Managing Hybrid Systems

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Agenda and Learning Objectives

- **Definition Hybrid Systems Approach**
  - Understand the approach and related basic implications
- **Examples of Hybrid Systems**
  - Getting an overview of practical examples of such systems
- **Considerations and Challenges**
  - Learn basic considerations and key challenges for implementations of hybrid systems

Definition Hybrid Systems Approach

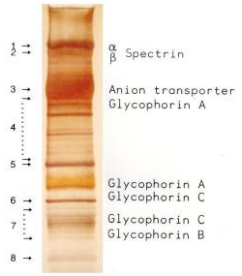
- **Hybrid systems approach** refers to the use of a computerized systems in which there is a **combination of original electronic records and paper records** that comprise the total record set that should be reviewed and retained

  (Source: WHO - Draft Guidance on Good Data and Record Management Practices)

- May also be applied whereby some recording is carried out on paper
  - In these cases, it must be ensured that the paper-based data is transferred contemporaneously to a computerized systems (e.g. LIMS) as a true copy
  - Can be also done using a scanner or other appropriate interfaces
  - Critical paper-based data that is transferred manually must be checked using four eyes principle
  - The creation of paper-based documentation and its transfer to an electronic system must be attributable

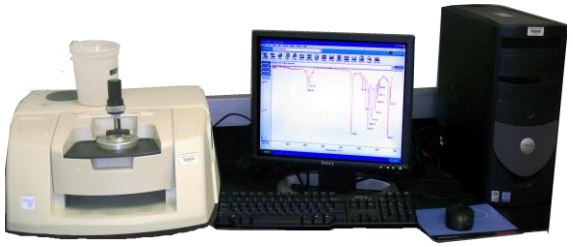
Examples of Hybrid Systems Overview

- Records obtained from the processing of **physical observations** such as processing of SDS-PAGE and other in-gel techniques



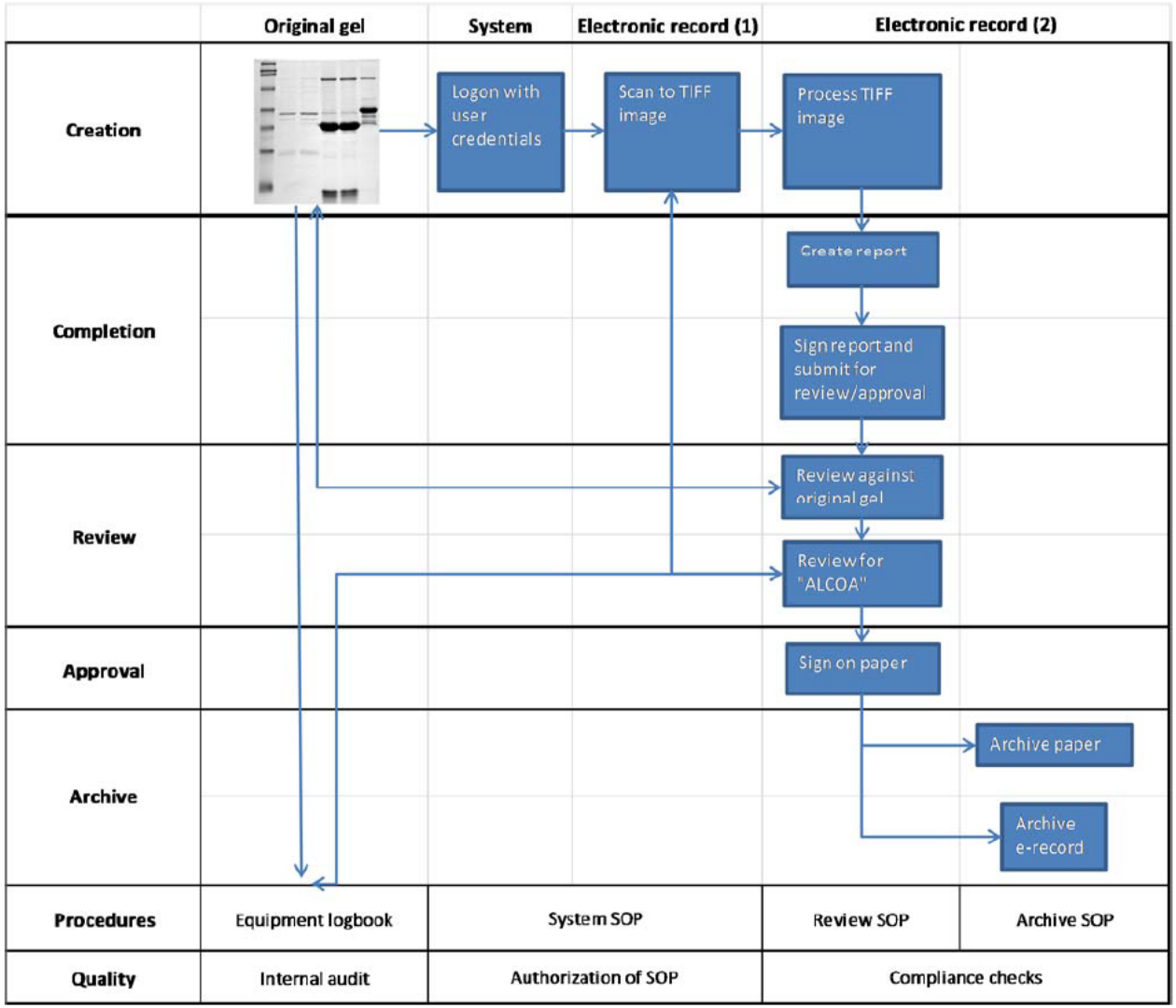
- Records obtained/originated **directly from** stand-alone computerized instruments such as spectrophotometers and FT-IR

