



# Discover Global Markets and Its Impact on Doing Business in Canada

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# About Canada



- **Prime Minister:** Stephen Harper
- Conservative Party of Canada
- **Population:** 35 Million
  
- **2<sup>nd</sup> Largest Country in the World**
- 10 provinces & 3 territories
- 6 time zones
- 2 official languages
  
- **Rich in Natural Resources**
- 2<sup>nd</sup> Largest Oil Reserves in the World
  
- **Common border with the U.S.** Longest land border in the world

# U.S. – Canadian Market

- **World's largest trading relationship**
- **\$1.3 Trillion Economic Relationship**
  - U.S. Exports to Canada surpassed \$365B in 2013 or 19% of total U.S. exports.
- **Our Largest Trading Partner**
  - Canada and the United States trade more than \$2B in goods and services daily.
- **Investment Partners**
  - The U.S. is Canada's primary source of direct investment, with investment stock totaling \$352B in 2013. Canada invested \$318B (4<sup>th</sup>).



*“No two nations match up more closely together, or are woven together more deeply, economically, culturally than the United States and Canada.” Barack Obama*

# “Doing Business” in Canada and U.S. – Canada Tax Treaty

## **Doing business in Canada**

- When soliciting orders, offering goods for sale, through an agent or employee.
- Not when through an independent sales representative.
- Must register with Canadian tax authorities
- Subject to Canadian tax legislation in all aspects, like a Canadian business

## **U.S. – Canada Tax Treaty**

Coverage - Must be a U.S. resident, and qualifying person under the Limitation on Benefits provision:

- Only business profits through a Permanent Establishment in Canada may be subject to Canadian tax.
- Branch tax of 5% may apply but exempt on first \$500K of taxable income.

# Moving Goods Across the Border

Consumer packaging and labeling

requirements: [compbureau@cb-bc.gc.ca](mailto:compbureau@cb-bc.gc.ca)

Sales Taxes applicable to sales in Canada: Harmonized Sales Tax (GST) and Provincial Sales Tax (PST) are collected by provinces

Non-Resident Importer (NRI) program: US company is exporter/importer, registered with Canadian tax authorities, without need of physical presence in Canada



# Canada's Anti-Spam Legislation

- Took effect July 1, 2014
- Applies to anyone sending a CEM to Canada
- Unless exemption applies, requirements are:
  - With consent (express or implied)
  - Identifying information must be provided about sender
  - An unsubscribe mechanism is available
- Express consent requires active 'opt-in'
- Max fines: \$1M for individuals/\$10M for corporations
- Contact a law firm to aid in developing marketing campaigns

# Product Certification



- Contact the Standards Council of Canada [www.scc.ca](http://www.scc.ca).
- **CSA International** – A complete list of products that CSA certifies for Canada; <http://www.csa.ca>
- **ULC** – A complete list of products that ULC certifies for Canada; <http://www.ulc.ca/>  
*Underwriters Laboratories (UL) in the United States and CSA have a memorandum to accept each other's test results. However, each issues its own certification marks.*
- **CGSB** – A complete list of products that CGSB certifies for Canada; <http://www.ihs.com/products/industry-standards/organizations/cgsb/index.aspx>
- **BNQ** – A complete list of products and services that BNQ certifies for Canada; <http://www.bnq.qc.ca/>

# U.S. – Canada Beyond The Border (BTB)

- A joint initiative to promote economic competitiveness and perimeter security
- Coordinates and plans border infrastructure improvements with a Border Infrastructure Investment Plan
- Nexus Trusted Traveler Program, and the Trusted Trader Program

# Beyond the Border Action Plan – Objectives

- Addressing Threats Early
- Trade Facilitation, Economic Growth, and Jobs
- Integrated Cross-Border Law Enforcement
- Critical Infrastructure and Cybersecurity
- Managing Our New Long-Term Partnership



# Nexus Trusted Traveler Program

- **The NEXUS program allows pre-screened travelers expedited processing** by U.S. and Canadian officials at dedicated processing lanes at designated northern border ports of entry, at NEXUS kiosks at Canadian Preclearance airports, access to **TSA Pre✓™** at US airports, and at marine reporting locations.
- NEXUS – Trusted Traveler - use the link to learn how to enroll <http://www.cbp.gov/travel/trusted-traveler-programs/nexus> .
- BTB facilitates cross border movement of business travelers, by allowing travelers to submit applications for a TN (Trade NAFTA) visa prior to arriving at the border and by efforts to achieve greater consistency in the process of NAFTA travelers.
- TN NAFTA Professionals – refer to the USCIS link for more information:  
<http://www.uscis.gov/working-united-states/temporary-workers/tn-nafta-professionals>

