Natural Health Products Regulatory Update

John Simon

TEC Edmonton

Where inventions inspire business.

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Joint Venture

TEC Edmonton

UNIVERSITY OF ALBERTA

EDMONTON ECONOMIC DEVELOPMENT CORPORATION

- Non-profit organization
- Commercialization service provider for the Greater Edmonton region
- Technology transfer agent for the University of Alberta

Mission

- TEC Edmonton develops a stronger Edmonton region by:
  - Accelerating success of emerging innovation-based companies
  - Commercializing technology from private, university, and public sources
  - Fostering and promoting innovation and new enterprise development

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Why we do it

- Keep benefits of regional R&D investment in the region
- Innovation ➔ productivity growth ➔ sustainable economy
- Most new jobs come from companies less than 5 yrs old
- Long term economic success comes from sustainable new companies

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TEC Services

TEC delivers services through

- Business Development
- Technology Management
- Entrepreneur Development

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John Simon

John has a B.Sc. from the University of Alberta, is a Senior Member of the American Society for Quality, a Certified Quality Auditor (CQA), a Registered Quality Assurance Professional in Good Laboratory Practice (RQAP-GLP) and maintains Regulatory Affairs Certification (RAC) through the Regulatory Affairs Professional Society. He has held a series of management positions in Quality Assurance and Regulatory Affairs and has worked as a consultant supporting clients in the Medical Device, Pharmaceutical, Biotechnology and Natural Health Product industries since 2003. John has been directly involved in FDA and Health Canada audits of medical device manufacturers, drug manufacturers, testing facilities, and clinical sites. He has experience with many submissions to Health Canada and the FDA.

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Darryl Prystawa

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Darryl has a B.Sc. from the University of Alberta and is an experienced quality and regulatory consultant with over 15 years of experience working in chemical, biologic and radiopharmaceutical production. He has worked with a diverse set of companies ranging from small startups in clinical trials to commercial manufacturers with licensed products. He has been the responsible head of quality control and quality assurance departments and has successfully hosted inspections by Health Canada and the College of Physicians and Surgeons of Alberta.

Functional Areas

1. Regulatory

- Authorization to market Devices, Pharmaceutical Products, Biotechnology Products or Natural Health Products in Canada and the USA
- 510(k) submissions
- Product License Applications
- NDA/IND/BLA Preparation
- GLP Testing
- GMP Manufacturing
- Pre-Meetings
- Investigational Testing Authorizations / Investigational Device Exemptions / Clinical Trial Applications

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Functional Areas

2. Quality Assurance

- Compliance with standards.
- ISO 13485 Certification
- Quality System Development
- Mentoring for new Quality Managers
- Product Specifications and Release

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Natural Health Products

The Natural Health Products Directorate (NHPD) has changed its name to the Natural and Non-prescription Health Products Directorate (NNHPD) subsequent to its recently expanded mandate to include the oversight of non-prescription and disinfectant drugs in addition to natural health products (NHPs). Please note that we are currently modifying documents to reflect this change.

Thank you for your patience and understanding.

Regulatory Update

- Role is to ensure Canadians have ready access to natural health products that are safe, effective and of high quality while respecting freedom of choice and philosophical and cultural diversity

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Health Canada Santé Canada

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Quality of Natural Health Products Guide

Natural Health Products Directorate

Regulatory Update

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a) Product specifications are established in accordance with the requirements described in this guidance document.
b) All quality information is documented, maintained, relevant, accurate and sufficient to support the quality of their NHPs.
c) The most recent version of the finished product specifications is submitted to the Natural Health Products Directorate (NHPD).

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Please note the following procedural changes that relate to the new approach to quality:

1) All applications are expected to include Finished Product Specifications (FPS) or attest to meeting the sample specifications included in this guide.
2) When referencing NHPD monographs, deviations from monograph specific specifications must follow the principles outlined in this guidance document.
3) NHPD will acknowledge receipt of quality amendments. However, it remains the responsibility of the licence holder to ensure that all quality changes meet the principles outlined in this guidance document.

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Health Canada Santé Canada

Your health and safety… our priority. *Votre santé et votre sécurité… notre priorité.*

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Pathway for Licensing Natural Health Products Making Modern Health Claims

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- Types of Health Claims
  - Claim by Health Condition
    - Serious Disease
    - Major Disease
    - Minor Disease
  - Claim by Health Effect
  - General Health Claims
- Safety Evidence Recommendations
- Efficacy Evidence Recommendations
  - Risk based

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