QUICKnotes™

Q&C SERVICES™

2023 Analysis of Health Canada GMP Inspections

Overview

Q&C Services sees more Health Canada activity than anyone else in Canada due to the sheer number of products we import and the amount we consult with industry. Our 2023 DEL Inspection Trends Report presents an analysis of data collected by Q&C Services from January 1, 2023 through December 31, 2023.

We identified Quality Control, Manufacturing, Records, and Personnel as the most frequently cited GMP sections.

Who Does This Apply To?

All domestic holders of a Drug Establishment License, including Fabrication, Package/Label, Importation, Distribution, Wholesaler, and Testing activities.

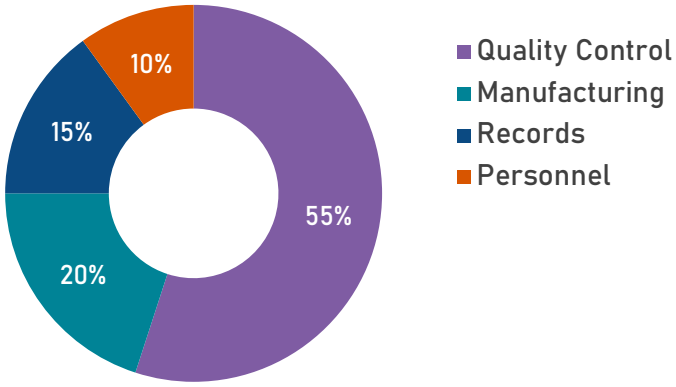
Key Points

Throughout the review period, Health Canada conducted a total of 317 inspections on domestic DEL holders, marking a decrease of 9%. These inspections led to the issuance of fifteen 'Non-Compliant' ratings, nearly doubling the figure recorded in 2022. Most of the findings leading to these ratings were related to section C.02.015 Quality Control of the GMP, indicating it as a significant compliance concern.

Health Canada placed a strong emphasis on compliance for companies holding an importing and/or distribution licence, which was the most frequently inspected activity among domestic DEL holders.

We conducted an analysis of the inspection findings. The following chart shows the most frequently cited GMP sections.

Most Frequently Cited GMP Findings

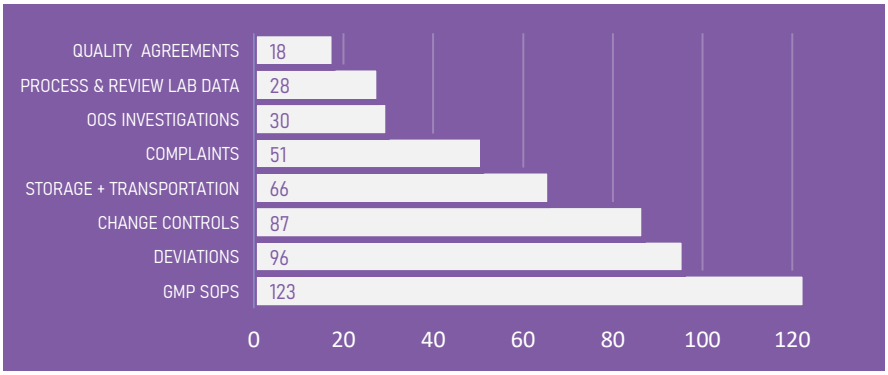


bsi ISO 9001 Quality Management Systems CERTIFIED ISO/IEC 27001 Information Security Management CERTIFIED

To gain deeper insights, we further analyzed these frequently cited GMP sections.

Most repeated findings within Quality Control and Manufacturing are shown in the graphs below:

Quality Control Findings (C.02.013 - C.02.015)



Manufacturing Findings (C.02.011)

