**Topic-** *Global Regulatory CMC strategies and challenges for Biologicals*

**Agenda Outline**

*8:00-8:30 am Welcome and Workshop Introduction*

*8:30-9:30 am Introduction of Biologics and Challenges*

*9:30 am-9:40 am Polling for Audience and Discussion
9:40-10:00 am Regulatory Pathways for Biologics*

*10:00-10:30 am Refreshment Break*

*10:30-11:30 am Stepwise Approach for Regulatory Strategies-Part 1*

*11:30-12:00 pm Group Exercise*

*12:00-1:00 pm Lunch
1:00-1:30 pm Stepwise Approach for Regulatory Strategies-Part 2*

*1:30-1:45 am Polling for Audience and Discussion*

*1:45-2:30 pm Case study: Real-life example of regulatory changes*

*2:30-3:00 pm Refreshment Break*

*3:00-3:45 pm Interactions with Regulatory authorities
3:45-4:15 pm Case study: Interactions with Health Authorities*

*4:15-4:30 pm* Q&A *for Audience and Discussion
4:30-5:00 pm Review of the Day: Tying It All Together
5:00 pm Adjourn*