



The Part 11 Advisor is the answer to all your 21 CFR Part 11, Electronic Record and Electronic Signature problems. This program will help you assess your systems with a gap analysis tool, build a Corrective Action Plan and track your progress towards compliance.

Step I. Setup and Training

- Build or import your list of systems to evaluate for compliance with Part 11
- Assign priorities and responsibilities
- Train the system owners – much of the evaluation is completed during the training session itself!

Schedule for Reviewing Systems				
Week of 1/20/01 to 01/26/2001 (2 Systems)				
System	Owner	Score	Review Date & Status	
Document Management System (EDMS)	Noah Weisler	17%	1/20/01 8:00 AM	<input type="checkbox"/>
HPLC	David Podlask	52%	1/20/01 10:00 AM	<input checked="" type="checkbox"/>

Step II. Evaluations and Review

- Collect and review data
- Choose from a list of solutions that industry is using today or enter your own
- Build your Corrective Action Plans (CAP) for each system
- Estimate dates, costs and time required for each part of the CAP
- Begin implementing short-term actions immediately while you review and approve your long-term plans for compliance

Document Management System (EDMS)

System Description and Specifications:

System Trained
 Backup Data Trained
 Site:
 Department:
 Record Type:
 Comments Base Default

General description:

Electronic Document Management System (EDMS) used to store CAP documents.

What kind of records are input or exported?

EDMS documentation, including SOPs, SPC, Analytical data and validation protocols.

Where and how is this data used?

This system is used to store electronic files and for the purpose of tracking and in printed documents for signatures.

Subpart C: Electronic Signatures		Electronic Signatures Score: 46.7%
11.100	Electronic Signature General Requirements	75.0%
11.200	Controls for Electronic Signatures	33.3%
11.300	Controls of Identification, Codes and Passwords	40.0%

HPLC 51.89%

Step III. Long Term Tracking of your Corrective Action Plan

- Track the completion of your short and long-term corrective actions
- Build corporate policies for how electronic records and signatures will be controlled
- Expect short-term gains of 10-25% simply by educating your workforce about Part 11 requirements

Review Proposed Solutions for Corrective Actions

Schedule for Corrective Actions					
Est. Date	Responsibility	System	Solution	Description	Status
Week of 5/20/01 to 5/26/01 (3 Items)					
05/02/01	David Podlask	HPLC	Validate the HPLC software	Allocate money for validation	Pending
05/01/01	Noah Weisler	Document Management System (EDMS)	Enforce unique logins	Add unique username logins	50% Done
05/03/01	Noah Weisler	Document Management System (EDMS)	Enforce unique logins	Update SOP for backup period	Pending

Additional Features

- Packed with Project Management tools
- Program is automatically customized for each user
- Interpretations and instructions are included for each section of Part 11, or you can customize the program with your own interpretations

Benefits

- Be ready for any audit in weeks, not months!
- Build a well-trained workforce for evaluating new systems
- Includes over 15 pre-formatted reports for scheduling and status updates

We also provide help with evaluations and training on Part 11. For more information, call (919) 844-2494 or visit us online.

Contact: Ofni Systems Inc.

www.OfniSystems.com
Info@OfniSystems.com