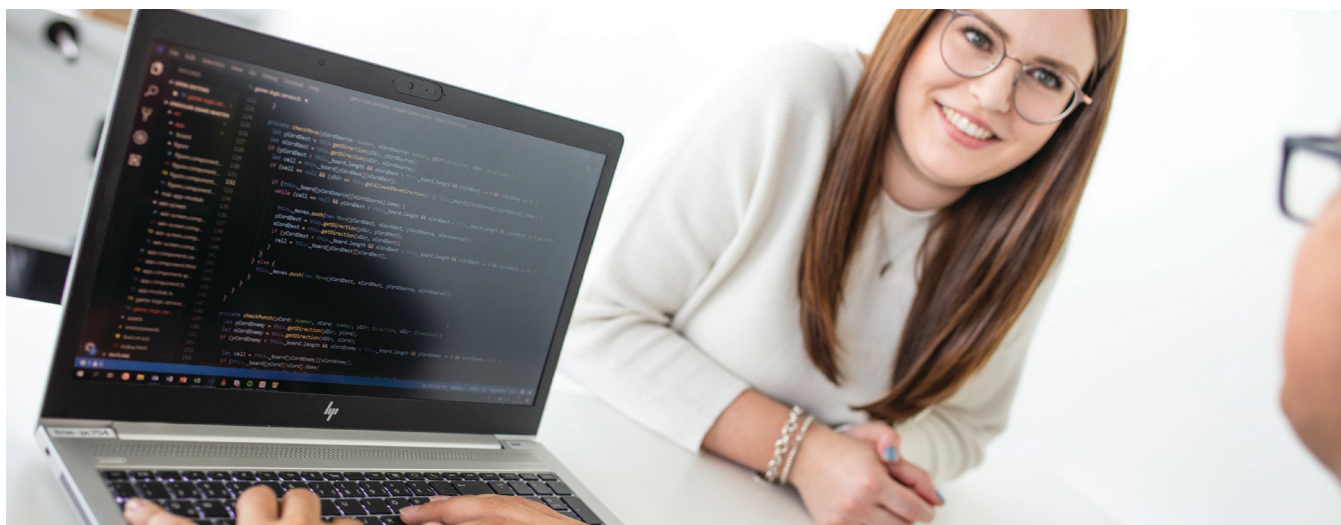


fme Life Sciences

Providing Technology Services Across All Leading Content Services Platforms



Industry and regulatory pressures are pushing life sciences companies to revolutionize the way they access, manage, and transfer content. Quick access to data is crucial to speed product launches, respond to queries from regulatory authorities, and ensure each department fully complies with legal and administrative requirements.

Benefit from efficiency and value for all your core and supporting processes across clinical, regulatory, and quality and manufacturing domains by leveraging our solutions and technical services tailored to the life sciences industry. Supported by long-standing experience and commitment to quality and compliance, our technology services provide a full range of implementation, integration and managed services capabilities for common Life Sciences business application platforms such as Veeva Vault, Generis CARA, OpenText and Sparta TrackWise, allowing you to achieve your goals across the value chain.

Comprehensive Technology Services

To scale to our clients' needs and quickly address changing business requirements, our end-to-end technology services are designed with flexibility in mind. Our dedicated global onshore and offshore teams support complex IT environments across clinical, regulatory and quality & manufacturing domains.



Solution Design and Configuration

A key part of our technology services is the solution design and configuration, in which we identify your specific application requirements and the necessary configurations or also customizations to implement the business needs. We handle the identified configuration and customization tasks, installations and deployments for the application components in scope and oversee the rollout process.

Requirements analysis: Our strong partner network allows us to offer client-specific product insights early on in the project through demonstrations and workshops, ensuring the right solution for our client. We work with you to analyze current processes and application functionalities in use against the target application of choice to identify potential gaps and possible configuration adjustments that will allow the future application to fulfill your business needs.

Data model and solution design: Typical configurations to fulfill standard requirements include updates to document inventories, properties pages, lifecycles and workflows. Our team makes sure to design the application adjustments within the platform specific implementation model and boundaries. Details are summarized in a design specification with focus on additional client-specific requirements to support the needed clinical, regulatory or quality capabilities.

Configuration and custom development: Our technical team is trained on the partner solutions and the configuration and customization services are based on the out-of-the-box solutions keeping the vendor implementation model and low impact solutions as priority in mind. Goal is to fulfill the business requirements and allow broader system usage while at the same time guaranteeing maintainability of the future application. A configuration specification document is maintained by the technology services team to allow traceability of changes made.

Testing and validation: Our team has experience with GxP needs across the regulatory, clinical and quality environment and understands that the testing and validation activities are an essential part of the actions necessary to make sure that the new application fulfills the intended requirements and will withstand any audits. Throughout the project we support you with the help of our Validation team, and put a special focus on testing plans, testing execution and summary report generation covering IQ, OQ and PQ processes as well as the end-to-end traceability.

Deployment and Go-Live Support: To deploy the required on-premise or cloud infrastructure we work directly with your IT departments. This is the foundation for the deployment of the product and application components based on Installation Qualifications developed by our subject matter experts early in the project. Our team stands by your side and supports you during the technology go-live to make sure everything goes smoothly. During a hypercare period our specialists stand by to assist if any questions or issues arise.



Managed Services

Do you want to reduce the need for IT infrastructure and resourcing? With the flexibility of a Software-as-a-Service financial model we have capabilities to manage and host both the application as well as the IT infrastructure in the cloud. Whether it is your own or fme's cloud, we can manage the environment for you.

Once the application is in regular run-mode, you will also be confronted with the daily maintenance and support topics. You additionally must stay on top of the new platform releases that will happen multiple times per year. As part of our Post Implementation Services, we make sure that you stay aligned with the help of Impact Assessments and Release Management, and that user requests and issues are resolved within provided SLAs. For that, our global support team can integrate with your helpdesk or provide their own ticket system.

This will allow you to put your main focus on more important topics and tasks!

Reach out to us today to discuss your current requirements and how fme can support you at info@fme-us.com!

About fme Life Sciences

fme Life Sciences is a leading provider of business and technology services supporting the deployment of Content Services and ECM solutions to its clients in the Life Sciences Industry. We act as trusted advisors and systems integration specialists across the Clinical, Regulatory and Quality and Manufacturing domains in Europe and North America. We do not exclusively recommend or promote any platform or vendor, but rather focus on providing our clients with an independent perspective of the solutions available in the market.