Records

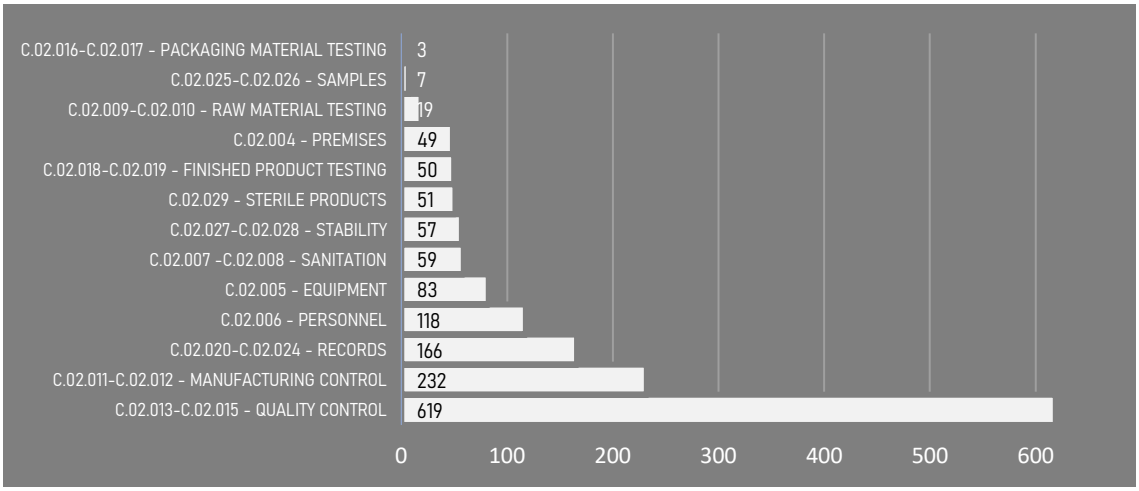
During the analysis, we determined that the "Records" section received a total of 166 citations. Most findings in this section indicated issues related to handling written GMP procedures, inadequate recording, maintenance, storage, and availability of records.

Personnel

Additionally, attention was drawn to the area of personnel, which garnered 118 citations. Among these citations, 52 findings specifically highlighted procedure deficiencies such as lack of clarity, detail or adherence, and/or inadequate GMP Training.

Complete Analysis

Eighty percent of all findings were from Quality Control through to Equipment as per the chart below.



What Do I Need to Do?

i. Review your most recent Health Canada inspection and confirm all CAPAs are complete

ii. Conduct your annual self-inspection, considering the following:

GMP SOPs

- Implement a procedure for creating, reviewing, approving, and maintaining all standard operating procedures (SOPs)
- Ensure core GMP processes (e.g., storage and transportation, returns, etc.) meet GMP expectations and are fully documented

Investigation, Deviation, Change Control, Complaint Handling, and Recall Processes:

- Establish well-defined and robust processes for these areas
- Ensure timely handling of specific occurrences
- Address any backlogs promptly

Quality Agreements:

- Verify that all necessary Quality Agreements are in place
- Regularly review and update agreements to ensure they cover all relevant GMP activities
- Clearly define the responsibilities of each party involved

Personnel:

- Ensure personnel have GMP training and experience for their roles beyond academic qualifications
- Ensure roles and responsibilities are documented in job descriptions
- Perform annual GMP training
- Train personnel before implementing new or revised procedures
- Document all training activities

GMP Data & Records:

- Ensure the completeness and accuracy of GMP data
- Implement appropriate controls for the creation, modification, storage, and retrieval of GMP records
- Establish processes for managing, protecting, and ensuring the integrity of data
- Validate all computerized systems used for GMP data management

Importers/Distributors Compliance:

- Review compliance with the current master production document and/or marketing authorizations
- Address any discrepancies or non-compliance promptly

How Can Q&C Services Help?

Q&C Services doesn't just meet standards – *it sets them.*

Q&C Services is recognized as a standard-setting organization that prioritizes insight, creativity, and innovation for a new level of excellence in quality and compliance. We bring 30 years of experience to our clients, providing deep expertise in quality, compliance, importing, and regulatory consulting.

GMP Compliance Services include:

- Health Canada Remediations
- Fractional Head of Quality
- Self-Inspections and Audits
- Addressing GMP Quality System Backlogs such as:
    - Deviations and CAPAs
    - Change controls
    - Annual Product Quality Reviews
    - Quality agreements
    - Complaints
    - Stability
- GMP Training

Our customized teams provide complimentary skill sets and built-in back-up to every project

From large, multi-faceted quality initiatives to the most specialized tasks, leverage Q&C's GMP compliance expertise and processes and receive instant, qualified headcount without the hiring costs.

- On- or off-site support
- Customized teams bring complimentary skill sets and built-in back-up to every project
- Ongoing access to experts when you need them
- Ability to address concerns quickly and efficiently

See how Q&C services can help improve your processes.