Risk classification guide for drug good manufacturing practices observations - summary

From Health Canada

Overview

These guidelines establish the approach applied for both the attribution of risk ratings to observations noted during drug establishment inspections, and the overall rating attributed to the inspection. These guidelines help ensure the uniform application of risk ratings to observations, and informs industry of the situations Health Canada considers unacceptable which will lead to Non-Compliant ratings following an inspection.

Guidance documents like this one are meant to help industry and health care professionals understand how to comply with regulations. They also provide guidance to Health Canada staff, so that the rules are enforced in a fair, consistent and effective way across Canada.

Health Canada inspects establishments to assess their compliance with the Food and Drugs Act and associated regulations. When we conduct an inspection, we will use this document as a guide in how we assign risk to the observations noted during the drug establishment inspection.

Who this guide is for

This guide is for people who work with drugs as:

- fabricators
- packagers
- labellers
- testers
- distributors
- importers
- wholesalers

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Related guides and help

- Good Manufacturing Practices (GMP) guidelines (GUI-0001)
- Guidance on Drug Establishment Licences and Drug Establishment Licensing Fees (GUI-

0002)
- Guidance: How to demonstrate foreign building compliance with drug good manufacturing practices (GUI-0080)
- 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)
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- Good manufacturing practices for medical gases (GUI-0031)

Related acts and regulations

- Food and Drugs Act
- Food and Drug Regulations

Related program

- Establishment Licences
- Good Manufacturing Practices

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For assistance

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