

NERC  
SQA



## *New England Regional Chapter Society of Quality Assurance*



**CCSQA**

Canadian Chapter of the  
Society of Quality Assurance

**FCSQA**

Filiale Canadienne de la  
Society of Quality Assurance

**Meeting will be held in North Conway, New Hampshire on June 11<sup>th</sup> and 12<sup>th</sup> 2019.**

7:30-8:30: Breakfast and meet the speakers social

8:30-9:00: Opening remarks by NERCSQA and CCSQA

9:00-10:00: First speaker: Running GLP Cell based Therapy Programs-Scientist from CBSET.

10:00-11:00: Second Speaker: OECD Guidance 19-Management, Characterization, and Use of Test Items-Franco Mancini-ITRLABs.

11:00-11:15-Break

11:15-12:15- Third speaker: ICH E6(R2) Compliance: Employing GMP Techniques in GCP for More Robust, Compliant Clinical Trials-Dr. Judy Carmody, Carmody Quality Solutions.

12:15-12:30: Summary of morning speakers and questions (round table)

12:30-13:45: Lunch (or longer to give people time to check e-mail etc.)

13:45-14:45: Fourth Speaker: Draft Immunogenicity Guidance-Nadia Bonvouloir, Charles River Labs.

14:45-15:45: Fifth Speaker: TBD

15:45-16:00 Break

16:00-16:45: Roundtable with speakers and wrap-up.

**Second Day:**

7:00-8:30: Buffet Breakfast and meet the speakers social

8:30-8:45: Summary wrap of yesterday speakers

8:45-10:15: First Speaker(s) Deviations in GLP – How to use them in the right way  
-Sherry Lee Dawson and Stephanie Rene, Charles River Labs.

10:15-10:45: Second Speaker: 2019 SQA Meeting Summary-Randi LaMadeleine,  
Toxikon.

10:45-11:00: Break

11:00-12:00: Third Speaker: Root Cause Analysis (RCA), Planning,  
Implementation, Expectations and Outcomes-Judyth Zahora, Sarepta Therapeutics

12:00-12:30: Wrap-up and questions