Good Manufacturing Practices and Drug Establishment Licensing for Schedule C Drugs (Radiopharmaceuticals)

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Health Canada’s Regulatory Operations and Enforcement Branch

The Regulatory Operations and Enforcement Branch is responsible to inform and protect Canadians from health risks associated with:

- products
- substances
- the environment

Delivering quality compliance and enforcement with complementary scientific programs help us achieve excellence in:

- field inspection
- compliance verification
- enforcement measures
- investigation
Drug Establishment Licensing (DEL) and Good Manufacturing Practices (GMP)

The Health Product Compliance Directorate, Health Product Inspection and Licensing Division is responsible for licencing and conduct of GMP inspections.

Drugs sold in Canada are subject to the *Food and Drug Regulations* (FDR):  
- Division 1A is about the licence required to perform licensable activities  
- Division 2 is about the GMP requirements that must be followed

These requirements apply to:  
- fabricators,  
- packagers/labellers  
- testers  
- importers  
- distributors  
- wholesalers

Prior to issuing a licence or adding an international building to a licence, Health Canada assesses the GMP compliance of the facility.
Good Manufacturing Practices (GMP)

- GMP are necessary to ensure that drugs are consistently produced and to control the quality standards appropriate to their intended use.

- The GMP requirements apply to:
  - Pharmaceuticals
    - Medical gases
    - Prescription drugs
    - Over-the-counter drugs
    - Veterinary drugs
  - Schedule C Drugs (e.g. radiopharmaceuticals)
  - Schedule D Drugs (e.g. biologics)
  - Active Ingredients
    - Active pharmaceutical ingredients (APIs)
    - Bulk process intermediates (BPIs)
  - NHPs exported to MRA jurisdictions
Product Lifecycle and Good Manufacturing Practices

Start of Lifecycle

Basic Research

Pre-clinical

Clinical

Manufacturing

Distribution

End of Lifecycle

Information about GMP

Good Manufacturing Practices

Premises
Equipment
Personnel
Sanitation
Manufacturing Control
Outsourced Activities
Product Recall
Records
Sample Retention
Stability
Sterile Product Manufacturing

Pharmaceutical Quality System
Quality Risk Management
Quality Control
Change Control
Complaints
Non-conformance Management
Raw Material Testing
Packaging Material Testing
Finished Product Testing
Storage and Transportation

Sample Retention
Stability
Sterile Product Manufacturing
GMP for Schedule C Drugs

• Health Canada has published a number of internationally harmonized guidance documents to support compliance with GMP requirements:
  – Good manufacturing practices guide for drug products (GUI-0001)
  – Good Manufacturing Practices (GMP) for Active Pharmaceutical Ingredients (API) - (GUI-0104)
  – Annex 1 to the Good manufacturing practices guide – Manufacture of sterile drugs (GUI-0119)
Health Canada collaborates with regulatory partners to enhance partnerships, work sharing, foster harmonisation, and share expertise.

- Mutual Recognition Agreements (MRA)
- Pharmaceutical Inspection Co-Operation Scheme (PIC/S)
- International Council on Harmonization (ICH)
- Regulatory Cooperation Council with the United States Food and Drug Administration (RCC HC - US FDA)
- Regulatory Cooperation Initiative with Australia’s Therapeutic Goods Administration (RCI HC-TGA)
- Regulatory Cooperation Forum with the European Union