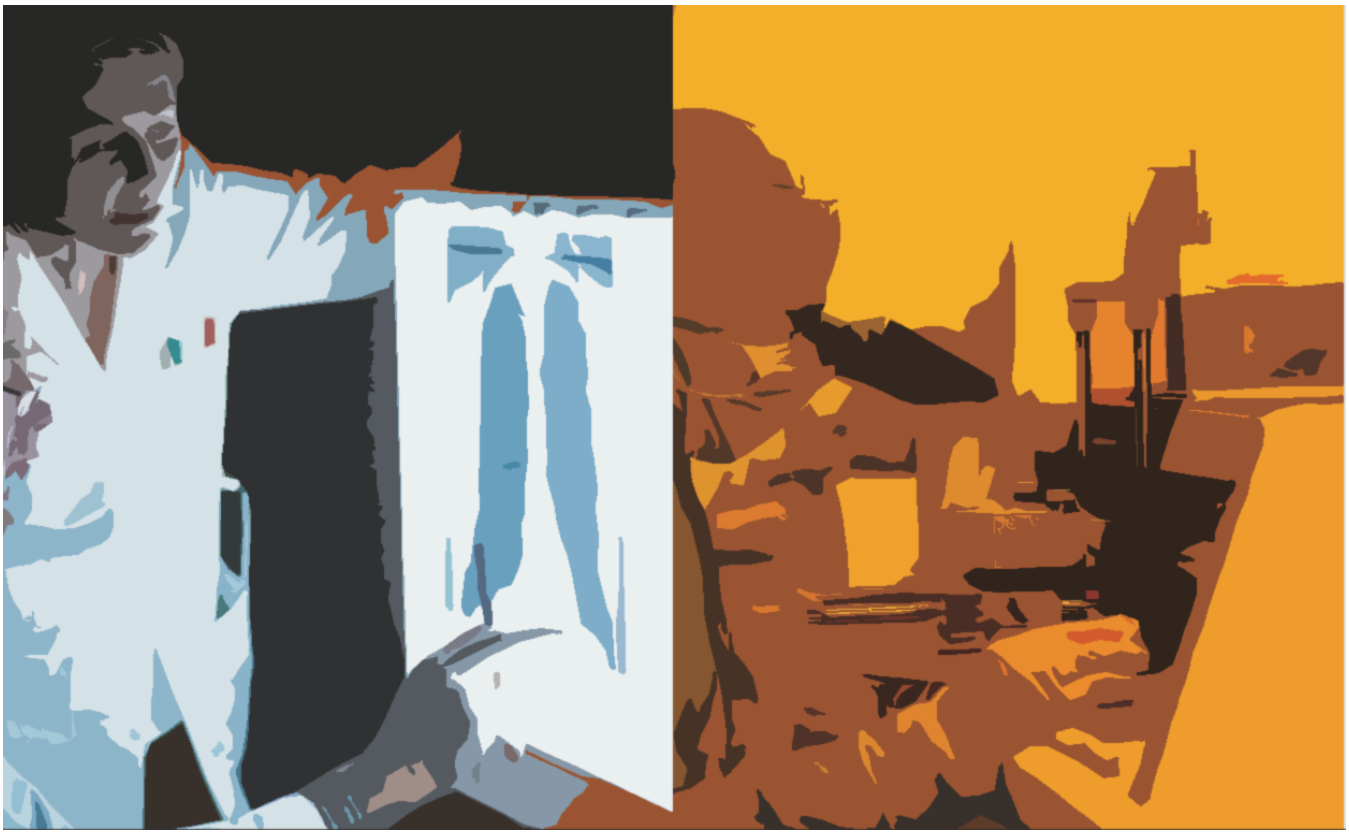
The Project Management by Critical Chain to accelerate the development of new products in the biomedical industry



Introduction

Inventing the products of tomorrow in the biomedical sector

Diagnostic devices, vascular prostheses, and more. All these products are imagined and industrialized through project-based approaches in a highly regulated environment.

