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*Votre santé et votre
sécurité... notre priorité.*

Health Canada's 2015 Regulatory Workshop on Radiopharmaceuticals

March 12 & 13, 2015
Confederation Room
John G. Diefenbaker Building
111 Sussex Drive
Ottawa, Ontario



Canada 

CONFERENCE INFORMATION

REGISTRATION

To register for the 2015 Radiopharmaceuticals Workshop please send your completed registration from to bgtd.opic@hc-sc.gc.ca.

Please register by February 20, 2015.

Workshop Sign-In

Location: Confederation Room Foyer
Thursday, March 12: 0800 – 1600
Friday, March 13: 0800 – 1200

WORKSHOP LOCATION

The 2015 Radiopharmaceutical Workshop is being held in the Confederation Room of the John G. Diefenbaker Building at 111 Sussex Drive in Ottawa. Area maps can be found on page 8 of this program.

HOTEL INFORMATION

The Westin Ottawa

11 Colonel By Drive
Ottawa, Ontario, Canada
Phone: 613-560-7000 or 1-888-627-8528
\$157-per night (price includes complimentary breakfast and wifi access)
Booking Code: HCC09A
<http://www.thewestinottawa.com/>

GETTING TO THE WORKSHOP

By Taxi

Blue Line (613) 238-1111 | **Capital Taxi** (613) 744-3333 | **West Way** (613) 727-0101
DJ's (613) 829-9900

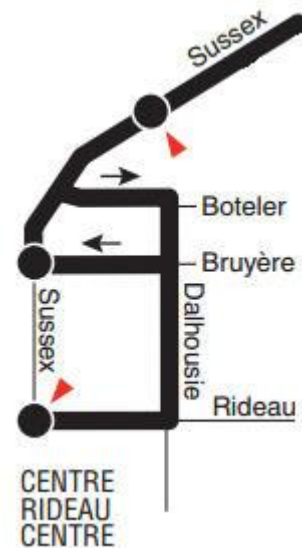
On Foot

The John D. Deifenbaker Building is a little over 2KM from the Westin Hotel. By walking down Sussex Drive you will reach the venue in about 25-30 minutes. That is, if

you aren't distracted by all the wonderful sights to see!

By Public Transit

The OCTranspo Route #9 passes by the Rideau Centre, which is connected to the Westin Hotel and goes to the venue. On the map below the triangles indicate your stops. The #9 departs Rideau Centre stop 3A every 7-10 minutes on weekday mornings and the cash fare is \$3.45. Visit <http://www.octranspo.com> for more information.



By Car

Paid parking is available in the underground parking garage.

GETTING TO OTTAWA

By Air

Ottawa International Airport (YOW) is located about 15KMs from the Westin Ottawa. A taxi from the airport to the Westin Ottawa would cost between \$35 and \$40 depending on traffic and rates. All taxis in Ottawa are metered.

OCTranspo provides regular bus service to and from the Airport on route #97, which

also provides service to downtown Ottawa and the Westin Ottawa via the stop at Mackenzie King Station.

There are also many car rental options available at Ottawa International Airport.

By Train

The Ottawa Train Station is located 5 KMs from the Westin Ottawa and has regular trains to/from Toronto, Montreal, and Quebec City. Note: there are two train stations in Ottawa; the downtown location on Tremblay Road is the more convenient option.

A taxi from the train station to the Westin Ottawa would cost around \$15.

OCTranspo provides regular and frequent bus service to the train station along the Transitway. To take the bus from the train station to the Westin take any regular route Westbound from the Train station stop.

There are also car rental options available at the Ottawa Train Station.

By Bus

Ottawa Central Station is located in downtown Ottawa about 4KMs from the Westin Ottawa and has regular service to/from a number of locations.

A taxi from Ottawa Central Station to the Westin Ottawa would be about \$15.

OCTranspo provides regular service to the bus station to other points downtown via Bank Street, 2 blocks from the station. Take any route northbound along Bank Street.

