

Gap Analysis Remediation

A Guide to Resourcing & Implementation

*Closing gaps in life science
quality management*

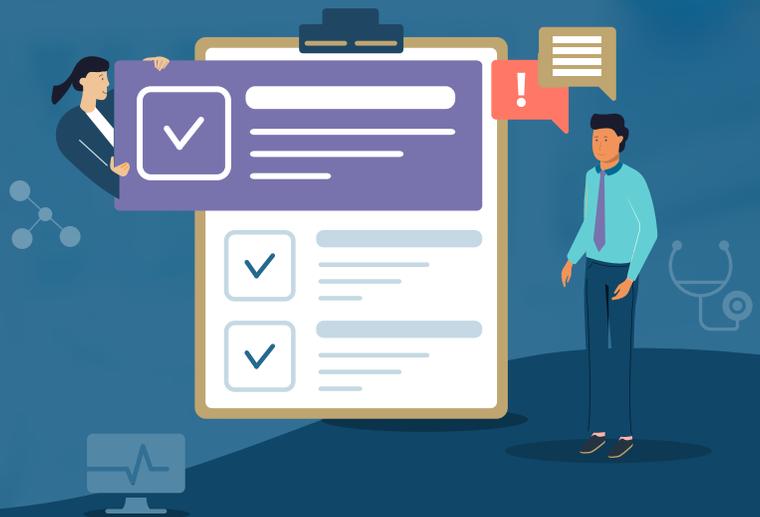


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Introduction

A completed gap analysis is like a travel itinerary for your quality system. Just like vacationing in an unfamiliar place, you know where you want to be, but need a guide to show you exactly where you are, which direction you need to go, and what you'll need to do to get there.

If your analysis was thorough, much of what you need to develop this remediation plan is already in front of you. The information you gathered during the analysis can largely be re-tooled into a set of actions for filling system gaps. That task is relatively straightforward.

What isn't so obvious, and where many teams get stuck, is what comes next: resourcing and implementing the fixes. These steps are rarely as easy and straightforward as they might seem to be and can involve tough discussions about capital and capacity that are often under-addressed or avoided altogether. Too often, firms rush into planning and executing remediation without taking stock of the resources they have and comparing it against the resources the plan demands. Without this critical planning step, busy schedules, competing priorities, and mismatched skill sets can all converge to bring the project to a screeching and expensive halt.

The good news: all of these threats can be mitigated from day one with a healthy dose of planning guided by strategy and a partner that can provide quick, flexible access to the resources you need to get projects done on time and on budget.

That's exactly what this guide is for. We'll explore exactly where quality departments get stuck during the planning phase following a quality system gap analysis and provide a strategy you can employ to ensure you have all the resources you need to be successful from the outset.

Before we jump into resourcing, however, let's take a moment to run through a few tips for conducting a gap analysis, explore two quality system gaps that are serious red flags to watch out for, and discuss what an effective remediation plan should include.



A Few Tips for Conducting a Gap Analysis

1. **A gap analysis should always result in the action items required to bridge the gap between the current and desired state.**
However, it should never be substituted for more detailed assessments that should be carried out once the remediation project is underway.
2. A gap analysis should be **performed at the preliminary stages of any change-related project.**
3. While trying to obtain information about the elements involved in gap analysis, **always make use of reliable tools** such as SWOT, Fishbone, McKinsey 7-S, etc.
4. Whenever possible, **data that is obtained should be quantifiable so it can be verified** if needed.
5. **Information collection should be focused on the processes, workflows, information, and interdependencies** rather than individuals.
6. **The end goal or future state and the respective scope of the change should be carefully defined.** Any mistake in doing so might turn the analysis in an altogether different direction.

Reviewing Your Gap Analysis Report

Once you've completed your gap analysis, you should have a report that clearly identifies each gap in the level of detail needed to close it. At this point, some corrective actions may be obvious. Others may be more complex and take some planning to formulate.