# Trusted Trader Programs

- Develop a joint approach for security screening of inbound cargo from offshore. This would reduce the number of shipments that are re-inspected at the border, benefiting shippers and consumers alike.
- U.S. Customs and Border Protection (CBP) Customs-Trade Partnership Against Terrorism (C-TPAT) and Canadian Border Services Agency (CBSA) Partners In Protection (PIP) expedite cross border transit for companies that follow best practices in securing their supply chain.
- C-TPAT harmonization project and PIP offer joint applications to importers that want to join both programs. <http://www.cbp.gov/border-security/ports-entry/cargo-security/c-tpat-customs-trade-partnership-against-terrorism>

# What is next with Beyond The Border (BTB)

- BTB has increased and harmonized value thresholds for expedited customs—meaning companies don't make formal entry for shipments valued at less than \$2500.
- Testing whether border wait times and border congestion can be decreased through a pre-inspection commercial truck pilot. The pilot involves the U.S. conducting its primary inspection of U.S.-bound truck cargo while still in Canada.
- For more information on the BTB Action Plan see [www.dhs.gov/beyond-the-border](http://www.dhs.gov/beyond-the-border), to learn more about the Trusted Traveler and Trusted Traded programs see [www.cbp.gov](http://www.cbp.gov)

# Regulatory Cooperation Council

The RCC is comprised of four distinct issue areas:

- Agriculture and Food
- Health and Consumer Products
- Transport
- The Environment

and two cross-sectoral areas

- Nanotechnology
- Small Business Lens

# Overview of the Canadian Medical Device Industry



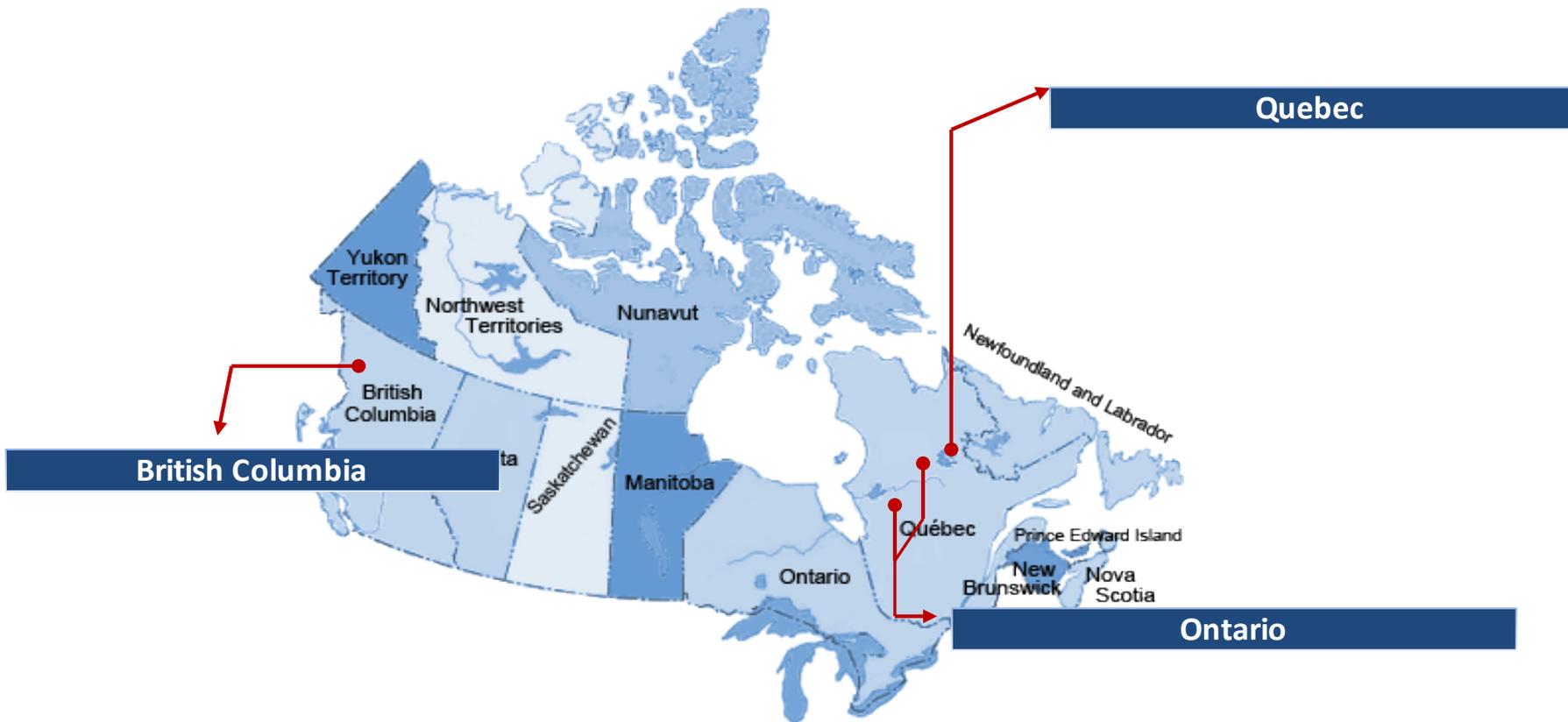
# Canada: Top Choice for Medical Device Industry

