Pharmaceutical Scheduling Issues: Bringing New Treatments to Market

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Abstract

Over the past fifteen years, the authors have worked with several of the top pharmaceutical companies in the world. In this paper they share the experiences and techniques they have used to help large pharma companies gain dramatic improvements in on-time performance and start-to-finish project durations (cycle times), without adding additional resources. The introduction outlines the overall situation in the pharma industry today, along with some of the potential for improvement. The second section describes where benefits can be attained: why, for example, a double-digit improvement in project cycle times is realistic. The paper continues by explaining how the Critical Chain scheduling approach can be used to gain these benefits, and then describes how to approach the needed culture changes.

Introduction

The world of pharmaceutical product development is undergoing significant changes. Hugely profitable blockbuster drugs are fewer and farther between. Development times are increasing, partly due to the complexity of products and partly due to increasing regulatory oversight. This leads to increased costs, along with a reduction in the time a compound is protected under patent law. And even when a profitable new product hits the market, competitors may follow quickly with drugs that have similar characteristics.

All this means that every day and every dollar is crucial for the pharma industry. For those rare products with potential sales of a billion dollar per year, each day earlier that it hits the market can be worth several million dollars. While many companies want to keep their competitive advantages confidential, the potential for benefits is clear. One large pharma company reported improvement of on-time performance from about 60% to 100% (Merrill, 2009, p 14); another spoke of 30% improvements in cycle times (Conard, 2011, p 5).

The pressures, and the potential for benefits, have led in recent years to adoption of various technologies in search of benefits. Project management has been of particular interest; we will focus primarily on Critical Chain management in late-stage drug development as an enabler of huge potential benefits in most large pharmaceutical organizations. However, this discussion is not just for pharma companies; we have found these same lessons be valid across many verticals and sizes of companies.

The Problem

In our experience, project scheduling is fairly similar throughout the pharmaceutical world. Various compounds are analyzed for potential in treating different kinds of conditions. The most promising ones, those that seem likely to be effective and safe based on scientific study and tests in animals, start several phases of clinical trials in order to test safety, efficacy, and dosages. These tests can last many years, and on average only one in 6 compounds starting this process actually appears on the market (Tufts Center for the Study of Drug Development, 2010, p 4). Different countries have different regulatory requirements. Meanwhile,

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approved compounds may be tested and approved for new uses, allowing companies to legally promote those new uses.

The pharma project environment can be extremely complex. A large company may have scores of drugs in the pipeline, each with multiple clinical trials in process, and each trial having hundreds or even thousands of patients across dozens of sites and many countries. Work involves many different disciplines, from chemistry and biology to manufacturing, packaging, and data analysis. Competitive pressures are pushing these companies to do more with less, meaning each person may be involved with several different projects. The need to manage this complexity in an efficient way has evolved into an approach we call "Deadline Management."

Deadline Management

From a project scheduling perspective, the ultimate indicator for managing a compound is its *final* milestones: expectations of when the compound should be on the market in different countries and generating revenue. These final milestones are typically set by analyzing anticipated requirements for the drug, coupled with baseline historical data. They are broken into *major* milestones that represent significant events along the development process: first human dose, first efficacy dose, and so on. Traditionally, these major milestones are broken into even smaller *mini*-milestones, for example individual clinical trials and pieces of clinical trials; and sometimes even smaller "inch-stones." Together, these milestones comprise the project's schedule, as shown in Exhibit 1.

