



Good Documentation Practice Guideline

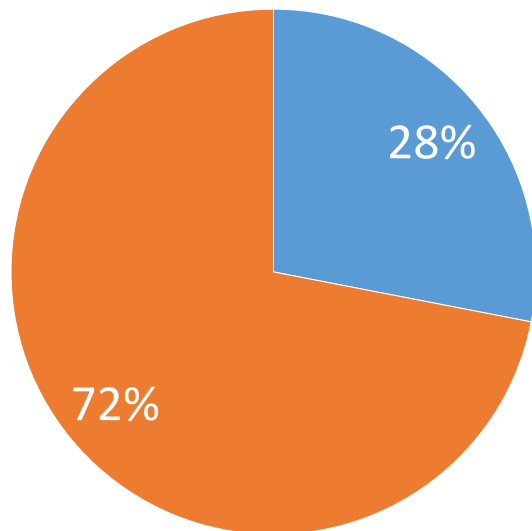
Report highlights | 23rd February 2018

Good documentation is critical!

Documentation accounts for a large share of observations

Percentage of observations in 2016, and 2017

- Documentation related
- Others



Significant share of work on the shop floor is actually documentation¹

Number of entries in typical Batch Manufacturing Record (BMR) 250+

Total number of templates with QA 25+

Number of document changes or change controls per 100 SOPs 30+

Time spent by QC analysts on documentation 25%+

¹ Based on observations from 2-3 leading Indian pharmacos

SOURCE: McKinsey warning letter database

The industry is moving towards increased electronic data documentation

- **Every company is in a state of transition** towards electronic documentation

- **Levels of electronification among companies vary widely**, ranging from 20% to 50%

- Within companies, the range of electronification across QA and QC is greater than 10%

- Even **within functions, electronification across stages is varied**; e.g., product recall documentation is completely manual while Deviations documentation is completely electronic

Each company now has to manage hybrid documentation

But mitigating risks during transition is critical !

Operating system

- **Multiple handover points** between manual and electronic
- **Duplication of process** in hybrid state
- No **standard approach** for migration

Management system

- Identification of **requirements for the IT system/tool**
- Need for **effective project management** to ensure on-time migration

People system

- **Adoption challenges**
- **Investment required** in terms of resources (new systems/instruments, etc.), and effort (tweaking an operational SOP)
- **Need for capabilities** in both, operations, and IT

Broad questions for the subgroup

- How can we ensure good documentation practices **across different stages of the lifecycle**

- How do you manage a **hybrid documentation system**

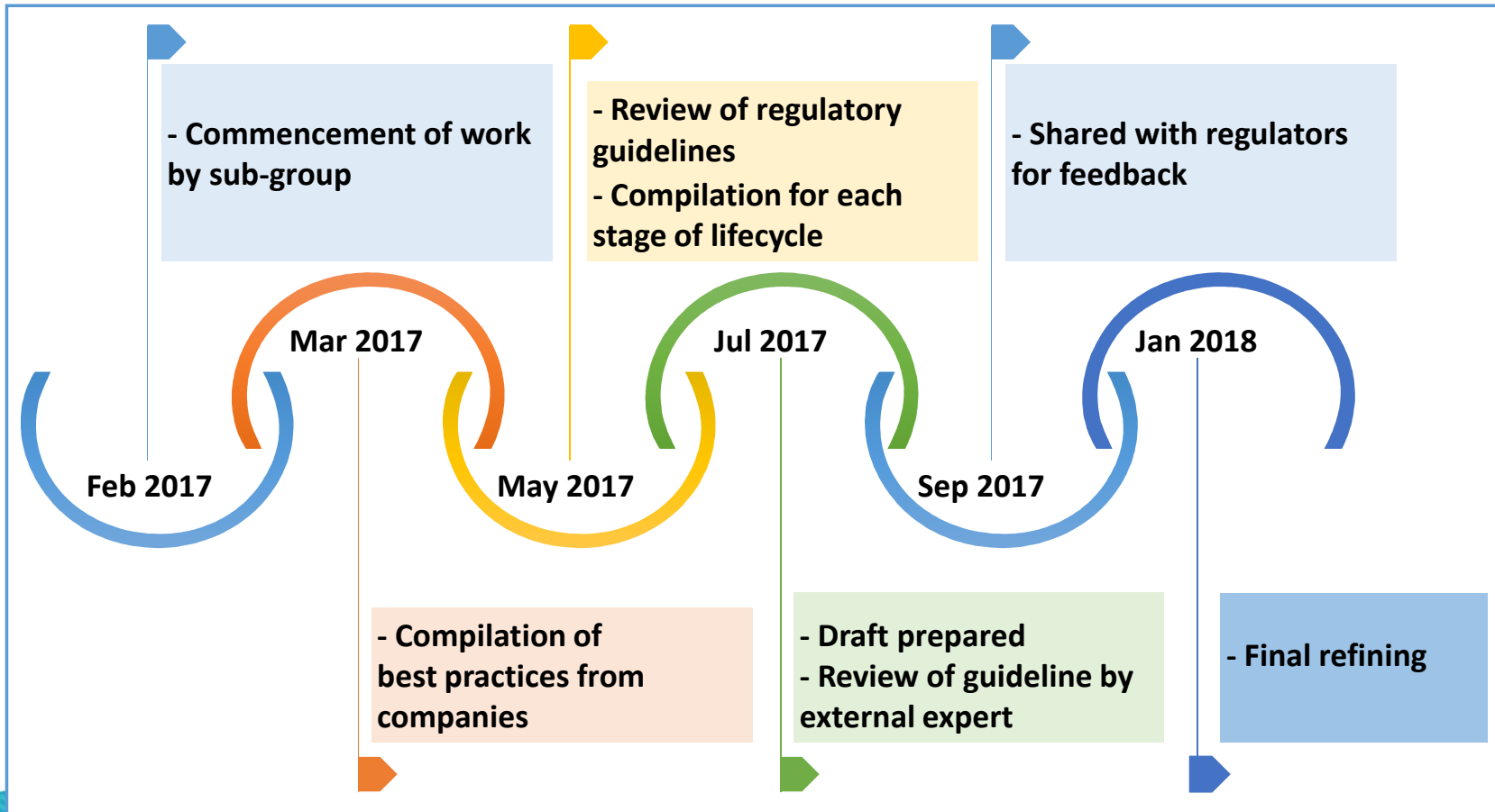
- How can we ensure smooth **transition to electronic documentation with minimal risk**



