PLANTA

Whitepaper

Using Project Management Software in Pharmceutical Companies

Efficient Management of Research, Development and Approval Processes

© PLANTA Projektmanagement-Systeme GmbH – www.planta.de

LEAN MORE

Here you will find more information for your projects:

Strategic cost planning

Strategic cost planning protects projects from going budget overruns.
Read our whitepaper and keep an eye on your project resources.

To the whitepaper

Hybrid project management

Hybrid systems allow you to react to any project situation, providing more flexibility than pure agile or traditional methods.
Read our whitepaper on hybrid project management and learn all you need to know about this subject.

To the whitepaper

Multi-project management

Managing multiple projects at the same time harbors many risks but also opportunities. Learn more about multiproject management and how you can keep an eye on all projects.

To the Whitepaper

Working successfully in dispersed teams.

Working successfully in dispersed teams. In a modern project world, not all project team members are located in one office. Teams need strategies and tools to ensure that projects still work.
Learn more in this white paper.

To the Whitepaper

© PLANTA Projektmanagement-Systeme GmbH – www.planta.de

SUMMARY

Content

01 **Project Management in the Pharmaceutical Industry** **1**

Importance of Project Management in the Pharmaceutical Industry 1

Use Cases from the Pharmaceutical Industry 1

02 **Typical Challenges in Pharmaceutical Projects** **4**

03 **Common Mistakes in Management of Pharmaceutical Projects** **7**

04 **Software Functions** **10**

Essential Software Functions in Project Management 10

05 **Supporting PM-Tools** **12**

Methods and Tools That Support Pharmaceutical Projects 12

Top 10 Best Project Management Tools for IT and Organizational Projects 13

06 **Testimonials** **15**

07 **Conclusion** **16**

08 **FAQs** **16**

© PLANTA Projektmanagement-Systeme GmbH – www.planta.de

CHAPTER 01

Project Management in the Pharmaceutical Industry

Project management plays a central role in the pharmaceutical industry when it comes to steering development processes and ensuring compliance with regulatory

Importance of Project Management in the Pharmaceutical Industry

According to PMI studies, ineffective communication is the cause of failure in 50% of projects in terms of time, cost or scope, and as many as 33% of projects fail altogether. This shows how important optimal communication is for the success of a project. **Centralized data storage** and the integration of all project participants in the information flow are crucial for **good communication**. The right software support can help you to achieve this.
Given the **complexity of pharmaceutical projects**, the use of suitable project management tools is essential for project success and enables you to make **efficient use of resources** and keep **project runtimes** as **short** as possible

Use Cases from the Pharmaceutical Industry

A pharmaceutical company developing a new drug for the treatment of rare diseases faces numerous challenges. Regulatory requirements, clinical studies, supply chain management and tight schedules must be precisely coordinated. Any delay can result in high costs or delay market entry.
Project management software helps to **efficiently control** the **individual phases** from research to development and production. It enables **complete documentation**, which is essential for regulatory authorities, as well as **precise resource planning** to optimize the deployment of research and production teams. A central platform for communication, task management and deadline tracking allows companies to maintain an overview and react quickly to unexpected changes.

1 Development of a New Vaccine: Coordination of Research and Clinicla Studies

A pharmaceutical manufacturer has developed a promising cancer drug, but production depends on the availability of rare active ingredients sourced from several international suppliers. **Delayed deliveries** could **delay** the **entire approval process**.

