21 CFR Part 11 Form: The Road Map to Compliance

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Introduction

Vendor may claim compliance but it is our responsibility as the user to verify that the software/computerized system meets 21 CFR Part 11
Introduction

Agenda

• Introduction
• Agenda
• 21 CFR PART 11 Form
• What is it?
• How it works?
• What is does?
• Why is it helpful?
• When to complete?
• What PHRI learned from assessment?
• Summary
• Questions
21 CFR Part 11 Form

• PHRI developed a form to assess compliance of computerized systems to Part 11

• PHRI used the form to assess DataFax (system), our processes, procedures, documents, training etc. against Part 11 requirements

How it Works?

<table>
<thead>
<tr>
<th>21 CFR Part 11 Assessment</th>
</tr>
</thead>
<tbody>
<tr>
<td>#</td>
</tr>
</tbody>
</table>

Column 1 – Numbering
Column 2 – Part 11 section (broken down into smaller pieces)
Column 3 – PHRI Interpretation Question (sometimes more than 1)
Column 4 – Answer (Yes/No/Not Applicable)
Column 5 – How PHRI complies – (System, Procedure, Documentation, Physical Environment/Not applicable etc.)
Column 6 – Comment/Explanation section – to provide more details/clarification
## 21 CFR Part 11 Form Example

### Table 1

<table>
<thead>
<tr>
<th>Section</th>
<th>Form No.</th>
<th>Applicability</th>
<th>Applicable for the specific system functions</th>
<th>Compliance</th>
<th>Note</th>
</tr>
</thead>
<tbody>
<tr>
<td>10.10.5</td>
<td>A.1.1</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
</tr>
<tr>
<td>10.10.5</td>
<td>A.1.2</td>
<td>Yes</td>
<td>Yes</td>
<td>No</td>
<td></td>
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<tr>
<td>10.10.5</td>
<td>A.1.3</td>
<td>Yes</td>
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### Table 2

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**Note:** Details are fictional. The actual content and context may vary.
What it does?

Examines (Current)
- DataFax System
- Process & Procedure
- Training
- Documentation

Identifies Gaps

Controls

There are two types of controls

- Technical
- Procedural
Technical Controls

Controls in the system
- It can be a workaround or temporary fix until a permanent solution is identified and implemented
- It can be a permanent solution

Examples:
- Installing the latest security patches
- Restricting access
- Installing a local backup device or copy files to a network server
- Disabling functions as necessary
- Installing a third party application to add or enhance security of the application

Procedural Controls

Written SOPs

Example:
- SOP for a hybrid system (electronic records and handwritten signatures on paper)
- SOP for manual workaround like a paper audit trail

Note that in some cases, both types of controls could be required.
Why it is Helpful?

Additional Benefits

- Generic Form – can be used for multiple computerized systems
  - Standard way of assessing system

- Core Procedure and Process established
  - Leverage for new system

- Documentation – Team communicates the same information

- Better understanding of the computerized system
When to Complete?

PHRI Recommendation:

Complete prior to validating a computerized system

But …it is never too late to start!!!

What PHRI Learned From Assessment?

- 31 Regulations reviewed
  - each regulation broken down into smaller pieces

- 51 Interpretation questions
  30 addressed by System or System and Procedures
    e.g. System: maintenance of documentation of deleted records
    System and Procedures: access to system functions limited by ensuring roles with different access levels are used
  8 addressed by existing Procedures, Documentation or Combination
    e.g. Procedures: controls over system documentation
    Documentation: training records to show users are qualified
    Combination: validation of systems
  1 addressed by System/Procedure/Physical Environment (protection of records)
  10 Not Applicable (e.g., use of biometric signature)

- 2 Gaps - Procedures
  1 User Administration Procedure (formal)
  1 Escalation of Security Violation
Summary

21 CFR Part 11 form

• Consists of
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• Assesses DataFax against Part 11
• Identifies where we are
• Identifies where we want be (i.e. Gaps)
Questions?

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