The investments made are significant, and the speed of market entry gives a huge competitive advantage to companies in this sector because the first one to market often wins. Teams are generally under pressure to create a **quality product** within **tight deadlines**... It is in this context that Critical Chain Project Management (CCPM) comes into play. This project management method, derived from the Theory of Constraints, allows projects to be significantly accelerated while improving work-life quality.

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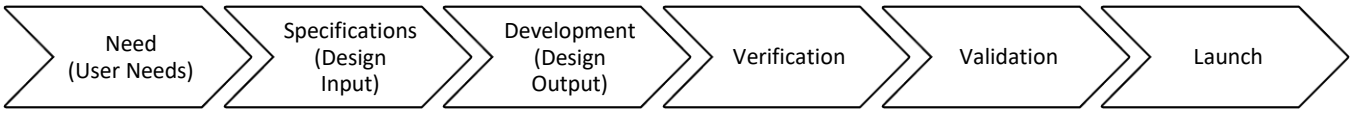
Study of the biomedical sector

The development projects of new products in this sector are **subject to control and approval by regulatory bodies**, such as the FDA in the United States. Market entry is therefore conditioned by a third-party organization.

The projects follow a typical pattern :

1. Collection of customer needs (**User Needs**) ;
2. Definition of specifications and requirements (**Design Input**) ;
3. Product development (**Design Output**) ;
4. Verification that the product meets the requirements of the specifications (**Design Verification**) ;
5. Validation that the product meets customer needs (**Design Validation**) ;
6. Market entry, including production transfer and project review by the appropriate organization (**Launch**).

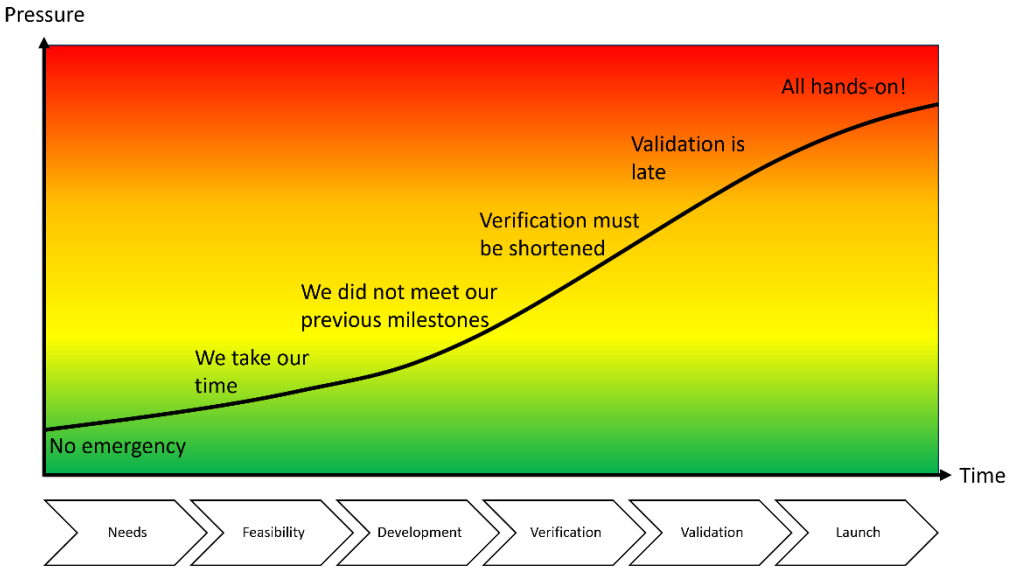


Highly skilled teams

These projects are carried out by **highly qualified personnel**, including scientists, engineers, doctors, and technicians. They work in an **unpredictable environment**: it is common to have to modify the initial design or repeat tests during the development phases.

The pressure increases

Furthermore, the development teams (scientists and technicians) are usually dedicated, but other functions and management often have to juggle multiple projects. Management pressure increases as a result of insufficient attention at the beginning of the project.



