Paperless Validation
The ones and zeros

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“There is a way to do it better – find it”

- Thomas Edison
Paperless Validation

● Lots of Paper
  ● Approx 20-30K protocol pages generated – Initial 8 NYA

● Data Integrity
  ● Contemporaneous Entry
  ● Legibility
  ● Traceability of changes
  ● Loss of Protocols

Price Waterhouse Coopers Study:

$122 spent on finding a lost document
~ 7.5% of all company documents are lost completely
Assume 10,000 documents (a very light figure) = 750 lost document
Costing the company $91,000

American Records Management Association:

• 7-14% of total costs is spent on processing in a paper environment
• Average organization spends 280 hours annually per employee looking for lost documents
Paperless Validation

Logistics and Clerical
• Physical movement of protocols
• Scanning for accessibility/approval
• Protocol attachment references
• Spreadsheets for tracking

IVT Network Case Study:

<table>
<thead>
<tr>
<th>Protocol Stage</th>
<th>Compared to Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-execution Approval</td>
<td>48% reduction on average</td>
</tr>
<tr>
<td>Post Execution Approval</td>
<td>58% reduction on average</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Overall</th>
<th>Compared to Paper</th>
</tr>
</thead>
<tbody>
<tr>
<td>Test Protocol Cycle Time</td>
<td>60% reduction on average</td>
</tr>
<tr>
<td>Time savings per protocol</td>
<td>23 hours based on their workflow</td>
</tr>
</tbody>
</table>
Paperless Validation

Secure Access

- Searchable
- Organized
- Smart Numbering
- One stop shop

Part 11 Compliant

• Searchable
• Organized
• Smart Numbering
• One stop shop
Paperless Validation

Smaller (No) Onsite Physical Footprint

No Offsite Records Management

Metrics!
Paperless Validation

More and More Improvements!

- Accessibility of documents
- Scalable
- Simultaneous review and approval
- Email notifications
- Shared information across documents
- Drives consistency of approach

<table>
<thead>
<tr>
<th>Validation processing step</th>
<th>Average processing time saved</th>
<th>Areas where savings realized</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protocol Generation</td>
<td>3</td>
<td>Content populated across multiple protocols simultaneously, template use, auto smart numbering</td>
</tr>
<tr>
<td>Protocol Routing for approval to execute</td>
<td>3</td>
<td>tracking, reporting, metrics, embedded submittals in protocols to aid review</td>
</tr>
<tr>
<td>Protocol Execution and Compiling</td>
<td>6</td>
<td>No exhibit referencing, no protocol number referencing, no printing, no organizing/compiling</td>
</tr>
<tr>
<td>Non Conformance (NC) processing</td>
<td>1</td>
<td>tracking, routing</td>
</tr>
<tr>
<td>Protocol final report writing</td>
<td>3</td>
<td>NCs summarized automatically</td>
</tr>
<tr>
<td>Protocol final report routing for review/approval</td>
<td>3</td>
<td>tracking, reporting, metrics, exhibits embedded into test table</td>
</tr>
<tr>
<td>Post approval management</td>
<td>4</td>
<td>scanning, records management, uploading to doc management system, ship offsite</td>
</tr>
</tbody>
</table>

Total Average Per Protocol
Savings (hours) 23
Paperless Validation

Trials and Tribulations

• What to do with the remaining paper?
  • Keep or Destroy?

• Generation of protocols
  • Forward thinking important.
    • E.g. No line out of tables

• Culture change
  • Manage Expectations – What would we do on paper?
  • Approval of a document – Does QA need to be last?
  • Infrastructure Challenges – Internet availability

• Challenges when considering complexity
  • Linkages to other applications?

Questions?
Please use the microphone indicated so our recording includes audio of your question
For further information, please contact

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