This U.S. Commercial Service webinar aims to help you gain expertise in Canada that is rated by the Economist Intelligence Unit as the number one place to do business in the G-7 for the next five years. Canada has an estimated \$6.4 billion (2012) medical device market accounting for about 2 percent of the global market demand. Approximately 80 percent of the market is supplied by imported medical devices.

# Canadian Medical Device Industry

- Highly diversified and encompasses more than 1,000 firms employing some 26,000 people
- Canadian market value for health care equipment & supplies grew by 3.9% in 2011 to reach a total value of CND\$10.2 billion
- Market growth is forecast to accelerate, which is expected to drive the total market to a value of CDN\$13.2 billion by the end of 2016
- Demographic trends, developments in science and engineering, and health care delivery changes are expected to contribute to the industry's growth in the years ahead
- The industry is primarily based in the three largest provinces— Ontario, Quebec and British Columbia—with over 80 percent of the medical device industry located in the provinces of Ontario and Quebec

# Canadian Medical Device Industry: Major Markets



# Canada's Health Care System

## **Mixed public-private system**

- Private sector delivers health care services
- Public sector is responsible for financing those services

## **Provincial health care regimes**

- Health care falls under the authority of the provinces
- Federal government has no power to pass laws regarding the health care system
- Health care system differs by province in terms of structure and operation



# Canadian Medical Devices

Top ten Canadian medical device imports			
Commodity	Harmonized System Code	2012 Imports (Value of Shipments)	% of Total Medical Device Imports
<i>Source: World Trade Atlas</i>			
Laboratory reagents	3822000020	\$520,561,808	7.4
Instruments & appliances parts	9018909090	\$493,728,085	7.1
Bougies, catheters, drains, sondes, and parts	9018390010	\$296,013,162	4.2
Artificial parts of the body	9021390000	\$294,396,764	4.2
Antisera & other human blood fractions for diagnostic purposes	3002100010	\$225,159,236	3.2
Artificial joints	9021310000	\$207,557,435	3.0
Orthopaedic & fracture appliances	9021100000	\$202,579,485	2.9
Mechano-therapy appliances	9019100010	\$195,962,690	2.8
Instruments and appliances, used in dental science	9018490000	\$191,919,927	2.7
Therapeutic respiration apparatus	9019200000	\$181,238,586	2.6
<b>Total Top 10 Imports</b>		<b>\$2,809,117,178</b>	<b>40.1</b>

# Industry Attractiveness

**Canada's medical device industry is one of the largest and richest in the world**

## **Favorable business environment**

- NAFTA eliminates trade barriers on a variety of goods providing a favorable position for U.S. exporters to Canada.
- The Economist Intelligence Unit rated Canada the number one place to do business in the G-7 for the next five years

## **Low tax rates**

- Corporate tax rates in Canada are among the lowest in the G-7

## **Regulatory process emphasizes harmonization with the United States**

- In recent years, Canadian authorities have worked at harmonizing their regulations for medical devices with those of Europe and the U.S.