When preparing to create your remediation plan, a healthy dose of due diligence is necessary to avoid showing up at the next meeting only to find out that nothing has



been done to address the gaps you found. After the analysis is complete and the subsequent report has been sent to management, the next steps should typically look something like this:

- 1. Follow-up with the management team to ensure they fully understand the findings.***
- 2. Make sure the project lead prepares a timely, complete remediation plan to address the gaps you've uncovered.***
- 3. Determine the feasibility of your existing resources to implement the approved plan and identify the people who will initiate and implement it and/or secure the external resources needed to do so.***
- 4. Implement the plan.***
- 5. Verify success, determine the need for surveillance audits, and put a plan in place to schedule those with the appropriate resources.***

Two Common “Red Flag” Gaps to Watch For

Before we dive into resource planning, let's step back to discuss a couple of quality system gaps that, when detected either before or during a gap analysis, almost always point to an underlying resource or process deficiency requiring serious attention (and typically many resources and man-hours to fix).

Backlogs

Backlogs are almost always a sign of either a process problem, a resourcing problem, or a dangerous combination of the two. While the existence of a backlog is usually obvious,



knowing how to get rid of it is much less so. This is especially true for lengthy backlogs and those that have gone unaddressed for some time.

Quality departments should be especially wary of a few types of backlogs that, as experience tells us, nearly always represent the tip of a much larger iceberg of issues lying underneath the surface. Backlogs in **analytical testing**, **CAPAs/deviations**, and **customer complaints** are three examples of these high-priority areas that should always be a cause for concern given that lapses in oversight could lead to serious risks in both regulatory compliance and product safety.

A backlog of **quality documents** should also prompt you to put processes and people under the microscope. Especially in busy, chronically understaffed units, competing priorities can prevent managers from reviewing and signing off on key reports in a timely manner. In the case of a backlog of batch records, for example, a back-up of documents may be directly causing a back-up of products, thereby creating a potentially serious yet completely avoidable financial and compliance liability that may or may not be on anyone's radar.

While it's impossible to capture all the types of backlogs that should serve as warning bells for your system, we'll lastly mention **long-standing investigations** as another gap to be particularly careful of. Both in gap analyses and internal audits, inadequate and/or delayed investigations remain one of the most persistent issues affecting quality units and a frequent red mark on gap analysis reports. The takeaway here is to be proactive to ensure if a red mark is spotted, it's on your gap analysis, not the FDA's.

The causes of these and other types of backlogs shouldn't be surprising. As we mentioned before, teams have a lot on their plates and may be dealing with a longstanding staffing or skill shortage. As a result of these and other constraints that put pressure on teams and their timelines, the intensive investigations and diligent corrective actions that are so critical after a gap analysis or other quality system assessment are often exactly where corners get cut.

But, as we've observed firsthand in quality units large and small, the ironic root cause of poor root cause analysis isn't the nature of the work itself, but the quality of the processes and people that support it.

Inefficient or inadequate investigation processes often get compounded with unqualified writers and reviewers to create the kind of quality management gaps that



pose serious compliance and safety risks when problems are allowed to go unresolved at the root. Remediation in these cases often starts with simple questions that, when answered honestly, can prompt meaningful steps toward improvement that alleviate these lingering burdens.

“ Issues with investigations come up a lot. A consistent backlog here almost always points to an underlying process or people problem that when left as-is, only compounds to create a bigger, more expensive and risky gap to fill. The questions we use to diagnose and treat the problem usually aren’t complex. ‘Is your investigation process as efficient as it could be?’ ‘Are the people responsible for conducting, writing, and reviewing investigations qualified to do so?’ ‘Is there a documented training system in place to ensure qualified resources support the process?’ ‘Have leaders made sure their teams are adequately resourced to conduct and review investigations thoroughly?’”

– ALAN GREATHOUSE, THE FDA GROUP

Procedure vs. Practice

In addition to backlogs, another major red flag worth noting for how frequently it shows up and how much remediation it can require is any quality system discrepancy between procedure and practice. When a procedure is routinely not being followed or otherwise doesn’t match what personnel are actually doing, it’s usually the procedure’s way of telling you it needs attention.

