

2020 PDA Pharmaceutical Manufacturing Data Science Workshop

April 2, 2020 | Raleigh Convention Center | Raleigh, NC

THURSDAY, APRIL 2

7:15 a.m. – 5:00 p.m. | Registration Open

7:15 a.m. – 8:15 a.m. | Continental Breakfast

8:15 a.m. – 10:00 a.m. | P1

In this opening session, participants will review the foundations of pharmaceutical manufacturing data science, including the industry 4.0 paradigm and the structure of a data science project. Principles for the day, vocabulary, and use cases will also be outlined. Then, participants will load the first use case and begin to assess the data quality.

8:15 a.m. | Welcome and Opening Remarks from Workshop Chair

Arne Zilian, PhD, Manufacturing Science and Technology, Global Head Systems and Standards, *Novartis*

8:30 a.m. | Foundations of Pharmaceutical Manufacturing Data Science

Arne Zilian, PhD, Manufacturing Science and Technology, Global Head Systems and Standards, *Novartis*

9:00 a.m. | Case 1: Data Transformation: Breaking Down Silos

Richard Love, Founder, *HarborView LLC*

10:00 a.m. – 10:30 a.m. | Refreshment Break in Exhibit Area

10:30 a.m. – 12:00 p.m. | P2

In the second plenary, participants will continue using the first use case to build a quality metrics dashboard for a product portfolio. Following this exercise, the predictive release concept will be introduced in preparation for the second use case.

10:30 a.m. | Case 1: Quality Metrics Dashboard

Richard Love, Founder, *HarborView LLC*

11:30 a.m. | Predictive Release

Toni Manzano, PhD, R&D Director and Founder, *Bigfinite*

12:00 p.m. – 1:00 p.m. | Lunch

1:00 p.m. – 2:30 p.m. | P3

Participants will take the second use case to build a predictive release model with the goal to improve the manufacturing processes through artificial intelligence (AI), glean knowledge from historical data, and apply knowledge in real-time. After the use case, the implementation roadmap will be analyzed to show how to start small to deliver results early and then how to extend the steps to work on more complex opportunities.

1:00 p.m. | Case 2: Data Assessment

Toni Manzano, PhD, R&D Director and Founder, *Bigfinite*

2:00 p.m. | Build the Roadmap

Vasu Rangadass, PhD, President and CEO, *L7 Informatics*

2:30 p.m. – 3:00 p.m. | Refreshment Break in Exhibit Area

3:00 p.m. – 5:00 p.m. | P4

In the final session, participants will review the agile ways of working and change management under GxP and then will finish their second use case checking the quality of the AI results. The workshop will end with feedback and shared learnings.

3:00 p.m. | Agile Methodology and Testing Tools

Frank Gorski, Director, Quality Assurance – Technology Audits, *Merck*

3:30 p.m. | Case 2: Required Quality around AI

Toni Manzano, PhD, R&D Director and Founder, *Bigfinite*

4:30 p.m. | Feedback and Closing Remarks

Arne Zilian, PhD, Manufacturing Science and Technology, Global Head Systems and Standards, *Novartis*