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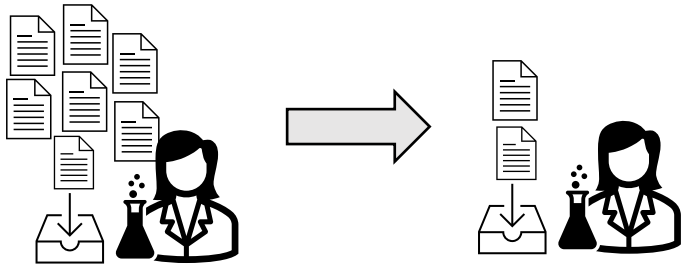
Critical Chain Project Management

Critical Chain Project Management is a component of the Theory of Constraints applied to project management. The Critical Chain should not be confused with the Critical Path, as it encompasses and complements it, taking into account resource constraints, for example. To improve team efficiency, this management approach advocates for protecting them from multitasking by avoiding asking the same person to simultaneously perform multiple tasks.

Reducing work in progress to enhance the focus of scientists and lab technicians

Reducing multitasking primarily involves reducing work in progress within the organization, which entails a decrease in the number of concurrent projects. Reducing the number of tasks on hold significantly improves productivity and work predictability: less multitasking, increased responsiveness from key individuals, and better visibility into the work that needs to be done. “Stop starting, and start finishing”.



Being ambitious when every day counts, but accounting for uncertainties

Furthermore, each project is carefully planned. For each task, the following aspects need to be considered :

- Focused duration: The time required to complete the task assuming everything goes well and resources are dedicated 100%.
- Resources: The functions and/or machines that will perform the tasks (a hood for sample preparation, scientists for conducting an experiment, etc.).
- Using this information, the planning tool highlights the Critical Chain (or project constraint) and a buffer at the end of the project.

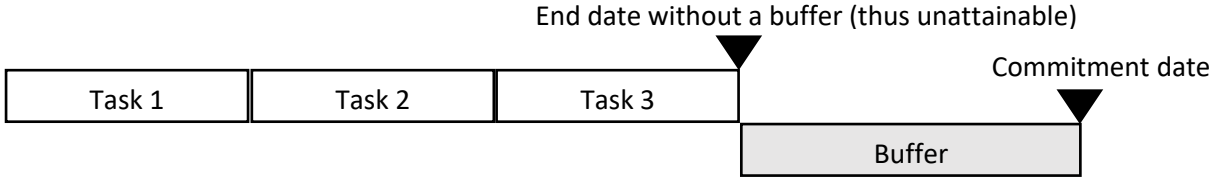


Figure 1: Critical Chain Planning - tasks are planned in a focused manner, but the project is protected by a buffer at the end

Committing to a project completion date based solely on focused (deterministic) task durations, in an environment as uncertain as new product development, is unrealistic. That is why a buffer added at the end of the project is necessary. Unlike traditional planning, the variability in task durations is made visible through this buffer, rather than being hidden in the provided estimates. The date to which we commit to delivering the project

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is the **buffer end date, including the protection**. This helps avoid overly optimistic commitments (a common ailment in this field).

The Fever Chart to assess project health

During project execution, frequent updates of the schedule are conducted with the teams, during which we identify the tasks that have been completed since the last update and the remaining work duration for ongoing tasks. Two values are sufficient to determine the health status of the project:

- **The percentage of completion of the Critical Chain**: It corresponds to the percentage of project completion. If the Critical Chain is completed at 100%, then the project is finished.
- **The percentage of buffer consumption**: It is possible for some tasks to take longer than initially planned durations, which is why the buffer is important as it absorbs these deviations and protects the project from uncertainties.

Thus, the project's **Fever Chart** is plotted, an indicator that compares these two values to estimate the chances of finishing on time.

