

# The INAUGURAL TOPRA NORTH AMERICA Meeting Report



## Scientific Advice: EU and US Considerations

*Comparison of Processes and Strategic Considerations in Timing and National Advice – Industry Perspective*

**Carolyn Kruse** (*Kruse Consulting Group*)

FDA communications can take place in different formats from telephone calls all the way to formal meetings. It is strongly recommended that all interactions are documented. **Carolyn Kruse** discussed the various types of meetings with the FDA in more detail, including setting meeting goals, scheduling meetings, minutes, requests, the meeting Background Package and the meeting itself.

Subsequently, she discussed the process of scientific advice in the European Union, including the scope of meetings, the process and timelines and how to conduct a meeting including the "do's and don'ts". It was strongly advised that companies seek early scientific advice to prevent situations that affect timing of approvability of an application due to conditions that could have been discussed and resolved early in the process.



Carolyn Kruse