

International Generic Pharmaceutical Association (IGPA)
Conference Workshop
Recent Issues in the World of APIs – International and Canadian Perspectives

September 30, 2009 - Ville-Marie Room, 9th floor, Le Westin Montreal, Canada

Workshop Directors: Luciano Calenti, ACIC and
Andrew Adams, Therapeutic Products Directorate, Health Canada

8:30 – 9:00 **Registration**

9:00 – 9:10 **Opening Remarks from Workshop co-chairs**

9:10 – 9:40 **Stephen Horne, Vice-President, Research and Development, Apotex Pharmachem**

9:40 – 10:40 **Featured Speaker: Sponsored by Infa Group**
Dr Trevor Laird, Managing Director, Scientific Update LLP
Cost of Goods in API manufacturing. How low can you go?



Manufacture of generic APIs must be, not only to high specification, but also low cost. In many instances API manufacturers are using synthetic routes which are patentable but non-optimal and can, even after extensive development, never achieve low cost of goods required to compete. Agrochemicals has the same problem of trying to make a complex molecule in high purity at low cost. Can we learn from the lessons of a different industry? I think we can. The talk will examine strategies for low cost manufacture of generics and explore techniques for cost reduction without losing quality. The importance of true optimisation of, not only yields, but space-time-yield and other measures of efficiency will be explored.

10:40 – 11:00 **Networking Break**

11:00 – 11:25 **Andrew Adams, Director, Bureau of Pharmaceutical Sciences, Health Canada**
Overview of the Canadian regulatory system as it applies to generic drugs

11:25 – 11:50 **Neil Barkat, Advisor, Bureau of Pharmaceutical Sciences, Health Canada**
An analysis of the Integrated Review Process of Abbreviated New Drug Submissions

11:50 – 12 noon **Questions and Answers**

12:00 to 13:00 **Lunch**

13:00 –13:30 **Pauline Gaudry, Publications and Information Officer, Bureau of Pharmaceutical Sciences, Health Canada**
DMF Guideline

13:30 –14:30 **Stéphanie Parra, Manager, Bureau of Pharmaceutical Sciences, Health Canada**
Quality data for drug substances: What to submit and common deficiencies to avoid

14:30- 15:00 **Questions and Answers**

15:00 – 15:30 **Networking Break**

15:30 –17:00

Debate: Pros and Cons of Separate DMF Review in Canada

Debate Master: Julie Tam, CGPA

Regulatory view: Andrew Adams, TPD

DMF View: Luciano Calenti, ACIC

Drug Sponsor View: Len Arsenault, Sandoz