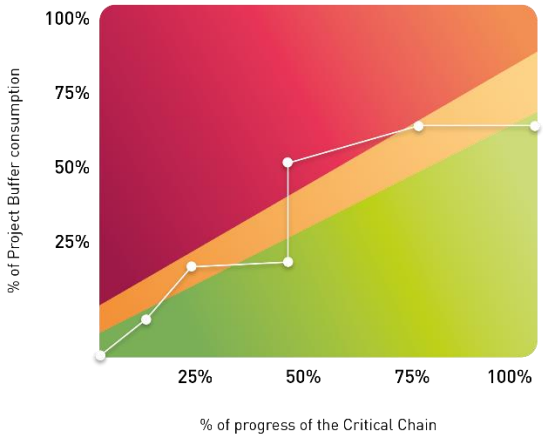

Figure 2: Example of a Fever Chart. A data point is added at each project update. In this case, the project finished with less than 100% buffer consumption, indicating that it was completed ahead of schedule.

Additional information is available on the websites critical-chain-projects.com and marris-consulting.com.

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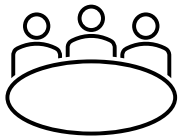
Project Planning is a collective effort to X-ray the project

The planning of a project is a collective effort, it cannot be emphasized enough! Each function must contribute and bring its expertise. It is by no means a solitary exercise for the project manager.



Furthermore, since projects within an organization are similar in terms of task and phase sequencing, it is relevant to establish a **standard planning** approach to avoid starting from scratch each time.

During the development of a new biomedical product, the nature of work and the functions involved differ according to the phases:

1. *User Needs* definition phase **Common challenges:** This stage primarily involves the functions of Marketing, Medical Affairs, and Management. It is difficult to plan but needs to be executed quickly. If the collection of customer needs is too slow, it indicates a lack of interest in the project. **Solutions**: organizing focused workshops of several hours instead of fragmenting the discussions. Involving the development teams helps to stay grounded. This phase is based on a fundamental effort to maintain strong connections with customers.

2. The *Design Input* and Feasibility Testing stage. **Common challenges:** there is a risk of **having to repeat a test, or change the design, components, or manufacturing process**. Often, this initial stage is entrusted to a team that is too small because the project is still in its early stages, and little emphasis is placed on deadlines due to numerous uncertainties There is also a highly **collaborative document-related work**. **Solutions:** appoint a properly sized team. Once the design input is defined, the project can be planned collectively through collaborative workshops. It is a misconception to consider planning unnecessary due to uncertainties: 75% of tasks (tests, documentation, planning, procurement) can be anticipated, prepared, and tracked. The Critical Chain manages uncertainties through the project buffer, and careful planning highlights the resource needs from the very beginning.

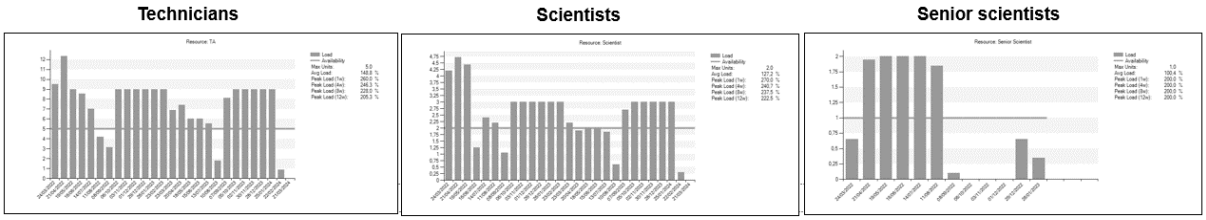


Figure 3: Example of workload/capacity analysis conducted on a portfolio of projects

3. Development (Design Output). **Challenges:** Lack of equipment and execution preparation. Solutions: At this stage of the project, the functions involved are production - responsible for manufacturing the initial batches - and R&D, which will conduct tests and optimize the product. It is important to **involve the Supply Chain as early as possible** to have all the necessary components for conducting the tests. It should be kept in mind that all tests require the writing and validation of a report, which will require allocating resources.

