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Enhancing Compliance and Efficiency with a Unified Quality Management System

Why CDMOs should consolidate their QMS landscape and how to do it well

Quality management systems (QMS) that are not continuously challenged and optimised pose compliance risks, slow down operations and consume valuable resources. For contract development and manufacturing organisations (CDMOs), the challenge is amplified; systems must meet both regulatory requirements and diverse customer expectations, often across multiple sites and modalities. This article outlines how a validated, integrated QMS eliminates fragmented system landscapes, prevents media breaks and delivers measurable gains in speed, consistency and audit readiness. Using Training, Document and Deviation Management as core examples, practical levers, realistic workload calculations and a platform-based selection approach that scales are highlighted.

When a QMS Turns into a Wave

In growing companies and fast-changing environments, adding "one more form," "one more step," or "one more approval" can feel like a pragmatic response to a change request by authorities, customers or internal findings. Over time, that mindset produces layered and locally optimised systems, paper here, spreadsheets there, a point solution somewhere else, each justified at the time, none optimised end-to-end. The result is a QMS wave; complex to navigate, costly to maintain and hard to govern consistently across sites or product lines.

Three questions reveal whether action is necessary:

- Are paper-based processes still used for core GMP activities despite growth, site diversity, or hybrid work?
- Do we accept media breaks, manual transfers and parallel systems interpreted differently by the site?
- Are special cases embedded in the base workflow, rather than documented as controlled exceptions?

Most companies agree that the answer to the first two questions should be a clear no, but start debating the third one. A crucial shift is recognising that exception-proofing standard flows increases complexity, slowing decision making while adding little real compliance value. Optimisation is not about recreating the status quo in an app; it is about simplifying work, standardising and eliminating exceptions.

Where to Start?

Any initiative for optimising the QMS should start with a detailed understanding of business processes and cycle times. Only by quantifying the baseline can improvements be assessed both from a compliance perspective and an economic one. Map ownership, handoffs and media breaks, then design scalable, automated workflows that eliminate manual rework, duplicate data entry and signature loops. The following sections outline three key areas of a QMS, setting out the challenges and benefits of optimisation in each area.

Training: Making Complexity Manageable

Regulations require structured training programmes, ongoing refreshers and effectiveness checks linked to roles and responsibilities. While this can be done without a digital system, it is inefficient and error-prone at scale.

The Challenge

During onboarding, an employee must receive numerous trainings. A manufacturing employee at a CDMO with different products can quickly be assigned more than 200 GMP-related trainings during onboarding. Additional non-GMP trainings, such as safety, are necessary. Prioritising and structuring the content to enable effective training consumes resources for training delivery and coordination. As a company grows, the manual effort multiplies and places supervisors and training coordinators before an almost unsolvable task. The consequences are missing training, resulting in deviations and poorly trained employees.

Not only initial training, but also continuous training is required. For a production site with 200 employees, this can amount to 28,000 individual trainings per year. If only five minutes are needed for documentation per training, that equals over 2,300 hours per year, slightly more than one full-time employee. Documentation alone does not ensure that outstanding training is identified and followed up on.

Advantages of Well-Designed Training Management

When setting up a training system, a training matrix will certainly be established that assigns training needs based on roles and responsibilities. The work involved in setting up such a matrix requires initial effort, but afterwards, companies only need to invest a small amount of effort to keep it up to date. Based on this matrix, all employees are trained uniformly, continuously and transparently for employees, supervisors and Quality Assurance.

Implementing such a training system significantly reduces administrative tasks and shifts from chasing signatures to improving content (e.g., short videos for critical tasks, microlearning for recurrent risks), freeing time for careful training delivery and effectiveness checks, resulting in consistent, auditable and scalable training.

Document Management: From Paper Repositories to a Validated Document Management System (DMS)

Documents are the backbone of the QMS; SOPs, manufacturing instructions, risk analyses, validation and qualification, reports and assessments, and executed GMP protocols. In mid-sized biotech/CDMO environments, the annual volume often reaches tens of thousands of documents. With such large quantities, it is difficult to maintain a consistent filing system that is maintained solely by the manual efforts of individual employees.

The Challenge

All documents must follow a defined process for creation, review, approval, publication, updating and archiving.

Depending on company size and portfolio, a large number of GMP documents accumulate quickly. When looking at the different types of documents, differences quickly become apparent, resulting in different requirements for workflows. A global Standard Operating Procedure (SOP) or a manufacturing instruction typically requires a more complex workflow than monitoring protocols or cleaning reports. At CDMOs, customer involvement may be necessary. Nevertheless, all these documents belong to the DMS.

Another challenge arises when using protocols that are filled out by hand during manufacturing or testing. These documents must be registered and accounted for. If a medium-sized biotechnology company has around 50,000 documents per year, this would require two full-time employees working at a rate of five minutes per document. This working time does not yet include the effort required for archiving, which, in the case of paper documents, requires physical space in addition to human resources. Archiving efforts are becoming more complex when electronic signatures are used outside of validated, electronic DMS. 21 CFR Part 11 compliance must be verified, and the documents must be archived securely in an unalterable manner in compliance with GMP, including all certificates.