Good Documentation Practice guidelines
Sub-group 6



Subgroup followed a structured process to develop the guideline



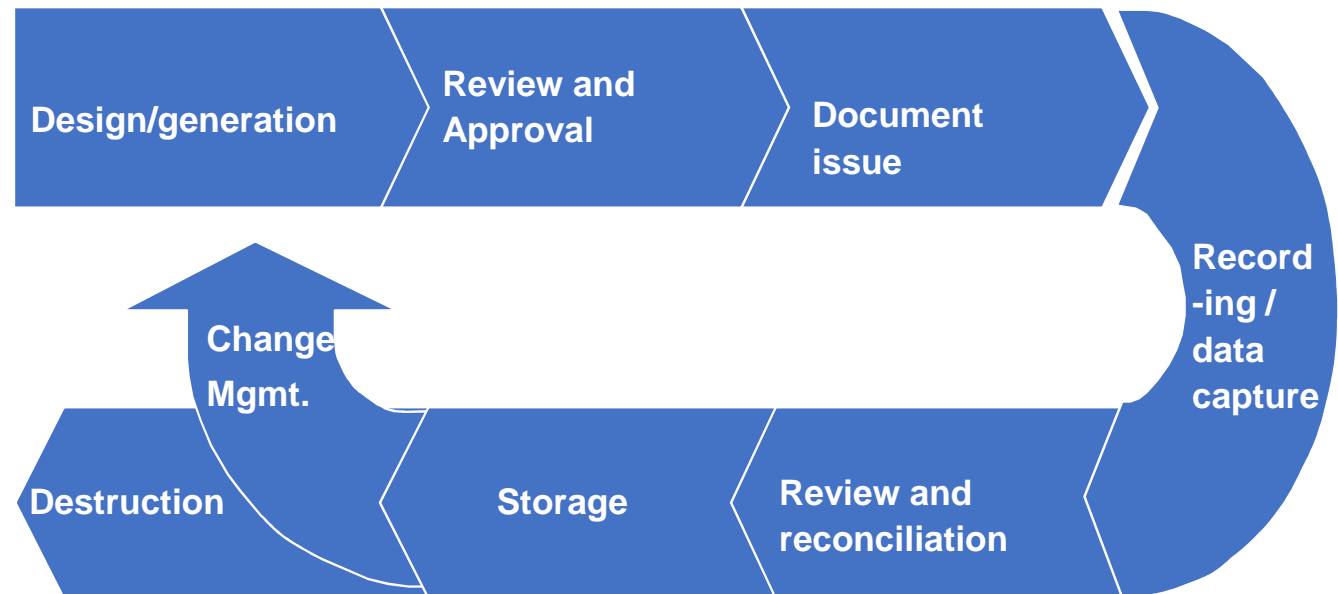
- 6+ individuals directly involved in writing the guidelines
- Extensive expert involvement (Ex FDA) for review and refinement

