Aseptic Processing Committee

**IFTPS Aseptic Processing December 11, 2020 Committee Meeting Agenda**

* Welcome and General Updates
* Gather topics for March online conference
* Develop a list of technical and regulatory questions
* Guidance documents updates

IFTPS 2020 Committee Meeting

* Corpus Perez, Aseptic Committee Chair
* Indaue Mello, Aseptic Committee Vice-Chair

**Committee Discussion Notes**

* There were approximately 50 attendees
* Aakash brought up a suggestion to leverage an outside party help on generating guidance documents drafts and content? Mark & Nate are ok with that.  Please share recommendations.
* For next year, a speaker to share best practices of pharmaceuticals which may be applicable to aseptics would be beneficial.
* Pablo Coronel, and also PTI have a contact and will share for presentation consideration.
* Sebastian Gutierrez has recommended all to visit pab.org, and to view the textbook Validation of Pharmaceutical Processes 3rd edition edited by James Agalloco and Frederick J. Carleton
* ESL validation was quite a popular topic with several attendees asking for validation requirements, information on best practices and definitions.  After the meeting several individuals asked if it’s possible for the Aseptic Committee session can be more focused on shelf stable topics.
* Post-It Notes were collected to gather the most common topics for IFTPS 2021 Aseptic Session, see final slide.

**Guidance Documents & Status**

**Aseptic Filter Validation and Maintenance Guideline**

* Ready for Final Expert Review & IFTPS Document Committee Approval

**ESL/Aseptic/Ultraclean Definitions**

* Fernanda Michelutti to kick-off.  Please inform if you want to participate.

**Sterile Barrier – Steam, Condensate specifically**

* Corpus will share draft version 2 to subcommittee shortly
* Please inform Corpus if you want to participate

**Hold Tube Sizing**

* Need a lead