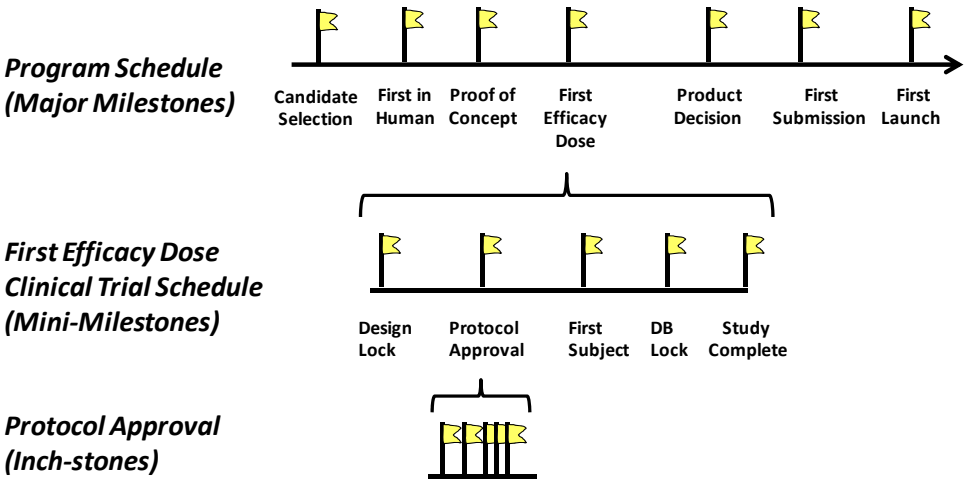

Exhibit 1: Milestone Plan

It is common practice in pharma for milestone dates to serve as more than a forecast of future events. They are also commonly used as the basis for both project control and personnel management. This is done by treating milestone dates at all levels as *deadlines*. The underlying theory is that if all the milestones are achieved on time, the project will be completed on time. Projects are considered "on track" if they hit their milestones/deadlines (at all levels), and in trouble if they are late. To provide stronger incentives, people are measured based on performance relative to deadlines. Bonuses depend on good performance; missing deadline dates can have serious consequences. As a result, milestones end up driving the schedules and driving urgency.

Treating what was originally intended to be a forecast as a deadline has some serious negative consequences.

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Each milestone date in the project has to be estimated. Everyone knows that there is some uncertainty to how long things will take, and meanwhile they know that their estimates will be used to set their deadlines. This creates a strong incentive at the work level to add safety time to estimates. This incentive is, of course, in direct conflict with incentives at the top of the organization to deliver new products faster. As a result, the estimating process is transformed into a negotiation process between managers who are looking for more speed and those who are measured by whether they hit the deadlines. The resulting milestone dates inevitably include safety time. The amount of safety time, rather than being dependent on the actual work required, is more often dependent on the experience and negotiating skills of the individuals involved.

Deadline Management introduces serious problems during project execution. First, since the milestone schedule is driving behavior, the widely accepted concept of critical path and slack has little influence on prioritization. Instead, urgency is determined by those deadlines that are most imminent. Some effects of this can be seen in Exhibit 2, a very simple project schedule with boxes representing tasks and arrows representing dependencies.

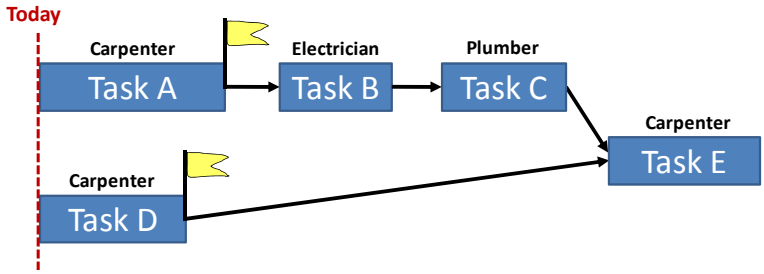

Exhibit 2: Milestone Urgency

If there is only one Carpenter resource to work on this project, the Carpenter must choose between working on Task A and Task D. In order to help the project complete as quickly as possible, Task A should clearly be worked first, because it is on the critical path. If the only data available to the Carpenter are the deadlines (milestone dates), there is a good chance she will start work on Task D because it is most imminent. When she makes this choice, she will be delaying the entire project. Thus, the priorities implied by deadlines can easily result in delayed projects.

A second execution problem is that tasks are rarely completed early. To complete a task prior to the deadline is to erode your negotiating position the next time a schedule is created. Suppose, for example, you were to negotiate for a commitment date of two weeks and then deliver in one week. Chances are you would not get a full two weeks the next time you were required to do a similar task. The cumulative effect of taking away the possibility of finishing tasks early is devastating to the chances to complete a project on time. If tasks can only be late, you may have trouble putting in enough safety time. Even if everything has a 90% chance of completing on time, putting ten such items in sequence gives you less than a 35% chance of finishing the last item on time.

