DEL Bulletin LEPP No. 118 - Notice of Publication - GUI-0050 / Avis de publication - GUI-0050

Dear Stakeholder,

On August 10, 2021, the Health Product Compliance Directorate posted the following good manufacturing practices (GMP) guidance document to the Health Canada website:

- *Annex 11 to the Good Manufacturing Practices Guide – Computerized Systems (GUI-0050)*

This guide is an annex to the *Good manufacturing practices guide for drug products* (GUI-0001) and will be implemented effective immediately as it describes the necessary requirements and controls which should be included in computerized systems to ensure GMP compliance.

GUI-0050 is a revised version of the currently posted document replacing *PIC/S Annex 11: Computerised Systems 'Guide to Good Manufacturing Practice for Medicinal Products' (*April 5, 2007). This guide is based on the Pharmaceutical Inspection Cooperation Scheme (PIC/S) document *Guide to Good Manufacturing Practice for Medicinal Products Annexes (PE 009-15 (Annexes))*.

Key changes to the revised document include:

- Addition of four new sections (Risk management, Periodic Evaluation, Electronic Signature and Archiving)
- Update to the new structure and formatting requirements for publication on the Health Canada website
- Aligning with Pharmaceutical Inspection Cooperation Scheme (PIC/S) guidance and international partners
- Adapting the text of the PIC/s document to meet Canadian requirements.

You may find the documents in the hyperlinks provided.

Sincerely,

Health Product Inspection and Licensing Division