A comprehensive guideline is designed covering each stage of the document lifecycle

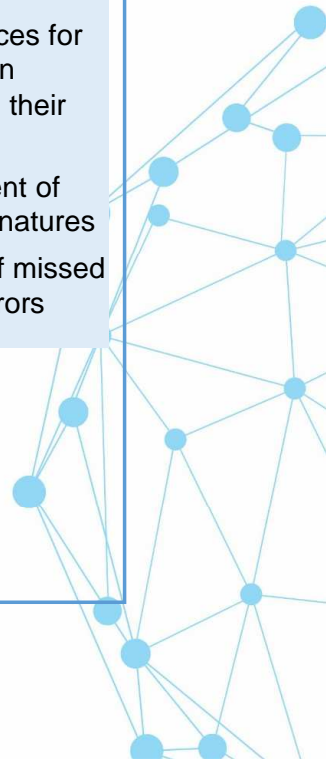
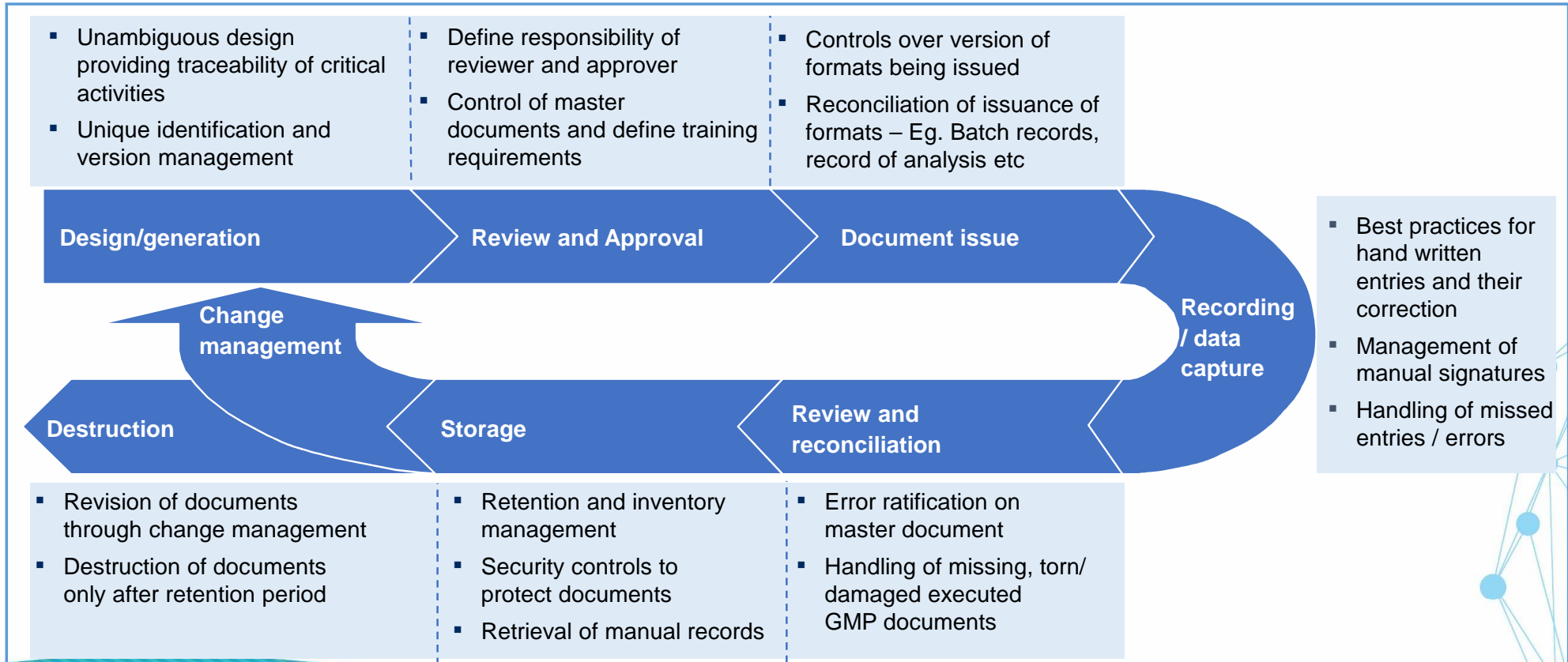
Guidance for Good Documentation Practice

