

## Pharma in brief - Canada

### Health Canada releases draft guidance documents for consultation related to good manufacturing practices and drug establishment licensing

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#### Summary

On January 18, 2017, Health Canada released five draft guidance documents for consultation relating to good manufacturing practices and drug establishment licensing:

- GUI-0001: Good manufacturing practices guide for drug products
- GUI-0023: Risk classification guide for drug good manufacturing practices observations
- GUI-0031: Good manufacturing practices for medical gases
- GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices
- GUI-0119: Annex 1 to the good manufacturing practices guide – manufacture of sterile drugs

Interested stakeholders can obtain copies of the draft guidance documents by emailing [HPIL-Consultation-IPSOP@hc-sc.gc.ca](mailto:HPIL-Consultation-IPSOP@hc-sc.gc.ca). The consultation period is open until **April 18, 2017**.

#### Overview of key changes

Many of the changes set out in the draft guidance documents relate to amendments to the *Food and Drug Regulations* that came into force on November 8, 2013, that extended the requirements of Divisions 1A (Establishment Licensing) and Division 2 (Good Manufacturing Practices) to active ingredients used in pharmaceutical drugs for human use. Although the amendments came into force on November 8, 2013, implementation occurred over a three-year period with full implementation by November 8, 2016.

The key changes to the guidance documents are set out below.

#### **GUI-0001: Good manufacturing practices guide for drug products**

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors and wholesalers who work with drugs. Highlights of this draft guidance document include:

- Content to address issues such as data integrity and new regulations pertaining to active pharmaceutical ingredients (API);

- Additional responsibility for importers of products from non-MRA (Mutual Recognition Agreement) countries, including requirements to conduct audits of foreign buildings and increased retesting of imported products;
- Removal of guidance related to sterile products and replacement with guidance published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S).

### **GUI-0023: Risk classification guide for drug good manufacturing practices observations**

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors and wholesalers who work with drugs. Highlights of this draft guidance document include:

- An expanded scope to include on-site inspections of domestic and foreign buildings relates to finished dosage form and API sites;
- Information on Health Canada's assessment of good manufacturing practices evidence to ensure information submitted by importers meets foreign building compliance requirements within Division 2 of the *Food and Drug Regulations*;
- New sample observations to reflect requirements being introduced by the draft guidance documents GUI-0001 (Good manufacturing practices guide for drug products) and GUI-0119 (Annex 1 to the good manufacturing practices guide – manufacture of sterile drug products).

### **GUI-0031: Good manufacturing practices for medical gases**

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, distributors, wholesalers and home care providers who work with medical gases. Highlights of this draft guidance document include:

- A revised definition for wholesaler based on amendments to the *Food and Drug Regulations* relating to APIs;
- Updates on quality risk management and quality management through a product's lifecycle;
- An expanded rationale related to senior management responsibilities, deviations and non-conformances, accuracy and reliability of data and records, and records expectations.

### **GUI-0080: How to demonstrate foreign building compliance with drug good manufacturing practices**

This guidance document is applicable to all Canadian importers who work with drugs. Highlights of this draft guidance document include:

- Incorporation of information related to foreign buildings that fabricate, package, label or test non-sterile APIs;
- Incorporation of the "new evidence required by date" to replace the expiry date on a drug establishment license;
- Revised evidence requirements for foreign building that fabricate, package, label or test finished dosage forms or APIs.

### **GUI-0119: Annex 1 to the good manufacturing practices guide – manufacture of sterile drugs**

This guidance document is applicable to all fabricators, packagers/labelers, testers, importers, and distributors who work with sterile drugs.

Health Canada is seeking feedback on whether to adopt the international good manufacturing practice guidance published by the Pharmaceutical Inspection Cooperation Scheme (PIC/S) as set out in this draft guidance document.

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## Link to Health Canada's Notice to Stakeholders

[Notice to Stakeholders – Release of Guidance Documents for Consultation: various good manufacturing practices and drug establishment licensing guidance documents](#)

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