There are no car rental agencies inside the bus terminal; however there are options close by within walking distance.

From Montreal certain routes will stop at the University of Ottawa on Laurier Ave, which would be a short walk to the Westin Ottawa.

MEALS AND REFRESHMENTS

Food provided at the Conference includes:

- Coffee and tea will be served daily during the mid-morning and mid-afternoon coffee breaks
- Daily lunches

There are many dining options close to The Westin Ottawa hotel. The hotel is connected to the Rideau Centre which has a food court. Please visit <http://www.rideaucentre.com/> for more information. The hotel is also walking distance to the Byward Market (<http://www.byward-market.com/>) which has over 80 dining options.

March 12th - Day 1

9:00 AM Opening Remarks

Welcome and Introductions

Anil Arora, Assistant Deputy Minister, HPFB & Catherine Parker, A/Director-General, BGTD

Objectives and Expected Outcomes of the Regulatory Workshop

Agnes Klein, BGTD Chair

Overview of Day 1 of the Regulatory Workshop

Anne Goodbody & Doug Abrams, CANM-CARS / NMA, Co-Chairs

9:15 AM Session 1: New Initiatives and Ongoing Challenges

HPFB Roadmap - Bill C-17 and Orphan Drugs

Lynn Mainland, Office of Legislative and Regulatory Modernization, PPIAD

Small Volume - Low Demand - Limited Use RPs Challenges on Availability, Access and Usage

Ingrid Koslowsky, Calgary Radiopharmaceutical Centre

Special Access Program – SAP

Therapeutics Products Directorate

Q&A Period

10:20 AM COFFEE BREAK

10:40 AM Session 2: Overview of the Regulatory Process

The Radiopharmaceutical Guidance - Overview of guidance - Comparison of requirements Single Photon Radiopharmaceuticals v. PERs

Jian Wang, Centre for Radiopharmaceuticals and Biotherapeutics, BGTD

The Radiopharmaceutical regulatory process - Development to Authorization - Challenges, and Past Experiences

Sandor Demeter, Winnipeg Regional Health Authority

DINs for Radiopharmaceuticals – A Voluntary Approach

Christopher Antonio, Office of Regulatory Affairs, BGTD

Basic Research Application Guidance for PERs

Christopher Antonio, Office of Regulatory Affairs, BGTD

Experience with new PERs for Basic Research Application Process

Radiopharmaceutical Community Speaker

Q&A Period

12:00 PM LUNCH (provided)

March 12th - Day 1

1:00 PM Session 3: Therapeutic Radiopharmaceuticals

Therapeutic Radiopharmaceuticals – Approval Process - An overview - Diagnostic v. Therapeutic

Corinne Bensimon, Centre for Radiopharmaceuticals and Biotherapeutics, BGTD

Therapeutic RPs - What's in the Pipelines?

Radiopharmaceutical Community Speaker

DINs: challenges to ensure national availability

Sandy McEwan, Department of Oncology, University of Alberta

Q&A Period

2:20 PM COFFEE BREAK

2:40 PM Session 4: The Reality of Shortages

Drug Shortages

Al Vachon, Strategic and Horizontal Policy Division, PPIAD

AECL re-structuring, the effort underway at the OECD regarding the coordination of the global supply chain, and the NRCan ITAP program

Jean Pruneau, Office of Pharmaceuticals Management Strategies, SPB

Alternative methods for manufacturing Tc-99m

Radiopharmaceutical Community Speaker

Strategies during Shortages - Isotope vs. Kits Shortages

Daniel P. Levin, Health Sciences Centre, Winnipeg

Q&A Period

4:00 PM Closing Remarks - Summary of Day 1 – [All Co-Chairs]

