PROGRAMME SCHEDULE:

7:30 am – 8:30 am  Registration and Hot Breakfast

8:30 am – 8:45 am  Welcoming Remarks

8:45 am – 9:30 am  Biosimilars: Regulatory Updates and “Hot Topics”.

Stephanie Hardy, Policy Unit Manager Office of Policy and
International Collaboration, Biologics and Genetic Therapies
Directorate, Health Products and Food Branch, Health Canada

Questions and Answers

9:30 am – 10:15 am  BGTD Perspective on NDS Quality and Post-NOC Changes Quality Guidance

Sherri Boucher, Senior Scientific Evaluator, Bacterial and
Combination Vaccines Division, Centre for Biologics Evaluation,
Biologics and Genetic Therapies Directorate, Health Products and
Food Branch, Health Canada

Questions and Answers

10:15 am – 10:45 am  Morning Break

10:45 am – 11:45 am  Best Practices to Consider When Filing - Plain Language Label

Veronica Yip, Manager, Labelling Division
Therapeutic Products Directorate/ Health Products and Food Branch
Health Canada / Government of Canada

Questions and Answers

11:45 am – 1:00 pm  Lunch
1:00 pm – 2:00 pm  
**Natural and Non-prescription Health Products Directorate (NNHPD): Self-Care Products Framework**

Amanda Moir, Director, Consumer Health Products Modernization  
Natural and Non-prescription Health Products Directorate, Health Products and Food Branch Health Canada / Government of Canada

Questions and Answers

2:00 pm – 2:45 pm  
**Food and Drug Act Changes due to CETA (Canadian-European Union Comprehensive Economic and Trade Agreement)**

Junyi Chen, Associate, Deeth Williams Wall LLP  
Heather Watts, Partner, Deeth Williams Wall LLP

Questions and Answers

2:45 pm – 3:15 pm  
**Afternoon Break**

3:15 pm – 4:00 pm  
**Strategies for Filing Efficient Submissions and Brief Overview of Project Management While Submissions are in Review**

Rachel Licari, Regulatory Project Manager, Health and Food Branch, Health Canada, Government of Canada

Questions and Answers

4:00 pm – 4:15 pm  
**Closing Remarks**  
CAPRA Education Day Committee