

eCHR Overview

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eCHR

In highly regulated industries such as aerospace and defence, and medical device manufacture, strict traceability and audit requirements demand exceptionally reliable record keeping demonstrating that products have been manufactured to good quality in accordance with their design.

In the medical device sector, one such requirement is to record device or batch history records (DHR). These must clearly show that products are manufactured according to approved processes (as defined by the device master record - DMR), ensuring patient safety is never compromised.

Key regulations in the medical device sector include FDA 21 CFR Part 820 and ISO 13485, though other regulated industries follow similar standards. A common requirement across them all is the ability to prove, through an immutable audit trail, that manufacturing has consistently met compliance standards.

Some records require signature and where the details are collected electronically, specific regulation defines the requirements for these signatures to be considered equivalent to a physical signature (FDA 21 CFR 820 Part 11).

Eyelit's Electronic Control History Record (eCHR) system is designed to meet these regulatory demands. It lets you define exactly what information should be included in the controlled history records, provides an immutable audit trail for this data based on blockchain storage and supports electronic signatures for approval of these records.

Eyelit eCHR Module

Digitising eCHR processes significantly reduces documentation errors and the time spent on manual data entry, which in turn minimises rework and speeds up completion. It also accelerates time to market by supporting well-defined processes that streamline new product introductions and the generation of Device Master Records (DMRs).

While large volumes of data are collected electronically during production, not all of it is necessary for regulatory compliance. Identifying only the essential records to include in the eCHR helps reduce administrative overhead and avoids sharing information that is not required.

Eyelit streamlines the creation of electronic Control History Records (eCHR) by allowing users to configure eCHR profiles that include only the information required for compliance.

Every step of the manufacturing process, such as material usage, equipment and tool utilisation, quality checks, and process parameters, is digitally recorded. This replaces traditional paper-based records with a secure, tamper-proof electronic version built on blockchain technology.

Authorised users can also review and approve eCHRs digitally, ensuring a fully electronic and traceable workflow.

Data Types Recorded in an eCHR

Line Types define the kinds of data you can record in an eCHR. For more information, see [Line Type](#) documentation.

The following Line Types can be configured:

- Action Completion
- BOM-Related Line Types
 - As Built

- BoM Definition (not supported for no-code configuration)
 - Build Record
- Case Data
- Checklist-Related Line Types
 - Check Result Set
- Documents
 - Checklist Document
 - Check Result Set Document
 - Checklist Step Document
 - Issue Document
 - Item Document
 - Operation Document
 - Product Document
 - Recipe Document
- eCHR-Related Line Types
 - eCHR On Closure
 - eCHR On Creation
 - eCHR Transfer
 - Generic eCHR Data WF Action
- Issue-Related Line Types
 - Issue
- Item-Related Line Types
 - Item Adjust Qty Actual
 - Item Adjust Qty WIP
 - Item Note
 - Item Serial Number Change
 - Item Split
 - Item Summary Data
- Job Document
- Label Print
- Operation-Related Line Types
 - Operation Quantity Completion
- Scrap-Related Line Types
 - Scrap Available Quantity
 - Scrap WIP
- Tool Use

eCHR Configuration

Configuring the eCHR consists of three things:

1. Workflows need to be configured to collect the required data.
2. Configure [eCHR Profile](#): to determine what subset of the collected data is stored in the eCHR. It defines what data is collected, what e-sign profiles are required to approve / reopen / delete a ECHR and how it is displayed in the final report for each of the configured [Line Types](#). Each Line Type defines what data is collected and what in the workflow triggers the record creation including any required language translations.
3. Set up [eSignature Profile](#): For many Line Types, you need to set up eSignature profiles to define the signature requirements for adding, editing and signing records as well as managing the overall approval of the final eCHR (see above). Eyelit MES complies with FDA 21 CFR Part 11 which specifies the requirements for the digital signature to be equivalent to a physical signature.

eCHR Management

During production eCHRs are viewed and managed through the [eCHR Listing](#) screen.