2 Optimization of Supply Chains for Cancer Drugs

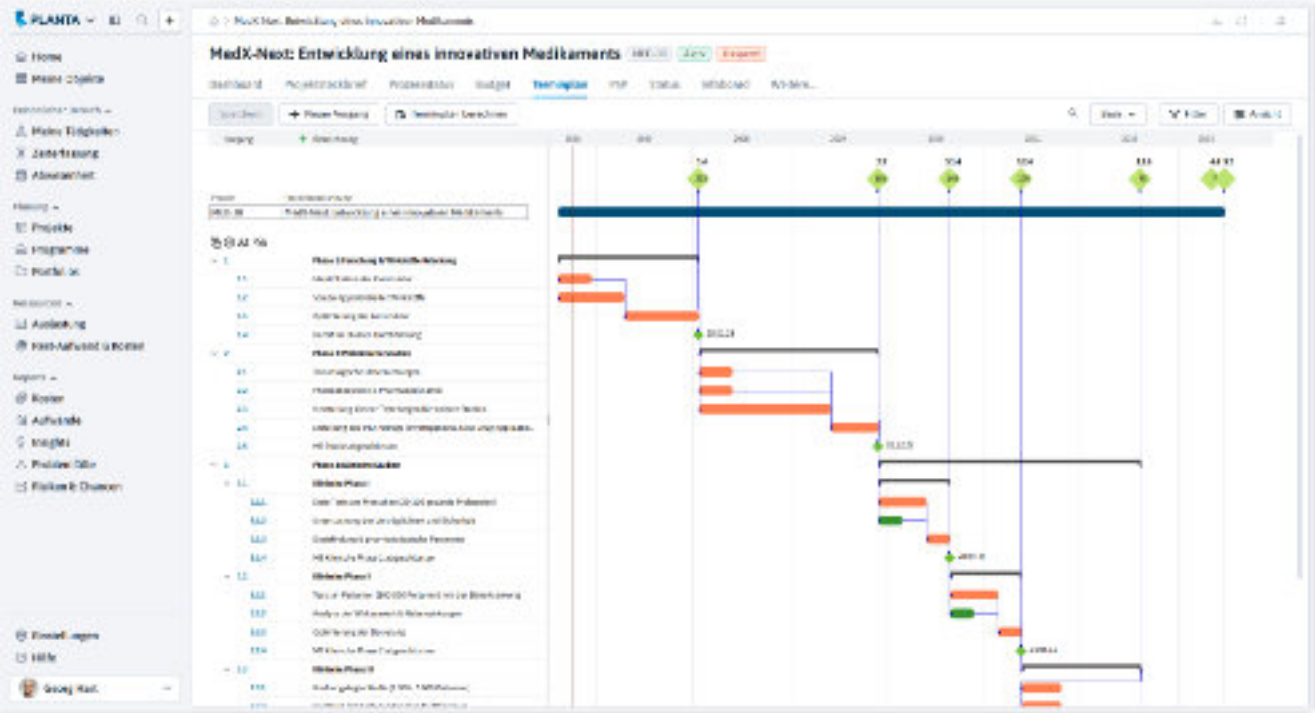
A pharmaceutical company is on the verge of launching a novel antibiotic that must be approved in several countries. The challenge lies in **maintaining complete documentation** and **complying** with national and international regulatory requirements (e.g., EMA, FDA).

3 Ensuring Regulatory Compliance for the Market Launch of a New Drug

A global pharmaceutical company is working on the development of a new vaccine against a viral infection. The challenge is to coordinate **several concurrent studies** in different countries and ensure that all clinical phases are completed on schedule.

4 Scaling up the Production of a Blockbuster Drug

Once a drug for the treatment of autoimmune diseases has been successfully approved, a pharmaceu tical company must quickly ramp up production in order to meet rising demand. This requires **precise control of production capacities, quality controls and distribution logistics.**



Time Schedule in PLANTA Project

PLANTA

One Software for Everything

PLANTA Project

Project management-software

PM-Methods

Plan your projects in an agile, traditional, or hybrid manner—according to your requirements

PPM

Don't take any risks—rely on project portfolio management

Integrations

Adjust the software to your needs and extend it using our interfaces.

