

Quality Policy

Quality is integrated into all of our clinical and business practices at PharmaNet/i3. Our team of professionals interacts directly with clients to understand their specific requirements for their clinical study or related service. PharmaNet/i3 quality and regulatory affairs specialists oversee conformance with client requirements, U.S. Food and Drug Administration (FDA) regulations, Canada's Health Products and Food Branch Inspectorate regulations, European Union directives and other applicable international agencies' regulations during each phase of the clinical trial process. Our experience and oversight ensures that our clinical, bioanalytical and related services comply with applicable Good Clinical Practices (GCP), Good Laboratory Practices (GLP) and International Conference on Harmonisation (ICH) GCP guidelines. At PharmaNet/i3, we build quality into all our services.

To this end, PharmaNet/i3 will:

- Meet or exceed all quality objectives and applicable regulatory requirements by:
 - Ensuring customer requirements are clearly understood and are met in a timely and cost effective manner and,
 - Ensuring all customer deliverables are inspected and released following rigorous quality reviews.
- Design and operate its facilities and processes in compliance with applicable regulations, directives and guidelines worldwide.
- Maintain expertise in GCP, GLP and ICH and other job skills impacting quality through ongoing training programs, including the training of employees to meet the specific requirements of each clinical study.
- Host internal, customer or regulatory agency audits to demonstrate product quality and compliance.
- Document, measure and periodically review the Company's quality systems and compliance with all applicable Standard Operating Procedures, country regulations and directives and client contracts.
- Investigate all out-of-specification events, deviations and discrepancies, report the findings and conclusions of the investigation and implement and document corrective and preventive action(s) (CAPA).
- Maintain preventative maintenance and calibration programs to ensure operational equipment is appropriately maintained and operating as defined.
- Measure, assess and report quality data and seek ways to continually improve quality performance and results.

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Operational Policies that Support Our Quality Policy

Facilities	Facilities and equipment are secure and equipment appropriately designed, constructed, installed, validated, cleaned and maintained to ensure quality.
Personnel	Sufficient personnel with the necessary education, training and experience conduct operations safely and correctly. Appropriately licensed, competent professionals are responsible and provide the highest level of scientific expertise. Personnel are trained to behave ethically when dealing with the confidentiality of study subjects or study subject matters. Personnel take all hygiene and safety measures to assure their protection and that of study subjects.
Training	PharmaNet/i3 Quality Assurance and other applicable employees receive training in GCP, cGMP, GLP and ICH as applicable. On the job training, seminars, presentations, self-paced modules and formal courses are offered and all training records are documented.
Documentation and Records	Documentation and records programs are administered by Quality Assurance and include but are not limited to: validation, materials control (receipt, handling and shipping of raw materials and components, equipment, supplies and product), protocols, procedures, test methods and labeling and package control. These programs govern the drafting, review and approval, distribution, implementation, use and revision and review of documents. Procedures for data acquisition/entry, compilation, review and approval, revisions and records retention demonstrate that business processes and operations are in compliance with GCP, GLP, and ICH as applicable.
Audit	Procedures are documented for conducting investigator site, internal and vendor audits that verify qualifications and compliance with established procedures and applicable regulations. The Company routinely hosts customer and regulatory agency audits to demonstrate proficiency and compliance with applicable requirements and regulations.
Vendors and consultants	Written evaluation procedures and audits are used to select primary vendor and service providers and to assure that specifications are met.

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Quality Practices

Electronic Records and Electronic Signatures	PharmaNet/i3 has documented its perspective of Title 21 CFR (Code of Federal Regulations) Part 11, for Electronic Records/ Electronic Signatures, and systems are validated to ensure compliance with Part 11 regulations.
Materials Control	Samples, investigational medicinal product, components, equipment and supplies are received, inspected, stored and handled in a manner designed to prevent damage, contamination, degradation and/or other adverse effects.
Labeling and Package Control	Labeling integrity and control are maintained during processing, packaging, storage, handling, distribution and use.
Validation	PharmaNet/i3's approach to the validation of software, equipment, methods, cleaning and processes is documented in Standard Operating Procedures (SOPs) which are used to train assigned personnel.
Preventative Maintenance and Calibration	Preventative maintenance (PM) and calibration programs ensure systems are appropriately maintained. PM and calibration are performed in accordance with equipment supplier recommendations and/or recognized quality standards.
Change Control	Change controls policies assure change(s) made to procedures, protocols, equipment, utilities, processes, etc. are justified, detailed, reviewed, approved and appropriately communicated prior to execution.
Out of Specification (OOS) Investigations, Deviations and CAPA	Procedures ensure OOS investigations, deviations and discrepancies are investigated, and the findings of the investigation, conclusions, implementation of corrective action(s) and preventive action(s) are documented. Corrective and preventive actions (CAPA) are tracked to resolution and trended.
Non-conformances and Customer Complaints	Written procedures govern the handling of discrepant/non-conforming material and customer complaints.

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