



AGXPE

Association for GXP Excellence

“Where Compliance meets Excellence ”
16-NOV-2018

<http://agxpe.wildapricot.org>





Mission

Our Mission: Develop and share quality and compliance resources to advance quality and compliance training, best practices with practical technical training information, and current compliance trends for all life science regulated companies through the expertise of our membership.



BOD

- John Lewis – Merck (CEO)
- Ken Petelinkar – BMS (CFO)
- Terry McGinn – Consultant (COO)
- Vince Ranieri – J&J (CAO)
- Tammy Cullen – Eli Lilly
- Chrissy Frey - Novartis
- Maryann Fox – Adaptimmune - Member-at-Large
- Bill Beyer – Life Science Training Institute - Member-at-Large
- John Clifton – Industry Standard Research - Member-at-Large



AGXPE Platform

The AGXPE offers a platform for private and public industry leaders to:

- Share best practices, and

- Communicate upcoming changes in regulations, practices or libraries:

 - i.e. GInAS version update



Membership Numbers

- AGXPE Membership:536
 - Represents ~20% increase since April 2018
- Web & Social Media presence
 - Twitter
 - LinkedIn – **1425** members
 - Represents 50% increase since April 2018
 - Facebook



Membership - Demographics

- Compliance Trainers from all organizations
- Quality Assurance/ Quality Operations
- Quality, Manufacturing & Packaging Leadership including:
 - Directors - Managers – Supervisors – Trainers - SMEs
- Manufacturing API, Specialty Chem., Excipients, Biologics, Vaccines, Food, Medical Device, Laboratory, Blood Systems, Dietary Supplements, etc.
- Academia
 - Professors - Students
- Vendors/Consultants
- FDA/DEA/DOH/EMA
- Reciprocal agreements with similar associations
- HR & Recruiters



2018 Conference

- Le Meridien, Cambridge, MA
 - October 28-31, 2018
- 95 attendees
- Segment make-up: Pharma, Medical Device, BioPharm
- Vendors – 10

Data Integrity



Data integrity has been a big focus for the AGXPE. The conference DI Panel was a huge plus with great info shared by our SMEs.



Data Integrity Takeaways

Panel – recommendations

1. SOPs drive visibility
2. Global Health Authority focus
3. It's not new!
4. Applies to all GXP areas



Collaboration Opportunities

AGXPE broad BOD and membership offer opportunity to bridge gaps between the agency & industry.

Welcome chance to lead collaboration for improvement of data transmission/submissions

Recommend finding industry and agency leaders, forming an advisory panel and creating a potential project team to explore options for improvement



Joint Ventures

- ASQ
- ATD
- Vendor Partnerships
- ISPE
- RAPS



Questions