

Why are most Manufacturing projects delayed?

Forty leaders on where the time goes, and it is not where you would expect

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The Episodes

All forty episodes reviewed for this report, and the full set every quotation is drawn from. Quotations are not attributed to individuals. All the episodes are free to watch, and each thumbnail links to one.



Timelines are compressing faster than suppliers can serve them

Seven guests describe schedule compression as the defining condition of pharmaceutical capital projects right now.

A global quality engineering lead at a large pharmaceutical company gave the clearest account of the trend.

> *It used to be four years, it went down to three years, and from three years it went to two years.*
>
> **Global quality engineering lead, large pharma**

He went on to describe a project presented at an industry conference, planned from concept design through to completed qualification in 28 months. The observation he attached to it is the important one, and it frames everything that follows.

> *Which is actually very interesting because it could take almost half of that time for an equipment supplier to build their machines.*
>
> **Global quality engineering lead, large pharma**

That is the squeeze. The equipment build alone consumes roughly half the total programme, which leaves very little room for anything to go wrong anywhere else.

A senior leader at a large biologics CDMO, describing his own company's build cycle, said a plant can be up and running from groundbreaking to cGMP in two years, and called that unheard of. It is a useful benchmark precisely because an insider treats it as exceptional.

A projects and engineering manager at an API manufacturer put the counterweight plainly when asked what mistakes he sees most often. He named over ambitious timelines first.

> *So if a project takes two years, it's two years.*
>
> **Projects and engineering manager, API manufacturer**

The project manager described where those dates actually come from.

> *The other thing is sometimes these schedules are just pulled out of thin air... we're going to do the commissioning in a six-month period. And it's like, who came up with that? Well, that's what fit into the schedule, just like the budget... There's no basis for some of these things.*
>
> **Project manager, large pharma**

Projects start before the design is mature

Seven guests locate the cause of lateness before execution begins. This is the strongest analytical claim available, and the most senior voices support it.

The project manager's answer to the direct question was that projects start before they're really ready. He then explained why parallel working, intended to save time, often costs it.

> *They'll even get to the point where it's like, let's start the design and as soon as we get a piece of it let's start building it, and they think that's going to get us to the end faster. But what happens is they start building, they get ahead of design, or they don't do enough of the verification of design, and then they have to go back and rework, and so they end up making it longer.*
>
> **Project manager, large pharma**

A guest who heads digital technology, QA and quality engineering at a biotech described the consequence at facility level. Design problems had to be fixed before qualification could even begin, and he noted that two neighbouring sites had similar issues, one severe enough to prevent a product tech transfer on an investment of a few hundred million.

> *You always have to go back and you have to have a number of deviation and requalification... every time that you touch the clean rooms you have to perform a full qualification from the beginning.*
>
> **Head of digital technology and quality engineering, biotech**

The projects and engineering manager reached the same conclusion from the equipment side, and drew the opposite operational lesson to the one most organisations draw under pressure.

> *I never push my teams or my colleagues to spend lesser time on design, because the more time we spend on design and basic engineering the better for the project.*
>
> **Projects and engineering manager, API manufacturer**

A computerised systems validation specialist described the automation equivalent: clients who want delivery faster while arriving with less definition.

> *More and more getting customers who don't really know what process they want to automate, and it actually needs to be based on quite a lot of detail.*
>
> **Computerised systems validation specialist**

> *That's where the project lives or dies really. You get off to a good start, you'll have a good project usually.*
>
> **Computerised systems validation specialist**

A CDMO chief executive made the development-stage version of the argument.

> *If you don't do that, slow down to speed up early phase on the development on the technical front, and you rush into a GMP process, you may later find that in fact it takes you longer, or you have to revalidate some part of a process.*
>
> **Chief executive, CDMO**

A GMP consultant and a senior manufacturing leader with fifteen years at a large pharmaceutical company both made the same point, from operational readiness and stakeholder alignment respectively. The second said getting the design right at the beginning to everybody's satisfaction was harder than the construction itself.

Long lead equipment and supplier failure set the critical path

Nine guests, more than for any other finding, describe long lead equipment and supplier failure as the real critical path.

The most instructive incident in the whole corpus came from the projects and engineering manager. A glass lined vessel for a critical project had completed manufacture. During loading, a crane lifted it badly and it fell.