A third execution problem is greatly diminished transparency into real status and real issues. Over time, the us-versus-them tenor inherent in schedule negotiations can erode trust to a level that real status and real issues are intentionally veiled. One associated syndrome is referred to as “schedule chicken” (Schedule chicken, 2009). If several people are late, the first one to admit it gets the blame; the others get a reprieve. So people don’t want to admit they’re going to be late, and serious problems may not be identified until it’s too late to recover from them. Proactive project management is extremely difficult when trust levels are low.

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Finally, we have the worst effect of Deadline Management. If you have a task that requires about one week of work, and the task is due in two weeks, you are under-utilized. When there's too much safety time, people take on (or are assigned) multiple tasks. Taking on multiple tasks seems logical, but it means that people are typically juggling many things at once. Since the choice of what to work on is driven by urgency rather than a credible schedule, and since there are many projects and managers in the mix, people are virtually forced to multitask.

Multitasking

Multitasking, sometimes called "switchtasking" (Crenshaw, 2008, p 17), means switching between several tasks without completing any of them. Many people multitask their reading, switching back and forth between several books that they've started. How many books do you have on your nightstand? How many important tasks do you have on your desk right now? Deadline Management and its associated negotiations promote multitasking. Most people, in most organizations, multitask. We have found it to be endemic to large organizations in general and pharmaceutical organizations in particular. Search "monster.com" for jobs requiring multitasking skills and see whether this is considered a good skill or a bad habit in today's corporate world.

How does all this multitasking play out in a project? Let's start with a simple example, as for example in Simpson and Lynch (2000, p 3). Suppose someone has four one-day tasks to work on, as shown by the colored boxes at the top of Exhibit 3.

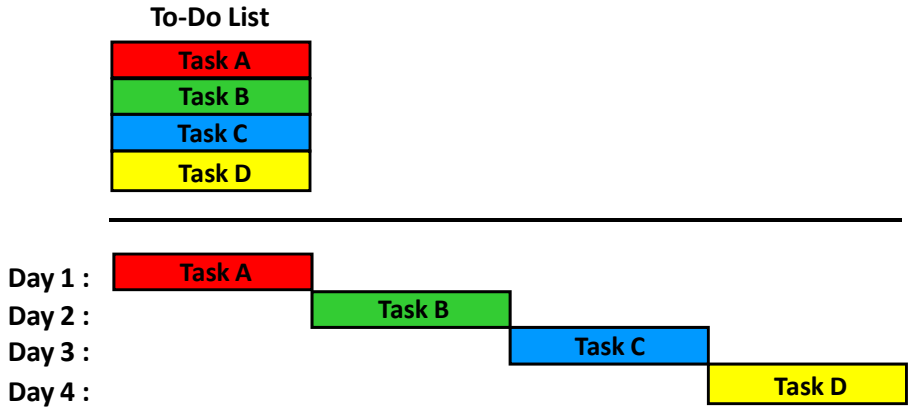

Exhibit 3: Multitasking (Ideal)

Ideally, these tasks would be worked one after the other, as shown at the bottom of Exhibit 3. Unfortunately, the reality is somewhat different, as people are subject to pressures from executives, various functional and project managers, and deadline dates. The work is most commonly multitasked, as shown in Exhibit 4.

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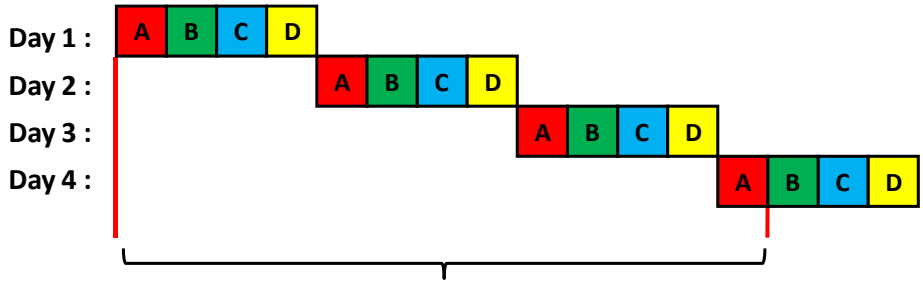

Exhibit 4: Multitasking (Reality)

This picture shows how, with one switch per day, each task takes over three times as long from start to finish. Notice that this does not include other penalties from multitasking. Task switching also creates quality problems (Loukopoulos et al, 2009) and adds time to projects through lost productivity (Crenshaw, 2008, pp 13-28).