Closing the gap here requires some investigation to determine what exactly the issue is. The best and most universal advice here is to start asking the questions that reveal the most common root causes:



- Is the procedure still in use?***
 - Is the procedure out of date?***
 - Is the procedure unnecessary long?***
 - Is the procedure unclear, complicated, or difficult to understand?***
 - Is the procedure hard to find or locate?***
 - Is the procedure currently controlled or uncontrolled?***
 - Is the procedure too generic, general, or simplistic?***
 - Is the procedure incorrect, wrong, or poorly written?***
 - Is the procedure poorly designed or hard to navigate?***
 - Is the procedure inconsistent in format from others?***
-

Developing a Remediation Plan to Close Quality System Gaps

As we mentioned before, the gap analysis report should do much of the heavy lifting in crafting a plan to close the gaps you've identified. Utilize your analysis as a starting point, building upon each finding to reveal what's needed to completely solve the problem. In practice, this means following a few general guidelines to ensure that every action you include in your remediation plan accurately captures the extent of the gaps and lays out a plan to fill them completely:

- 1. *Build your remediation plan using the information you discovered while identifying the gaps.*** As we said before, very often the details you uncovered about the nature of a gap offer the best way to fill it. If, for example, it's clear that a deficiency was caused by staff being too busy to devote themselves to one of their responsibilities because of another being introduced, the best solutions are evident by the nature of the problem. Either reallocate existing resources and adjust any project timelines that are impacted so capacity can be maintained, or add the qualified resources needed to fill the gap without affecting other initiatives. In short, don't overcomplicate or under-complicate your findings. *Listen to what your gaps tell you about the nature of their root causes.*



- 2. Consider what is needed to implement each solution from the outset.**
While some gap remediation can be done internally, other gaps—especially those that point to larger issues within the system that may involve many interdependencies or significant process or resourcing problems—should be highlighted as tasks that will require external resourcing to augment internal efforts. Note these needs as soon as possible along with the skills, knowledge, and level of experience you'll need in a contracted resource.
- 3. Identify known dates and timeline considerations for the subsequent project plan.** You may discover that some gaps threaten other projects or initiatives within your organization. In these situations (or others where time constraints prompt priority action) document *who* will be needed, *when* they'll be needed, and consider how an external resourcing partner could quickly provide the resources you need to protect your project deadlines.

Although these general steps can be used to craft an action plan for closing gaps for which solutions are more or less apparent, gaps that point to more complex problems (and thus more complex fixes) should be treated with a more comprehensive investigation and analysis in order to determine the full scope of the issue and the best path toward solving it.

As noted before, backlogs are a prime example of a complex problem that requires a more in-depth follow-up analysis. And while backlogs are often the result of a number of contributing factors that need to be untangled and addressed one by one, eliminating them can be relatively straightforward when approached systematically. Consider the following steps when facing a backlog or use them as a generalized template for addressing other kinds of complex issues.

- 1. Delineate and confine the backlog.** Separate currently scheduled work from backlogged work and define a clear boundary between them, usually with a date. This is critical for scoping the work needed to eliminate the backlog and measure the progress of that work, all while not getting in the way of other ongoing projects.
- 2. Quantify the backlog.** With the backlog identified and separated, you can measure the scope of the problem. While different metrics lend themselves to different situations, the result should be in the form of hard numbers. (For example, the number of impacted documents or the hours of work required to process them).



3. **Map your processes.** Once you have a handle on the size and scope of the backlog, turn your attention to the processes that may be contributing to it. Process mapping is the best way to visualize any weak points or bottlenecks that might exist. Keep in mind, the entire root cause probably won't be something you can circle on a chart. It's often a combination of factors you have to untangle. For example, perhaps productivity is stalling despite having brand new manufacturing equipment in the facility. In this situation, the requirements of operating the new equipment may not be reflected in the processes currently in place. By mapping this process out, you can spot the weak link as a resourcing problem in validation, for instance. Conduct a kind of "mini root cause analysis" to evaluate the effectiveness and relevance of the process and whether you have the right people and the right number of people in place to support it.

“ When you map out your processes, you may find bottlenecks where resources are constrained in multiple areas. Your remediation plan needs to capture those bottlenecks so you can resource the project accurately from the start. The plan has to address each individual bottleneck before you move forward.”