- Clarifies application of data management procedures **throughout the lifecycle of the document** – includes preparation, recording and correction of data and maintenance of records
- Provides guidance for best practices for **both manual and electronic documentation**
- Provides guidance on shifting from manual to electronic documentation

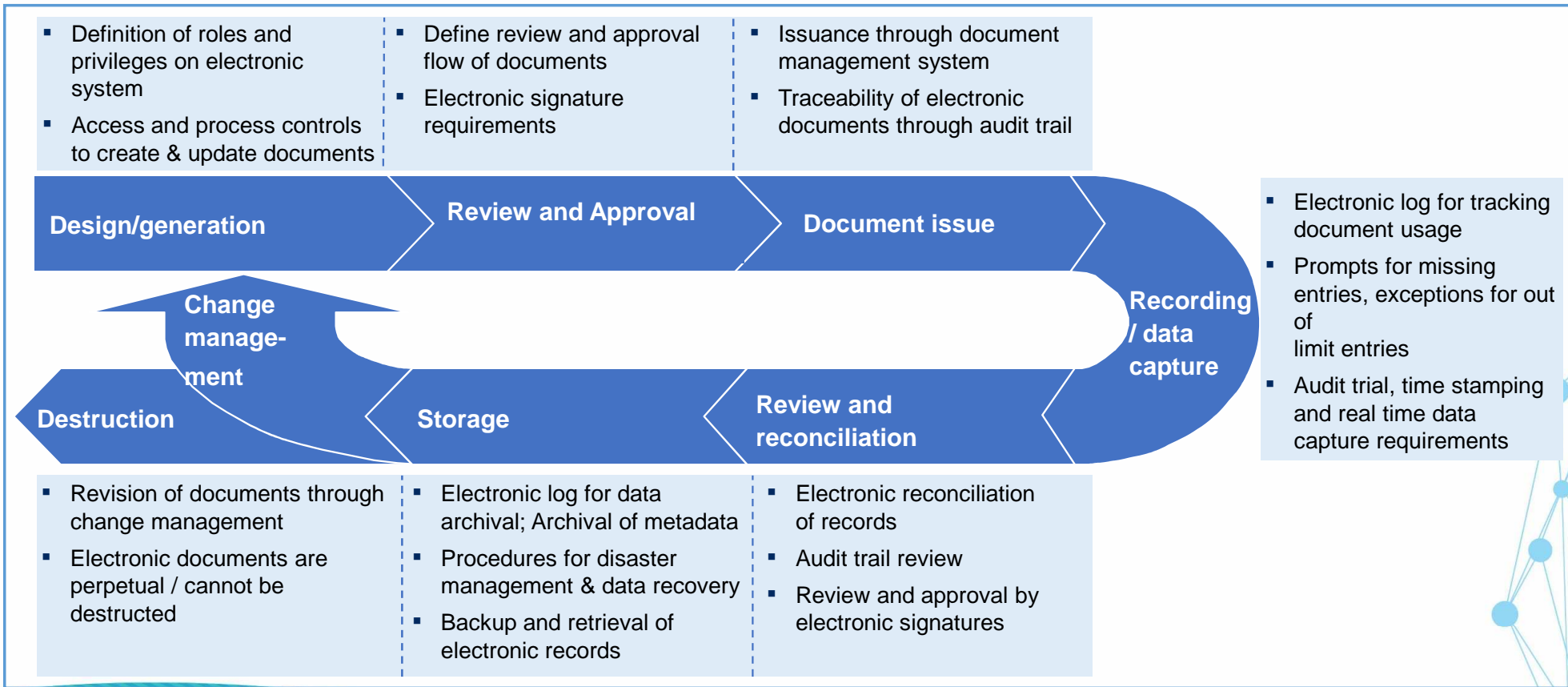
Define controls at each stage from generation to destruction



Guidance includes best practices from all 6 companies across the document life cycle for both manual documents...



