

# Project Management in a Regulated Environment

Transparent planning, consistent management, and regular reporting from under one roof

In a regulated environment, strict compliance with provisions and industry-specific guidelines is indispensable. Companies must also act cost-efficiently and coordinate different locations, some of which are global. In addition, they must react flexibly to tasks that often involve multiple departments and locations – with increasing complexity. If this does not happen, they will not be able to withstand the rapid changes in the life sciences industry and thus endanger their market position.

Efficient project management is therefore indispensable, especially in the life sciences industry. But many companies lack time resources or employees with the necessary project management skills and qualifications.

## What We Offer

We plan, coordinate, manage, monitor, and document your projects in a regulated environment. From an overarching program to individual projects, fme will support you comprehensively in reaching your objectives and mastering your digital transformation.

As program or project manager or project assistant we complete your (global) team over weeks, months or even years, on-site or remote. We employ tried-and-tested methods and tools and adapt these to your unique framework conditions. Our experts have PRINCE2 and scrum certifications and, among other things, rely on a successfully applied, long-standing fme project management method based on PRINCE2.

### Concept and management

We ensure transparent project planning and consistent management for your project, drawing on our well-rounded industry and IT expertise as well as our project management skills.

### Project management office, reporting, and quality assurance

We take on the operational implementation of project management and thus ensure transparent project communication, full project documentation in the form of regular reports, such as for C-level positions, and the consistent delivery of project tasks and results. Upon request, the fme Communication Services Team will support you with project-related human change management.

## Your Benefits

- Ensuring project success with professional project management from fme\*
- Punctual project completion according to your project plan\*
- Improved predictability and traceability of project costs
- Improved cooperation between project members
- Compliance specifications upheld

*\* based on coordinated framework conditions (e.g., resources and deliverable project phases)*



## Why fme?

### Experienced project management experts

Project management activities, such as the introduction of a global contract management system or the introduction and roll-out of a global SOP management solution for well-known life sciences clients are part of fme's daily business. Our experienced and certified project management experts have extensive industry knowledge in the life sciences, as well as expertise in IT and document management.

### Well-founded best practices

We know your industry, solution approaches, software products, and numerous service providers down to a T and are thus well able to incorporate and optimally weigh up a wealth of experience and options.

### Familiar with regulated environments

fme has been successfully audited numerous times within the area of software development projects. We are highly familiar with regulations and provisions, as we consistently build upon our knowledge of topics specific to the life sciences. We ensure strict compliance and document seamlessly so that your project will successfully undergo auditing.

### Experience in complex and global projects

We have over ten years of project experience in the life sciences with medium-sized and global companies. Integrating nearshore and offshore resources has become part of everyday project life.

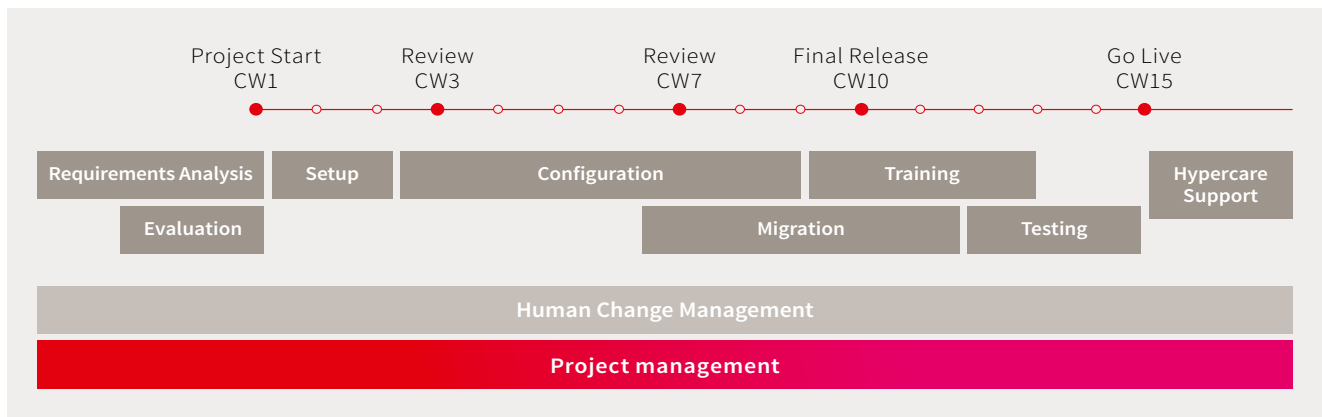
## Quickfacts: Specific Requirements For Regulated Environments

Strict compliance with specifications is indispensable within a regulated environment. Regulations comprise of legal provisions, policies and intra-industry guidelines.

fme

- is familiar with regulations within the life sciences industry
- ensures strict compliance with intra-industry requirements in project planning, management, and documentation
- is familiar with provisions such as 21 CFR Part 11 and EU Annex 11, guidelines such as GxP and guides like GAMP
- has project managers certified in various fields such as »Computer Systems Validation« or »Electronic Data Integrity in a GxP Environment«
- has been successfully audited numerous times within the area of software development projects

**We look forward to accepting your challenge!**



*Project approach for rolling out a global document management system*