> *...they went through all the manufacturing process of the equipment, and while loading the equipment they had a small mistake lifting with a crane and the equipment fell down, and it is a glass line equipment, it got a crack.*
>
> **Projects and engineering manager, API manufacturer**

> *It takes again 3 to 6 months to coat it with a glass lining and cure it, and we need to wait a certain period of time to get it cured. If it takes 6 months it takes 6 months. We cannot make it 3 months because it's the process which it needs to go through.*
>
> **Projects and engineering manager, API manufacturer**

No amount of escalation recovers that time. The annealing and curing cycle is set by physics.

The numbers elsewhere are equally hard. The project manager described bioreactor lead times of around two years determining the critical path outright. A chief commercial officer at a CDMO gave the figure for aseptic filling capacity.

> *It takes three to three and a half years... when you get it implemented. So we know that we need to start that process now.*
>
> **Chief commercial officer, CDMO**

The projects and engineering manager also named the exposure that buyers consistently underestimate, which is not their supplier but their supplier's supplier.

> *To make one big machine there are lot of different parts to assemble together, and this particular manufacturer depends on their sub suppliers... we don't have any direct control over their sub suppliers. So if my supplier, my key partners outside my company... if they fail we fail together.*
>
> **Projects and engineering manager, API manufacturer**

A projects director at a sterile CDMO described the same fragility from a contract manufacturing perspective, saying organisations always think they can do more than they actually can and must build in contingency for materials that do not arrive. A vice president at a CDMO said any breakdown in a distributed supply chain causes big delays in the timeline. A chief executive noted meeting many potential customers who had been let down by their suppliers.

The digital technology and quality engineering lead added a failure mode that procurement rarely screens for.

> *You get a business bringing a supplier that might be good on paper, but when you start to really work with them they are lacking the necessary compliance knowledge.*
>
> **Head of digital technology and quality engineering, biotech**

Two countermeasures were named. The projects and engineering manager applies a 10% buffer to long lead items, and a chief commercial officer dual sources critical raw materials or holds stock. Neither should be read as an industry norm. Each is one practitioner's rule.

Change control and scope are where time and budget escape

Five guests identify change control and scope as the mechanism by which budget and time actually escape. The project manager, asked who is responsible when a project goes over budget, was unambiguous.

> *Normally, to be honest, the client controls the budget, and when I see things go over it's usually because it's not so much the EPC as the client managing the change control process.*
>
> **Project manager, large pharma**

He described the root cause as a client organisation unable to staff its own input in time. Decisions get made without it, then reversed when the client's own people finally engage. He also described unauthorised direction reaching engineers informally, through individuals rather than through process, as a routine source of rework.

The projects and engineering manager described the construction-phase version, where late client changes destroy contractors' ability to plan their own resources and materials, and produce conflict rather than cooperation.

A senior manufacturing leader, asked what he would do differently on the largest project of his career, named scope creep as his single regret.

> *Then I have definitely set stop at some point, when the scope creep just kept going.*
>
> **Senior manufacturing leader, large pharma**

The quality engineering lead placed the same issue at the front of his answer on why projects are delayed, naming clear scope and an executive sponsor as the two foundations.

> *Any project without sponsor is basically a project that could be stopped at any time, could be derailed at any time, decisions could change at any time... The sponsor basically acts as the filter between the capital project team and executive leadership.*
>
> **Global quality engineering lead, large pharma**

There is a genuine tension here worth stating. The project manager wants more formal change control, noting that many organisations simply do not have a process in place. A GMP consultant identifies regulated change control as the reason rapid improvement is so hard in pharma, saying that as soon as you put in a regulated change control process, Kaizen does not work. They are describing different mechanisms, project change control and GMP change control, but the tension is real.

Demand moves faster than capital approval

Six guests describe capacity being wrong before it is finished. This is the least covered and most distinctive finding in the corpus.

A board member at a pharmaceutical manufacturer, previously in senior manufacturing leadership at a large pharmaceutical company, described the early GLP-1 ramp. Capacity was not close to being adequate, and the forecasts the business was working from did not reflect what was actually happening. A factory head kept raising the issue in weekly meetings because orders were arriving at a rate nobody had seen. The investment could not be justified on the forecast, so it was made anyway.

> *We cannot justify this but we better expand capacity so we ordered equipment we got it qualified and... we were following it minute to minute because we were behind and we just needed that extra capacity.*
>
> **Board member, pharmaceutical manufacturer**

A senior manufacturing leader described the same dynamic on an API expansion. The asset was scoped at three tons. Before construction started the requirement had doubled, and before the build was finished it had quadrupled.

The capital approval process is itself the delay mechanism here. A business case built on a forecast cannot authorise capacity the forecast does not show.

