eCHR Overview

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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 eSignature Module

Some data that is collected digitally will require a signature. Eyelit MES complies with FDA 21 CFR Part 11 which specifies the requirements for the digital signature to be equivalent to a physical signature. For more detail, refer to eSignatures.

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) - the eCHR parts.

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 DHRs 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.