# Industry Attractiveness

## **Financial stability**

- Over the past three years, Canada's banking system has repeatedly been declared the soundest in the world by the World Economic Forum

## **Sound economy**

- Since the third quarter of 2009, Canada's economy has grown at an average rate of 0.6% and has now fully recovered job and output losses that occurred during the global economic crisis
- According to IMF, Canada is the only country in the G7 expected to run a surplus by 2015

## **Scientific Research & Experimental Development**

- Canada has a very generous Scientific Research and Experimental Development Program (SR & ED)
- Canada has the lowest costs in R&D-driven sectors in the G-7

# Prospective Buyers

## Hospitals and public health institutions

- Principal buyers of medical equipment and supplies; with 38% of domestic producers operating in this sector
- Account for approximately 70% of total market demand in Canada
- Buy directly from manufacturers for capital equipment
- Utilize group procurement and distribution for regular medical equipment including devices, instruments and supplies

## Private clinics

- Growing demand for imaging diagnostic equipment

## Outpatient's facilities

## Medical offices



# Market Entry

**Partnerships, distributors and sales reps in the medical device industry are the best way for U.S. companies to enter the Canadian market**

- Best way to overcome the cumbersome regulatory process, expenses related to R&D and commercialization obstacles
- Opportunity to plug into local distribution networks for very niche products



# Goals of the Regulatory System in Canada

- Risk based approach
- Post-market surveillance
- Global Harmonization
- International standards
- Quality systems approach
- Transparency and communication

# International Standards

- Canadian medical devices conformity (CMDCAS) was established using international standards and guidance documents wherever possible to minimize barriers and to maximize understanding of requirements
- ISO 13485:2003 (medical device QMS)
- ISO 17021 (accreditation requirements)
- ISO 17011 (accreditation body requirements)
- ISO 19011 (audit standard)
- GHTF SG3 & SG4 guidance

# Definition of a Medical Device

- **“DEVICE”** means any article, instrument, apparatus of contrivance, including any component, part or accessory thereof, manufactured, sold or represented for use in:
  - a) The diagnosis, treatment, mitigation, or prevention of a disease, disorder, or abnormal physical state, or its symptoms, in human beings or animals,
  - b) Restoring, correcting or modifying a body function or the body structure of human beings or animals
  - c) The diagnosis of pregnancy in human beings or animals, or
  - d) The care of human beings or animals during pregnancy and at and after birth of the offspring, including care of the offspring, and includes a contraceptive device but does not include a drug.
- **“MEDICAL DEVICE”** means a device within the meaning of the Act, but does not include any device that is intended for use in relation to animals

# Regulatory Provisions: Essential

- All devices offered for sale in Canada must comply with the Food and Drugs Act in that they:
  - cannot advertise or represent by label a treatment for a Schedule A disease or disorder;
  - Cannot sell or advertise a device that may cause harm; and
  - Cannot sell or advertise a device in a misleading or deceptive way.
- All medical devices (those used on human beings) must also comply with the Medical Devices Regulations
- For more information regarding the definition of a medical device, please refer to the following link [http://www.hc-sc.gc.ca/dhp-mps/alt\\_formats/pdf/md-im/activit/fs-fi/meddevfs\\_matmedfd-eng.pdf](http://www.hc-sc.gc.ca/dhp-mps/alt_formats/pdf/md-im/activit/fs-fi/meddevfs_matmedfd-eng.pdf)

# Regulatory Provisions: Essential

- A manufacturer in the Regulations:
  - Sells a medical device under their own name, trade-mark, design, trade name or other name owned or controlled by the person
  - Is responsible for designing, manufacturing, assembling, processing, labelling, packaging, refurbishing or modifying the device, assigning it a purpose
  - Performs or has someone perform on their behalf
- The Regulations apply to:
  - The sale and advertising for sale of a medical device
  - The importation of a medical device for sale or for use on individuals, other than importation for personal use

The U.S. Commercial Service in Canada offers a wide range of programs designed to help U.S. companies succeed in the Canadian market

- **Trade Show Delegations**
- **Seminars / Webinars**
- **Gold Keys**
- **Single Company Promotions (SCP)**
- **International Partner Searches (IPS)**
- **Market Research Reports**

# Webinar Series

## Upcoming:

- November 5, 2014: Canada's Anti Spam Legislation, What Do You Need to Know?
- November 12, 2014: Exporting to Canada, Where Do We Begin?
- November 19, 2014: Temporarily Moving Goods & Tools Across the Border
- December 3, 2014: Sending Temporary Workers to Canada
- December 10, 2014: Handling Duties and Taxes, NAFTA, HST
- Spring 2014: Licensing your Natural Health Products with Health Canada
- Spring 2014: Licensing your Medical Devices with Health Canada



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# Questions?



Thank you for  
participating!

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