The handover into that capacity fails just as often. Six guests describe tech transfer breaking, and a general manager commercial at a CDMO named the physical cause most precisely.

> *That synapse sometimes could be the death of a project. All of a sudden you try to transfer it to a plant that has, I don't know, XYZ homogenizer. It's not the same as what they did on the lab. Now it doesn't work. Now we don't get the suspension.*
>
> **General manager commercial, CDMO**

The board member described a footprint change and tech transfer that hit unknowns and left the company unable to supply a critical medicine, a failure he later had to explain in person to more than three hundred doctors. A division president at a CDMO said site integration runs a year or two before a team feels settled. A chief executive noted that US sterile CDMOs are

over booked, which puts pressure on tech transfers. A GMP consultant described the queue effect: a failed batch at a CDMO can put a programme at the back of a long line, with licence submission and launch plans behind it.

Validation effort is misallocated, and rework is built in

Six guests describe validation and qualification effort being misallocated, with rework built into the standard model.

The digital technology and quality engineering lead provided the clearest before and after. A first validation using full CSV scope, against gaps in business process, documentation and supplier, took a painful year. Version two, using a risk-based approach with an external test team and some test automation, did not.

> *That cut down the validation of the system from one year to 4 and 1/2 months.*
>
> **Head of digital technology and quality engineering, biotech**

He also warned that without a clear framework, teams over qualify simple equipment that only needed commissioning.

The validation specialist described where the effort goes instead.

> *Sometimes the whole focus got on to be the evidence that it worked rather than making the software work.*
>
> **Computerised systems validation specialist**

Writing an industry good practice guide on process control systems, she and a co-author identified duplication that is structural rather than accidental: a siloed split between commissioning and qualification teams handling process equipment and computer systems validation teams handling the systems that control it, with the same risk analysis performed twice. As they put it, there is no need at all for the computer systems people to be doing that same analysis over again, but traditionally they have been.

A quality and compliance lead at a contract research organisation named the cultural driver.

> *Just to be sure. So the risk management, the critical thinking test, nothing can happen, but just to be sure we still do it.*
>
> **Quality and compliance lead, contract research**

A manufacturing technology manager at a biopharma company described the opposite failure, sites avoiding revalidation for decades and losing the time and money that optimisation would return. He also described inspection variability directly: an observation raised, fixed, and then queried the following year by a different inspector from the same authority who could not see why it had been an observation in the first place.

The quality engineering lead added a practical trap at the construction interface. Construction documentation and qualification documentation demand different rigour, and teams that do not know which is which create rework on systems like water for injection that must be qualified but are built by a construction contractor.

Skilled people are the constraint, and standardisation the one recovery

Seven guests describe skilled resource as the binding constraint. The quality engineering lead connected it directly to compression.

> *There is a huge demand from every manufacturer out there on people to accelerate projects... So at certain point of time, you're going to have a shortage of resources or skilled professionals who are capable of doing this.*
>
> **Global quality engineering lead, large pharma**

A senior manufacturing leader described the structural fix his former employer adopted, separating the capital organisation from operations so that projects stop competing with production for the same people, because that is a fight nobody can win.

A CDMO chief executive named a subtle failure during hiring ramps.

> *Suddenly that batch record that worked for the last 5 years with an experienced team might not work so well anymore with somebody who reads for the first time.*
>
> **Chief executive, CDMO**

A division president described the same pressure on standards during scale up, and its schedule consequence.

> *If you see somebody kind of shortcut quality, it's going to kill the timeline because you're going to end up with rework.*
>
> **Division president, CDMO**

Five guests point to the same answer, and it is not working faster. It is needing less bespoke engineering. The chief executive of a biologics CDMO gave the numbers.

> *Our brand new facility... was 5 years in the making... A second phase will be four years. We know we have already saved 70% of the engineering cost and time... and the next phase will be 3 years.*
>
> **Chief executive, biologics CDMO**

He also named the habit standardisation removes, saying engineers are creative people who want a slightly better way of emptying a tank, but that it does not necessarily matter for patients.

The senior manufacturing leader quantified the same effect at design stage, saying a repeat build cuts easily a year out of the design phase because the conceptual work has already been done. The quality engineering lead described modular construction and parallel working, shipping equipment to a modular builder and delivering complete rooms to site. The GMP consultant described prefabricated single-use facilities mobilised in eighteen months.

This does not contradict the front-end finding. These leaders compress schedules by removing work through replication, not by doing the same work faster.



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