Now let's consider how multitasking might affect an individual project. Exhibit 5 shows an ideal project plan, *after the project has been completed*. The boxes represent tasks and the lines represent links between them. Every task had a deadline and every deadline date was met; consequently, the project was delivered on time. This appears to be a wonderful success for Deadline Management.

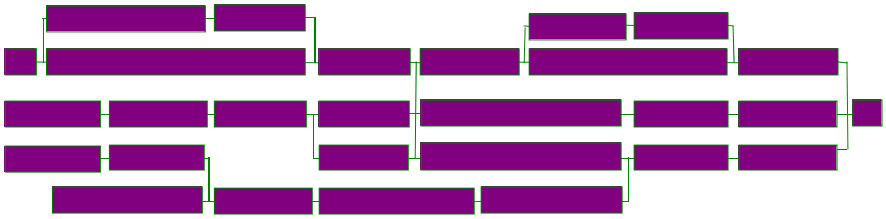

Exhibit 5: Perfect Project Plan

In Exhibit 6, the green boxes show the actual work that was performed. Work was put down and picked up many times, on many tasks. With the circled task, for example, someone may have started a little late, worked it enough to figure out they weren't in trouble, put it on the back burner for a while, and then put in a spurt of focused time – possibly involving weekends – to finish on time.

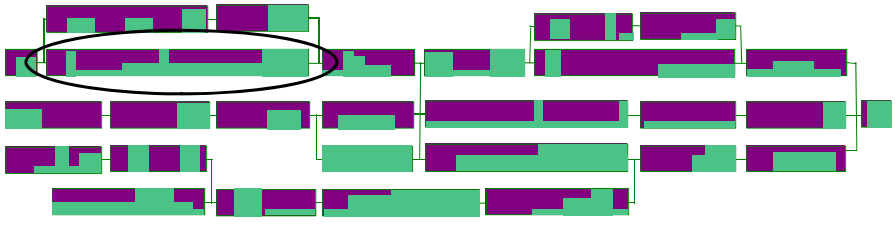

Exhibit 6: Reality

The picture depicted in Exhibit 6 clarifies several big problems with multitasking. First, we have no idea where the real critical path is at any time; it really depends on how much multitasking people do. So it's hard to tell people where to focus on any given project and have a real impact on the overall completion. Second, given the level of multitasking, management has poor information on the loading of individuals. That means

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they don't really know how many projects to start. The only way to be sure people are staying busy is to make sure there's more than enough work to keep everyone busy, which ironically is also enough to keep people multitasking. And third, the work sits around a lot. There is a lot of whitespace.

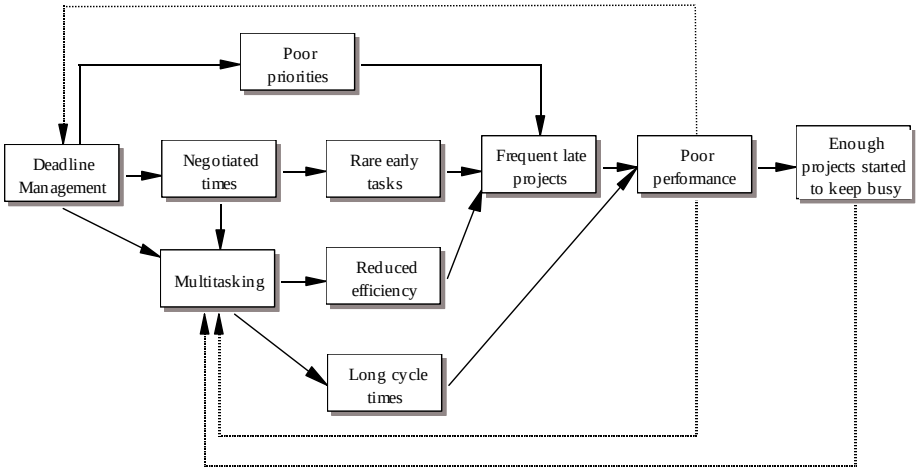

Exhibit 7: The Problem

Exhibit 7 shows schematically the cause-and-effect logic of the problem we have just outlined. We have seen it over and over in many industries, especially in the pharma world. Deadline Management leads to negotiated times, multitasking, and poor priorities; multitasking leads to reduced efficiency and long cycle times; and so on. The key to this picture is the dotted lines, which show *reinforcing loops*. Due to the poor performance, management places an ever stronger emphasis on hitting deadlines. People also have an even greater desire to have work queued up – that is, to multitask. And if we start enough projects to be sure people will be kept busy, we will have more projects active than can be worked without multitasking. The key question is, how can we keep work flowing and get rid of the whitespace? How can we get rid of the multitasking and chaos and move from Exhibit 6 to Exhibit 8?

