



Regulatory

- Product classification (drug, NHP or cosmetic)
- DIN submissions
- Drug Establishment Licence submissions (DEL)
- Common Technical Document (CTD):
 - Quality Overall Summary
 - Quality Module (formerly CMC section)

Laboratory

- Finished Product Testing
- Release Testing
- Identity Testing
- Confirmatory Testing
- Unique Identifiers
- Stability Programs
- Analytical Method Transfer

Audits

- The GMP Gap Analysis™
- Self-Inspections
- Third-Party Supplier Audits
- API Audits

Quality Control Officer (QCO)

- Full quality control services for importers, distributors, wholesalers
- GMP quality systems meeting Health Canada requirements
- Addressing Health Canada audit findings

Large Compliance Project Consulting

- Compliance project management
- GMP for clinical trial materials
- Health Canada audit corrective actions
- Audit responses
- Backlog cleanups
 - stability reports, change controls, deviations, batch record reviews, etc.
- Interim QCO Services for fabricators
 - managing your quality system during periods of growth and/or transition

Technical Writing

- Standard Operating Procedures (SOPs)
- Work Instructions
- Specifications
- Site Reference Files
- Quality Manuals & Policies



VALIDAPHARM™

Easier Compliance for Drugs



GMP Training

- Fundamentals of GMP
- GMPs for Importers & Distributors
- GMPs for Wholesalers
- Preparing for a Regulatory Inspection
- Procedure Writing (SOPs)
- Good Documentation Practices (GDP)
- Conducting GMP Audits

Product Disposition

The Rapid Release Team™ -
24-hour turnaround for product releases

Validation Projects

- The Validation Gap Analysis™
- Validation Master Plans
- Validation Project Plans

Warehouse/Facility Qualification

- Temperature mapping studies
- Full Qualification (IQ, OQ, PQ)
- Utilities, HVAC, Water Validation
- Process Validation

Computer Validation

- User requirement specifications (URS)
- Hardware & software qualification (IQ, OQ, PQ)



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Shipping Validation

- Packaging configuration qualification
- Transportation validation (point A to point B)
- Cold chain & temperature controlled product management

Cleaning Validation

- Grouping and worst case selection
- Residue acceptance limits calculation
- Selection of sampling and analytical methods
- Sampling procedures
- Sampling recovery studies
- Characterization studies

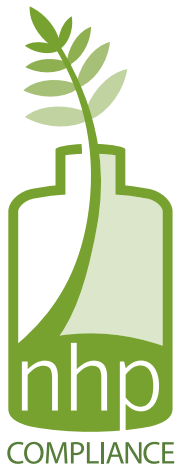
Analytical Method Validation

- Assays (HPLC, GC, IR, UV, etc)
- Compendial
- Non-compendial

Fridge, Freezer, Stability Chamber Qualification

- Temperature mapping studies
- Humidity mapping studies
- Full Qualification (IQ, OQ, PQ)





The
Compliance
Leaders™

EASIER COMPLIANCE FOR NATURAL HEALTH PRODUCTS & DIETARY SUPPLEMENTS

GMP Training

- NHP Good Manufacturing Practices
- NHPs for Management
- NHP Overview

Regulatory

- Product Classification (drug, NHP or cosmetic)
- Product Licences (PLA)
- Site Licences (SLA)
- Quality Assurance Reports (QAR)



Audits

- The GMP Gap Analysis™
- QAR Audits
- Contractor Inspections
- Third Party Audits

Technical Writing

- Procedures (SOPs)
- Specifications
- Quality Manuals & Policies
- Work Instructions

Importer Quality Control Officer (QCO)

- Full quality assurance services for importers - The GMP Importing Solution™
- Create and/or maintain documentation meeting Health Canada requirements
- Address Health Canada audit findings

Laboratory

- Finished Product Testing
- Release Testing
- Identity Testing
- Confirmatory Testing

Product Disposition

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NHPSEV-R1Dec