

Quality Assurance

Janette Panhuis,
Director, Quality Assurance

Quality Assurance Principles

1. Ethics and Safety
 - Informed Consent
 - SAE Reporting

2. Accountability
 - Qualifications
 - Supervision

3. Traceability
 - Data
 - Actions

Quality Assurance Principles

4. Control and Consistency

- Standard Operating Procedures
- Quality Control
- Quality Assurance Audits

5. Data Integrity

- Acquisition
- Receipt
- Storage
- Reporting
- Computer Systems Validation

Quality Assurance

- QA Department provides:
 - Management of operating standards (SOPs)
 - Regulatory Training
 - Expertise in Regulations (interpretation)
 - Arms-length monitoring of regulated activities.

Quality Assurance Objectives



PHRI QA Objectives:

- Standard Operating Procedures
 - Development, training and implementation of improved procedures
- Audit Program
 - Internal Audits, Sub-contract Audits
 - Coordination of External Audits
- Regulatory Training
 - Health Canada, FDA, EMEA

Quality Assurance



PHRI Approach

- Risk approach to regulatory compliance in Clinical Trials
 - Most efficient
 - Identifies and Focus is on areas with potentially higher risk for compliance.
- Sensible Guidelines

Questions?



Janette Panhuis

Director, Quality Assurance, P HRI,

P: 905-527-4322 x.40386

M: 289-244-0315

F: 905-297-3780

Email: janette.panhuis@phri.ca

Craig Horsman

Quality Assurance Coordinator, P HRI,

P: 905-527-4322 x.40402

F: 905-297-3780

Email: craig.horsman@phri.ca