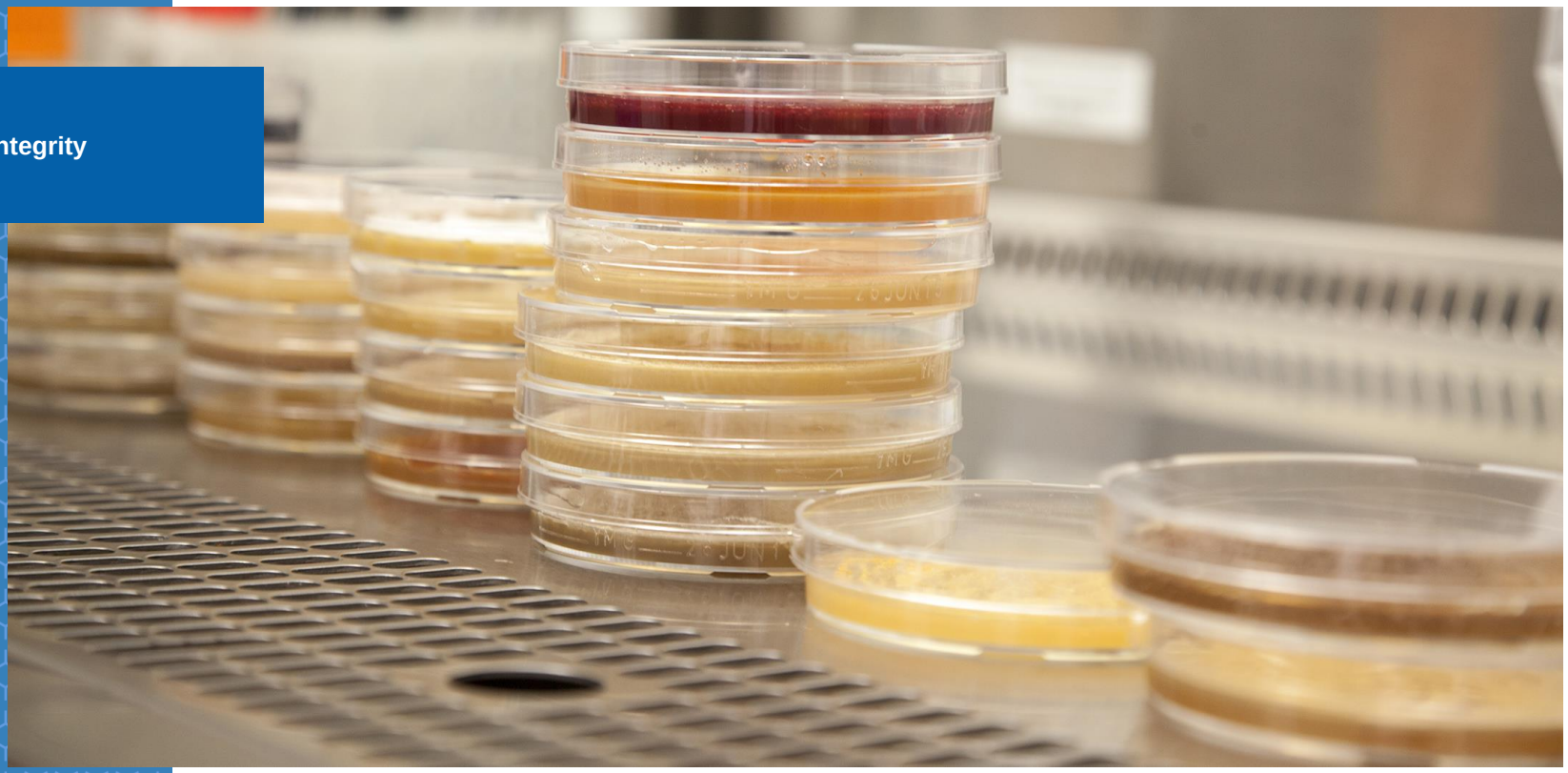
Data Integrity



Data integrity overview and case study examples

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National Validation & GMP Forum, Melbourne
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Overview

