

IPEC-Americas 2019 Year in Review

FDA Engagements

17



- ~ 13 docket comments
- ~ 3 official correspondences
- ~ 1 public FDA presentation



Global Comments Submitted

20



Publications

4



- ~ TiO2 Safety - 2 Published in Eye on Excipients;
- ~ Managing Risk for Gluten Content in Pharmaceutical Excipients
- ~ Perspective for Pharmaceutical CM
- ~ Additive and Processing Aids in Pharmaceutical Excipients

Position Papers

6



- ~ Supply Chain Security
- ~ Data Integrity
- ~ Qualification
- ~ Comparing Requirements for Excipients, Dietary Supplements and Food Additives.
- ~ Good Manufacturing Practices for Atypical Actives
- ~ Qualifying an Excipient Site that will Not Allow an Audit

Guides Under Development

13

- ~ Validation
- ~ Good Distribution Practices
- ~ Excipient Information Package
- ~ Qualification
- ~ Quality by Design
- ~ Composition



Collaboration with Other Associations



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Workshops and Webinars

- ~ Safety
- ~ GMP Compliance
- ~ Compendia
- ~ Global Regulations
- ~ Microplastics
- ~ Elemental Impurities

