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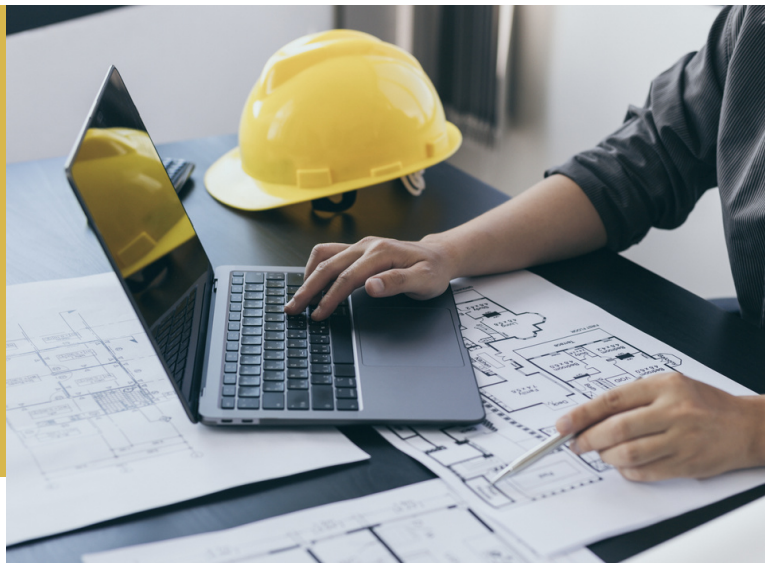
Data Sheet

21 CFR PART 11 COMPLIANCE



INTRODUCTION

Manufacturers in life sciences industries such as medical device manufacture or the pharmaceutical industry will probably be aware of the U.S. Food and Drug Administration's (FDA) Code of Federal Regulations Title 21 Part 11. The primary objective of this CFR is to implement controls in order to maintain the trustworthiness, reliability and integrity of electronic records and electronic signatures.

The modules and core functionality within EFACS E/8 enable full compliance with 21 CFR Part 11. Robust security and permissions control ensure that system access is fully controlled and auditable, thereby providing the requisite accountability.

AT A GLANCE

ERP solutions in themselves cannot be certified as FDA compliant, they can however provide your business with the tools and technology to enable compliance. This data sheet will look at the requirements of 21 CFR Part 11 for medical device and pharmaceutical manufacturers.

REQUIREMENTS SUMMARY

EFACS provides organisations with a fully integrated business system that spans the full breadth of operations, and therefore is key in assisting companies to achieve their compliance objectives.

EFACS can assist in the following areas:

System Security and Permissions
EFACS provides full role based security. Different levels of access for individual people and departments can be defined both at the application and field level to ensure that sensitive information is kept secure.

Audit Trail
Enables companies to log, track and investigate data that is changed within the business system. The Audit Trail functionality provides a precise, detailed and easy to use method of recording when information within EFACS E/8 is changed, who changed it and how it was changed. Workflow can be used to monitor the audit trail and flag up specific transactions.

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Electronic Signatures
A key requirement of the FDA regulations is the need for additional security checks at specific key points within the manufacturing and distribution process. Configurable rules within the EFACS system allow specific activities to be set to require an additional level of authentication.

Full Part Revision Control and Change Control
A fundamental requirement for companies within this industry sector. EFACS provides a proven, flexible system for companies with simple or complex requirements in this area.

Document Management
This fully integrated module allows users to store, access and amend a wide variety of documents in a secure, controlled and auditable manner. Revision management, the ability to check documents in and out of the system, and the capacity to assign attributes to a document for easy retrieval make this a very powerful tool.

Integrated Workflow
Automatically circulates information and documents within the organisation for approval and revision, ensures that all the relevant people and departments are kept informed as required.

Fully Traceable Stock and Batch Controls
For traceable and serial products a framework is provided to allow for complete forward and backward traceability.

Quality Concerns module
Allows companies to record and drive incidents and quality concerns within their organisation. Use of 'management stages' allows recording and tracking of actions and communications throughout the life cycle concerned.

BUSINESS BENEFITS

EFACS can help companies adhere to 21 CFR Part 11 by the implementation of the items described previously. Whilst it can still be time consuming to achieve compliance the introduction of an appropriate ERP system will provide:

- **Increased speed of disseminating information between departments and externally**
- **Shorter timescales for product life cycle development**
- **Greater employee ownership of quality issues**
- **Reduced issues associated with over or under stocking of finished products and raw materials**
- **Improved data security**
- **Easier monitoring of individuals within sensitive areas of an organisation**
- **Reduced timescales to meet the ever changing compliance regulations**
- **Increased accuracy and authenticity of electronic data**

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