- ALAN GREATHOUSE, THE FDA GROUP

4. **Remediate the backlog.** Based on the nature of the problem that prompted the backlog and its now-quantified scope, there are two practical ways to eliminate it: either get more resources (such as hiring contracted specialists), change the way you do things, (for example, adopting an ad-hoc process for managing the backlog through expedited procedures, shorter forms, etc.), or ideally **both**. Use the simple comparison matrix below to understand the relative advantages and disadvantages of each approach and how a combination can offer extreme value in terms of efficiency and corrective/preventive action.



Remediation Decision Matrix	Existing Resources	Additional Resources
Same Processes	<p>No progress</p> <p>The root causes of inefficiency remain while the personnel are tasked with untenable workloads. Changing nothing and demanding more invites cut corners and mistakes while stealing time from current projects.</p>	<p>Short-sighted grind</p> <p>Augmenting your staff with external resources helps eliminate the issue, but at the added cost of operating in a potentially inefficient process. Root causes related to the process remain only to appear again in the future.</p>
Process Improvement	<p>Short-sighted efficiency</p> <p>An ad-hoc or simplified process may allow for expedited review, but at the cost of completeness. Shorter forms and lost steps introduce serious risks.</p>	<p>Maximum efficiency, effectiveness, and confidence</p> <p>A combination of process improvement and experienced external resource support results in the fastest, most complete issue resolution while improving efficiency going forward.</p>

5. **Review.** It's one thing to get rid of a backlog, but it's another to eliminate it in a way that prevents it from coming right back. After closing the process gaps and eliminating the backlog, have a meaningful close-out meeting around a few key questions:

- **What caused the backlog in the first place, and was this source external or internal?**
- **How could you have seen this coming, and what indicators should you monitor going forward to prevent it from happening again?**
- **What new systems, processes, procedures, and resources need to be put in place and are they there now?**



Planning Resources for Remediation

After developing a plan for remediation, the critical next step is often the most overlooked: understanding the project's resource needs and planning accordingly.

In projects like this, where serious gaps need to be addressed, it's extremely difficult and risky to kick-off remediation without planning who's responsible for what and when each action can be implemented.

Yet, many firms, in the interest of saving time and getting projects underway as quickly as possible, continue to rely on ad-hoc resource allocation and a naively hopeful attitude about who is qualified and capable of bringing the plan to life.

This problem isn't unique to the life sciences, either. A 2017 survey by the Project Management Institute found that only 62% of organizations surveyed admitted that they "always" or "often" use resource management to estimate and allocate their resources.

What's more, the very same study showed that insufficient resource allocation is exactly what throws projects into peril. When asked about the primary causes of their past projects' failures, 23% of respondents cited "inadequate resource forecasting" and "resource dependency." This is particularly frustrating knowing that despite not being the top problem in project management, it's one factor that can be tightly controlled from the start.

The reason why resource allocation is so critical and deserving of time and energy is simple: Without a realistic view of who makes up your workforce, how much time they have to spend on project tasks, and what they need to get the job done, a project simply isn't set up for success.

With so much riding on resourcing, and given the challenges we've seen firsthand throughout the industry, we've developed a malleable strategy for resource planning, specifically for remediating gaps following this type of assessment.

Before we jump in, though, a note about terminology here: While the word "resources" generally implies all of the things that a project manager or organization depends on to deliver products and services, we're using it in this context to refer to human resources,



in particular. In truth, people planning is different from physical resource planning, so such a distinction is important.

Determining the people needed to carry your plan through to completion can pose a whole new set of challenges, so doing it right matters. Over-resourcing wastes time and money. Under-resourcing risks missing critical milestones. The wrong resources won't meet your expectations. Project managers need to understand what resources a project needs and what resources the project already has at its disposal before putting hard dates to any part of the plan.

