 p.m. ..... **P2: Pragmatic Applications of Quality Risk Management to Data Integrity**
5:30 p.m. – 6:30 p.m. ..... **Networking Reception**

THURSDAY, SEPTEMBER 19

7:00 a.m. – 8:30 a.m. ..... **Continental Breakfast**
7:15 a.m. – 8:15 a.m. ..... **Breakfast Session: The Intersection Between Mindfulness and Data Integrity**
8:30 a.m. – 10:00 a.m. ..... **P3: How Do You Apply Data Integrity Concepts Over the Lifecycle of a Product?**
10:00 a.m. – 10:30 a.m. ..... **Refreshment Break**
10:30 a.m. – 12:00 p.m. ..... **P4: Quality Culture: What is all the Buzz About?**
12:00 p.m. – 1:00 p.m. ..... **Networking Lunch**
1:00 p.m. – 2:15 p.m. ..... **Concurrent Breakouts**
Breakout 1: Organizational Failure: Impact of Management and Employees Not Understanding Data Integrity Concepts
Breakout 2: Quality Culture: Milestones and Metrics in Support of Data Integrity
2:15 p.m. – 2:30 p.m. ..... **Break**
2:30 p.m. – 3:30 p.m. ..... **Group Discussions: Report Out**
3:30 p.m. – 4:00 p.m. ..... **Refreshment Break**
4:00 p.m. – 5:45 p.m. ..... **P5: Big Data Integrity**
5:45 p.m. **Adjournment**

