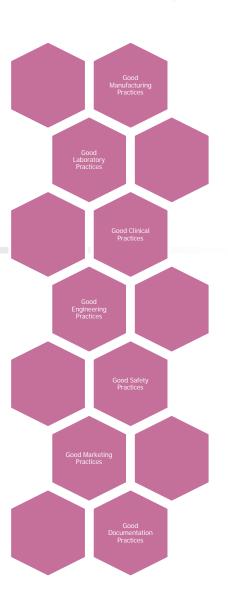


AGXPE

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





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





- 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

- SOPs drive visibility
- 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