

The GMP Distribution Solution™



The GMP Gap Analysis™

Evaluate existing quality systems and identify needed activities

The Quality Control System Setup™

Build GMP quality foundation of systems and documentation meeting Health Canada (HPFBI) requirements

The Quality Control Officer Method™

Provide full Quality Control Officer Services meeting Health Canada requirements

Ongoing

Perform day-to-day quality activities to ensure supply of quality drug products to marketplace

As Needed

Address Health Canada audits and queries, and provide regulatory services as required

ISO 9001:2000



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The Quality Control System Setup™

ACTIVITY

DELIVERABLE

Collect background information and set up Quality Control Officer files



- Contact sheet (list of names and products)
- QCO box
- Product binders

Collect, review and file documents from fabricator:

- GMP evidence (HPFBI Establishment Licence)
- Regulatory commitment



- Valid HPFBI EL
- Reviewed documents
- Completed submissions (DIN, ANDA, etc.) allowing sale of product in Canada
- Drug Notification Forms

Perform GMP Gap Analysis™



- Gap analysis report

Source suppliers (e.g., pest control), if required



- Approved suppliers list

Develop and/or review and approve key contracts. Ensure all appropriate contracts are in place



- Reviewed agreements
- Signed contract agreements between key groups:
 - Client – Q&C
 - Client – warehouse (if applicable)
 - Client – fabricator
 - Client – testing lab (if applicable)

The Quality Control System Setup™

ACTIVITY

DELIVERABLE

Collect, review and file information from distributor/warehouse as applicable:

- Premises
- Personnel
- Equipment
- Sanitation



- Reviewed documents
- Master Document Summary Sheet

Collect, review and file documents from fabricator:

- Master Product Documents (manufacturing, packaging)
- Product Specifications
- Test Methods
- Printed packaging components and labels
- Validation evidence



- Reviewed documents
- Reviewed printed packaging components and labels reviewed against Health Canada approved labels
- Product binders
- Master Documents Summary Sheet
- Validation reports

Review analytical testing requirements



- Valid Certificate of Analysis

Collect, review and file documents from fabricator: Stability data



- Reviewed documents
- Product binders
- Updated Master Document Summary Sheet
- Up-to-date stability programme

Prepare key procedures (SOPs)



- Quality Manual
- Associated binders (e.g., Deviations, Change Control, Receiving and Disposition Log)

The Quality Control System Setup™

ACTIVITY

DELIVERABLE

Train personnel on SOPs and GMP



- Training records

Prepare and/or review Establishment Licence (EL) application/amendments



- EL application or amendment submitted to Health Canada

Follow up to the Gap Analysis



- Updated action plan (memo or report) to close the QCO setup process

The Quality Control Officer Method™

Ongoing

ACTIVITY

DELIVERABLE

Prepare and update plan for annual activities and review with client



- Approved plan (SDCP) for year
- Client agreement

Release (disposition) product



- Appropriate client-related records
- Annual summary report

Collect, review and file Quality Records and/or documentation for Warehouse



- Faxed documents (e.g., pest control, temperature monitoring records)
- Reviewed Quality Records
- Reviewed Quality Documentation

Perform self-inspection:

- Complete action items, if required
- Follow up to ensure action items are completed



- Self-inspection report
- Completed action items

Perform ongoing procedure (SOP) training



- Training records

The Quality Control Officer Method™

Ongoing

ACTIVITY

DELIVERABLE

Perform ongoing GMP training



- Training records

Collect, review and file documentation from fabricator:

- Master Production documents (manufacturing, packaging)
- Validation evidence
- Customer complaints
- Batch records



- Reviewed documents
- Master Document Summary Sheet
- Validation reports

Collect, review and file documentation from fabricator: Stability data



- Reviewed documents
- Master Document Summary Sheet
- Validation reports

Review and update Unique ID (if applicable)



- Unique ID certificate

Prepare and submit Annual Drug Notification, if applicable



- Forms submitted to Health Canada

The Quality Control Officer Method™

Ongoing

ACTIVITY

DELIVERABLE

Prepare and submit Establishment Licence (EL) renewal



- Completed/updated EL application submitted to Health Canada

Review, and summarize/trend annual activities (product disposition, customer complaints, deviations, recall)



- Annual summary report

Update client information, when necessary



- Current contact sheet
- Current Organization chart

File and Archive materials



- QCO box includes: Quality Manual, GMP agreements/contracts, records
- Main office: Legal contracts/agreements/SDAPs, closed SDCPs (after annual update), dispositions (archived)

The Quality Control Officer Method™

As Needed

ACTIVITY

DELIVERABLE

Handle product deviations, if required



- Completed deviation report

Handle product change controls, if required



- Completed change controls

Handle returned product, if required



- Completed Return Goods Checklist

Handle customer complaints, if required



- Completed Customer Complaint Checklist

Handle product recall, if required



- Completed recall

The Quality Control Officer Method™

As Needed

ACTIVITY

DELIVERABLE

Review and revise procedures (SOPs) as necessary



- Updated Quality Manual

Review GMP assessment of Canadian suppliers, where applicable (fabricators, packagers, laboratory)



- Signed contracts available
- Copy of Establishment Licences

Prepare for and host Health Canada audit
- Follow-up activities



- Response letter to Health Canada, if applicable
- Completed action items

Perform regulatory services, if requested



- Responses to queries
- Completed applications, etc.

Review product labels, if required



- Approved labels

The Quality Control Officer Method™

As Needed

ACTIVITY

Set up QCO system for new DIN products, if required



DELIVERABLE

- Set up QCO system for new DIN products, if required
- Updated Document Master List
- Updated Master Binders