4. La vérification. **Challenges :** This stage is entirely carried out by R&D and Quality. A series of tests are conducted to confirm the product's performance against the previously defined specifications. The

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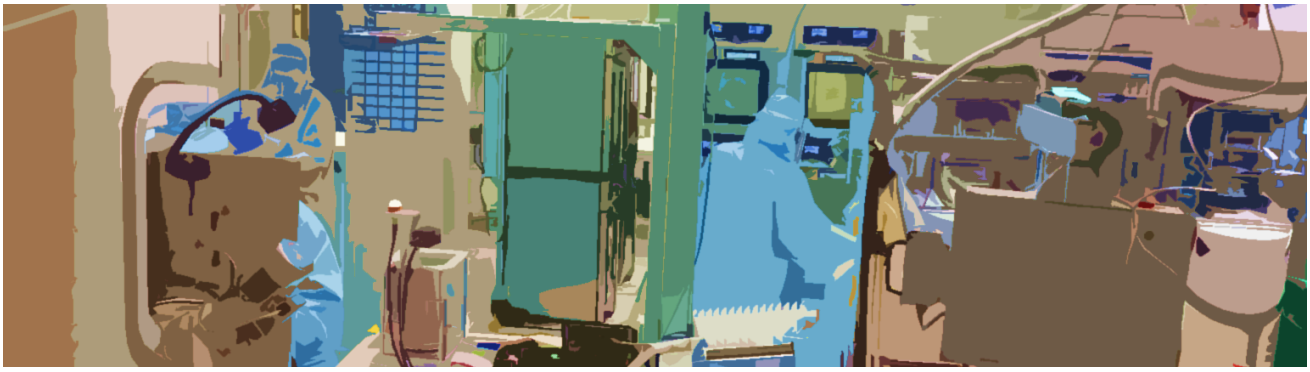
R&D teams have the **expertise in conducting the necessary tests and are aware of the risks or issues that may arise** The project manager must assist in planning this phase (parallelizing tests, allocating resources, engaging subcontractors, etc.). Verification is an important step in the project, but it is also one that can be significantly **optimized to reduce the overall project duration**. **Solutions:** The development team should establish a detailed schedule of tests (duration and required resources), from protocol definition to report writing. Planning the tests using the Critical Chain method helps highlight the constraint of the tests. The schedule is built by indicating the dependencies between tasks and the allocated resources. **It is very common to find schedules where all tests are performed sequentially, even though it would be possible to further parallelize the work if additional resources were made available and focused**.

5. Validation. **Challenges:** This stage involves multiple functions, including Clinical Affairs, R&D, Production, as well as the Statistics department (if applicable) and Quality for result analysis and report review. The product is tested in real-world conditions during clinical trials. **Solutions:** It is crucial to prepare for this stage as early as possible, starting from the definition of the design input, to anticipate the recruitment of clinical sites and define the strategy. **Increasing the number of sites can lead to higher costs but shorter duration**. This stage can be partially or fully parallelized with verification tests. The necessary conditions for parallelization should be defined in advance and agreed upon by the entire project team based on regulations and risk analysis. While the preparation of clinical trials is important, it is equally important not to neglect the management of clinical sites during the trials (regular communication, availability of support teams, etc.).

6. Market release. **Challenges:** This is the final stage of the project where all functions must come together to gather all the necessary documents and **prepare a complete and compliant submission to regulatory authorities**. Once the submission is made, teams work in parallel to **transfer the product to Production and Sales** enabling them to commercialize the product. **Solutions:** Organize review workshops and perform translations as needed. The project is not yet complete at this stage. The team must remain engaged and responsive to address any questions from regulatory authorities.