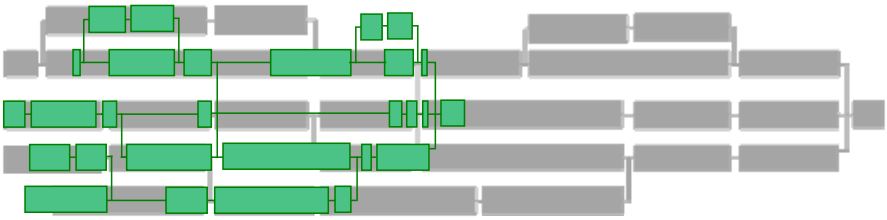

Exhibit 8: Objective

This is not just a theoretical exercise. There are tremendous benefits to be had. For most organizations, there are substantial differences between the best and the worst in terms of cycle times for similar projects. Within a single pharma organization we have seen multiple instances where there is a variation of a factor of 10 or more in cycle times for similar clinical trials. Applying the processes and discipline to reduce this variation and the average cycle times is potentially worth billions of dollars to a large pharma company.

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The Solution

The typical approach to Exhibit 7 is to do the same things better. If only we could create project plans that better supported our milestones, we would be able to set better deadlines, and then we could better hit our dates. This has, for example, led to a tremendous increase in the deployment of Enterprise Project Management systems in the pharma world. One leading EPM provider claims eight of the ten largest pharmaceutical organizations as clients (Planisware: Life Sciences, n.d.). Unfortunately, our direct observation of five of the top pharma companies in the world indicates that years of EPM implementation have resulted in minimal improvements to cycle times or on-time performance. In helping people to more easily apply the same Deadline Management techniques, these systems typically just reinforce the negative consequences outlined above.

We recommend attacking the core problems directly. Replace Deadline Management with a more credible and nimble planning and control system. Reduce multitasking by setting and promoting clear priorities. Change behaviors from "don't be late" to "as soon as possible." Our experience is that these three changes consistently produce dramatic improvements in speed, on-time performance, and productivity. They produce Exhibit 8. For some examples of potential benefits see Newbold (2008, p 5) and Simpson (2010).

Nimble Planning with Critical Chain

Milestones that serve as deadlines are first of all a measurement system. They create a sense of urgency because we are expected to hit the dates. In eliminating Deadline Management, the first question must be what measurement system to use to replace them. What will determine the urgency and drive it when needed? The answer we have found to be effective in pharma companies is "Critical Chain scheduling."

Critical Chain Scheduling

The single-project scheduling approach is described elsewhere in great detail, for example in Goldratt (1997), Newbold (1998), and Newbold (2008); but the basic pieces can be seen in Exhibit 9. Each green box represents a task and the green lines represent links between the tasks. Various elements of Critical Chain schedules are labeled from A to E.