Single and multi-project management

Comprehensive project management software for every project

Read more

© PLANTA Projektmanagement-Systeme GmbH – www.planta.de

02 CHAPTER

Typical Challenges in Pharmaceutical Projects

It is important to know the most common mistakes in order to avoid them:

Pharmaceutical projects are under high pressure, both in terms of time and compliance. Compliance with international standards such as Good Manufacturing Practices (GMP) and Good Clinical Practices (GCP) is essential, as is the management of all phases from research and clinical trials to production and market launch. The large number of stakeholders - from scientists, clinicians and suppliers to regulatory authorities - makes efficient coordination essential.
In order to cope with complexity, companies must **recognize challenges at an early stage** and take **targeted countermeasures**. Project management software helps to create transparency, automate processes and ensure complete documentation.

Complex and Lengthy Development Processes

Pharmaceutical projects are characterized by **long development cycles**. It can take **ten to fifteen years** from preclinical research to clinical trials and approval. During this process, **numerous processe**s have to be managed **in parallel**, such as the testing of active substances, the recruitment of test subjects and compliance with regulatory requirements.
The large number of parties involved requires precise coordination between teams, locations and partners.
Project management software helps to map development plans transparently, set clear milestones and recognize dependencies between teams. A central platform makes it easier to monitor study progress, allocate resources dynamically and identify delays at an early stage

High Regulatory Requirements

The pharmaceutical industry is one of the most heavily regulated sectors. Authorities such as the FDA (USA), EMA (Europe) and BfArM (Germany) require **complete documentatio**n of all processes in order to ensure the safety and efficacy of new drugs. **Every step** - from laboratory research to market launch - must be **recorded, audited and accessible at all times.**

Project management software helps companies to meet these requirements efficiently. Automated documentation, central storage of test reports and standardized approval processes ensure systematic compliance with requirements. Workflows enable clear assignment of responsibilities so that regula tory approvals do not lead to delays

Adherence to Budget and Time Targets

The development of new drugs is extremely **cost-intensive**. According to studies, the average costs of a new drug often amount to **several billion euros**. Delays can have considerable financial consequences, especially when patent protection periods apply or investors expect rapid progress. At the same time, companies need to ensure that studies are not only on time, but also on budget.
Integrated budget and resource management allows companies to retain control over financial resources. Real-time analyses help to identify deviations at an early stage and reprioritize resources.

Progress reports enable well-founded decisions to be made in order to avoid costly delays.

High Dependence on Suppliers and Partners

Pharmaceutical companies work closely with external suppliers and partners - be it for active ingredi ents, laboratory services or clinical studies. However, these dependencies can cause problems if **supply bottleneck**s occur, partners do **not deliver the required qualit**y or **coordination problems** arise.
Project management software creates transparency across all supply and production chains. By inte grating supplier and partner management, companies can recognize early on when delays are immi nent and initiate countermeasures. Automatic escalation mechanisms help to control critical processes and avoid bottlenecks.

Data Management and Complete Documentation

Pharmaceutical projects generate an **immense amount of data** - from research results to laboratory reports and regulatory submissions. This data must not only be stored securely but must also be retrievable and traceable at all times. Without a centralized system for managing documents and study data, there is a **risk of data loss, version conflicts and inefficient knowledge sharin**g between teams.
The use of project management software with integrated document management ensures that all relevant data is stored in a structured manner and assigned with authorizations. Versioning systems prevent outdated documents from being used and workflows enable efficient approval and further processing of regulatory reports

Risk Management and Crisis Management

The development of a new drug is associated with **numerous uncertainties**. Clinical studies can deliver **unexpected results, legal requirements** can **change** or **approval procedures** can take **longer** than planned. Without effective risk management, a single problem can jeopardize the entire development schedule.
Project management software enables proactive risk monitoring by identifying and assessing potential hazards at an early stage. With the help of risk assessment tools and escalation mechanisms, companies can create contingency plans and run through alternative scenarios in order to be prepared for unforeseen challenges.

PLANTA

Have a look at our Webinars

Project Management-Knowledge for Everyone

Resource management, agile task management, working in dispersed teams and more:

planta.de/web-seminare

© PLANTA Projektmanagement-Systeme GmbH – www.planta.de

CHAPTER 03

Common Mistakes in Management of Pharmaceutical Projects

The pharmaceutical industry is subject to complex development processes, strict regulatory requirements and long project lead times. Errors in project management can lead to delays, inefficient use of resources and **high costs**. The following common mistakes occur particularly in pharmaceutical projects - and there are proven solutions to avoid them.