***Session locations can be found within the agenda**

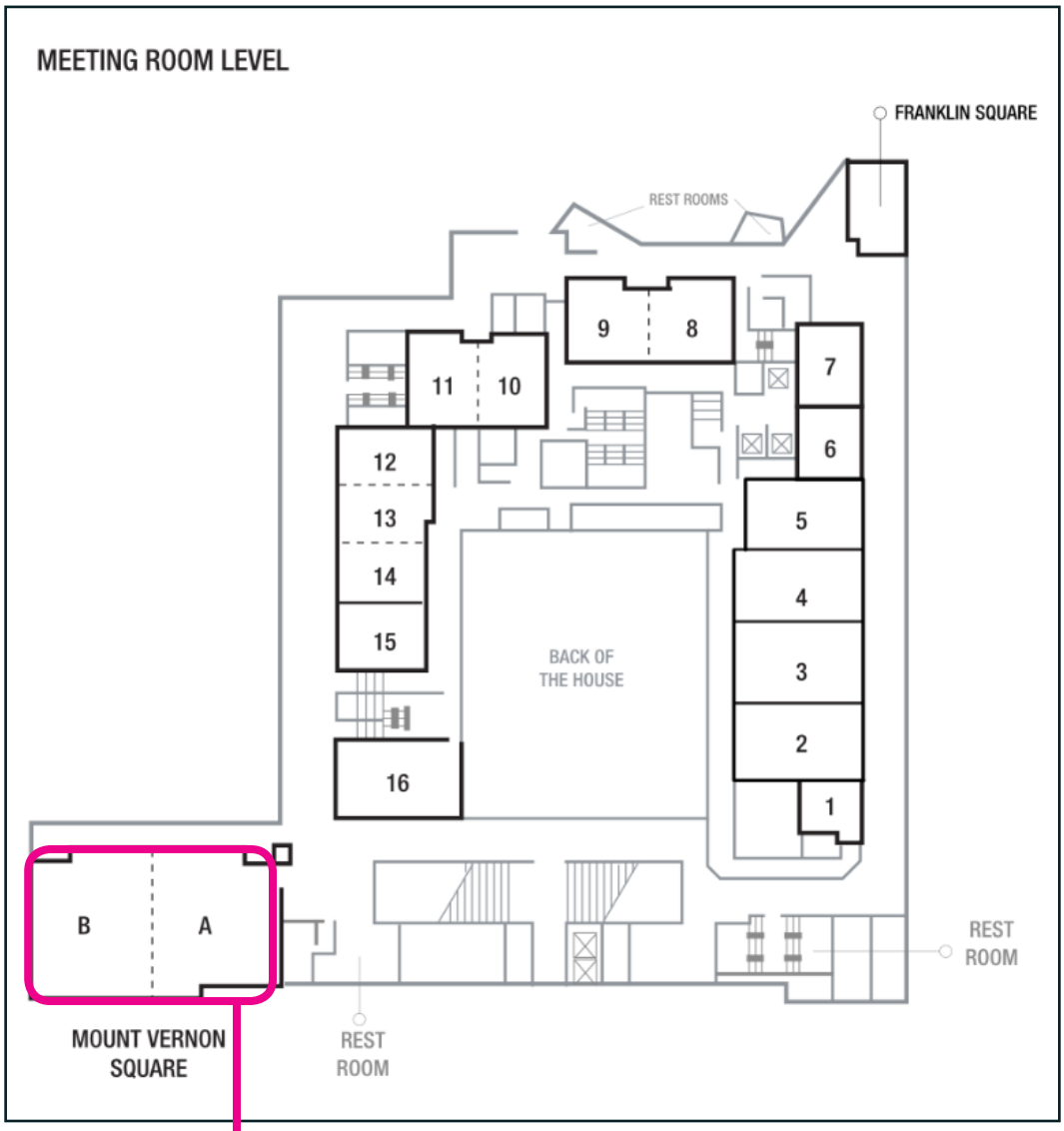
CONFERENCE FLOOR PLAN



CONGRESSIONAL BALLROOM A/B
Plenary Sessions
Breakout A

CONGRESSIONAL BALLROOM C
Breakout B

CONFERENCE FLOOR PLAN



MOUNT VERNON SQUARE
Networking Lunch

WEDNESDAY, SEPTEMBER 18

1:45 p.m. – 3:30 p.m. ..... **P1: Overcoming Data Integrity Challenges**
Location: Congressional Ballroom A/B

Moderator: Ronald F. Tetzlaff, PhD, Corporate Vice President, *PAREXEL International*

This session is designed to understand the current state of data integrity from the regulatory and industry perspective. Regulators will discuss current guidance and where we need to transition as an industry. Industry will present challenges of remediation efforts, what failed, and what they would have done differently.

1:45 p.m. **Welcome and Opening Remarks from Workshop Co-Chair**
Jackie Veivia-Panter, Senior Director, Quality Systems and Compliance, *Legend Biotech*

2:00 p.m. **Where Does Data Integrity Start and End? Understanding Data Integrity Expectations throughout a Drug Product's Lifecycle**
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

2:30 p.m. **The Data Integrity Challenges around the Transition from Paper to Digital**
Els Poff, Executive Director, Data Integrity Center of Excellence, *Merck & Co., Inc.*

3:00 p.m. **Q&A Panel with Additional Panelists**
David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), *MHRA, UK*
Aditi S. Thakur, MS, Acting Quality Assessment Lead, Office of Pharmaceutical Quality, CDER, *U.S. FDA*

3:30 p.m. – 4:00 p.m. ..... **Refreshment Break in Exhibit Area**
Location: Congressional Foyer

HAVE YOU VOTED YET?
Online voting is now open for the 2020 PDA Board of Directors and Officers Election! Use your PDA Member ID and last name to log in at www.pda.org/vote

WEDNESDAY, SEPTEMBER 18

4:00 p.m. – 5:30 p.m. ..... **P2: Pragmatic Applications of Quality Risk Management to Data Integrity**

Location: Congressional Ballroom A/B

Moderator: Amanda M. McFarland, MS, Senior Consultant, *Valsource LLC*

On the second stop of our workshop journey, we will evaluate data integrity through the lens of quality risk management. Data management is a rapidly evolving discipline with the initiation of electronic data gathering, cloud technologies, and automation. The need to both identify and remediate data integrity risks has become a regulatory focal point. This session will provide insight into the quality risk management and data integrity regulatory expectations and what these expectations look like when they are put into practice.

4:00 p.m. **Regulatory Perspective on Pragmatic Quality Risk Management for Data Integrity**
David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), *MHRA, UK*

4:30 p.m. **Facilitating Data Integrity through Confirmation**
James L. Vesper, MPH, PhD, Director, Learning Solutions, *Valsource LLC*

5:00 p.m. **Q&A Panel with Additional Panelists**
Peter E. Baker, MS, Vice President, *Green Mountain Quality Assurance* and formerly with the *U.S. FDA*
Tom Cosgrove, JD, Partner, *Covington & Burling LLP* and formerly with the *U.S. FDA*
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

5:30 p.m. – 6:30 p.m. ..... **Networking Reception in Exhibit Area**

Location: Congressional Foyer

THURSDAY, SEPTEMBER 19

7:00 a.m. – 8:30 a.m. ..... **Continental Breakfast**
Location: Congressional Foyer