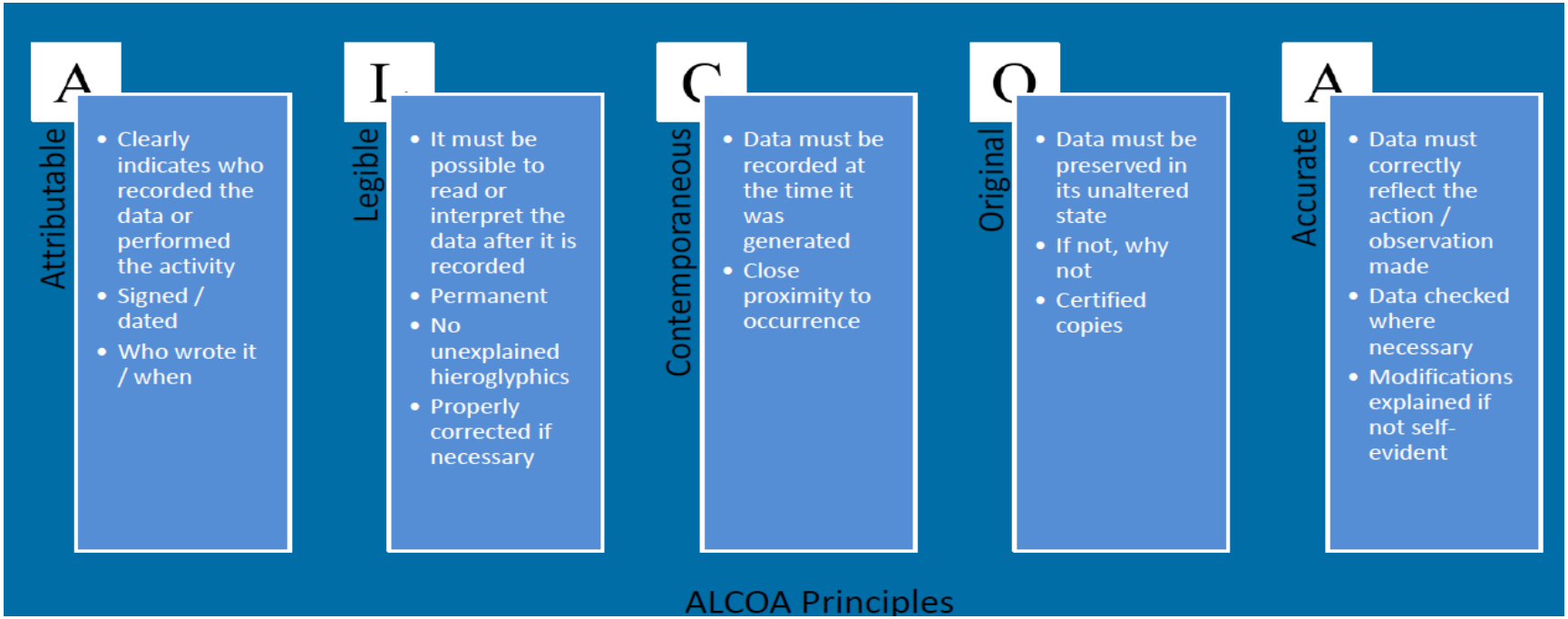
- Definition of data integrity
- Recap on the ALCOA + concept
- Regulatory guidance's in 2015, 2016 and 2017
- Workshop data integrity examples
- Conclusion

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 2015)

ALCOA + Principles:



*(Data Integrity: TGA Expectations, PDA Australia July 2015.)

ALCOA: Records are traceable, permanent, recorded timely, original, valid and reliable. Implicit in ALCOA principles is records to be **complete**, a**vailable, consistent**, **enduring –** these underpin the trustworthy record characteristics of reliable, authentic, integrity and can be located, retrieved and interpreted.

ALCOA+ Principles

ALCOA

- **Attributable**

Information is captured that identifies the source of the data. Audit Trails and Electronic Signatures.

- **Legible**

Information is human-readable. Reports, tables, and listings should be legible.