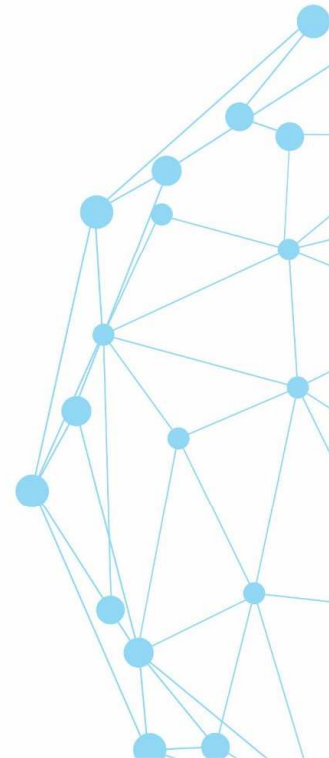
... As well as electronic documents



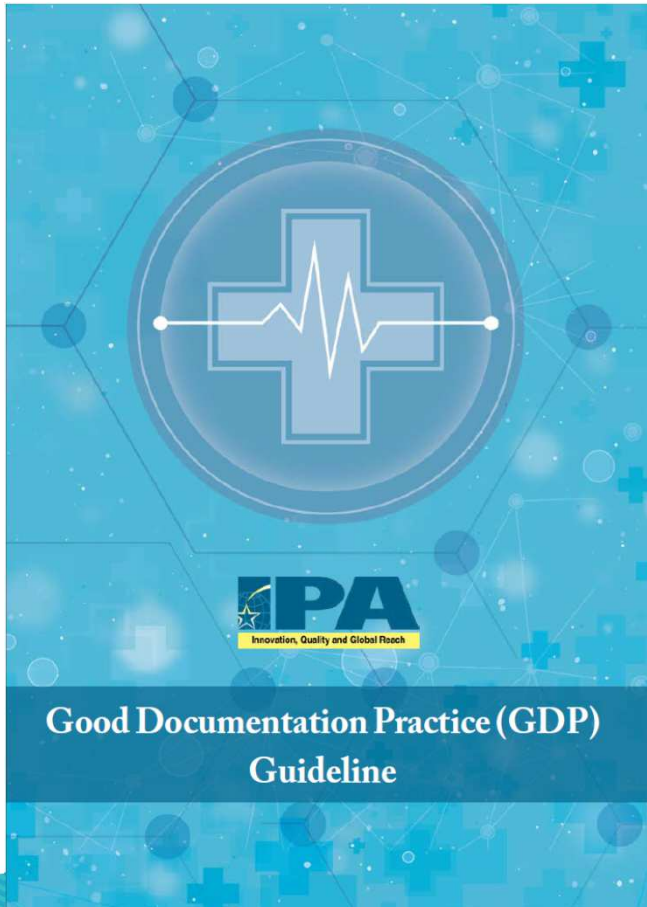
SOURCE: Team analysis

This GDP guideline combines inputs from regulatory guidelines and best practices from the 6 companies

- Single document which captures controls required across document lifecycle serving as the **single source of truth** which is usually covered across multiple documents in the industry
- The document provides processes and controls for **both manual and electronic documentation**
- It incorporates the **best practices from all 6 companies** and hence bringing out best of the best from the current industry practices
- Provides a forward looking view that documents will be increasingly electronic. Vision for transition from manual to electronic documents is being built into the guideline



The final guideline adds to, and standardizes the existing best practices across individual companies



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7. Procedure

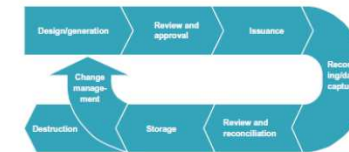
Approach towards record & data management:

The risk-based approach to record and data management shall ensure that adequate control strategies are in place for assurance of the integrity of GxP data. Risk mitigation with respect to record and data integrity risks associated with a process or system or throughout the data lifecycle shall be considered during preparation of risk assessment.

The approach also revolves around managing the entire document lifecycle for paper-based and electronic documentation as per Exhibit 1.

Exhibit 1

A comprehensive deliverable as a guidance for both manual and electronic document is designed



The guideline should articulate that key controls and best practices are captured separately for manual and electronic documents; for a hybrid flow, elements for both flows will be required as may be appropriate.

SOURCE: IPA QP sub-group 6

Good documentation practices for manual/paper documentation:

1. Design/generation of manual/paper-based documentation

- 1.1 All documents must be accurate and written in a manner that prevents errors and ensures consistency.
- 1.2 Documents shall have unambiguous contents; the title, nature and purpose shall be clearly stated.
- 1.3 Pages in the master document shall be numbered as X of Y (e.g., Page 2 of 20).
- 1.4 Full text spelling with the abbreviations in brackets shall be used for the first time. Abbreviations may be used in place of full text spelling in the remaining part of the document.
- 1.5 Definitions shall be included in the document for reference. This is most effectively done by including the definitions in a table format, at the start or end of the document.
- 1.6 Reproduced documents shall be clear and legible. The reproduction of working documents from master documents must not allow any error to be introduced through the reproduction

