



Bureau of Pharmaceutical Sciences – DIN Workshop

Sponsored by Groupement provincial de l'industrie du médicament (GPIM)

Thursday, October 2, 2003

8:30 a.m. to 12:00 noon

Auberge Universel, Salle Viau

5000, rue Sherbrooke Est
Montréal, Québec

**This is a must attend Workshop for anyone involved in preparing or submitting
DIN plus Appendix submissions.**

AGENDA

8:30 a.m. REGISTRATION / CONTINENTAL BREAKFAST

9:00 a.m. **Welcome and Opening Remarks**

q Ms. Suzanne Levesque, President, GPIM

q Mr. Sultan Ghani, Director, Bureau of Pharmaceutical Sciences (BPS)

Overview of the BPS organizational structure and activities. Strategic and operational priorities for 2003-2004 will be highlighted.

9:30 a.m. **Submission Screening Process for DIN Submissions Involving Form and Supporting**

*q Ms Joyce Pon, Senior Regulatory Project Manager,
BPS*

This presentation will provide an overview of the process of a submission upon receipt by Health Canada to the issuance of a Drug Identification Number.

9:45 a.m. **Common Issues Identified in the Screening of DIN Submissions**

q Ms Joyce Pon, Senior Regulatory Project Manager, BPS

This presentation will provide deficiencies, omissions or issues commonly encountered in the screening of DIN submissions.



- 10:00 a.m. **Common Issues Identified in the Review of DIN Submissions**
 q *Mr. Michel Bourdon,, Manager, Clinical Trials Quality Division, BPS*

This presentation will provide deficiencies, omissions or issues commonly encountered in the review of DIN submissions.
- 10:15 a.m. BREAK
- 10:30 a.m. **Highlights of the Quality (Chemistry and Manufacturing) Data Requirements in the New Draft DIN Guidance Documents**
 q *Mr. Gary Condran, Scientific Policy Advisor, BPS*

This presentation will provide an overview and highlights of new draft documents to provide guidance on the content and format of the Quality portion of DIN submissions.
- 11:00 a.m. **BSE/TSE Update**
 q *Mr. Arvin Naperstkow, Manager, Oral-Topical Quality Division, BPS*

This presentation will focus on the current status of issues concerning BSE/TSE.
- 11:15 a.m. **Question & Answer Panel Session**
- 11:55 a.m. **Closing Remarks**
 q *Ms. Suzanne Levesque, President, GPIM*