- **Contemporaneous (at the same time)**

Information is recorded at the time of data generation or event observation.

- **Original**

Source of data is available. Data is not a copy (unless 100% verified)

- **Accurate**

Verified as correct via repeatable calculation, algorithm or analysis.

ALCOA +

- **Complete**

All data are present, none has been selectively left out.

- **Available**

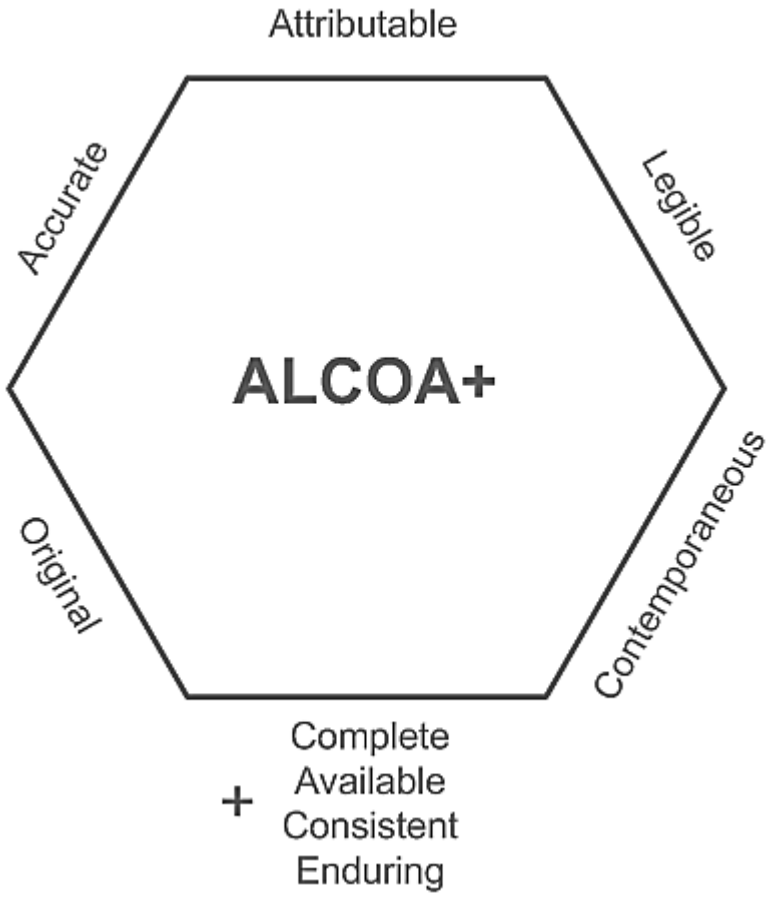
Anytime, by anyone who needs the data to perform their role

- **Consistent**

Data are compatible, free from variation and non-contradictory.

- **Enduring**

Data are preserved and retrievable during its lifetime according to the data type retention period.



Recent DI publications include:

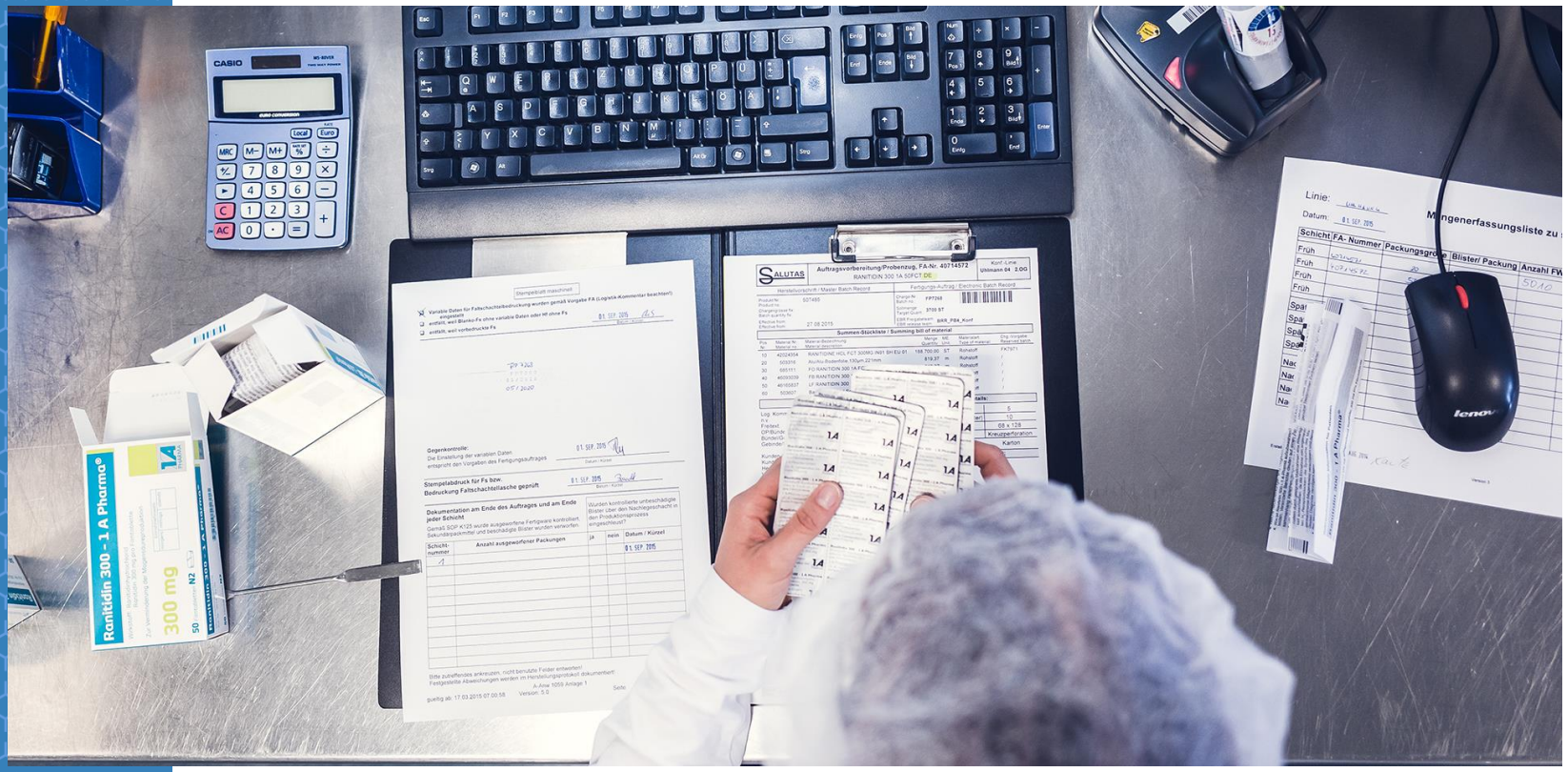
- MHRA GMP Data Integrity Definitions & Guidance for Industry, Jan & March 2015
- MHRA DI blogs: organisation behaviour, ALCOA principles
- WHO Annex 5 Guidance on good data and record management practices, June 2016
- FDA draft guidance Q&A style, June 2016
- TGA Data Management and Data Integrity (DMDI),Apr 2017
- PIC/S PI 041-1 (Draft 2) DMDI in regulated environments
- FDA Warning Letters & Import Alerts
- EUDRA GMP non-compliance database
- Industry Associations & Regulator training events

Regulatory guidance: themes

- Promotes collaboration between regulatory bodies
- ALCOA+ concept in good documentation practices
- Control strategies include:
  - QRM & data lifecycle approach
  - Appropriate design and maintenance of systems to comply with GMP
  - Technical measures in preference to procedural controls
  - Training in good data and record management
  - Correct behaviours and culture of quality
  - Open communication
- Gives examples of poor practices or systems applicable
- Provides expectations for prevention of DI issues

Data integrity at your site

- Misconception that DI problems are not found in Australia
  - What controls are implemented to prevent DI breaches?
  - How are they evaluated, monitored, periodic reviewed?
  - Will they detect data integrity issues?
  - Are all data integrity issues reported?
  - Are staff trained to detect and prevent data integrity as part of GMP
  - Does outsourced activities have appropriate systems to prevent DI issues