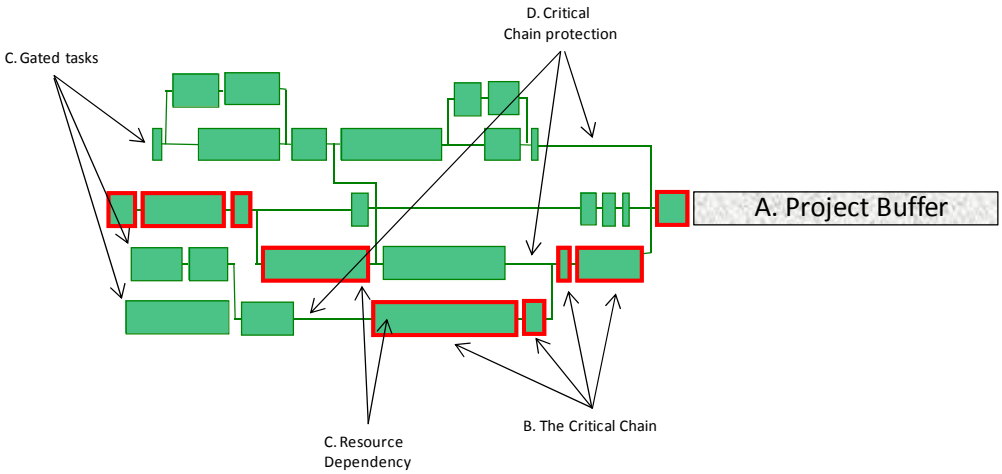

Exhibit 9: Critical Chain Elements

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Safety time is taken from individual tasks and consolidated into a "project buffer" (A) – a period of time designed to protect the customer. That means individual tasks are allowed to be late, and therefore their estimates need no safety time. We calculate the Critical Chain (B), defined as the longest chain of tasks taking into account resource dependencies and shown here in red. It shows which tasks are most important to early completion of the project. A *resource dependency* between two unlinked Critical Chain tasks is pointed to by (C). These tasks use the same resource and must therefore be scheduled to be performed sequentially. Note that a good Critical Chain schedule will solve the prioritization problem shown in Exhibit 2.

Non-critical tasks are backed off from the Critical Chain in order to protect it, and hence the commitment date, from variation on non-Critical Chain tasks (D); this is often done with the "feeding buffer" concept (Newbold, 2008, pp101-102). And non-critical tasks are moved or "gated" to the future when possible (E), in order that the task times will provide reasonable prioritization. The Critical Chain approach is designed to give a credible, well-protected schedule that allows us to correct many of the ills of Deadline Management.

The Project Buffer

The most important component of a Critical Chain schedule is the Project Buffer. By taking safety time from individual tasks, we allow safety time to protect delivery of the entire project. Project commitment dates are given as the end of the project buffer. People may be early or late on individual tasks, as long as the project buffer is not fully consumed.

The project buffer gives a sense of relative importance of lateness. As tasks move later or earlier due to inevitable delays and recovery plans, the buffer can be consumed or regained. The story of a project can be told from its "fever chart" as shown in Exhibit 10 and in Newbold (2008, pp111-115) and Newbold (2011, p 11). The horizontal dimension is percent of project complete: the current duration of the Critical Chain divided by the original duration, times 100. The vertical dimension is percent of project buffer consumed. As buffer is consumed, the project's status point may move from green to yellow to red, indicating a greater and greater likelihood of completing the project late.

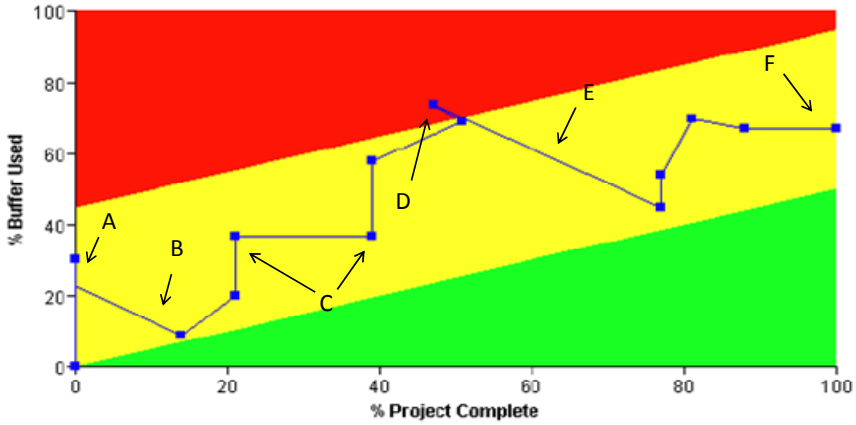

Exhibit 10: Fever Chart

Exhibit 10 shows a real, if somewhat simple, example from a small clinical pharmacology organization. The project started consuming buffer immediately (A) as samples were late from the customer, but was able to

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recover some time by alert execution (B). Unexpected equipment failures caused further buffer consumption (C). As the project status moved into the red zone (D), management visibility increased. Management instigated a buffer recovery plan consisting of working certain tasks in parallel and adding a resource for a short time period. The recovery plan was successful (E), resulting in project completion with buffer time remaining (F).

