

**PPAR meeting at Pfizer**

**Groton, CT, October 24-26, 2016**

**Agenda**

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| Monday, October 24, 2016 | |
| 6:00- 9:00 PM | Informal Reception and Registration at Mystic Hilton Hotel. |
| Tuesday, October 25, 2016 | |
| 8:30 - 8:35 AM | Welcome/Introductions/Agenda – Sonja Sekulic, Pfizer. |
| 8:35 – 9:00 AM | Introductory remarks – David DeAntonis, VP Pharmaceutical Sciences Analytical R&D, Pfizer Worldwide Medicinal Sciences |
| 9:15– 10:30 AM | Session 1: Continuous Drug Product Manufacturing  *Facilitator*: Steve Hammond, Pfizer Inc |
| 10:30 – 10:45 AM | Break |
| 10:45 – 12:00 | Session 2: Infrastructure: Data Management/Historians/Automation  *Facilitators*: Cenk Undey, Christian Airiau, Martin Warman |
| 12:00-12:45 PM | Lunch |
| 1:00 – 2:00 PM | PCMM tour |
| 2:15 – 2:30 PM | Break |
| 2:30 – 3:30 PM | Session 3: Batch to Continuous Conversions  *Facilitator*: Tim Stevens, BMS |
| 3:30 – 4:30 PM | Session 4: Guidance Landscape  *Facilitators*: Justin Pritchard (Vertex), Martin Warman, Lorentz Liesum (Novartis) |
| 4:30 – 5:30 PM | Session 5: Regulatory  *Facilitators*: Sonja Sekulic (Pfizer), Gary McGeorge (BMS), Busolo Wabuyle (Merck) |
| 5:45 PM | Bus/Shuttle leaves from meeting to Mystic Hilton. |
| 6:15 PM | Bus/Shuttle leaves from Mystic Hilton to DPI. |
| 6:30 PM | Dinner at DPI (http://danielpacker.com) |
| 9:00 PM | Bus/Shuttle returns to Mystic Hilton Hotel. |
| Wednesday, October 26, 2016 | |
| 8:30 - 8:35 AM | Recap/Agenda – Sonja Sekulic, Pfizer |
| 8:35 – 9:30 AM | Session 6: Cleaning – Dial in Newbridge site  *Facilitator*: Joep Timmermans |
| 9:30-10:45 AM | Session 7: Continuous API Manufacturing  *Facilitator*: Steve Doherty (Abbvie) |
| 10:45-11:00 AM | Break |
| 11:00-12:15 AM | Session 8: Implementation Topics: Model maintenance, sensor robustness etc.  *Facilitators*: Christian Airiau (GSK) & Victor Saucedo (Genentech) |
| 12:15-1:00 PM | Lunch |
| 1:00-2:00 PM | Wrap up/2017 PPAR/Mission and Vision for future PPARs (more than just a yearly meeting) (l)  Sonja Sekulic & Joep Timmermans (Pfizer) |
| 2:00 PM | Departures |

***Additional Topic Information:***

**Session 1: Continuous Drug Product Manufacture**

* Are we using PAT for information only, for control or release?
* What is the current practice across industry and why?
* Where are we going as an industry?

**Session 2: Infrastructure**

* Data management and data integrity for continuous mfg.
* Update on excipient harmonization/standardization.
* Experiences in connectivity with data historians, process control and automation systems, LIMS etc (e.g. Sipat, Optimal, PharmaMV or home grown systems).
* What works well, what needs some attention based on our collective experiences?

**Session 3: Batch to Continuous Conversions**

* Filing continuous processes for an existing batch product.
* What are the approaches being taken? Amount of data being provided? What is being demonstrated?
* What are the regulatory expectations vs benefits of such filings?
* Commercial benefit for these changes?

**Session 4: Guidance Landscape**

* Recent guidance in US and EU. Similarities/differences/issues.
* USP 858 to replace USP 1119 – how to influence these types of efforts
* Additional efforts in ASTM and ISPE – how to pull together?
* Rutgers working on guidance for continuous manufacture also.

**Session 5: Regulatory**

* Shared experiences: For those that have filed-what would you change if you had it to do over? For those that have not – what is the biggest challenges inside and outside your organization?

**Session 6: Cleaning**

* With continuous manufacture, the cleaning steps become the larger portion of cycle times especially with small batch sizes.
* Can we look to technologies to replace swab testing?
* Share experiences from Pfizer Newbridge site and discuss if there is potential to broaden such experiences to a broader portion of the industry?
* Canvas other approaches that have been tried?

**Session 7: Continuous API Manufacturing**

* Are we using PAT for release or for control of API processes?
* How complex are the controls and what is being filed?
* Any impact/connectivity to drug product manufacture?

**Session 8: Implementation Topics: Model Maintenance, Sensor Robustness etc.**

* Metrology, model maintenance, mean time to instrument failure/robustness, instrument capabilities, how do we compare with other industries?
* Soft sensors: who is using them, for what, pros/cons.