TRENDS IN THE INSPECTION OF CROs

Elham Kossary
Technical officer
PQ-Inspection Services

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Objectives

1. Highlighting emerging trends
2. Sharing findings from recent inspections
3. Discussing the impact of technology

Emerging Trends in WHO Inspections

❑ Close collaboration with National inspectorate

Increasing international collaboration and data sharing.

❑ Advanced Data Analytics

Utilizing advanced IT software for data analysis.

❑ Remote and Virtual Inspections

Enhancing efficiency and accessibility.

❑ Focus on Digitalization of data management

Evaluating the impact of digital technologies.

❑ Patient-Centric Approaches

Putting patients at the center of the inspection process.

Examples of Recent Inspection Findings

- Absence of Instrument & Project Audit Trail for Study Period

- Inadequate Backup of Study Data

- Insufficient Quality Management System (QMS): for example:
  - Use of Uncontrolled Templates and Forms
  - Lack of Audit Trail Review

- Unreported Calibration Range Modifications during Method Validation

- Failure in Method Selectivity Determination

Impact of Technology on Inspections

Technology has improved the world of CRO inspections, significantly transforming the inspection process:

✓ Enhanced accuracy in data analysis and detection of irregularities

✓ Streamlined processes leading to quicker and more efficient inspections

✓ Advanced data analytics IT-tools for in-depth analysis.

Enhancing inspection effectiveness

✓ Ability to predict issues before they occur (Preventive actions)

✓ Visual representation of complex data for better insights

✓ Creation of comprehensive reports for Inspectee.

PREDICTIVE ANALYTICS

Utilizing Technology in Data Analysis

Technology plays a pivotal role in modernizing data analysis during inspections, leading to more accurate and insightful outcomes:

✓ Sophisticated algorithms identify trends and anomalies in large datasets

✓ Using inspection data improves the accuracy

✓ Pattern recognition tools identify recurring issues for proactive resolution

Ensuring Data Security

Data security is paramount in the age of technology, especially when handling sensitive information during inspections:

✓ Access control measures restrict data access to authorized personnel only

✓ Data is stored in secure environments with fail-safe system

✓ Regular audits ensure compliance with data protection standards

✓ Anonymizing sensitive data for added privacy and protection

Training and Expertise

Regular Workshop & Conference Participation: Balancing Technology & Human Expertise

✓ Proper training equips inspectors with the skills to integrate technology into their workflow seamlessly

✓ Human inspectors provide contextual understanding, considering unique inspection scenarios

✓ Human judgment and ethical considerations play a pivotal role in inspections.

Collaborative efforts between trained inspectors and technology lead to comprehensive inspections.

Recommendations for CROs

Nurturing a Culture of Compliance:

✓ Embrace Technology: Adopt advanced technology for data management and analysis.

✓ Ensure Compliance: Prioritize adherence to regulatory standards.

✓ Foster Improvement: Cultivate a culture of continuous enhancement and transparency

THANK YOU FOR YOUR ATTENTION

Together, we move towards more efficient, accurate, and compliant inspections

Email address: kossarye@who.int