After several projects have been scheduled with Critical Chain, senior management will want to watch the multi-project fever chart, shown in Exhibit 11.

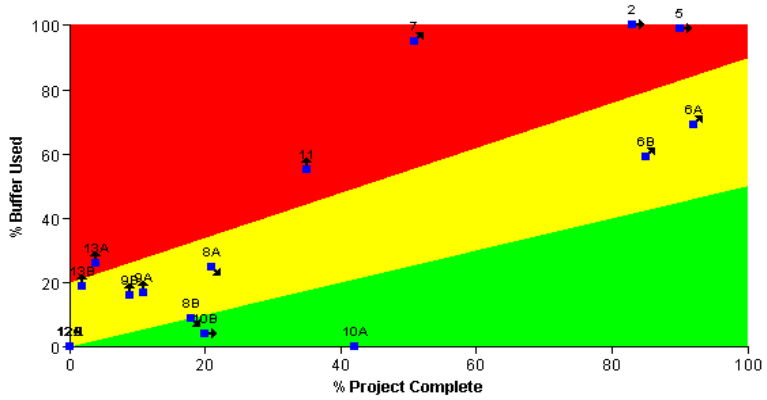

Exhibit 11: Multi-Project Fever Chart

The dimensions of this fever chart are the same as those in Exhibit 10. However, instead of displaying an individual project's progress, this chart shows a snapshot of a whole portfolio of projects. Management need not scrutinize each project; instead, they will probably focus attention and resources on projects that are in the red zone.

Here are some of the ways that the Critical Chain schedule helps to overcome Deadline Management and multitasking:

- Credible, visible plans, lack of safety time, and clear task priorities through task gating all help to inhibit multitasking.
- The replacement of milestones with buffers for status measurement reduces the need to make multiple, overlapping commitments.
- Critical Chain analysis allows us to identify key tasks and opportunities for speeding them up.
- Buffer management allows us to examine the impact of delays and determine whether or not they are significant.

Pharma projects can be scheduled with Critical Chain at the level of the molecule or the clinical trial, as shown in Exhibit 1. In our experience, the greatest benefits can be had by synchronizing entire molecules (and, ultimately, the entire portfolio). Even when Critical Chain is used only on individual clinical trials, we have found it to be straightforward to improve on baseline cycle times for key milestones by 30% or more. The project buffers provide protection that dramatically increases on-time performance, and the clearer priorities increase efficiency by reducing multitasking.

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Running the Relay Race

All this may seem straightforward, but there is a catch: there are no improvements without changed behaviors. Real, lasting benefits from Critical Chain scheduling require not just tools, but real culture change. And Deadline Management is strongly embedded in every pharma organization we have seen. The larger the organization, the more discipline, focus, and determination needed to make the needed changes. In this section, we describe a few of the techniques that we have found helpful; we recommend that you also consult Newbold (2008, pp195-231), Simpson (2010), and Scherer (2011) for a more complete picture.

We describe the needed switch from Deadline Management as the change from a "train schedule" to a "relay race" (Newbold, 2008, p 164). Milestones must be hit, in the same way that the times in a train schedule must be hit. In an ideal world, the train schedule's times will be neither early nor late. The "relay race," on the other hand, relies on speed and quick handoffs. There is a "get it, work it, move it" mentality that contrasts sharply with the train schedule mentality of "don't be late."

The relay race requires clear priorities. If people are not sure what to work on, there is a good chance they'll multitask. Task-level priorities can come from Critical Chain schedules. In order to minimize multitasking between projects, we also need project-level priorities that come from portfolio management. A discussion of portfolio management is beyond the scope of this paper, but a reasonable starting point is Levine (2005).

Exhibit 11 compares the train schedule with the relay race.

Train Schedule	Relay Race
Hit your milestone dates.	Make or exceed *project* commitments. (We care about the project, not the individual tasks.)
Make steady progress on multiple, overlapping commitments.	Work one task at a time, as quickly as possible, without multitasking.
Track the likelihood of milestones being met.	Identify opportunities for improvement.
Play "schedule chicken."	Identify obstacles early.
Negotiate.	Analyze.
Add hidden safety.	Manage the buffer time.

Exhibit 11: Train Schedule vs. Relay Race

The culture change is typically implemented in three main phases, outlined in the following sections.

