Australian Government
Department of Health
Therapeutic Goods Administration

Data Integrity – an international regulatory perspective

Gaye Camm
Senior Inspector, Manufacturing Quality Branch
Medical Devices and Product Quality Division, TGA
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TGA Health Safety Regulation

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Presentation overview

- What is Data Integrity?
- International regulatory perspective
- Highlights of recent guidance documents
- Common misconceptions
- In summary

What is Data Integrity?

- The extent to which all data are complete, consistent and accurate throughout the data lifecycle

- From initial data generation and recording through processing (including transformation or migration), use, retention, archiving, retrieval and destruction

(MHRA Guidance March 2015)

Data Integrity – International regulatory perspective

- Increased regulatory oversight:
  - MHRA guidance document
  - FDA Guidance
  - Health Canada policy
  - WHO guidance
  - PIC/S Guidance (anticipated soon)

- Widespread inspectorate training in DI principles and techniques

Data Integrity – International regulatory perspective

- Outcomes:
  - Increased focus and scrutiny of data management practices within industry.
  - Increased expectations upon inspectorates
- Leading to:
  - **Collaboration**

International regulatory collaboration

- International convergence in data integrity guidance
- Cooperation between regulators
  - Exchange of information
  - Joint inspections
  - Coordinated market actions
- Inspectorates better equipped to
  - Identify data integrity failures
  - Manage post-inspection actions and remediation plans

Regulatory guidance: Common themes

- Guidance promotes quality risk management & lifecycle approach
- ‘Designing systems to comply’ with existing GMP norms
- Integration of behaviour with organisational and technical measures
- Describes common bad practices, and methods of prevention

ALCOA Principles

A – Attributable

- Clearly indicates who recorded the data or performed the activity
- Signed / dated
- Who wrote it / when

L – Legible

- It must be possible to read or interpret the data after it is recorded
- Permanent
- No unexplained hieroglyphics
- Properly corrected if necessary

C – Contemporaneous

- Data must be recorded at the time it was generated
- Close proximity to occurrence

O – Original

- Data must be preserved in its unaltered state
- If not, why not
- Certified copies

A – Accurate

- Data must correctly reflect the action / observation made
- Data checked where necessary
- Modifications explained if not self-evident

Common misconceptions about Data Integrity

1 – Data integrity is a new requirement

Common misconceptions about Data Integrity

~~# 1 – Data integrity is a new requirement~~

Basic Data Integrity expectations from the Manufacturing Principles

- **PIC/S Guide PE009-8:** Chapter 4 & Annex 11
- **Australian Code GMP human blood, blood components, human tissues and human cellular therapy products:** Sections 400 – 415
- **ISO 13485:** Sections 4.2.3, 4.2.4

Common misconceptions about Data Integrity

2 – Data integrity issues are restricted to certain countries

2a – We don't have these problems in Australia

Common misconceptions about Data Integrity

~~# 2 – Data integrity issues are restricted to certain countries~~

- Data Integrity issues have been reported by every Regulator, in every country inspected

Common misconceptions about Data Integrity

3 – Data Integrity is all about fraudulent data

Common misconceptions about Data Integrity

~~# 3 – Data Integrity is all about fraudulent data~~

Data Integrity is the extent to which data is:

- Complete
- Consistent
- Accurate

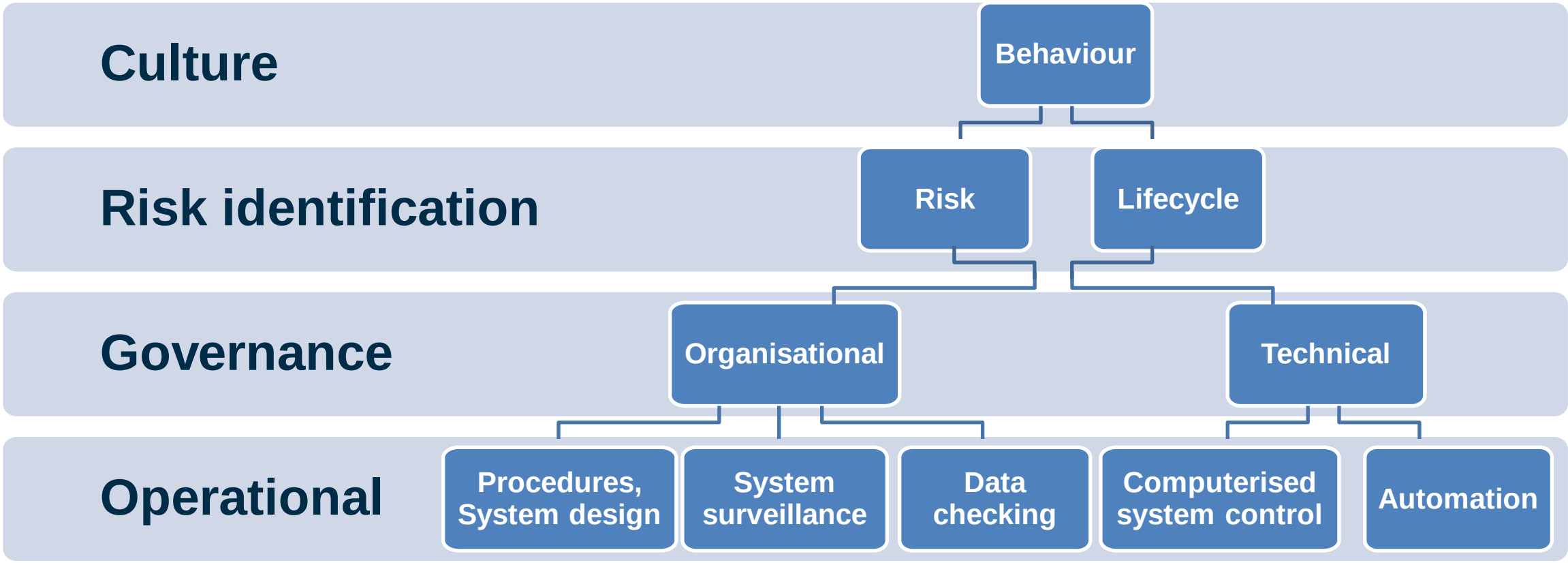
Throughout the Data lifecycle

- There was no written description for the site's computer system that detailed the objectives, security measures and scope of the system/s, and the main features of the way in which the systems/s were used and how they interact with other systems (both computerised and non computerised) and procedures.
- There was no defined procedure for the issue, cancellation and alteration of authorisation to enter and amend data (i.e. computer systems access).
- No system had been implemented in the QC laboratory to record the identity of operators entering or confirming critical data as staff in the laboratory used a shared account for each of the individual computerised data acquisition systems (HPLC, GC, FTIR, and UV/Vis).
- Data associated with QC laboratory data acquisition systems was not adequately secured by physical or electronic means against willful or accidental damage.
- Data back up frequency for laboratory data acquisition systems was not adequate. The monthly back up did not ensure that data used to support the release of product for supply would be readily available throughout the required period of data retention.

Common misconceptions about Data Integrity

~~# 4 – It's difficult to comply with data integrity expectations~~

Data integrity: Risk reducing strategies



Understand vulnerabilities

- Design systems to prevent DI issues
- Ensure the data is authentic and retrievable
- Train staff and encourage correct behaviours and practices
- Open communication
- Encourage feedback
- System for ongoing review

- Not just about your site

Summary

- Data Integrity is not a new requirement
- We are all learning & can learn from each other
- Get started
- TGA Data Integrity policy under development

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