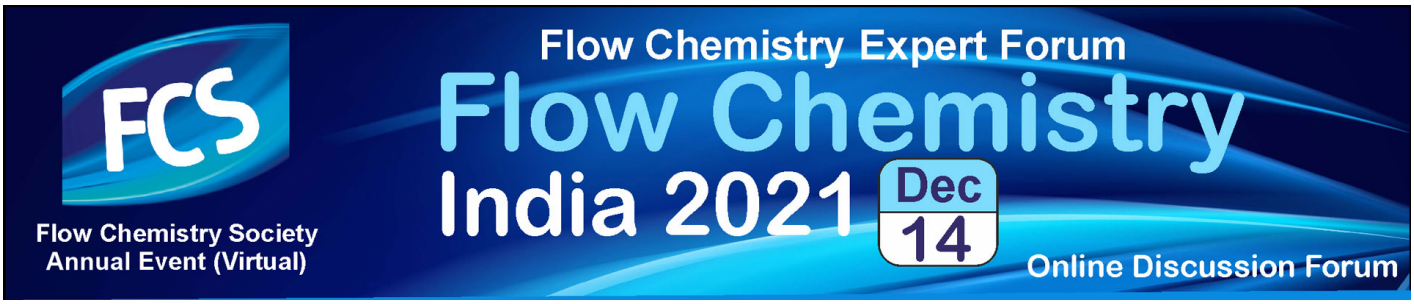

Flow Chemistry India 2021

14 Dec 2021 - 14 Dec 2021

CONFERENCE PROGRAMME

Thursday, 20th January 2022

14:00	**ICH E8 (R1) FINAL Guideline on General Considerations for Clinical Studies**
14:00	**Welcome and Introduction to the Tutor** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India
14:05	**Technical Session 1** **Liz Wool** , President & CEO , Wool Consulting Group , USA 1. Describe the General Principles in ICH E8 (R1) 2. Discuss designing QUALTY into clinical trials 3. Explain drug development planning
15:30	**Break**
15:40	**post lunch**
15:40	**Technical Session II** **Liz Wool** , President & CEO , Wool Consulting Group , USA 4. Identify clinical study design elements and data sources for clinical studies 5. Assess trial execution activities that includes study conduct, participant safety and study reporting 6. Interpret considerations in identifying critical to quality factors
17:00	**Q/A Session**
17:30	**Closing of Day 1**

Friday, 21st January 2022

14:00	**International Conference for Harmonisation (ICH) E6 Good Clinical Practice (GCP) Pending Revision 3 in 2022**

14:05	**Technical Session I** **Liz Wool** , President & CEO , Wool Consulting Group , USA 1. Describe the reasons for a third revision (R3) to ICH E6 GCP 2. Discuss the overarching principles document added to ICH E6 GCP (R3)
15:30	**Break**
15:40	**Technical Session II** **Liz Wool** , President & CEO , Wool Consulting Group , USA 3. Explain the new ANNEXEs that are added to ICH E6 E6 GCP (R3)
17:00	**Q/A Session**
17:25	**Closing Remarks** **Sanjay Bajaj** , CEO & MD , Glostem Private Limited , India