Veeva Vault-based EDMS tailored for biotech

Emerging biotech companies need an easy-to-use Electronic Document Management System (EDMS) that ensures document control and is pre-configured specifically for biotech

An ever-increasing number of documents
Document management is an important discipline for all biotech companies, and the number of documents is ever-increasing.

Proper management of documents arising from a GxP regulated process is essential to ensure complete reconstruction and traceability of GxP activities.

Documents resulting from exploratory activities are not bound by the same requirements. However, they still need to be effectively managed to ensure easy retrieval.

Various EDMS solutions are available
Emerging biotech companies require a user-friendly EDMS that guarantees compliance with GxP regulations and streamlines processes.

Currently, multiple EDMS options are available in the market. While some are easy to deploy and use, they may not fully meet GxP requirements or support features like audit trails and electronic signoffs on documents (e-Signature and R&U).

Other EDMS solutions are specifically designed to fulfill GxP standards but demand significant internal resources for implementation and maintenance. These systems are typically configured for large pharmaceutical companies and may not be suitable for emerging biotech firms.

An EDMS solution based on Veeva Vault tailored for biotech
KLIFO has designed a user-friendly and compliant EDMS solution specifically for the biotech industry within Veeva Vault. This secure and trustworthy solution enhances the value for emerging biotech companies by ensuring complete control and easy retrieval of documents.

The Veeva Vault/KLIFO Biotech EDMS solution:

- Includes classifications and metadata to support biotech EDMS needs
- Supports reports and dashboard including R&U tracking on documents
- Is fully GxP compliant and 21 CFR Part 11 compliant for eSignatures
- Facilitates Due Diligence processes
- Provides access for both internal and external stakeholders
- Supports content migration to another Veeva Vault, if and when relevant.

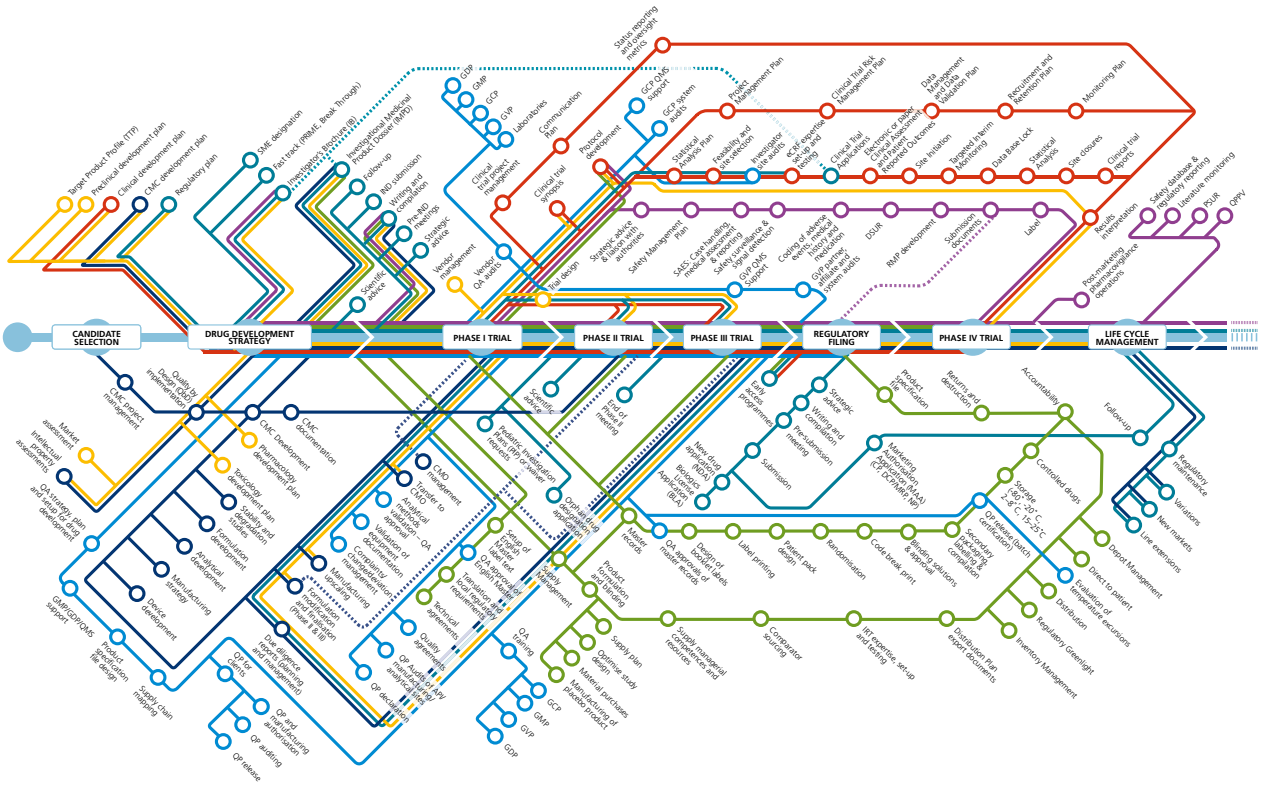
eTMF
eTMF hosting and archiving services can also be provided. The services can be part of the EDMS solution or they can be provided separately.

Easy to implement and maintain
The Veeva Vault/KLIFO Biotech EDMS solution is plug and play and designed to be easily implemented and used. KLIFO will take care of system maintenance, handle Veeva General Releases, and manage user administration. Technical support, quick guides and best practice guidance for document management are also available.

KLIFO is an integrated drug development consultancy

KLIFO is an integrated North-European drug development consultancy with significant experience in partnering with pharmaceutical and biotech companies.

We offer end to end solutions across all drug development areas, incl. strategic project management, regulatory affairs, clinical development, clinical trial supply, QA, CMC development, non-clinical development and pharmacovigilance. We provide strategic advice as well as operational support in all these areas.



To learn more about the Veeva Vault/KLIFO Biotech EDMS solution, please contact

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