



Automating Regulatory Compliance and IT Best Practices Reporting

21 CFR Compliance Reporting

Why Ecora Auditor Professional for Regulatory Compliance Reporting?

Ecora Auditor Pro is the only solution to automate regulatory compliance and ITIL best practices reporting for IT Systems Management. Using Auditor Pro, organizations are able to audit and identify configuration changes in virtually all operating systems, database management systems, applications, and network devices. Auditor Professional collects over a million asset, security and configuration settings into a CMDB for reporting, auditing, baselining, and change tracking.

Agentless, non-invasive, and easy-to-use, Ecora's Auditor Pro solution is used by the Fortune 1000 to ensure effective IT systems control over the regulatory compliance and best practices areas of most concern to leading IT operations.

Automated 21 CFR Part 11 Regulatory Compliance Reporting

Let's face it. You need to provide an audit trail showing you have control over your infrastructure. You also need to have documented evidence that provides assurance a specific system is configured to operate in accordance with predetermined requirements and specifications as set forth in 21 CFR Part 11.

Over 500 companies use Ecora Auditor Professional to generate reports for the IT Audit portion of the 21 CFR Part 11 compliance process.

The most popular reports found within Auditor Pro that are required as part of the 21 CFR Part 11 IT Audit process include:

- Password Aging
- User Privileges
- System Privileges
- Remote Access
- Consolidated Change Logs
- NTFS Permissions
- Role Permissions & Membership
- User Access
- Auditing Enabled

21 CFR Part 11 Reports in a Box with Auditor Pro!

Auditor Professional gives you the answers to the most critical 21 CFR related questions such as:

- Who has access to systems holding financial records?
- Who has access to Share information?
- Where are internal security vulnerabilities?
- What patch levels are we at?
- Are configuration changes being tracked and documented?
- What policies are changing within Active Directory?
- Can we show an audit trail?
- And much more...

Server Affected	Type of Change	Description of Change	Account / Who made the change	Date of change
BOSTON_DC	User/Group Account Management	System failure (DOMAINSE) from workstation (REHOMERED) with address - Reason: Unknown user name or local password	NT AUTHORITY\SYSTEM	2006-09-1
	User/Group Account Management	Security enabled global group: ECRASE\domain Admins changed	DOMAIN\jake	2006-09-1

Domain Server	Share Name	Share Permission	NTFS Permission	Account with Permission	Applies To
DOMAIN\RACERX	ADMIN	Allow - Full	Allow - Main/Read	Everyone (well-known group)	This folder only
			Allow - Main/Read & Execute	BUILTIN\Users (alias)	Subst files
			Allow - Main/Modify	BUILTIN\Power Users (alias)	Subst files
			Allow - Main/Full	BUILTIN\Administrators (alias)	Subst files
				BUILTIN\Administrators (alias)	Subst files
				CREATOR OWNER (well-known group)	Subst files
				NT AUTHORITY\SYSTEM (well-known group)	Subst files
				NT AUTHORITY\SYSTEM (well-known group)	Subst files
			Allow - Main/Change	BUILTIN\Power Users (alias)	This sub
			Allow - Full	Everyone (well-known group)	This sub
			Allow - Special (Create folders/Append Data)	BUILTIN\Users (alias)	Subst files

Ecora's solutions provide hundreds of audit-ready report templates and a policy-based dashboard for effective 21 CFR Compliance



“Changes constantly happen and we need to provide audit-ready reports that prove we're in compliance. Ecora Auditor Professional's reporting capabilities allow us to automatically manage configurations and changes throughout our infrastructure.”

*– Director of Technical Operations
SISU Medical Systems*

The Challenge

Pharmaceutical companies and **medical-device manufacturers** are increasingly using the Internet to automate business processes such as clinical trials, drug research collaboration, and drug approvals. As a result, there is mandatory interest in compliance with the Food and Drug Administration (FDA) standard for electronic records and electronic signatures. The IT infrastructures of these companies need to manage, report and prove access, control, change and configuration policies on the servers and systems are in compliance with 21CFR Part 11.

The Ecora Solution

Ecora Auditor Professional helps automate the 21 CFR Part 11 validation process by collecting thousands of configuration settings into easy to understand audit-ready reports. Our solution provides you with the documented evidence that states your systems are configured to your compliance policies. Ecora's Auditor Pro solution goes to work automating the reporting on: Who has access to systems holding financial records?

Which servers house which data? Who has access to Share information? Where are there internal security vulnerabilities? What patch levels are we at? Are configuration changes being tracked and documented? What policies are changing within Active Directory? Can we show an audit trail? And hundreds of other out-of-the-box reports.

Ecora's Auditor Pro Compliance Dashboard gives you at-a-glance reporting on these critical areas to allow you to achieve and maintain 21 CFR Part 11 compliance. It's that simple!

Ecora is the One!

Ecora's Auditor Professional helps provide automated solutions for all major regulatory compliance mandates and ITIL best practices reporting. Evaluate it for yourself—visit <http://www.ecora.com/auditorpro> for a no-obligation, free trial and join with over 1,100 active worldwide customers. Learn for yourself how customers are realizing such a significant savings that they have “achieved a return on investment many times over.” It's time to step up to Auditor Pro and automate regulatory compliance and best practices reporting for IT Systems Management.

More Information

To find out how Ecora can help with your regulatory compliance and IT best practice initiatives by automating detailed configuration and change reporting within your IT infrastructure, call **877.923.2672** or **+1 (603) 436.1616** outside the United States, email sales@ecora.com, or visit us on the web at www.ecora.com.

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