Public Meeting on ICH E8(R1)- General Considerations for Clinical Studies
FDA Great Room, Building 31, Room 1503
10903 New Hampshire Avenue, Silver Spring, MD 20993-0002

October 31, 2019

DRAFT AGENDA OUTLINE

8:30 a.m.	**Welcome, Opening Remarks**
8:45 a.m.	**Session I: The role of E8 as part of the ICH GCP Renovation, and next steps- 60 minutes**
	Presentations
10:00 a.m.	**Session II: Drug Development Plan – 60 Minutes**
	Presentation **Stakeholder Panelist Perspective** **Public Input**
11:00 a.m.	**Session III: Components of Study Design – 60 minutes**
	Presentation: **Stakeholder Panelist Perspective** **Public Input**
1:00 p.m.	**Session IV: Quality by Design/ Critical to quality factors – 90 minutes**
	Presentation: **Stakeholder Panelist Perspective** **Public Input**
2:45 p.m.	**Session V: Data sources – 90 minutes**
	Presentation **Stakeholder Panel Perspective** **Public Input**
4:15 p.m.	**Open Comment**
4:45 p.m.	**Closing Remarks, Adjournment**