USP Biologics Stakeholder Forum

In Vitro Assays for Assessing Immunogenicity Risk in CMC

June 17-18, 2025

Virtual Event 9:00 a.m. – 11:25 a.m.

All times are in Eastern Daylight Time (EDT) – Washington DC time zone

https://www.usp.org/events-training/in-vitro-assays-for-assessing-immunogenicity-risk-in-cmc

Preliminary Agenda

Day One: Tuesday, June 17th, 2025: In Vitro Immunogenicity Assays

09:00 a.m. – 09:10 a.m.	**USP Welcome and Opening Remarks** Diane McCarthy, USP, Global Biologics
09:10 a.m. – 09:15 a.m.	**Introduction** Moderator: Robert Siegel, Lilly
09:15 a.m. – 09:45 a.m.	**In Vitro Assays: Perspectives for Innovators and Generics** Andrew Graves, Teva
09:45 a.m. – 10:15 a.m.	**T cell Assay Harmonization Efforts Using HESI Standard Material** Laurent Malherbe, Lilly (HESI)
10:15 a.m. – 10:45 a.m.	**Regulatory Perspective for In Vitro Assays for Immunogenicity Risk Assessment in CMC** Montserrat Puig, FDA, CDER
10:45 a.m. – 11:15 a.m.	**Moderated Discussion** Moderator: Robert Siegel, Lilly
11:15 a.m. – 11:20 a.m.	**Closing Remarks** Robert Siegel, Lilly
11:20 a.m.	**Adjourn**

Day Two: Wednesday, June 18th, 2025: Host Cell Protein Immunogenicity

09:00 a.m. – 09:05 a.m.	**Welcome** Ben Clarke, USP, Global Biologics
09:05 a.m. – 09:20 a.m.	**Introduction to Assays for HCP Immunogenicity Risk Assessment** Moderator: Ned Mozier
09:20 a.m. – 09:50 a.m.	**HCP Immunogenicity** Vibha Jawa, Bristol Myers Squibb
09:50 a.m. – 10:20 a.m.	**Regulatory Perspective for Immunogenicity Assessment of Host Cell Proteins in Biotherapeutics** Mohanraj Manangeeswaran, FDA, CDER
10:20 a.m. – 10:50 a.m.	**In vitro, In vivo, and In clinic impact of Attributes** Ahmed Elbaradei, Amgen
10:50 a.m. – 11:20 a.m.	**PLBL2 and Immunogenic HCPs** Christina de Zafra, Pfizer
11:20 a.m. – 11:50 a.m..	**Moderated Discussion** Moderator: Ned Mozier
11:50 a.m.– 11:55 a.m.	**Closing Remarks** Ned Mozier
11:55 a.m.	**Adjourn**