Workshop DI examples

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Workshop DI examples

1) **Identify the ALCOA+ principle(s) of concern for these examples:**

Backdating of record; pre-filling a record; incomplete record; omission of entries; inaccurate recorded information; no raw data; discarded data; fabricated record;

Signing for a step not completed by you and/or you were not present

Workshop DI examples

1) **Identify the ALCOA+ principle(s) of concern for these examples:**

Backdating of record; contemporaneous,accurate

pre-filling a record; contemporaneous,accutare

incomplete record; omission of entries; accurate,complete, consistent,available

inaccurate recorded information; accurate,complete,consistent

no raw data; discarded data; fabricated record; accurate

Signing for a step not completed by you and/or you were not present, attributable,accurate, contemporaneous

Example - incomplete records

2) A batch document has been sent back to production after QA batch review/release stage found missing signatures/dates and missing data entries.

It is returned a day later with all entries filled in with dates/time and signatures of when it should have been completed. No explanations/comments are recorded.

a) Which ALCOA+ principles are relevant?

b) Is there a data integrity risk?

c) How should this is be handled by the company?

d) How do you assess the scope?

e) How can this issue be prevented?

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a) Which ALCOA+ principles are relevant? Attributable (who),contemporaneous, complete, consistent

b) Is there a data integrity risk? Yes, not GDP

c) How should this is be handled by the company? Document comment e.g. completed retrospectively, verified by telephone contact doer, why delayed or deviation from procedure; risk assessment (id, risk analysis,control,review,monitor)

d) How do you assess the scope? If backdated – trust is lost records not true or accurate

e) How can this issue be prevented? Check/verification before next step (contemporaneous); end of session/end of shift/handover. GDP training; acceptable behaviours

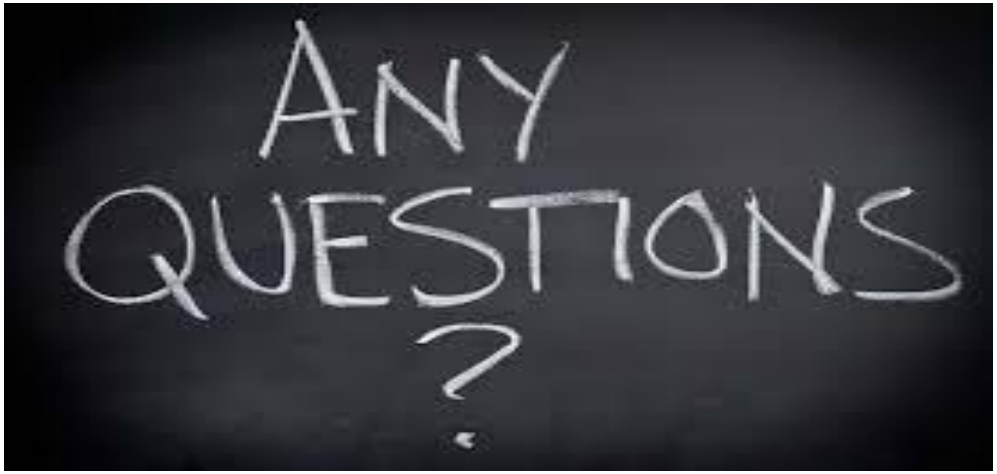
Summary

- Know the vulnerabilities and risks for each paper, hybrid or computerised recording system used for the entire life cycle (of the product or process).
- Implement control strategies including:
  - QRM & data lifecycle approach
  - Appropriate design and maintenance of systems to comply with GMP
  - Technical measures in preference to procedural controls
  - Training in good data and record management
  - Correct behaviours and culture of quality
  - Open communication
- Know the consequences of poor data integrity controls

Consider the risks

Is the quality, safety and efficacy of the product and our patients affected?
Is there a regulatory risk?
Is there a business risk?

Is there a risk to patient?



Thank you

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