Lack of Transparency and Unclear Role Assignment

In pharmaceutical projects, interdisciplinary teams from research, clinical development, production and regulatory departments often work together. If roles and responsibilities are not clearly defined, this leads to misunderstandings and inefficient work.
Who is responsible for coordinating the clinical trials? Who ensures that production capacities are available on time? Who do you escalate to if things are not running smoothly?
Unclear responsibilities lead to tasks not being completed or being processed twice, which costs time and resources.

Solution: A clear definition of roles and responsibilities is crucial. Project management software offers role management functions in which tasks and responsibilities are clearly defined and made visible to all participants. By integrating communication and approval processes into a central platform, misunderstandings can be avoided and responsibilities can be presented transparently

Poor Resource Planning

Pharmaceutical projects require the deployment of highly specialized experts, laboratory capacities and production resources. Without precise resource planning, bottlenecks can occur, especially if several projects are running in parallel or unforeseen delays occur. Research and development teams can be overloaded when several studies are running simultaneously. Production capacities often have to be divided between different active ingredients or drugs. External service providers or suppliers can cause delays if their capacities are not scheduled in good time.

Solution: Detailed resource planning supported by project management software helps to identify bottlenecks at an early stage and allocate capacities efficiently. With the help of real-time dashboards and capacity analyses, project managers can immediately see whether bottlenecks are imminent and take countermeasures in good time.

Insufficient Documentation and Traceability

In the pharmaceutical industry, all project steps must be fully documented in order to ensure compliance with regulatory requirements. Missing or incomplete documentation can lead to delays in approvals or make clinical studies unusable. Changes in study protocols or production processes must be documented in a traceable manner. Regulatory requirements (e.g. from the EMA or FDA) demand precise tracking of all activities. Without a structured reporting system, important information is lost or difficult to find.

Solution: Project management software with integrated document management ensures that all relevant documents are stored centrally, categorized and provided with approval processes. This means that project documents can be found quickly by everyone involved

Lack of Coordination Between Departments

Pharmaceutical projects are often highly fragmented, with separate teams for research, development, clinical trials, production and regulatory affairs. If these teams do not work closely together, there are information gaps that can lead to inefficient processes.
The research team is developing a new active substance formulation, but the production team is not involved in the feasibility testing at an early stage. Regulatory authorities require additional data, but the development team has not been informed of the requirements. Delays in clinical trials affect the entire market launch because the planning has not been not coordinated

Solution: A central platform for collaboration facilitates coordination between different departments. Project management software with integrated workflows and communication channels ensures that all teams are always on the same page and can exchange information about dependencies and challenges at an early stage.

Poor Coordination Between Departments

Pharmaceutical projects require close collaboration between research, clinical development, regulatory affairs, production and external partners. Without good coordination, data gaps, duplication of work or delays in the implementation of new findings arise.

Solution: A central project management platform with real-time collaboration functions enables smooth communication and direct exchange between teams. Dashboards and status reports keep everyone involved up to date and improve decision-making processes.

Missing Risk Management

Pharmaceutical projects are associated with high risks - from unexpected results in clinical trials to regulatory challenges and supply bottlenecks. Without anticipatory risk management, companies can be caught off guard by problems that jeopardize the entire project schedule.
One active substance shows unexpected side effects in a late clinical phase. A supplier is unable to deliver a critical substance on time. Regulatory authorities demand additional safety studies, which leads to delays

Solution: Proactive risk management helps to identify potential problems at an early stage and plan countermeasures. Project management software can provide risk catalogs, action plans and real-time monitoring so that project teams can react quickly to unexpected developments.

