**Winter Meeting**

Date & Time: 24-Feb-17 – 9:00am – 3:30 pm

Location: PTC Therapeutics, Inc., 100 Corporate Court ▪ South Plainfield, NJ 07080 ▪[**www.ptcbio.com**](http://www.ptcbio.com/).

Access AGXPE Website: <http://www.agxpe.wildapricot.org/>

|  |  |  |
| --- | --- | --- |
| **AGXPE WINTER MEETING, 24FEB2017** | **Presented by:** | **Time** |
| ***Coffee and Networking*** |  | 8:30 – 9:00 a.m. |
| ***Welcome and Logistics*** | ***John Lewis*** – CEO, AGXPE  ***Chrissy Frey*** – Director, Compliance Learning, and ***Stuart W. Peltz***, CEO,  PTC Therapeutics, Inc. | 9:00 – 9:15 a.m.  9:15 – 9:30 a.m. |
| ***Are You Ready?  FDA’s “Live Review” Approach to Inspecting Quality System Documentation*** | ***Teresa Gorecki***, Practice Lead, Compliance Architects LLC | 9:30 – 10:30 a.m. |
| ***Networking Break*** |  | 10:30 – 11:00 a.m. |
| ***Contamination Control in Manufacturing: Safety & Quality Management of Foreign Object Debris – an Aerospace Industry perspective*** | ***Patrick Boyle***, President, Skillpad Canada Inc. | 11:00 a.m. to 12:00 p.m. |
| ***Lunch*** |  | 12:00 –   1:00 p.m. |
| ***Panel Discussion:***  ***Data Integrity – a Global Perspective*** | ***David Young***, Dir. Regulatory Affairs, CMC  ***Christine LaRock***, Dir of Clinical Development PTC Therapeutics, Inc  ***Bijal Shah***, Associate Director, Clinical Data Management – Early Development, Merck Research Laboratories  ***Vince Ranieri***, Manager, Laboratory Analyst Training & Certification Program, Johnson & Johnson  ***Santosh Tharkude***, Bristol-Myers Squibb. Associate Director, ERES Compliance | 1:00 –   2:00 p.m. |
| ***Networking Break*** |  | 2:00 – 2:30 p.m. |
| ***Training Strategies to Promote Learning*** | ***Chrissy Frey***,  Director, Compliance Learning,  PTC Therapeutics, Inc. | 2:30 – 3:30 p.m. |
| ***Meeting Close***  ***AGXPE Organization Update:   Future Meetings, Sponsors, Topics*** | ***John Lewis***, CEO, AGXPE,  ***AGXPE Board of Directors*** | 3:30 – 3:45 p.m. |