**2018 PDA Manufacturing Intelligence Workshop**

*Digital Strategies to Drive Manufacturing and Supply Chain Reliability*

**March 21-22, 2018 | Loews Sapphire Falls | Orlando, FL**

*As of March 16, 2018*

## Wednesday, March 21

3:00 p.m. – 6:00 p.m.
**Registration Open**

4:15 p.m. - 4:30 p.m.
**Welcome and Opening Remarks from the Chairs of the 2018 Manufacturing Intelligence Workshop**
**Michele D'Alessandro,** Vice President and CIO, Manufacturing IT, *Merck & Co., Inc.*
**Aaron R. Goerke, PhD,** Director, Head of MSAT, Singapore Technical Operations, *F. Hoffmann-La Roche Ltd.*

4:30 p.m. – 6:00 p.m.
**P1: Leveraging the Power of Modern Data to Solve Problems and Improve Manufacturing**
**Moderator: Aaron R. Goerke, PhD,** Director, Head of MSAT, Singapore Technical Operations, *F. Hoffmann-La Roche Ltd.*

**Session Description:** The manufacturing world is undergoing its fourth industrial revolution, spurred by the proliferation of digital capabilities and the integration of these capabilities into existing production and supply systems. The Pharmaceutical industry cannot ignore technology's impact on the way manufacturers conduct business. Because the information age has created these mountains of data, the aim of this session is to generate a common understanding of the fundamentals of big/modern data. A "box of chocolate" summary of the collaborative efforts to transpire throughout the workshop will follow via Pecha Kucha format presentations, where we uncover the unexpected. A final session take away will be an example disruption in the way data is made available, processed, and ultimately used to drive outcomes in product development, quality control, process analytics, or beyond.

4:30 p.m. – 4:50 p.m.
**Beyond the Buzz – What Big Data, Artificial Intelligence, and the Internet of Things Really Mean to Pharmaceutical Manufacturing**
**Chris Garvin,** Principal Engineer, Digital Integration and Predictive Technologies, *Amgen, Inc.*

4:50 p.m. – 4:55 p.m.
**Breakout Session 1 Preview**
**Richard F. Shakour,** Director, IT Account Management, *Merck & Co., Inc.*

4:55 p.m. – 5:00 p.m.
**Session P4 Preview**
**Mark DiMartino,** Director, Quality Engineering, *Amgen, Inc.*

5:00 p.m. – 5:20 p.m.
**Next Generation Manufacturing – A Step Towards Industry 4.0**
**Rob Guenard, PhD,** Senior Director, Global Manufacturing Sciences, *Biogen*

5:20 p.m. – 6:00 p.m.
**Poster Highlights from Session Moderators**

7:00 p.m. – 10:00 p.m.
**2018 PDA Annual Meeting Closing Reception: A Night in Havana**
*(Your full conference badge will be needed to access this reception)*

## Thursday, March 22

7:30 a.m. - 5:00 p.m.
**Registration Open**

7:30 a.m. - 8:30 a.m.
**Continental Breakfast**

8:30 a.m. - 9:15 a.m.
**P2: Key Note Session 1**
**Moderator: Emma Ramnarine,** Head, Global Biologics Quality Control, *Genentech, A Member of the Roche Group*

**Session Description:** Insights from outside of the pharmaceutical industry will be explored when going from traditional manufacturing to a fully digitized enterprise. The journey has transformed nearly every part of the business, from supply chain and logistics, to factory planning and utilization, quality assurance and even research and development. Discussion will occur surrounding the importance of moving past simple metrics and data analytics and how the true benefits come from combining pervasive digitization with proactive modeling and simulation. Future directions for the digital enterprise will be highlighted and how these same principles might be effectively applied in the pharmaceutical industry.