CHAPTER 04

Software Functions

Essential Software Functions in Project Management

Project management software for the pharmaceutical industry includes a range of functions that are specifically tailored to the complex requirements of this sector:

Project portfolio management

This function enables the management of multiple projects in a portfolio and supports **prioritization** and **strategic alignment with corporate goals**. Project portfolio management helps to allocate re sources efficiently and ensure that all projects are aligned with an overarching strategy. This allows pharmaceutical companies not only to view projects in isolation, but also to plan and implement them in the context of overarching corporate objectives

Resource management and capazity planning

Resource management ensures the **allocation and optimization of personnel, machines and other resources** across different projects. Capacity planning allows potential bottlenecks to be identified at an early stage and overloads to be avoided by optimally deploying resources. This is crucial to ensure that all projects can be completed on time and without delays.

Financial and budget management

This function provides a clear overview and control of all the financial resources of a project. By monitoring the budget, cost risks can be identified at an early stage and measures can be taken to ensure that projects remain within the specified budget.

Risk management

Risk management enables the **early identification, assessment and management of risks** that may arise in the course of a project. This function helps to take proactive measures to keep project progress stable and minimize potential risks, which is particularly important in the pharmaceutical industry.

Reporting and dashboarding

Real-time reports and dashboards offer compre-hensive visualization options to keep an eye on the **status and progress of projects**. This function supports fast decision-making, as all relevant data is always available. Individual KPIs (Key Performance Indicators) for a project can be entered manually, e.g. to quantify savings, revenue a.o.

Dependencies and milestones

Visualizing the dependencies between different projects and tasks helps to coordinate critical mile stones. This enables all teams involved to ensure that their **tasks are completed in line with the overall schedule** and that potential bottlenecks are identified at an early stage.

Automation and workflows

Automated workflows simplify recurring processes and minimize manual intervention, which **increases efficiency and reduces the error rate**. Thanks to automation, tasks can be completed and re leased more quickly, resulting in optimized project handling.

Role and access management

This function ensures **control by regulating access to sensitive project data**, i.e. only authorized team members have access to certain information. In addition to maintaining data security and confidentiality, it has the advantage that **project staff** can work

specifically with the **data and program parts** that are relevant to them.

Monitoring and reporting

By continuously monitoring the progress of the project, **deviations from schedules or budgets can be recognized at an early stage and corrective measures** can be taken. This function provides project managers with a real-time overview of the status and possible deviations from the original plan.

Quality management

In the pharmaceutical industry, quality management plays a central role. The integration of quality checks into the project process ensures that each phase meets the defined standards. An **approval process** and **complete documentation** help to ensure the quality of the results and eliminate potential defects at an early stage

05 CHAPTER

Supporting PM-Tools

With the right tools, even complex projects in the pharmaceutical industry become easier to manage.

Methods and Tools That Support Pharmaceutical Projects

Projects in the pharmaceutical industry are highly complex and often involve long development times.
They range from early drug discovery and clinical trials to the production and market launch of new drugs. Different project management methods are used depending on the project phase and objective.

While **research and development** benefit from a **high** degree of **flexibility** and often **use agile approaches, clinical studies, regulatory processes and production are highly standardized** and require **structured procedure**s such as the waterfall model. Many pharmaceutical companies therefore rely on hybrid approaches, combining both methods to ensure efficiency and agility.

Agile Project Management: Flexibility in Research and Development

Agile methods enable rapid adaptation to new scientific findings and regulatory requirements. In the pharmaceutical industry, this approach is used particularly in the early phase of drug development and in preclinical studies

One example is the development of a new active substance for a rare disease:

• Research and development teams work **iteratively** on various **formulations** and **dosages**, test them continuously and adapt the strategy flexibly to new findings.

• By using **scrum** methods, multidisciplinary teams can test and validate in short development cycles before planning larger studies.

• Kanban boards help to **organize** the large number of **experiments** that run **simultaneously** and to identify bottlenecks at an early stage.

Agility also plays a decisive role in the development of new technologies for customized medicine, as individualized therapies often have to be tested and further developed in smaller batches.

