Data Integrity: Points of view from a regulator

David Churchward, Expert GMP Inspector, MHRA UK
Introduction

- Important daily decisions regarding safety, efficacy and quality of medicines are based on data.

- Unreliable data has become a global issue
  - Significant barrier to providing safe and effective medicines.

- Good data and record management has always been a requirement
  - Ensures that data supporting decisions is complete and reliable.
Agenda

Data Integrity: impact to patient, healthcare and industry
MHRA inspection experience
Benefits of good data management
Developing a data integrity action plan
  • Organisational behaviour
  • Risk identification
  • Technical measures.
Data integrity: definition

The extent to which all data are complete, consistent and accurate throughout the data lifecycle.
Data integrity failure: patient and healthcare impact

Safety / efficacy risks from substandard or falsified medicines

Unavoidable regulatory action may lead to shortage

– Less effective / more expensive alternative treatments
– Treatment errors (unfamiliar administration regimes)
– No treatment.
Data integrity failure: industry impact

Recall
Regulatory actions
Cost of remediation
Reputational damage
  – Loss of future business
  – Financial impact.
Reputation – impact on share price

Company A; growth
Reputation – impact on share price

Company A; data integrity failure = share price decline

Inspection
Data integrity in the supply chain

- Data Integrity failure
- Supply chain reputational damage
- Shortage, poor quality medicine
- Health impact

[Diagram showing the flow of a supply chain with various labels and symbols.]
Regulatory response

Detection of data integrity failure is increasing
International convergence in data integrity norms
Inspectorates better equipped to:
- Identify data integrity failures
- Manage post-inspection actions and remediation plans
- Cooperate with other regulators
  - Exchange information
  - Joint inspections
  - Coordinated market actions.
Inspection experience: spectrum of issues

System Failure

Bad Practice

Wilful falsification
Benefits of good data management

- Reduce defects
- Increase process understanding
- Increase efficiency

Quality medicines & consistent supply
Action plan:
Good data management practices

Culture

Risk identification

Governance

Organisational

Operational

Technical

Behaviour

Risk

Lifecycle

Procedures, System design

System surveillance

Data checking

Computerised system control

Automation
Organisational behaviour and system maturity

- Ineffective data controls
- Poor decision making
- Unaware
  - Awareness
  - Management understanding
- Learning
  - ‘Policing’
  - Monitoring for failure
- Basic controls
- Advanced systems
  - System maturity
  - Automatic good practice
Management understanding

Understand that ‘it can happen here’
  – Not someone else’s problem

Being prepared to challenge the existing culture

Organisational behaviour
  – Embedded into the Pharmaceutical Quality System
  – Senior management responsibility

Open reporting culture
  – Proportionate investigation of data integrity failure.
Organisational behaviours and values

Leadership and empowerment

- Communicating realistic expectations
  - Organisation and individuals
- Understanding importance of reliable data
  - “My actions impact the patient and our organisation”
- Management trusting employees.
Data Lifecycle

- Generation / recording
- Processing
- Reporting / checking
- Decision
- Retention
- [Disposal]
Risk Based Review

- Decision
- Data impact
- Data Vulnerability
- Detection
- Risk Balance
Action plan: Good data management practices
Operational and technical measures

Applicable to electronic and paper-based systems

- Procedures
- Training
- Data lifecycle controls

Controls ensuring that ALCOA principles are achieved

Technical guidance from regulators in progress.
Published guidance

MHRA Data Integrity Guidance:

MHRA Data Integrity Blog:
https://mhrainspectorate.blog.gov.uk

WHO consultation on good data management practices:
Summary: Data integrity action plan

Communicate the benefits of compliance (not just risks from non-compliance)

DI compliance plan – acknowledging gaps, and risk based actions to address

- Data lifecycle and risk management approach to implementing guidance
- Planning for success, not just monitoring for failure

Data integrity in supply chain audit and self inspection.
Questions?