1. **Determine how accurate your estimate needs to be.** Typically, the more accurate the estimate, the more detail is needed, and the more time is needed. If you are asked for a rough order of magnitude (ROM) estimate (-25% - +75%), you may be able to complete the work quickly, at a high-level, and with a minimum amount of detail. On the other hand, if you must provide an accurate estimate within 10%, you might need to spend quite a bit more time and understand the work at a lower level of detail.
2. **Create an initial estimate of man-hours for each activity and for the entire project.** There are many techniques you can use to estimate the effort required, but for this type of project, a task decomposition (or work breakdown structure) is likely ideal. This should break down the remediation plan to describe the project in terms of what needs to be done and delivered at each step, making the needs plainly visible and easier to manage while giving you a tool to know what specific skills and capacity will be needed when and where.

A Sample Template of a Work Breakdown Structure:

PROJECT NAME	TASK 1	SUBTASK 1.1	WORK PACKAGE 1.1.1
			WORK PACKAGE 1.1.2
		SUBTASK 1.2	WORK PACKAGE 1.2.1
			WORK PACKAGE 1.2.2
	TASK 2	SUBTASK 2.1	WORK PACKAGE 2.1.1
			WORK PACKAGE 2.1.2



3. **Estimate the duration of project tasks.** Using past experience, the knowledge of an experienced team member, or guidance from an external expert, estimate the time required to complete each activity. The Critical Path Method (CPM) (which we'll explain in greater detail later) is perfect for this as it illustrates the project structure and includes dependencies for each task along with milestones and durations. Using CPM as a tool, you can calculate the total estimated time for the project with generally reliable accuracy.
4. **Identify qualified internal resources and gauge their availability.** Once the scope is determined, designate members of your internal project team and how their skills and capabilities correspond with the tasks they will be assigned to. Make sure that these individuals are available for the estimated period for each task and that any risks are mitigated through a resourcing contingency plan. If possible, use historical data from past projects to inform your estimates. This can serve as a baseline for setting up a new project, thereby reducing "guesstimates."
5. **Add project management time.** This is the effort required to successfully and proactively manage a project. In general, add 15% of the man-hours for project management.
6. **Determine which project roles or capacity needs should be filled through external staff augmentation.** Note any and all areas where internal resources are either unqualified or otherwise unavailable due to capacity needs. These are the areas where your staff will likely need to be augmented with the appropriate external resource(s) to fill the personnel gap. In each area of need, consider the following questions to better understand what skills and experience are required in an external resource:
 - **Which specific operations will they need to support?**
 - **Which skills, capabilities, or experience are essential to ensuring those operations can be adequately supported?**
 - **What specific requirements exist for the process, equipment, or project in question?**

**TIP**

The FDA Group's dedicated account management team lifts the burden off internal leaders while ensuring projects are completed on time and on budget.

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- **What specific qualities, capabilities, or experience must a specialist have to satisfy these requirements? (For example, is previous sterile room experience critical?)**
- **What is the expectation for specialists in terms of protocol drafting and execution?**
- **What is the training or onboarding process required prior to gaining access to the internal documentation control system?**
- **Will the specialists be required to initiate and drive change controls?**
- **Which specifications are relevant to the project or program?**
- **What specific qualities, capabilities, or experience must a specialist have to perform a thorough review?**
- **Which training and onboarding activities will be needed for this specialist before they can begin work?**
- **Have you accounted for training and onboarding in your budget?**
- **Are project timelines realistic given the amount of time needed for training and onboarding?**

“ Before reaching out for external resourcing support, organizations should have a clear picture of the skillsets they need. That way, they can get the right resources. If you just start bringing people on, it can look like a free-for-all, and you lose so much time and money.”

- ALAN GREATHOUSE, THE FDA GROUP

7. **Calculate the total effort by adding up all the detailed work components and review and adjust as necessary.** Sometimes, when adding up all the components, the estimate may seem obviously high or low. If your estimate doesn't look right, go back and make adjustments to your estimating assumptions to better reflect how a project will likely pan out. If your sponsor thinks the estimate is too



high, and you don't feel comfortable to defend it, you have more work to do on the estimate. Make sure it seems reasonable to you and that you are prepared to defend it.