A real-life challenge is that electronically signed documents that are created outside of electronic DMS must be transferred for archiving. Depending on the number of people responsible for the documents, the level of care can vary greatly and lead to an incomplete electronic archive, which in turn represents a high compliance risk. Documents that cannot be found are considered nonexistent documents.

Advantages of Well-Designed Document Management

When setting up a document management system, the existing document structure is analysed to identify differences and similarities. Instructional documents must certainly be treated differently from reporting documents. This results in different requirements, which are reflected in perhaps three different lifecycle processes. Firstly, the documents must be mapped to the new lifecycles. Once this initial work has been done, new documents are automatically assigned to the necessary workflows, user tasks are created and finally, the documents are clearly archived, providing employees with a central searchable library as a single source of truth for all authorised documents. This, in turn, has a direct impact on effectiveness. In addition, the system takes care of protocol creation and accounting, freeing up staff for other tasks.

The use of fully validated and carefully designed DMS provides a tool that complies with regulations and can be used throughout a company's entire GMP area, improving its compliance.

Deviation Management: Standardise to Avoid Ping-pong

The handling of deviations offers a variety of possible workflows that all have the same goal: identify root causes, assess risk and implement effective actions. The opportunity to design any workflow can result in slow, approval-heavy processes that cloud accountability and extend cycle times.

The Challenge

When developing these workflows, responsibilities and exact procedures must be defined in detail. Who acts when, and what is their task at that point? It must be defined at which point quality assurance must be involved. As a CDMO, customers must be informed of or involved in the investigation and assessment at defined stages. If the Workflow is not fully thought through and every eventiuality is included in the standard workflow, a company quickly runs the risk of ending up with inefficient processes and a ping-pong game between departments.

For example, if a deviation process involves five steps with two to three departments each, 10–15 approvals may be required. Each task within the deviation workflow requires a brief familiarisation with the deviation topic, at least five minutes, before the task can be performed. There is a difference between having to gain an overview two times versus five times. By consolidating work steps and eliminating only two individual steps involving two departments, a medium-sized company with 1,000 deviations per year could save over 300 hours of familiarisation time. Please keep in mind that during this time, no root cause analysis has been performed and no corrective or preventive measures have been defined.

Another challenge to keep in mind is multi-site collaboration. If manufacturing is located at a different site than quality control, which may provide data for deviation assessment, it is necessary that both departments have access to all relevant data. Without electronic workflows, forms are used that are filled out manually or electronically and circulated by hand or email. The risk that an item is overlooked at a desk or in an inbox is significant and constitutes a compliance risk.

Advantages of Well-Designed Deviation Management

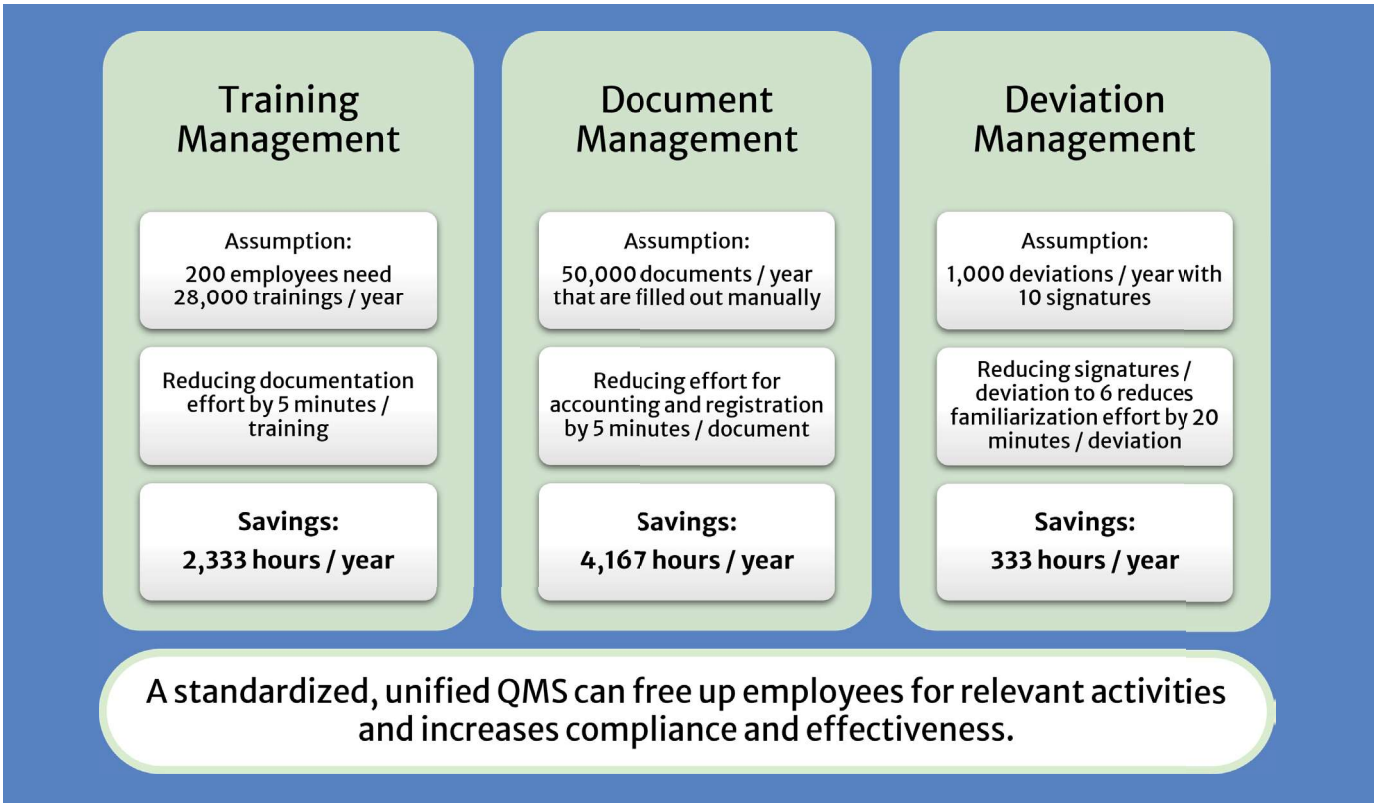
When setting up a well-thought-out deviation management system, it is important to examine the requirements of the majority of deviations. Special cases should not be considered when creating standard workflows, as these usually complicate the forms and require additional steps. By reducing the number of topics to those that are truly relevant, processes can be simplified. Of course, special cases must be carefully documented, but additional attachments are likely to suffice for this purpose. Don't fall into the trap of thinking that managers can only stay informed about what's going on in their department by signing documents. It's better to reduce the number of signatures and keep managers informed using well-designed reporting tools. This requires well-written, comparable deviation reports and sensibly linked data records.

