Good documentation is critical!

Documentation accounts for a large share of observations

<table>
<thead>
<tr>
<th>Percentage of observations in 2016, and 2017</th>
</tr>
</thead>
<tbody>
<tr>
<td>Documentation related</td>
</tr>
<tr>
<td>Others</td>
</tr>
<tr>
<td>72%</td>
</tr>
<tr>
<td>28%</td>
</tr>
</tbody>
</table>

Significant share of work on the shop floor is actually documentation

<table>
<thead>
<tr>
<th>Number of entries in typical Batch Manufacturing Record (BMR)</th>
</tr>
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<tbody>
<tr>
<td>250+</td>
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</table>

<table>
<thead>
<tr>
<th>Total number of templates with QA</th>
</tr>
</thead>
<tbody>
<tr>
<td>25+</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>Number of document changes or change controls per 100 SOPs</th>
</tr>
</thead>
<tbody>
<tr>
<td>30</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Time spent by QC analysts on documentation</th>
</tr>
</thead>
<tbody>
<tr>
<td>25% +</td>
</tr>
</tbody>
</table>

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

SOURCE: Subgroup 6 benchmarking
But mitigating risks during transition is critical!

<table>
<thead>
<tr>
<th>Operating system</th>
<th>Operating system</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Multiple handover points between manual and electronic</td>
<td>Management system</td>
</tr>
<tr>
<td>• Duplication of process in hybrid state</td>
<td>• Identification of requirements for the IT system/tool</td>
</tr>
<tr>
<td>• No standard approach for migration</td>
<td>• Need for effective project management to ensure on-time migration</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>People system</th>
<th>People system</th>
</tr>
</thead>
<tbody>
<tr>
<td>• Adoption challenges</td>
<td>• Investment required in terms of resources (new systems/instruments, etc.), and effort (tweaking an operational SOP)</td>
</tr>
<tr>
<td></td>
<td>• Need for capabilities in both, operations, and IT</td>
</tr>
</tbody>
</table>
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
Indian Pharmaceutical Alliance

Good Documentation Practice guidelines
Sub-group 6
Subgroup followed a structured process to develop the guideline

- Commencement of work by sub-group
- Review of regulatory guidelines - Compilation for each stage of lifecycle
- Shared with regulators for feedback

- Compilation of best practices from companies
- Draft prepared - Review of guideline by external expert
- Final refining

- 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**

- Design/generation
- Review and Approval
- Document issue
- Change Mgmt.
- Storage
- Review and reconciliation
- Destruction
- Record-ing / data capture
Guidance includes best practices from all 6 companies across the document life cycle for both manual documents...

<table>
<thead>
<tr>
<th>Design/generation</th>
<th>Review and Approval</th>
<th>Document issue</th>
</tr>
</thead>
<tbody>
<tr>
<td>Unambiguous design providing traceability of critical activities</td>
<td>Define responsibility of reviewer and approver</td>
<td>Controls over version of formats being issued</td>
</tr>
<tr>
<td>Unique identification and version management</td>
<td>Control of master documents and define training requirements</td>
<td>Reconciliation of issuance of formats – Eg. Batch records, record of analysis etc</td>
</tr>
</tbody>
</table>

- Best practices for handwritten entries and their correction
- Management of manual signatures
- Handling of missed entries / errors

- Change management
- Recording / data capture
- Destruction

- Revision of documents through change management
- Destruction of documents only after retention period
- Retention and inventory management
- Security controls to protect documents
- Error ratification on master document
- Handling of missing, torn/ damaged executed GMP documents
- Retrieval of manual records

SOURCE: Team analysis
... As well as electronic documents

- Definition of roles and privileges on electronic system
- Access and process controls to create & update documents
- Define review and approval flow of documents
- Electronic signature requirements
- Issuance through document management system
- Traceability of electronic documents through audit trail

**Design/generation** → **Review and Approval** → **Document issue** → **Recording/data capture** → **Review and reconciliation** → **Storage** → **Change management** → **Destruction**

- Revision of documents through change management
- Electronic documents are perpetual / cannot be destructed
- Electronic log for data archival; Archival of metadata
- Procedures for disaster management & data recovery
- Backup and retrieval of electronic records
- Electronic reconciliation of records
- Audit trail review
- Review and approval by electronic signatures

- Electronic log for tracking document usage
- Prompts for missing entries, exceptions for out of limit entries
- Audit trial, time stamping and real time data capture requirements

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

SOURCE: Team analysis
The final guideline adds to, and standardizes the existing best practices across individual companies.