Phase 1: Initial Planning

There are several key elements to planning for a major culture change. First is to identify the area in which the implementation will take place. For example, it could be for all projects in a clinical area such as oncology. It could be for all clinical trials.

An important early action is to establish a *senior leadership team* (SLT). The SLT is responsible for learning about the culture change and "walking the talk." They are responsible for setting implementation goals and

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evaluating progress. They should help to overcome obstacles. Most important, they must decide whether and when to roll out the approach to the entire organization.

You will need an *implementation charter* to define implementation success; this charter must be approved by the SLT. You will also need a *communication plan* that describes how you will set and maintain expectations in the organization. If you do not actively manage expectations, people will do it for you, in ways you don't expect.

And finally, you will need to identify some likely candidate projects for a pilot. We do not recommend attempting a Critical Chain implementation in a large organization without piloting. The pilot is an essential low-risk way of finding out what will be required in order to roll out the methodology.

Phase 2: Piloting and Measurement

The pilot process involves working with several project teams to implement the Critical Chain approach. The projects don't need to be brand-new. We have found that for clinical trials, pilots will generally start at some well-defined milestone (such as "study design approved"). Ideally the projects will be high priority, so that people will care about the benefits of success.

As the projects are scheduled and managed with Critical Chain during the pilot, various obstacles will arise. For example, in the pharma world various aspects of clinical operations are often outsourced, so it may be important to also have vendors run the relay race. Existing computer systems and tools will have to be considered for eventual integration with any Critical Chain software you use. Sometimes the project portfolio must be re-evaluated in order to provide clear project priorities. These obstacles may give rise to various *enabling projects* during the rollout.

During the piloting process, we have found it very useful to collect various measurements, for example:

- Clear value obtained during the scheduling process can often pay for the rollout all by itself. A disciplined scheduling approach can uncover significant new opportunities for speed and efficiency.
- Surveys help show how well the culture change is taking effect.
- Fever charts, as shown in Exhibit 10 and provided regularly to the SLT, show the Critical Chain approach in action.
- Lists of obstacles can be evaluated for importance and ultimately addressed with enabling projects.

These data are useful in determining whether to move to a rollout and how the rollout should be structured.

Phase 3: Rollout

A rollout consists of spreading the scheduling approach and the relay race culture to the entire organization. While detailed planning of a rollout depends on the specific circumstances, it will typically contain the following pieces:

- Continuing to schedule individual projects with the Critical Chain approach.
- Creation of internal Critical Chain experts, preferably through a rigorous certification process.
- Ongoing identification of opportunities for further improvement initiatives.

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- Ongoing monitoring of the implementation by the SLT.

The rollout in a large pharma organization should produce clear bottom-line benefits immediately, but the culture change could take two years or more to be firmly established.

Conclusions

Organizations that rely on Deadline Management, and as a consequence experience ubiquitous multitasking, have huge opportunities for improvement. Our experience in pharmaceutical organizations has demonstrated this many times. Promises of 15% reductions in cycle times during the first year with over 90% on-time performance are conservative.

We have found that Critical Chain scheduling provides an important toolset for addressing the root problems associated with Deadline Management and gaining these improvements. Management of Critical Chain buffers, coupled with the clear priorities from the schedules, can help to overcome Deadline Management and multitasking. In addition, we recommend a strong culture change effort, including explicit communication planning and formal senior leadership oversight, in order to help people run relay races rather than manage train schedules. We have found that most improvement initiatives do not address these highly leveraged areas and therefore tend to produce minimal bottom-line benefits.

We do not recommend embarking on a move to Critical Chain scheduling unless senior management has expressed a real determination to improve. Without that determination and leadership, people will take a "wait and see" attitude that will sap forward momentum and make the needed culture changes slow and painful.

The discipline established through Critical Chain scheduling and running the relay race also opens the door to further improvements. For example:

- Disciplined project management, including credible activity-based schedules, is a key foundation for good pipeline and portfolio management.
- World-class speed gives great competitive advantages when trying to address new markets.
- Skills of internal Six Sigma experts can be leveraged by having them address problems that cause frequent Critical Chain delays or buffer consumption.

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Originally published as part of the 2011 PMI Global Congress Proceedings – Dallas, TX