8:30 a.m. - 9:00 a.m.
**The Digital Enterprise Insights from Non-Pharma Branches**
**Alastair Orchard,** Vice President, Digital Enterprise, *Siemens*

9:00 a.m. – 9:15 a.m.
**Questions and Answers/Discussion**

9:15 a.m. - 9:45 a.m.
**Refreshment Break**

9:45 a.m. - 12:00 p.m.
**Breakout Sessions**

| **A: Manufacturing Information Model: Key Enabler for Pharma Digital Transformation** | **B: Big Data Analytics – A Key Enabler for Process Robustness – Explore the Space where you Don't Know what you Don't Know** | **C: Inexactitude vs. Precision – Designing and implementing a Big Data Strategy in a Regulated Environment** |
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| **Facilitator:**<br>**Arne Zilian,** Head, MS&T Processes and Standards, *Novartis Pharma AG* | **Facilitator:**<br>**Leo Xu,** Director, *GlaxoSmithKline* | **Facilitator:**<br>**Richard F. Shakour,** Director, IT Account Management, *Merck & Co., Inc.* |
| **Session Description:** A recent big data PDA ideation session identified a cross-industry, standardized Manufacturing Information Model (MIM) as being a key enabler for a Pharmaceutical industry digital transformation. This breakout session will first bring to you the voice of the customer and define the Pharmaceutical Manufacturing Information Model. It will also summarize preliminary studies, explore why a cross-industry MIM is important, identify what applications are available commercially and opportunities for their enhancement. In an interactive session, we will look into MIM use cases offering most benefit, or deficiencies impairing | **Session Description:** The goal of a manufacturing strategy is to consistently deliver high quality and affordable products to customers every time and all the time. Excellence in manufacturing process robustness is an essential element of a successful manufacturing strategy.<br>With ever increasing advances in the digital technology, large amounts of process data are available for analysis. In addition to the traditionally monitored process parameters, many additional sources of data can be captured such as all other process parameters, time-based equipment performance parameters, raw material characterization data, and analytical testing results. Application of advanced mathematical and statistical methodology will significantly enhance the ability to integrate and analyze | **Session Description:** The emergence of the Internet has fundamentally transformed many industries; however, it is only since the rise of the Industry 4.0 concept that the digital revolution has reached the core of industrial manufacturing. The PDA Taskforce will consider the applicability of structured and unstructured manufacturing data/information (GxP vs non GxP) as it relates to the new paradigm |

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| benefit to be overcome. As a result of this workshop, we will have identified opportunities for PDA member companies and potential MIM collaborations. | manufacturing big data, improve fundamental process understanding, detect problem before it occurs, and ultimately achieve the goal of process robustness<br>In the workshop, we will work together to understand the challenges that our industry is facing in process robustness, share the best practice in data analytics, identify areas for process robustness improvement, explore the collaboration among the companies, and establish the milestones for deliverables. | |
| 9:45 a.m. – 10:15 a.m.<br>**Introduction and Manufacturing Information Model Review**<br><br>10:15 a.m. – 10:35 a.m.<br>**Building the Use Cases – Interactive discussion**<br><br>10:35 a.m. – 10:55 a.m.<br>**Identifying the Challenges – Interactive discussion**<br><br>10:55 a.m. – 11:15 a.m.<br>**Potential Areas for Collaboration – Interactive discussion**<br><br>11:15 a.m. – 11:45 a.m.<br>**Define next steps/Team definition**<br><br>11:45 a.m. – 12:00 p.m.<br>**Closing Remarks/Questions** | 9:45 a.m. – 10:05 a.m.<br>**Introduction**<br><br>10:05 a.m. – 10:30 a.m.<br>**Evolution of Large Molecule Process Monitoring Program**<br>**Stephen Dorsch,** Associate Director, Global Technical Operations, *Merck & Co., Inc.*<br><br>10:30 a.m. – 10:55 a.m.<br>**Case Study 2**<br><br>10:55 a.m. – 11:35 a.m.<br>**Roundtable Discussion**<br><br>11:35 a.m. – 11:45 a.m.<br>**Closing Remarks/Questions** | 9:45 a.m. – 10:00 a.m.<br>**Introduction**<br><br>10:00 a.m. – 10:20 a.m.<br>**Use Case 1 - Using industry 4.0 Concepts to Improve Decision-Making by Machines and People**<br>**Chris Garvin,** Principal Engineer, Digital Integration and Predictive Technologies, *Amgen, Inc.*<br><br>10:20 a.m. – 10:30 a.m.<br>**Roundtable Discussion**<br><br>10:30 a.m. – 10:50 a.m.<br>**Use Case 2 - Utilizing Agile and Risk-Based validation and change management methodologies to enable Comprehensive Data Analytics and Process Monitoring in Bio Manufacturing**<br>**Robert Dimitri,** Associate Director, Manufacturing Systems, *Shire*<br><br>10:50 a.m. – 11:00 a.m.<br>**Roundtable Discussion**<br><br>11:00 a.m. – 11:30 a.m.<br>**Use Case 3 - Does the Data Lake have to be Validated?**<br>**Sonia Banerjee, PMP,** Director, IT Architecture, *Merck & Co., Inc.*<br>**Dan Wasser**, Associate Director, Process Intelligence and Technology, *Bristol Myers Squibb*<br><br>10:50 a.m. – 11:00 a.m.<br>**Roundtable Discussion**<br><br>11:30 a.m. – 11:45 a.m.<br>**Closing Remarks/Questions** |