7:15 a.m. – 8:15 a.m. ..... **Breakfast Session: What is the Connection between Mindfulness and Data Integrity?**
Location: Congressional Ballroom A/B

Moderator: Peter E. Baker, MS, Vice President, *Green Mountain Quality Assurance* and formerly with the *U.S. FDA*

Sponsored by ultragenyx pharmaceutical

Data integrity issues, whether unintentional human error or intentional, will never disappear completely; people are complex and driven by many motivations. However, the industry can respond in a more holistic way to both understand and address these issues and understanding the human element is a critical piece to address data integrity lapses. Mindfulness is a tool that can help you and your teams create capacity and focused awareness. By introducing the ability to pause during stressful situations, we can achieve thoughtful responses versus stress or fear-induced reactions. Can we expand our line of sight to include mindfulness and meditation in addition to the usual tactile tools already in place for ensuring good decision making with regard to data integrity?

7:15 a.m. **What is the Connection between Mindfulness and Data Integrity?**
Amy L. McLaren, Senior Director, Quality and Compliance, *Ultragenyx Pharmaceutical*
Julie C. Maurhoff, CQA, Senior Director, GxP Compliance, *Ultragenyx Pharmaceutical*

7:45 a.m. **Practice Exercise**

7:55 a.m. **Q&A Panel**

8:30 a.m. – 10:00 a.m..... **P3: How Do You Apply Data Integrity Concepts over the Lifecycle of a Product?**
Location: Congressional Ballroom A/B

Moderator: Jackie Veivia-Panter, Senior Director, Quality Systems and Compliance, *Legend Biotech*

Just as industry and regulators have discussed phase appropriate GMPs throughout the years, are there phase appropriate data integrity requirements? What does this mean for your data integrity program? During this session, we will hear from a consultant and a U.S. FDA representative with their perspectives on what this means, how to apply them, and challenges you may face.

8:30 a.m. **Assuring Data Integrity in Drug Applications Submissions: Regulatory Expectation Challenges and Case Study**
Aditi S. Thakur, MS, Acting Quality Assessment Lead, Office of Pharmaceutical Quality, CDER, *U.S. FDA*

9:00 a.m. **The Tricky Transition from Development to Commercial Manufacturing: Compliance and Quality Risks**
Tom Cosgrove, JD, Partner, *Covington & Burling LLP* and formerly with the *U.S. FDA*

9:30 a.m. **Q&A Panel with Additional Panelists**
Peter E. Baker, MS, Vice President, *Green Mountain Quality Assurance* and formerly with the *U.S. FDA*
Els Poff, Executive Director, Data Integrity Center of Excellence, *Merck & Co., Inc.*
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

THURSDAY, SEPTEMBER 19

10:00 a.m. – 10:30 a.m. ..... **Refreshment Break in Exhibit Area**
Location: Congressional Foyer

10:30 a.m. – 12:00 p.m. ..... **P4: Quality Culture: What is All the Buzz About?**
Location: Congressional Ballroom A/B

Moderator: Peter E. Baker, MS, Vice President, *Green Mountain Quality Assurance* and formerly with the *U.S. FDA*

Many of the new guidance and regulatory communications have specifically called out how important it is to have a good quality culture as the basis for data integrity. Join us for understanding why this is so important and how it is measured. In addition, a GlaxoSmithKline representative will present how they have effectively influenced their quality culture to support a robust data integrity program.

10:30 a.m. **Does Quality Culture Matter? A Data-Based Analysis**
Thomas Friedli, PhD, Director, Institute of Technology Management, *University of St. Gallen*

11:00 a.m. **Integrating Human Factors into our Data Integrity Strategy**
Ervin A. Rodriguez, MS, Vice President, Quality Systems, Pharmaceutical Supply Chain, *GlaxoSmithKline*

11:30 a.m. **Q&A Panel with Additional Panelists**
Cylia Chen-Ooi, Director Quality External Affairs, *Amgen Inc.*
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

12:00 p.m. – 1:00 p.m. ..... **Networking Lunch**
Location: Mount Vernon Square (Meeting Room Level, one floor up)

GET INVOLVED WITH PDA - BECOME A VOLUNTEER!
Volunteering is a powerful way to connect with the global PDA community, advance professionally, and contribute to the industry. Learn more and see available volunteer opportunities at www.pda.org/getinvolved

THURSDAY, SEPTEMBER 19

1:00 p.m. – 2:15 p.m. ..... **Concurrent Breakouts**

BREAKOUT 1

Organizational Failure: Impact of Management and Employees Not Understanding Data Integrity Concepts

Location: Congressional Ballroom A

Moderator: Ronald F. Tetzlaff, PhD, Corporate Vice President, *PAREXEL International*

Speaker: David M. Churchward, MSc, Deputy Unit Manager, Inspectorate Strategy and Innovation (Expert GMP Inspector), *MHRA, UK*

This session will explore examples of management failure to prevent and detect data integrity issues, how regulators are able to detect significant data integrity issues, and how to fix gaps.