March 13th - Day 2

9:00 AM Opening Remarks

Welcome

Agnes Klein, BGTD Chair

Overview of Day 2 of the Regulatory Workshop

Anne Goodbody & Doug Abrams, CANM-CARS/NMA Chairs

9:10 AM Session 5: Compliance and Enforcement

GMP Requirements for PERs – Update on revisions to GUI-0071

Monica Groves, Inspectorate Program, Atlantic, RAPB

PERS - GMP Compliance and Regulatory Challenges

Shadreck Mzengeza, Winnipeg Cyclotron Facility, Health Sciences Centre

GMP Inspections - Trends in Findings (Single Photon versus PERs)

Joan Muria, Inspectorate Program, Ontario, RAPB

Perspective from the community

Radiopharmaceutical Community Speaker

Q&A Period

10:20 AM COFFEE BREAK

10:40 AM Session 6: Compliance and Enforcement (continued)

Active Pharmaceutical Ingredients (APIs) – Establishment Licensing and Good Manufacturing Practices (GMP) Requirements for Schedule C Drugs

Paul Gustafson, Good Manufacturing Practices Unit, HPFB Inspectorate

Industry's Perspective on API GMP Requirements - Challenges and Brainstorming on the definition

Radiopharmaceutical Community Speaker

GMP Requirements for Schedule C Drugs, including Annual Product Quality Review (APQR) and Recalls

Roy Thaller, Inspectorate Program BC, RAPB

Q&A Period

12:00 PM LUNCH (provided)

March 13th - Day 2

1:00 PM

Session 7:

Adverse Drug Reaction Reporting

Jenny Lee Choon, Marketed Health Products Safety and Effectiveness Information Bureau, MHPD

Foreign Reviews

Louise Dery, International Affairs Division, PPIAD

ICH: An Overview

Anthony Ridgway, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics, BGTD

Q&A Period

2:20 PM

COFFEE BREAK

2:40 PM

Session 8: Open Engagement

Discussion Session

Facilitator : Fern Levine, Centre for Evaluation of Radiopharmaceuticals and Biotherapeutics

4:00 PM

Closing Remarks

Summary of Day 2

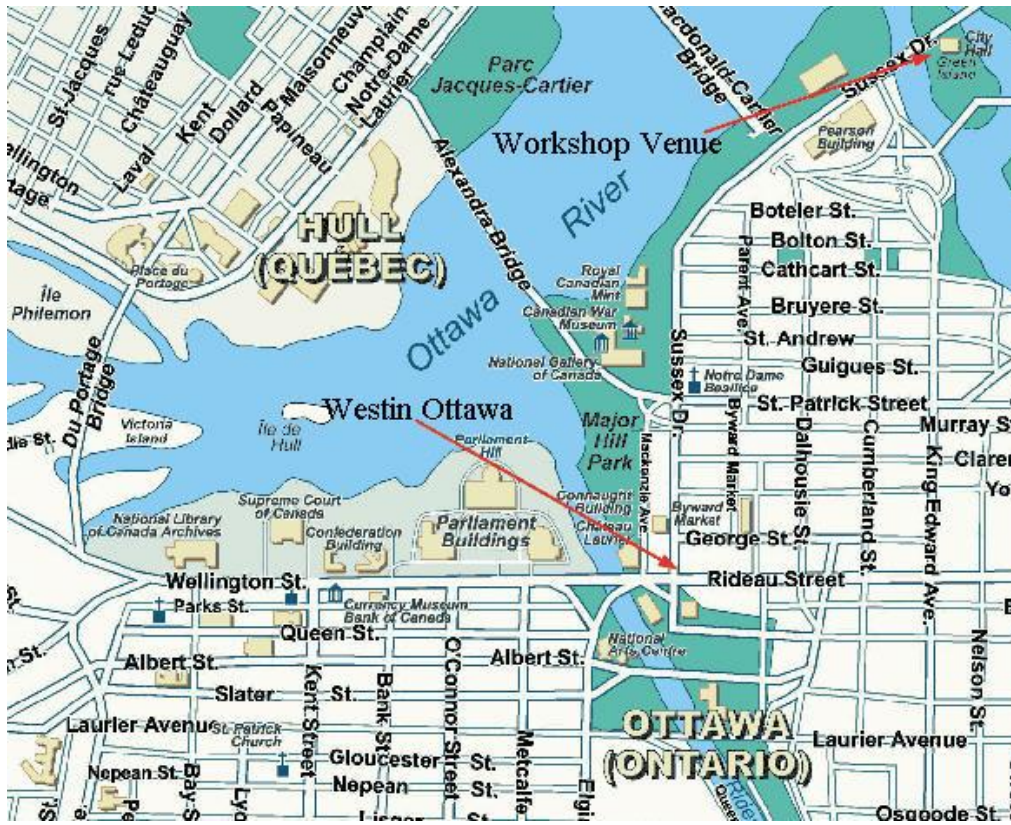
[All Co-Chairs]