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Plan, but not under a microscope

Based on this rather general observation of the structure of each phase, the project manager can propose a high-level plan It is not necessary to go into detail but rather seeks to define a network of tasks including **all deliverables and milestones necessary for project completion**. This high-level plan will **be regularly updated, for example, on a weekly basis, throughout the project and communicated to the teams during project reviews as well as to management.**

The high-level plan establishes links between tasks belonging to different phases of the project. One way to shorten the time to market for a product is to parallelize certain activities. In the biomedical industry, unlike in other sectors, **regulatory authorities may require a specific sequence of tasks;** a thorough understanding of the classification of the developed product and the limitations imposed by regulatory bodies will be necessary to determine what is feasible.

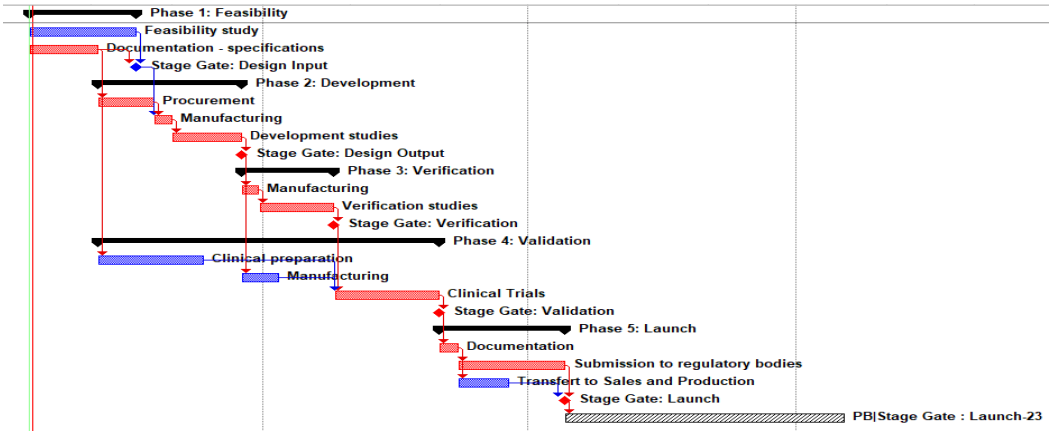

Figure 4: Example of a simplified high-level plan representing phases and tasks - using the Critical Chain method, highlighting the critical sequence of the project (in red) and a buffer

The functions create "low-level" plans to detail certain phases**. The modelling of work in the plan should be different depending on the nature of the task**: on one hand, there is very operational development work (feasibility tests, development tests, verification tests), and on the other hand, there is highly collaborative and iterative documentary work at each milestone.

For **operational tasks**, having a Critical Chain Gantt chart is necessary. These plans are jointly constructed by the project manager and the team in order to **optimize the work to be done, identify the testing constraint from the beginning of the project** (preparation, number of human or material resources, space or number of workstations), and identify risks. It is important to keep in mind the **unpredictable nature of these tests, which may involve multiple iterations**. However, project management using the Critical Chain protects the project from uncertainties through buffers.

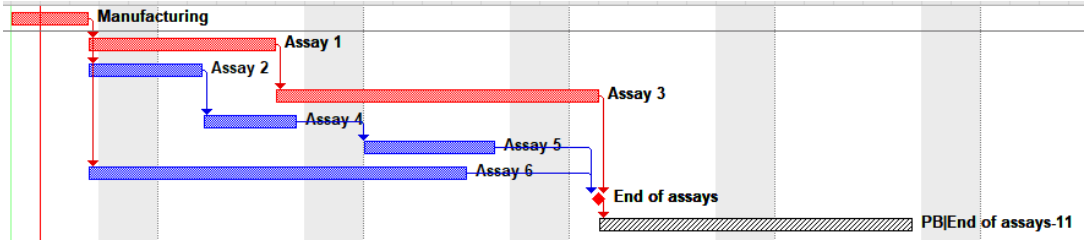

Figure 5: Example of a detailed plan for tests. The plan is protected by a buffer, as there is a significant risk of having to redo a test. The duration of the Critical Chain for this test is the focused duration to be specified in the high-level plan