8. Put it all together in a resource management plan. Once you've identified what you have versus what you'll need to implement the project, organize your findings into a resource management plan that makes this information useful for project leaders. In addition to being a management resource, this plan can help earn stakeholder buy-in and get project budgets approved as well. While a physical resource management plan advises on the use of materials and equipment, human resource plans should specify the type of skilled people needed to complete a project, and the quantity, estimated cost, and scheduled duration of their given activities. Before implementing your project plan, modify and organize it to assign every individual project task to the appropriate person.

An effective resource plan should include the following information:

- **Resource Identification:** The type of people needed, and once identified, their name, title, source (if contracted), and the assigned project team.
- **Resource Requirements:** The relevant information about the resources available, including when they're available, any conditions to that availability, and the duration of their availability.
- **Roles and Responsibilities:** The specific function(s) that the resources will perform for the project. This information might list the resource authority, including decision-making and approval authority.
- **Resource Cost:** The direct or estimated resource cost (if contracted).
- **Resource Quantity:** The amount of this type of resource (for example the number of labor hours).
- **Resource States:** The current state of the resource (planned, requested, approved, denied, allocated, confirmed).
- **Resource Locations:** Where the resource is located, including virtual resources and co-located teams.
- **Resource Organization:** A display of the project team and their relationship to other project team resources.
- **Resource Calendar:** The scheduled working days, shift hours, start and end dates for different project milestones, and scheduled holidays. (This should identify the duration of work for specific resources.)
- **Resource Issue Log:** The information on resource planning challenges, for example, in acquiring skilled resources and problem-solving steps that worked to keep project resource plans on track.



Methods for Project Implementation and Management

While closing gaps within your QMS may be straightforward and simple to manage, more complex remediation may benefit from or even require a set of guiding principles and processes via a project management methodology.

What methodology you choose can have a profound and ongoing impact on how your team works. Different project management methodologies have their own pros and cons for different project types. Some are geared for speed, others for comprehensiveness.

For the sake of simplicity, we'll give a practical overview two that lend themselves well to remediation following a gap analysis: Waterfall and Critical Path Method (CPM).

Each has been written about extensively and can be adopted relatively easily if you're not using them already. Note that these are just two among many methodologies that can provide a useful framework for managing a remediation project.

Waterfall

The Waterfall methodology is a tried-and-true project management process that first emerged over forty years ago in response to growing complexities in development-focused industries. Today, it's still a widely used methodology prized for its simplicity and versatility.

How it works

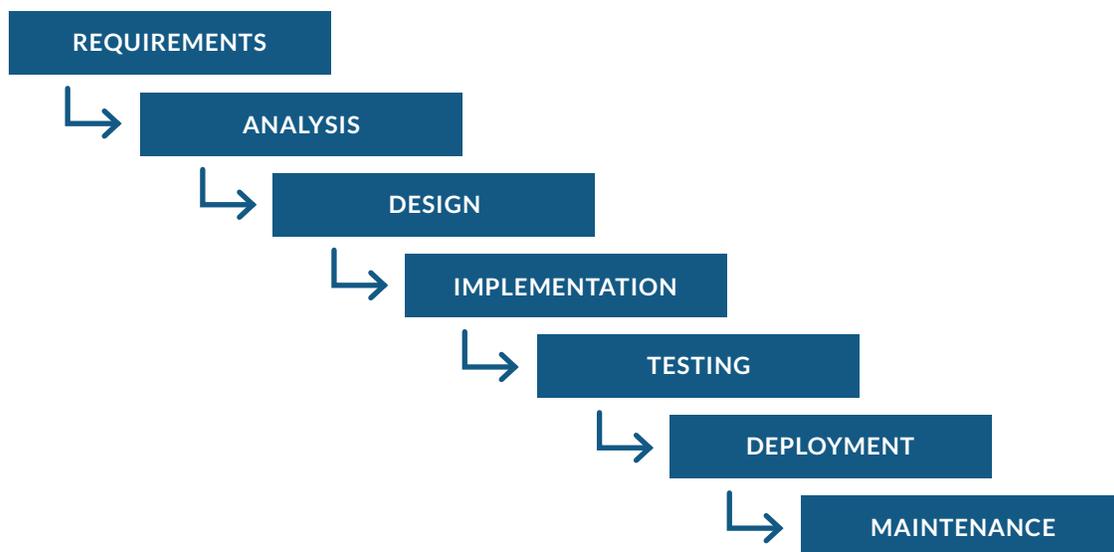
The Waterfall methodology is a sequential set of discrete steps, heavily focused on the requirements of each. Project leaders must have a clear idea of what the project demands before proceeding. As a side effect of its simplicity, there is no scope for a correction once the project is underway.



