**Summer Meeting**

Date & Time: 16-Jun –9:00am – 3:45 pm

J&J, Titusville, NJ

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

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| **AGXPE SUMMER MEETING, 16JUN2017** | **Presented by:** | **Time** |
| ***Coffee and Networking*** |  | 8:30 – 9:00 a.m. |
| ***Welcome and Logistics*** | ***John Lewis*** – CEO, AGXPE**Joyce Hansen –** Johnson and Johnson, VP Sterility Assurance, Sterile Process Technology | 9:00 – 9:05 a.m.9:05 – 9:15 a.m. |
| ***Data Integrity:    Risk Based Approach to Audit Trail Reviews***Building quality into our data management systems and a look at possible strategies for audit trail review. | ***Vince Ranieri,***  Manager, Laboratory Analyst Training & Certification Program | 9:15 – 10:00 a.m. |
| ***H.E.A.T. – Human Error Analysis Tool:***Introduce the audience to the application of human error analysis techniques (H.E.A.T.)  used to predict possible errors that may occur in a task.  Furthering the learning will be a look into the next stage of error analysis - identifying error recovery possibilities implicit within the task, and to specify possible remedial strategies to eliminate the causes of errors or to enhance their likelihood of recovery before the consequences occur. | **George T Lopac III,** Lead Trainer Catalent Pharma Solutions | 10:00 – 10:40 am |
| ***Networking Break*** |  | 10:40 – 11:00 a.m. |
| ***New Labeling Regulation***An in depth review of FDAs Clinical Pharmacology Section of Labeling for Human Prescription Drug and Biological Products focusing on NDA submittals | **Barbara Fanelli**, Professor, **Regulatory Affairs and Quality Assurance Graduate Program of Temple University School of Pharmacy** | 11:00 to 12:00 p.m. |
| ***Lunch*** |  | 12:00 –   1:00 p.m. |
| ***Quality Culture, Leadership and Learning in Pharma R&D*** A look at the inter-relationships between the various aspects of the Pharmaceutical Quality System   | **Shawn Millhiem**, Training Director at Pfizer | 1:00 –   2:00 p.m. |
| ***Networking Break*** |  | 2:00 – 2:30 p.m. |
| ***Looking Beyond the LMS***You don’t have to be limited by your LMS platform anymore. You also don’t have to start over and make another large investment. Instead, learn how virtual training tools and mobile learning environments can integrate with and extend the life of your existing legacy systems and LMS platform(s). Specific Strategies, Design and Technology Aspects, as well as Use Cases from global companies across various industries will be discussed.      | **Elena Coarse**, Director of Business Development, SCRIMMAGE | 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. |