Sticking to this will result in a deviation management system that not only complies with regulations and ensures products and systems meet quality standards but is also transparent and does not waste valuable resources.

How to Choose the Right System for Your Company

The number of providers of electronic QMS seems endless, so choosing the right system for your company is essential. Before a decision can be made, it is necessary to determine what the expectations are. Start by answering the following questions:

- Which QMS processes should be available?
- Do you want a fully validated standard system, or do you want a completely customised one?
- Should the system be scalable for growing companies or adding new processes?



- Are there interfaces with existing systems (e.g. ERP) that are essential?
- Do you want the market leader where your company is one of many customers or a small provider where your company is the most important client?
- What stakeholders need to be involved in the decision making?
- Do you want regular updates of the software, or do you not want any changes after implementation?

The list is certainly only an incomplete starting point for launching an optimisation project for your QMS. Please keep in mind not to get lost in the details, especially at the beginning.

Returning to the example of deviation management, let's look at how standard workflows can help. If, as suggested above, special cases are neglected when defining workflows, most providers offer standard workflows. If these out-of-the-box workflows come from widely used providers, they can be considered industry standards that are frequently reviewed by authorities and customers for GMP compliance. Therefore, using standard workflows from established software providers can be associated with a lower compliance risk.

Conclusion: Unified Systems Pay Off Twice

The individual aspects demonstrate the significant potential for optimisation. If topics are addressed separately by different well-chosen project teams, improvements in compliance and efficiency will certainly occur. However, this approach can also result in multiple systems that do not, or only with additional effort, communicate with each other, leading to manual transfers, duplicate master data maintenance and suboptimal use of digital capabilities and efficiency. Therefore, topics should not be considered in isolation; project planning should include an overview of which QMS must be considered so that candidate systems can be evaluated for suitability across all aspects, resulting in a well-thought trough roadmap. If selection is made carefully and a single platform is chosen, further efficiency gains follow automatically. Employees need to learn only the general operation of one system and the specifics of individual applications. Data sets do not need to be created multiple times, but can be used by different applications within a platform.

The idea is clear. Optimisation in the areas of training, document and deviation management requires standardisation and automation. Thoroughly evaluating the systems under consideration in all relevant areas prevents a fragmented landscape. Investing in a validated, integrated QMS platform ensures scalability, audit readiness and operational excellence, providing benefits such as freed-up human resources, shorter cycle times and higher data quality. Consequently, selecting a unified, GMP-compliant quality management system with foresight is an investment in an efficient working environment, enabling the costs associated with digital systems to be amortised over time.

Birte Müller

In her 15 years of experience in quality assurance, Birte Müller has gained extensive knowledge of biotech products' entire life cycle. She has a strong interest in digitalisation and has been involved in various systems implementations, such as Quality Management Systems and Laboratory Information Management Systems. Most recently, in addition to her GMP compliance team leader role at Richter BioLogics, she led the implementation of a document management and training system.