OVERVIEW

- Health Canada recently fully implemented Good Manufacturing Practices (GMPs) for APIs
- As of November 8, 2016, Health Canada requires a fully compliant API GMP program
- API importers are required to complete the following documents for Health Canada:
  - Updated Table A per instructions for new and amending drug establishment licence (DEL) applications related to importing drugs, including APIs
  - Complete GMP evidence for API foreign buildings
  - Written Quality Agreements with all API suppliers

WHO DOES THIS APPLY TO?

- API importers (API GMPs apply to anyone who wishes to fabricate, package/label, test, import, distribute or wholesale an API in Canada; this GMP update applies to API importers)
- Finished Dosage Form drug fabricators who import APIs for use in manufacturing
- Finished Dosage Form importers
- The amended regulations do not apply to:
  - Veterinary drugs
  - Dilute drug premixes
  - Medicated feeds
  - Drugs to be used only for the purpose of an experimental study
  - Cosmetics
  - Natural health products
  - Medical gases
KEY POINTS:

- Health Canada’s GMP Guidelines for Active Pharmaceutical Ingredients (Guide-0104):
  - Extends Drug Establishment Licensing and GMPs to APIs
  - Specifies the GMP requirements that establishments conducting the fabrication, packaging/labelling, testing, importing, distributing, or wholesaling of APIs are required to meet

- API importers are not allowed to import APIs manufactured at any foreign building unless it is listed on their Table A. Instances of non-compliance will be subject to compliance and enforcement actions

- API and Finished Dosage Form importers maintain GMP evidence of all foreign API buildings and send a DEL application in which they attest to their GMP compliance

- Importers are required to maintain evidence of GMP compliance at their buildings in Canada and have it readily available upon request.

WHAT DO I NEED TO DO?

- Collect GMP evidence of your API supplier

- Apply for a DEL or an amendment using Health Canada’s DEL application form (FRM-0033) and the API Foreign Building Table A

- Provide complete DEL applications, as incomplete applications will not be screened. Service standard for screening is 20 business days

- Do not import from newly added foreign buildings until Health Canada completes screening and sends an "Acknowledgement of Acceptance"

- Importers must submit a comprehensive Table A with their next amendment or annual licence review application

- Conduct a GMP self-inspection of your facility to ensure you are meeting the requirements of the GMPs for APIs, in preparation for a Health Canada inspection
FAQ

1. What is acceptable GMP evidence?

Acceptable types of inspections include:

- Certificate from Health Canada inspector with a ‘Compliant Rating,’ OR
- Recognized regulatory authorities and organizations:
  - Mutual Recognition Agreement (MRA) countries
  - Pharmaceutical Inspection Convention and/or Pharmaceutical Inspection Co-operation Scheme (PIC/s)
  - International organizations such as European Directorate for the Quality of Medicines (EDQM) and World Health Organization (WHO) who inspect against ICH Q7 guidelines
- Consultant or Corporate audits: Only for over-the-counter (OTC) products, not for drugs listed on the Prescription Drug List

Note: Importers may ask Health Canada to conduct an inspection

2. How do I apply for a Drug Establishment License (DEL)?

To get a DEL, you need to file an initial DEL application. Within three months, Health Canada will schedule an inspection (audit) of your site. A DEL will be issued within 250 days of your initial application if your audit is successful. Q&C can help you file your application, set up your API quality systems, and/or help you prepare for your Health Canada audit.

3. How do I conduct a GMP inspection to ensure I’m meeting the API GMP requirements?

You can perform a self-inspection or you can ask Q&C to help. We can confirm that you are compliant, or identify compliance gaps, if there are any.
4. How do I add an API foreign site to my existing DEL?

Refer to Guidance on Evidence to Demonstrate Drug GMP Compliance of Foreign Sites (GUI-0080). This document is currently being revised by Health Canada to incorporate API GMP requirements. Or give us a call, we can help.

Call us today at 1-877-877-5152 ext. 232 or visit www.QualityAndCompliance.com