BREAKOUT 2

Quality Culture: Milestones and Metrics in Support of Data Integrity

Location: Congressional Ballroom C

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

Speakers: Ronald D. Gunn, MS, MBA, Chief Operating Officer, *Kaleo, Inc.* and **Gregory L. Tewalt, PhD,** Director, Quality Systems and Compliance, *Kaleo, Inc.*

This breakout will explore the insights, challenges, and big wins of a quality culture and data Integrity Initiative.

2:15 p.m. – 2:30 p.m..... **Break**

Location: Congressional Foyer

2:30 p.m. – 3:30 p.m..... **Group Discussion: Report Out**

Location: Congressional Ballroom A/B

Moderators: Jackie Veivia-Panter, Senior Director, Quality Systems and Compliance, *Legend Biotech*

Learn from all the case studies! Each breakout session will present a case, challenges identified, and possible solutions.

THURSDAY, SEPTEMBER 19

3:30 p.m. – 4:00 p.m. ..... **Refreshment Break in Exhibit Area**
Location: Congressional Foyer

4:00 p.m. – 5:45 p.m. ..... **P5: Big Data Integrity**
Location: Congressional Ballroom A/B

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

This session invites data integrity futurists to explore the 21st century Big Data boom; taking a glimpse at technological innovations and intelligence trends and the ensuing paradox of challenges and rewards facing stewards of Data Integrity. Participants will have the opportunity to exchange ideas during the Q&A following speaker presentations.

4:00 p.m. **Big Data: The Not-So-Basics**
Mark A. DiMartino, MS, Director, Quality Data Sciences, *Amgen Inc.*

4:30 p.m. **Big Data Integrity**
Peter E. Baker, MS, Vice President, *Green Mountain Quality Assurance* and formerly with the *U.S. FDA*

5:00 p.m. **Q&A Panel with Additional Panelist**
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

5:30 p.m. **Closing Remarks from the Workshop Co-Chair**
Carmelo Rosa, PsyD, Division Director, Office of Manufacturing and Product Quality, CDER, *U.S. FDA*

2019 PDA Quality Week

Mastering Risk Management for Organizational Success

Register by Oct. 25 and save up to $600!

HIGHLIGHTS OF THE WEEK

Tuesday, Dec. 10
Get the latest industry and regulatory perspectives on ICH Q9

Friday, Dec. 13
In this compliance update, regulatory experts will share their thoughts on the regulators' use of QRM

Make plans to attend the inaugural *2019 PDA Quality Week*!

THREE EVENTS. ONE GOAL.

Gain the skills you need to implement and optimize a quality risk management (QRM) program in your organization – directly from global industry and regulatory experts!

- ***Risk Management in the Regulatory Landscape Conference*** **| December 9-10**
  Discover the current QRM global regulatory expectations and how regulatory agencies are using risk-based decisions to determine inspection frequencies and provide oversight.
- ***Building a Foundation and Culture for Quality Risk Management Integration Workshop*** **| December 11**
  Real-world case studies from organizations that have established QRM programs and find out how to create a strong quality culture as a prerequisite for a successful QRM program.
- ***Optimizing Quality Risk Management Conference*** **| December 12-13**
  See how risk-based approaches can foster success in your organization and optimize the overall lifecycle management of a product, as envisioned by ICH Q12.

With three events from which to choose, there is something for everyone!

Register for two events and save 10% or register for all three events and save 15%!

To learn more and register, visit *pda.org/2019QualityWeek*

DECEMBER 9-13 | WASHINGTON, DC

EXHIBITION: **DEC. 9-11**
RISK MANAGEMENT IN THE REGULATORY LANDSCAPE CONFERENCE: **DEC. 9-10**
BUILDING A FOUNDATION AND CULTURE FOR QUALITY RISK MANAGEMENT INTEGRATION WORKSHOP: **DEC. 11**
OPTIMIZING QUALITY RISK MANAGEMENT CONFERENCE: **DEC. 12-13**
#PDAQualityWeek

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