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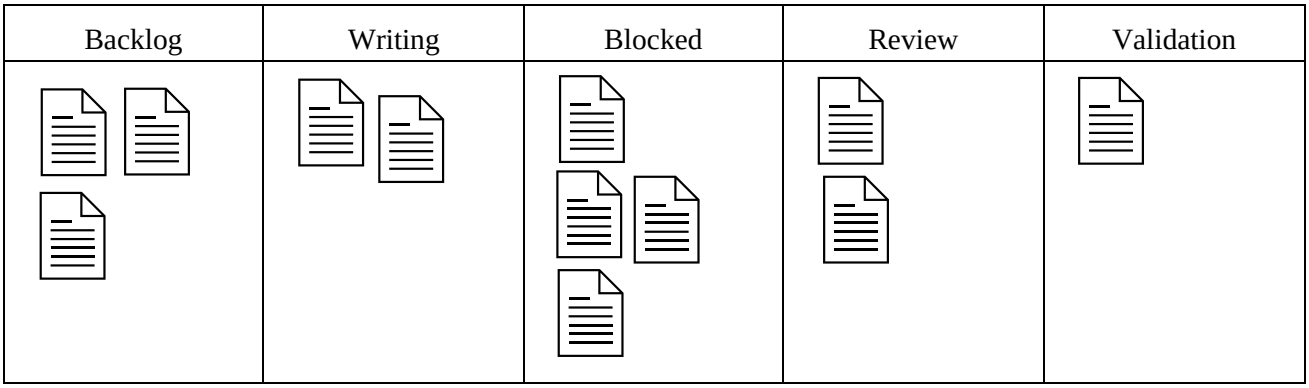
Agile methodology and Kanban project documents

For **writing tasks, a more Agile approach is recommended**. The key is to have a clear understanding of all the necessary deliverables, identify logical dependencies between them, and track the progress of document writing on a weekly basis. Is the document in the backlog? Is it being written by the responsible person? Is it blocked? Or is it available for review? Does it require a collaborative working session, or has it finally been validated by quality assurance and the signatories?

Estimating the duration of these writing tasks in the high-level plan is challenging in the early stages of the projects. However, experience allows us to determine whether it will take a week, a month, or three months to complete all the deliverables. **This work is crucial for the project and requires dedicated representatives from each function**. Often, a document considered less important may wait for days or even weeks for feedback from a manager or expert, while it is actually blocking subsequent tasks.

The project manager should actively manage this documentation work on a frequent basis. Establishing a short routine, 2 to 5 times per week, will help teams reduce waiting times and accelerate the production of documents.



Executing the project and problem solution

Identifying bottlenecks, ensuring smooth flow

During project execution, it is **necessary to have dedicated resources during the phases where they are required**. It is not uncommon to discover that a 'support' function that only intervenes occasionally or in certain project phases slows down the execution. The reasons can be multiple: parallel projects, a shared resource having to respond to daily demands, lack of communication regarding the progress of phases, etc.

Do not overlook the logistics of testing

Non-critical at the beginning of the project, production and logistics activities can quickly jeopardize the smooth execution of the plan. The project manager and the team must ensure the progress of these tasks related to test preparation, development, and clinical trials in particular.

The requirements for raw materials, equipment, samples, etc., must be identified and communicated as early as possible. It is important to identify key steps that validate the specifications of these requirements in order to anticipate their procurement and, if necessary, include their production in the production line's workload.

The availability of clinical sites to start the trials on time is also crucial, hence, tracking the selection, contracting, and training of clinical sites is performed.

These activities require coordination among a large number of stakeholders. Progress checklists serve as an effective tool for tracking and managing the project.

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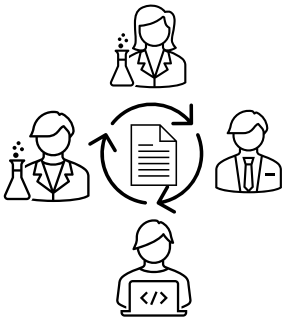
Beware of excessive meetings, take the time to work together in the same room

In many phases of the project and during problem-solving, it is necessary to have smooth communication among different stakeholders and ensure that the individuals involved have sufficient time to address the issues. Instead of multiplying meetings, it is strongly recommended to organize work sessions to increase team alignment, expedite decision-making, and improve team cohesion.