Closing Remarks

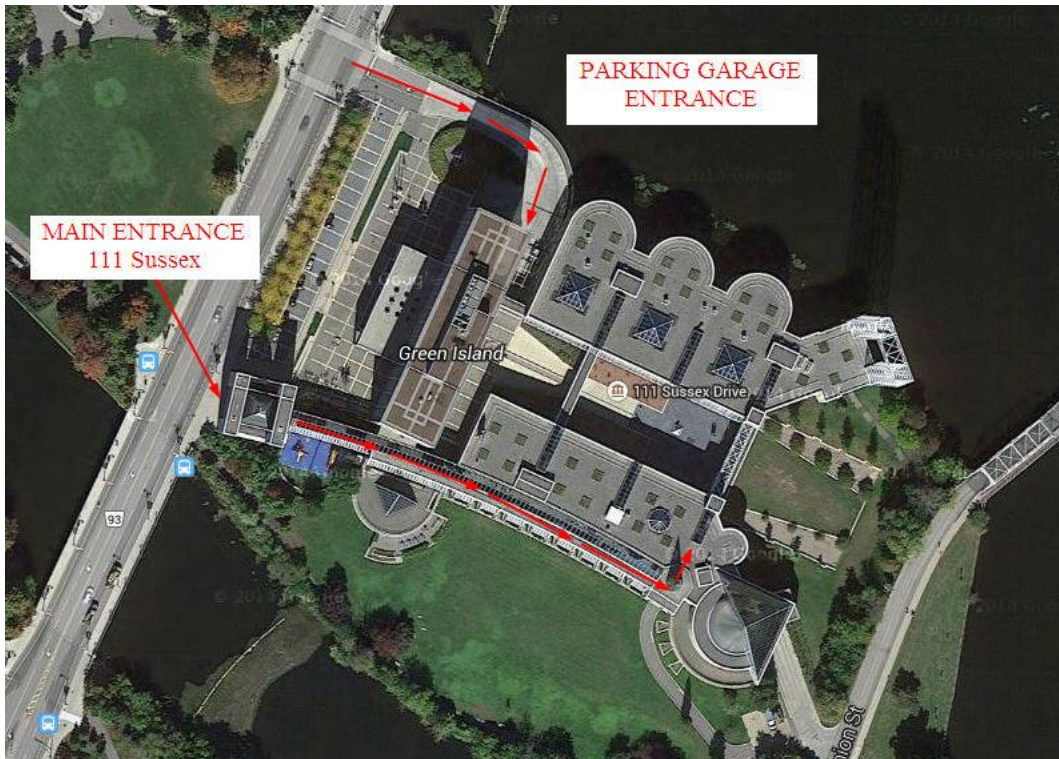
[All Co-Chairs]

Maps of the John G. Diefenbaker Building, 111 Sussex Drive

Map



Satellite View of the Building Exterior



Maps of the John G. Diefenbaker Building, 111 Sussex Drive

Interior Map with directions to the Confederation Room