Waterfall Approach: Structure for Regulated Processes and Clinical Studies

Pharmaceutical projects are subject to strict regulatory requirements from authorities such as the FDA, EMA or BfArM, which stipulate that processes must be systematically documented and carried out in clearly defined phases.
The **waterfall** approach is particularly suitable here, as **each phase requires a release** before the next one begins.

One example would be the process of clinical trials:

• Phase I: First tests on humans to assess safety.

• Phase II: Testing of efficacy and dose finding in a limited patient group.

• Phase III: Large-scale studies to confirm efficacy and record side effects.

• Approval process: Submission of all collected data to the authorities for approval.

As extensive documentation is required in every phase, the waterfall approach is particularly suitable for recording data in a structured manner, setting milestones and ensuring regulatory checks.

In pharmaceutical production, a structured approach is essential:

• GMP guidelines (Good Manufacturing Practice) require defined processes.

• Validation processes for production systems and quality controls require a linear, standardized approach.

• Supply chains for active pharmaceutical ingredients must be traceable and auditable.

Here, the waterfall approach ensures clear processes and compliance with legal requirements.

Hybrid Approach: The Optimale Combination for Pharmaceutical Projects

The hybrid approach **combines** the **agility of research** with the **structured planning and documentation of clinical development and production.**

One example is the development and market launch of a new vaccine:

• In the **research and development phase**, the team works in an **agile** manner to test different formulations and vaccine platforms.

• The **waterfall approach** is used in **clinical trials**, as each phase must be reviewed and approved by the regulatory authorities.

• In **production and market launch**, **structured planning** ensures the timely scaling of production, while **agile methods in logistics** make it possible to **adapt to delivery bottlenecks.**

A hybrid approach offers the optimal balance between flexibility and control, especially in projects with high uncertainties in research but fixed regulatory requirements in later implementation.

Conclusion

In the pharmaceutical industry, the choice of the right project management method depends to a large extent on the respective project phase.
Agile methods are ideal for flexible and research-inten sive areas, while the waterfall approach forms an indispensable basis for regulatory-compliant workflows and production processes.
Many companies therefore rely on hybrid approaches that combine the advantages of both methods and make pharmaceutical projects more efficient, faster and safer

Top 10 Best Project Management Tools for IT and Organizational Projects

The pharmaceutical industry requires precise control and documentation of all project phases - from research and development to clinical trials, production and market launch.
Choosing the right **project management software** is crucial in order to **meet regulatory requirements, make optimum use of resources and design efficient development processes**.
Here are ten proven project management tools that are specifically tailored to the needs of the pharmaceutical industry.

1 PLANTA Project

PLANTA Project offers a comprehensive solution for multi-project management in the pharmaceutical industry. The software enables structured planning of clinical trials, detailed resource management and precise budget monitoring. Thanks to integrated milestone and risk management functions, pharmaceutical companies can comply with regulatory requirements and efficiently manage complex development projects.

2 Microsoft Project

Microsoft Project is a widely used solution for traditional project management and is particularly suitable for structured processes in the pharmaceutical industry that require documentation. The software offers Gantt charts, resource allocation and milestone planning, making it ideal for clinical trials or the introduction of new drugs.

3 Smartsheet

Smartsheet combines a spreadsheet-based interface with powerful project management functions. It is particularly suitable for pharmaceutical companies looking for a flexible solution for managing clinical trials, approval processes and regulatory documentation. Inspection processes can be simplified through workflows and automation

4 Wrike

Wrike offers a comprehensive platform for collaboration and documentation management, which is particularly beneficial for interdisciplinary pharmaceutical teams. Especially in drug development, Wrike helps to efficiently link research, quality assurance and regulatory requirements.

5 ClickUp

ClickUp is a flexible platform that can be adapted to agile and traditional project management methods. Pharmaceutical companies can use it to manage clinical studies, approval documentation and re search projects. Processes can be optimized with integrated time recording and automation functions.