Often, short meetings are spread out over several weeks and scheduled with participants who have limited availability, which is inefficient. The lack of focus significantly slows down the execution.

This point relates to a crucial question in portfolio management regarding the level of work in progress. The more projects there are, the more delays in problem-solving and difficulties in organizing the work.



Developing versatility and training laboratory technicians

For certain activities or phases of the project, acceleration is possible by increasing the number of allocated resources. Therefore, it is crucial to have flexible and versatile teams capable of quickly transitioning to another project. This potential is often underestimated, but its significance is very important in environments where human resources (scientists, technicians, etc.) are the constraint. By working on versatility, activities can be assigned to a greater number of individuals. For example, assigning report writing to an experienced technician rather than a scientist can alleviate the workload on scientists, who are often a limiting factor during development or clinical trial preparation phases.

Check-up: The project manager updates the schedule at least once a week

To quickly identify problems and anticipate deviations, the project manager must update the schedule regularly, with a preferred frequency of once a week.

Attention is focused on critical activities that jeopardize the project's completion date. However, it is important to remember that with the Critical Chain approach, durations are only estimates and not commitments. Therefore, the role of the project manager is no longer to monitor the completion of tasks on the planned date but to ensure that their execution is as fast as possible (complete and in compliance, anticipating the need for additional resources, etc.).

Frequent exchanges for increased responsiveness. Through regular updates with the teams, the project manager can generate a weekly Fever Chart for the project and communicate its status.

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Conclusion

In the regulated environment of the biomedical industry, Critical Chain Project Management offers powerful solutions to consistently go faster. It is not about taking thoughtless shortcuts because there is no time (making hasty decisions without properly estimating the consequences) but rather about **anticipating, identifying the system constraint, and seeking to exploit it to accelerate projects without compromising the final product quality**. Reducing the number of ongoing projects, improving visibility into the project portfolio, and implementing a robust filter before initiating new projects yield impressive results.

The project execution is carried out more smoothly, creating a more stable environment for the development teams, and significantly **improving communication within the team and with management.** The Critical Chain approach promotes greater transparency in the organization. The buffer protects the team's commitment to the project's end date against uncertainties, providing visibility and time for the teams and management to implement the necessary solutions to achieve the objective.

If Critical Chain Project Management primarily aims to **accelerate project completion**, it also provides an additional benefit in this sector **by reinforcing the structure that ensures the quality of the product** submitted to regulatory bodies, ultimately satisfying customers.

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Lessons Learned and health assessment

- Do not confuse speed with haste: Excessive ambition and unrealistic commitments are counterproductive as they increase the work in progress, promote multitasking, reduce management attention, and slow down problem solutions.
- Plan tasks with optimistic estimates but committing to deadlines without allowing for margins in an uncertain environment is suicidal. The buffer is not an option
- Project planning is a collective effort, and it cannot be emphasized enough. It is not a solitary exercise for the project manager.
- During the requirement definition phase, it is preferable to organize focused workshops of several hours on the same site rather than fragmenting discussions through short remote meetings or emails.
- Feasibility tests should be separately planned and allocated with a dedicated team and sufficient resources.
- It is important to involve the Supply Chain as early as possible to ensure the availability of all necessary components for the initial tests.
- Verification is an important project stage but also one that can be significantly improved to reduce the overall project duration.
- It is common to find schedules where all tests are performed sequentially, but more parallelization could be achieved if additional resources were made available.
- In validation, increasing the number of sites generally results in increased costs for this phase but also a reduction in its duration. Clinical sites should be supported to maximize their operational efficiency. Establish long-term partnerships.
- The validation phase can be partially or completely parallelized with verification tests.
- The progress of launch preparations can be monitored and facilitated with advancement checklists.

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