The Waterfall method is divided into discrete stages, starting with collecting and analyzing requirements, designing the solution (and your approach), implementing the solution, and fixing issues, if any.

Again, each stage in this process is self-contained. One stage must be finished before moving on to the next. Many project leaders opt for the Waterfall methodology when they're able to invest time in the early stages of a project, ensuring requirements have been met so they can save time retroactively correcting problems.

Visually, this is a simple “step” chart.



Advantages:

- 1. Easy to use.** This model can easily be adopted. It's intuitive and easy to grasp whether you have experience or not.
- 2. Simply structured.** The Waterfall's simple structure can be a liability when it's misapplied, but a strength when it fits the nature of the work. Clear delineation between stages helps organize and divide straightforward projects and the inability to “go back” forces full completion at each stage, which can lead to better results.
- 3. Focused on documentation.** Collecting and understanding requirements from the start make this model particularly well-suited for projects for which resources are reliant on documentation. This makes it easy for new resources to familiarize themselves with the project and begin work quickly.

Disadvantages:

1. **May present risks.** The Waterfall method is rigid, so errors and changes often require teams to start again from the beginning. In complex projects, this increases the risk of project failure.
2. **Front-heavy structure.** The Waterfall method depends on the team's ability to understand and analyze requirements correctly. Again, this lack of flexibility makes it a poor choice for long and complex projects.

When to use it:

- **Projects that are short and simple**
 - **Projects with fixed requirements that are clear from the start**
 - **Projects where resources may change and depend on documentation to guide them**
-

Critical Path Method (CPM)

CPM is a more sophisticated project management method that recognizes every project, regardless of its size or budget, has some core tasks that are crucial to its completion.

In CPM, project teams categorize all the activities needed to complete the project within a work breakdown structure like the one we described earlier. The team then maps the projected duration of each activity and the dependencies between them. This helps project managers identify activities that can be completed simultaneously, and those that should be completed before others can start.



How it works:

In practice, the steps of CPM typically follow this sequence:

1. Identify the **activities required for project deliverables** as laid out in the WBS and the **maximum time duration for each**.
2. Identify all the **dependent and concurrent tasks**.
3. Create a network diagram or “**critical path analysis chart**” laying out tasks and using arrows to note dependencies (fig. 1).
4. Estimate the **actual duration** of each activity (based on experience, past project data, industry benchmarks, etc.) and **add those numbers to the chart** (fig. 2).
5. **Calculate the critical path** by adding start and end times to each activity to arrive at a **cumulative total duration for each sequence** (fig. 3).
The activity sequence with the **longest duration** is the critical path.