6 Monday.com

Monday.com is particularly suitable for managing large, cross-functional projects in the pharmaceutical industry. The platform allows for a simplified visualization of study progress, quality control and compliance requirements. Automated workflows help to speed up approval processes.

7 OpenProject

OpenProject is an open source solution that supports traditional and agile project management. Especially in research projects and product development, OpenProject offers a high degree of adaptability and data protection control, which is of great importance for pharmaceutical companies.

8 Jira

Jira is particularly suitable for agile project management in research and development. Pharmaceuti cal companies use it to manage research projects, develop software for medical applications and manage internal innovation teams. Sprint planning and backlog management helps to design iterative development processes efficiently

9 Asana

Asana offers a user-friendly interface for coordinating teams and projects. The option of assigning de pendencies, deadlines and responsibilities to tasks is particularly helpful for regulatory processes. Pharmaceutical companies can use it to manage approval processes and internal audits.

10 Zoho Projects

Zoho Projects is a cost-effective but powerful solution for pharmaceutical companies that need clear project planning and integrated time tracking. Especially for smaller research teams or start-ups in biotechnology it can be an ideal choice.

06 CHAPTER

Testimonials

Field reports and testimonials from experts and companies that have successfully implemented multi-project management offer valuable insights into how theoretical concepts can actually lead to success when applied in practice.

Case Stury: Losan Pharma and the Imple mentation of Hybrid PM

Losan Pharma uses PLANTA software to comprehensively optimize the management of its complex development projects. **By introducing a hybrid project management approach, Losan Pharma is able to involve both project planners and operational employees in project implementation.**
The hybrid methodology makes it possible to reliably adhere to structural planning phases and at the same time create operational flexibility. Project planners benefit from clearly defined milestones and strategic resource allocation, while operational employees can manage their tasks in an agile manner and report their working hours directly in the system.
This approach allows all project participants to react proactively to project changes, giving Losan Pharma a considerable advantage when it comes to efficiency and adaptability.
The entire workforce is involved in project management so that all team members - from planners to operational specialists - develop a common understanding of the project objectives and their respective contribution to the project's success. This holistic approach promotes company-wide cooperation and leads to greater acceptance of project management processes in all departments.

Losan Pharma GmbH

„All employees can work on their tasks in the boards and benefit from significantly better communication and collaboration“



Read how our customers managed to improve their projects:

planta.de/references

Conclusion

Pharmaceutical projects require precise planning, complete documentation and efficient resource management.
Without appropriate control, delays, cost overruns and regulatory problems can arise.
Project management software optimizes processes, increases transparency and facilitates compliance with regulatory requirements. Hybrid methods combine structured planning with agile adaptability so that companies can work flexibly and efficiently.
The right software allows you to shorten development times, utilize resources optimally and improve collaboration between research, production and authorities - for a faster and safer market launch of new drugs.

FAQs

What advantages do hybrid project management methods offer for pharmaceutical companies in particular?

Hybrid methods offer pharmaceutical companies a flexible and structured approach.
They make it possible to set fixed milestones and adapt to new requirements at the same time, so that both legal regulations and the needs of the teams are taken into account.

How does project management software support compliance with regulatory requirements?

Functions such as compliance tracking and document management ensure that regulatory requirements are systematically recorded and evidence is always documented in an audit-proof manner.

PLANTA Germany
PLANTA Projektmanagement-Systeme GmbH
Bunsenstraße 14 · 76135 Karlsruhe
t +49 721 8281111
@ kontakt@planta.de
www.planta.de

PLANTA Switzland
PLANTA Projektmanagement-Systeme GmbH
Stadthausstrasse 39 · CH - 8400 Winterthur
t +41 52 2690303 · Fax +41 52 2690304
@ info@planta-gmbh.ch
www.planta.de

© PLANTA Projektmanagement-Systeme GmbH. All rights reserved. PLANTA, PLANTA Project and other PLANTA products and services mentioned in the text as well as the corresponding logos are brands or registered trademarks of PLANTA GmbH in Germany and other countries.

Author Whitepaper: PLANTA, marketing@planta.de