

Plastics Packaging Working Group Update



Purpose



- To present the perspective of the pharmaceutical industry with respect to the following revised General Chapters
 - <659>/<661>/<661.1>/<661.2>/<1661>
 - Describe impact of the chapter revisions to various functions in industry
 - Provide a case study industry impact to implementation
- Create a collaborative dialog between industry, FDA, & USP

Danita Broyles

Plastics Packaging Working Group



Members	CoE Observers	FDA
Danita Broyles	Jeffrey Carrico	Lana Bruney
Anne M. Cook	Glaucia Karime Braga	Jennifer Goode
Amber Day	Bernard Olsen	Christine Harman
Ives De Busser		Jin Hyen Baek
Lisa Eichler-Johnson		Kai Kwok
Yan-Bo Yang		Yana Mille
Larry Pavlinac		Kevin Rice
Greg J. Mathieu		
Serap Erisken		

Implementation Timeline



▶ Is May 1, 2020 the right implementation date?

- To explore this question the Plastic working group was formed to discuss if the current implementation date is appropriate and if not what should be it

▶ Plastic Working Group

- Composition
 - FDA
 - Industry
 - USP
- Scope
 - To review the implementation timeline of the revision for Chapters <659>, <661>, <661.1>, and <661.2>.
- Objective
 - Make recommendations for an implementation date to the USP.
 - This recommendation will be based upon requirements for regulatory filing and pre-approval and to set an implementation date in consideration of regulatory implications and processes.

Plastic Working Group Activities



- ▶ The working group has met twice since its formation
 - May 1, 2018
 - June 7, 2018
 - Next meeting August 23rd

- ▶ Discussion Topic
 - questions need to be discussed/answered to make the appropriate recommendation?
 - For USP
 - For Industry
 - For FDA

Questions



Empowering a healthy tomorrow

Thank You



Empowering a healthy tomorrow