12:00 p.m. - 1:00 p.m.
**Lunch**

1:00 p.m. – 1:45 p.m.
**P3: Key Note Session 2**
**Moderator: John Moehnke,** Project Manager, *Engineering Software Solutions, LLC*

**Session Description:** Attendees will gain cross industry insights from Disney's innovative decisions sciences team, focused on driving sustainable value capture. It's a great opportunity to gain an outside-in perspective on a digital journey applied in another industry, including lessons learned and critical success factors.

1:00 p.m. – 1:30 p.m.
**Decision Science: Learnings from the Front Line**
**Hai D. Chu,** Vice President, *The Walt Disney Company*

1:30 p.m. – 1:45 p.m.
**Questions and Answers/Discussion**

1:45 p.m. – 2:15 p.m.
**Refreshment Break in Exhibit Area**

2:15 p.m. - 3:45 p.m.
**P4: Opportunities and Risks with Modern Data Analysis Techniques in Regulated Pharmaceutical Manufacturing Environment**
**Facilitators: Mark DiMartino,** Director, Quality Engineering, *Amgen, Inc.*
**Brett Duersch**, Director, Engineering, *Merck & Company, Inc.*

**Session Description:** Advances in computing power and storage have not only resulted in the ability to collect and store vast amounts of data, it has also led to the development of powerful and innovative data analysis and computing methodologies to extract insights from the data and automate repetitive tasks. These methodologies include artificial intelligence applications such as machine learning, neural networks, natural language processing, and robotic process automation capabilities. The goal of this session is to discuss the application of these techniques in the quality and manufacturing environments, and to solicit ideas for topics that would benefit from joint discussion and collaboration across regulatory, industry and academic groups to improve the quality, cost and reliability for Pharmaceutical Manufacturing. After the workshop key topics will be presented to the PDA for creation of future PDA workstreams. After the workshop key topics will be presented to the PDA for creation of future PDA workstreams.

3:45 p.m. - 4:00 p.m.
**Refreshment Break in Exhibit Area**

4:00 p.m. - 5:00 p.m.
**P5: Panel Discussion and Key Takeaways**
**Moderator: Michele D'Alessandro,** Vice President and CIO, Manufacturing IT, *Merck & Co., Inc.*

**Session Description:** Panel discussion with industry experts on opportunities and challenges of digital strategies in Manufacturing. Additionally, hear a synthesis of the 1.5-day PDA workshop on Manufacturing Intelligence.

**Panel/Q&A:**

**Hai D. Chu,** Vice President, *The Walt Disney Company*
**Rob Guenard, PhD,** Senior Director, Global Manufacturing Sciences, *Biogen*
**Alastair Orchard,** Vice President, Digital Enterprise, *Siemens*
**Jack Prior,** Head, Manufacturing Science, Global MSAT, *Sanofi*

5:00 p.m.
**Thank You and Closing Remarks from the Co-Chairs of the 2018 Manufacturing Intelligence Workshop**
**Michele D'Alessandro,** Vice President and CIO, Manufacturing IT, *Merck & Co., Inc.*
**Aaron R. Goerke, PhD,** Director, Head of MSAT in Singapore, *F. Hoffmann-La Roche Ltd.*