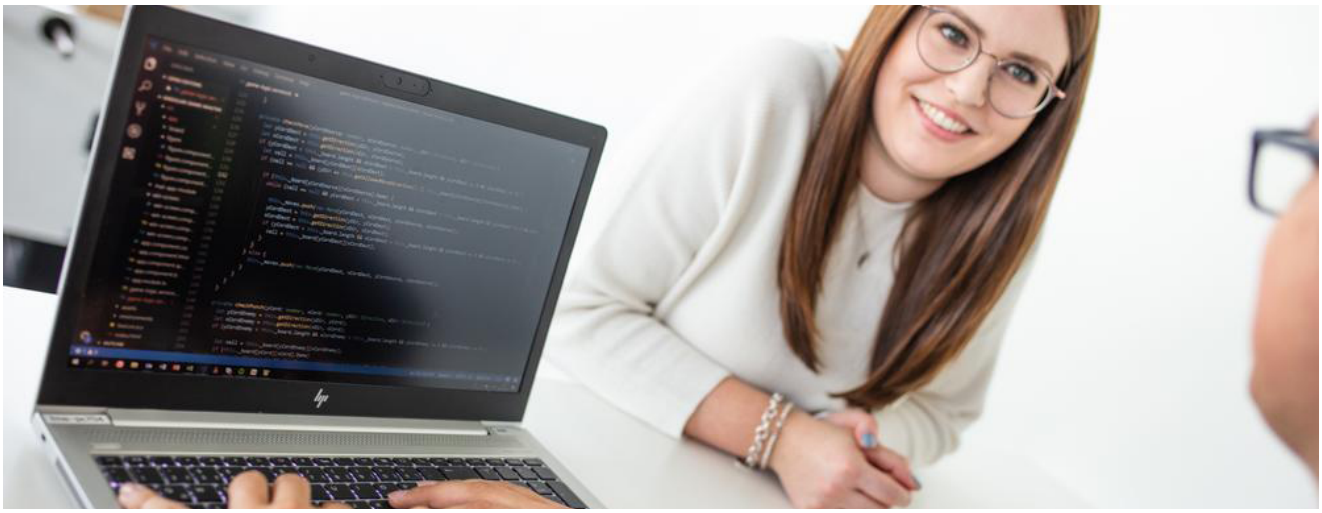
DATASHEET

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.

Additionally, companies are adopting a more strategic approach to regulatory information management (RIM) as they transition to enterprise-wide capabilities to leverage more insights and data across all business functions.

Our technology services provide a full range of implementation, integration and support capabilites for our partner platforms, allowing you, our clients, 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. Our technology services span:

- Solution design and configuration
- Integration, testing and validation
- Training
- Managed Services: On-premise and cloud deployments

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 to implement the needs. We handle the identified configuration tasks, installations and deployments for the application components in scope and oversee the rollout process.

Product walk-throughs, demos and workshops: 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 the right client. In these sessions we walk you through the different target application functionalities.

Requirements analysis and gap analysis: 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.

Design specification: Typical configurations to fulfill standard requirements include updates to document inventories, properties pages, lifecycles and workflows. Details are summarized in a design specification with additional client-specific requirements to support the needed clinical, regulatory or quality capabilities.

Solutions build and implementation: Complete configuration and customization services are based on out-of-the-box solutions as well as custom development and interface / integration work to fulfill the business requirements and allow broader system usage. A configuration specification document is maintained by the technology services team.

Integrations: To provide a unified platform and greatest value for the users our team will work closely with you to identify interface and integration needs. Our team will collect the integration requirements, design the most fitting implementation approach (for example synchronous versus asynchronous integration) and implement the solution.

Unit testing: Configurations and integrations across various solutions— including quality, regulatory information management and clinical applications —are thoroughly tested to ensure solutions meet your individual needs.

Product and application deployment: To deploy the required on-premise or cloud infrastructure we work 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.

Go-Live support: Our team 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.

Integration testing and validation

Benefit from our experience with GxP needs across the regulatory, clinical and quality environment. We support any of your methodologies and templates or can provide templates from previous project experience. Deliverables to support the full validation of the application and platform include:

Validation plan support: The validation plan summarizes the project's validation needs, process and deliverables. Our experts support you by identifying the specific validation needs and how they can be met with the new platform and application.

Test case creation, execution and summary reports: Based on the project needs the team can create or support the necessary Installation Qualification (IQ), Operational Qualification (OQ) and Performance Qualification (PQ) documentation. These documents describe the required test cases to fulfil the validation requirements.

Traceability Matrix: Our consultants ensure completion of the end-to-end validation by supporting the creation of the traceability from requirement to configuration to test case.

Training

To make sure that the new application is adopted by the users, training sessions for the different user roles are necessary. Our technology services team provides you with training support to ensure your end-to-end solutions are properly understood and leveraged by your end users. Services include:

Training assessment and planning: Our team evaluates the training requirements for the different user roles and develops a training plan to fulfil those needs.

Preparation of role-based training material: Create role-based training presentations, based on product guides as well as your changes and additions with the guidance of our consultants.

Train-the-trainer sessions: Our consultants conduct onsite or remote training sessions with identified key users ensuring ongoing staff support even after project go-live.

Role-based user training sessions: The onsite or remote role-based training sessions to accommodate user-specific needs and questions can be provided by our consultants.

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 applications as well as the IT infrastructure in the cloud.

Realize greater control and agility with your document management applications by working with us.

- Hosting on your cloud tenant or fme's Cloud (single tenant, Partner hosted) technology
- Flexible software licensing options
- Fully managed service – cloud hosting, infrastructure and application management
- Change control process to maintain a GxP validated state
- Full application management support services, including help desk and support for system updates. This can be integrated with your IT support structure.

fme Life Sciences is a leading provider of business and technology services supporting the deployment of Business Applications and Content Services/ECM solutions to its clients in the Life Sciences Industry. We act as a trusted advisor and systems integration specialist across the Clinical, Regulatory and Quality and Manufacturing domains in Europe and North America.

Our capabilities, experience and know-how allow us to provide a high quality end-to-end approach to supporting our clients implement solutions from all the leading Content Services / ECM platforms. These capabilities are focused on Business Consulting, Technology Services and Migration Services.

We provide these services for many large and midsize Life Sciences companies, leveraging our local client facing teams in North America and Europe and our Centers of Excellence in Romania and India.