  Records can be paper, electronic or hybrid (electronic records with signatures on the associated paper printouts)



- Records obtained from fully electronic computerized systems but firms have **defined paper as raw data** (has no place in the current GMP requirements)

Examples of Hybrid Systems
Data Lifecycle in a SDS gel techique for separation of proteins



Source: ECA Analytical Quality Working Group – IT Compliance Group, Guidance Document: Data Governance and Data Integrity for GMP Regulated Facilities

Examples of Hybrid Systems

Hybrid System

- Printouts from the system
- Additional paper records
- Wet Signatures
- Electronic Datasets
- Audit Trails

«Fully» Electronic System

- Electronic Datasets
- Audit Trails
- Electronic Signatures

Considerations and Challenges
Basic Considerations

- Where hybrid systems are used, it should be clearly documented what constitutes the whole data set and all records that are defined by the data set should be reviewed and retained

- Hybrid systems should be designed to ensure they meet the desired objective

- Where hybrid records are stored, references between physical and electronic records must be maintained such that full verification of events is possible throughout the retention period

(Source: MHRA - 'GXP' Data Integrity Guidance and Definitions)

Considerations and Challenges
Basic Considerations

- Hybrid approach is likely to be more burdensome than fully-electronic approach; therefore; utilizing electronic signatures, when available, is recommended

- The use of hybrid systems is discouraged, but where legacy systems are awaiting replacement, mitigating controls should be in place

- Replacement of hybrid systems should be a priority

(Source: *WHO - Draft Guidance on Good Data and Record Management Practices)*

Considerations and Challenges
Challenges

- Increased data review is likely to be required for hybrid systems because they are vulnerable to non-attributable data changes
- To rely upon the printed summaries of the results a second person verification of the original electronic data and relevant metadata (such as audit trails) is required
- It is expected that companies should be implementing systems that comply with current regulatory expectations
- Data (paper, hybrid or electronic) can only be excluded if there is a justified and documented scientific rationale e.g. out of specification result following a laboratory investigation

Considerations and Challenges

Challenges

- Typically hybrid records are often created by legacy systems. This kind of systems often lack audit trails and features for electronic signatures
- Another problem with legacy system is that they usually have shared or generic logon credentials. Thus, actions on electronic records cannot be attributable. A possible mitigation would be to establish signatures on paper records or a logbook of actions and persons that accessed the system
- The hybrid approach requires a secure link between all record types throughout the records retention period
- The readability of proprietary data for the entire period of retention can be a major challenge. In some cases, this means that systems that run on operating systems or hardware that are/is upwardly compatible must be retained after decommissioning. An example of this would be old devices that are required to read data that is stored on floppy disks

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