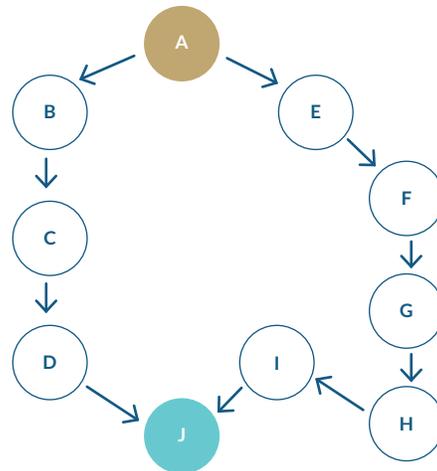


figure 1

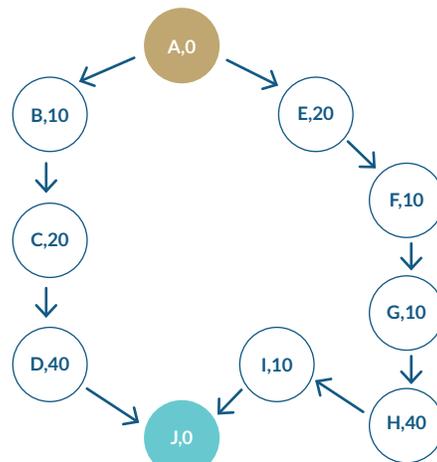


figure 2

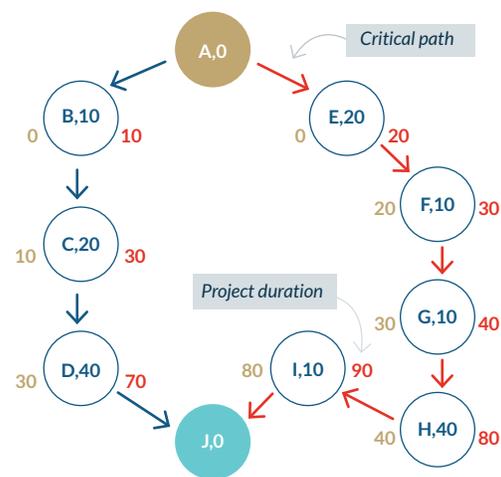


figure 3

- Optionally, you can **determine “floats,”** or the amount of time activities can be delayed without affecting the project (fig. 4). This can help in **resource planning** as high-float activities can have their resources diverted for higher priority tasks.

To calculate float, subtract the total duration of the second-longest sequence of activities from the duration of the critical path sequence.

The difference is the float for each activity in the second sequence. If

there are any common activities in both sequences, it will have a float of 0 since it’s also on the critical path. Do this for other sequences to measure float for each activity.

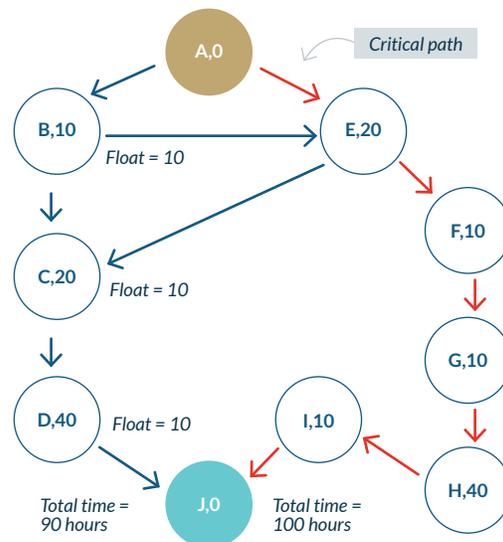


figure 4

Advantages:

- Effective scheduling.** Mapping the duration of activities and their interdependencies helps in scheduling tasks. If one task depends on another to be finished first, CPM will help you identify and schedule accordingly.
- Prioritization.** CPM’s success depends on identifying and mapping critical and non-critical activities. Once you’ve mapped these activities, you can prioritize resources better.

Disadvantages:

- Some experience required.** Estimates tend to be optimistic. If you don’t have actual experience with scheduling, you are bound to miscalculate time for each activity.
- Rigidity.** Like the Waterfall method, CPM requires everything to be planned out at the start. Changes can ruin scheduling, so if you foresee requirements changing, choose another model.

When to use it:

CPM is great for projects with interdependent parts. If you require tasks to be completed simultaneously, or for one task to end before another can begin, it's ideal.

NEXT STEPS

Need expert assistance identifying or closing gaps quickly and completely following a gap analysis?

The FDA Group's large network of quality and compliance specialists have extensive knowledge and experience in relevant regulations, guidance, and best practices related to quality system management throughout the regulated life science industries.

Our resources can be utilized to meet the wide range of quality and compliance requirements throughout the life sciences, as well as to support staffing assignments, lead and manage related activities, bridge staffing gaps, and provide long-term or interim leadership.

Contact us to learn more about fulfilling specific quality and compliance staffing needs. We help life science organizations secure a wide variety of specialists with the perfect combination of qualifications, experience, and motivation for succeeding in challenging and demanding projects--all at a competitive rate and backed by a Total Quality Guarantee.

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