

Get agile – deliver faster

Trish Melton describes the faster-track approach to project management

THE biotech business has set engineering consultancies and contractors a new challenge: design, build, commission and validate new facilities to manufacture biotech products as quickly as possible. This isn't a false need – just look at the business drivers facing biotech companies, such as the growth in biopharm/biotech products, the overall shortfall in worldwide capacity, and the real customer need for a speedier time to market for drugs.

faster track

A faster-track approach involves doing things differently, not just speeding up individual activities, although that's important too. It is all about being agile. Agility in today's engineering and manufacturing environment means reducing waste and getting it right first time. 'Waste' is anything that doesn't add value to the end customer. A truly agile company can reduce the overall cycle time of activities generating its product or service whilst still being effective and efficient in meeting clients' often differing needs.

So, how do we do this? There are a number of areas that form the basis of the development of a faster track delivery strategy on behalf of a client. Of prime importance is the formation of a 'real' partnership with the client. This is

because client-contractor conflict is pure waste and rarely adds value to either side.

Secondly, it is essential to develop an understanding of a client's business drivers, and so determine what is truly adding value in the project lifecycle. Anything else is waste – get rid of as much of it as you can. And thirdly, it is important to empower the team to make professional judgements to move the project forwards, and so become agile.

There are a number of considerations we need to address right from the start. For example, what are the decisions we can make early on, based on less certain information, to help move the project forwards? What are the critical decisions linked to the business lifecycle, that require detailed information? Make these as late as possible, based on the most up-to-date information available, to ensure they are right.

Then, we need to consider the criticality of change control and management in this 'flexible engineering' environment. Be innovative and develop non-traditional design, procurement and construction strategies, and make sure you build in regulatory compliance – so that compliance is part of the process of delivery of customer value. Using 'best practice' project management – essentially good delivery planning linked to the needs of the project – will have the effect of pulling everything together.

case study

A medium-sized biotech company making small-scale clinical trial material already had customers for the large-scale manufacture of material for launch into the market. The company had demonstrated a technical capability, but at a completely different scale and within a different regulatory framework.

The first hurdle the company had to jump was to understand the scale required in manufacturing terms, so it could determine whether this required changes to its existing manufacturing plant – for example, to make more small batches and make them faster – or if it needed to build something entirely new, perhaps to produce appropriately sized batches at a cycle time to meet its customers needs. For each option the company also needed to assess the regulatory requirements. For example, the company may want to ask itself if it could meet the compliance needs of the Food and Drug Administration.

A decision flowchart (Figure 1) demonstrates that the only route to manage the business is to find a way to design, build, commission and validate a new facility at a larger scale within a 15-month timescale.

The key to success in this particular case involved developing a unique approach to each phase of the project – from set-up, through design and procurement to commissioning and start-up (see Figure 2).

Figure 2 shows how the information flows. The interfaces between the various project phases show where a change in approach is needed. It highlights, for example, the importance of removing functional engineering, operational and organisational boundaries, the elimination of 'handover' between the design and site teams, and parallel working and a constant flow of information.

The project team – a single team – is already seeing the benefits of this combined innovative approach, and the additional time spent planning 'up front' is reaping benefits now as the build progresses at a rapid pace.

Several innovative strategies can be identified in this case:

- client management – this aimed to avoid the 'typical' client-contractor relationship, particularly regarding the management of change. In this case, change is the norm. It has to be if the critical path is to be shortened. And by

agile (adj)
1. able to move quickly and with suppleness, skill, and control
2. able to think quickly and intelligently

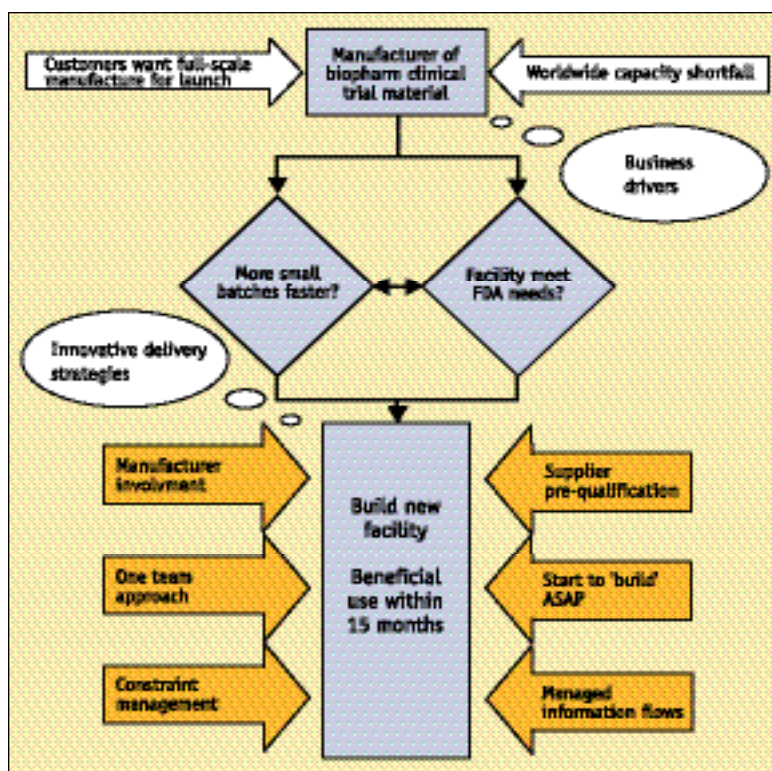


Figure 1: Fast track strategies

building relationships with all stakeholders in the client organisation, it is possible to understand their differing perspectives.

- design – starting design without a process' meant that in order to reduce the critical path the process and the building needed to be designed in different time frames whilst maintaining an integrated compliant approach. This was achieved by determining the generic nature of the process from fermentation to purification to separation, and by building in good manufacturing practices (GMP) to each aspect of the design. 'Freezing' the design progressively assured integration of the process and building. Other strategies included determining the client's operational requirements during all aspects of the design, and identifying non-critical constraints that we can flexibly engineer the plant within, (such as utility requirements, etc).

- procurement – this started when the project started or, to put it another way, the contract strategy for all parts of the facility was developed at an early stage. The project time-line was effectively 'procurement-led'. This identified those areas where single source procurement or competitive tender were the appropriate approaches – negotiating with the 'best in breed' gave more added value in some cases than a typical tender/bid appraisal process. In any event, all vendors were pre-qualified before design was complete, and the link between detailed design and vendor was formally managed as a critical part of the project process.

- construction – the first element of design to be frozen was the footprint and so the civil engineering work could start; next was the building framework so that the steelwork could commence. From then on we looked at innovative ways to reduce construction on site. An example of the main solutions were the use of a specific building cladding which reduced the level of secondary steelwork required, maximising off-site build, and using the best contractors, even if this meant we had more interfaces on site. After all, as professionals at managing contractors we are not introducing additional risk.

Validation must also be considered. What was once an exercise in pulling together a paperwork trial is now an effective value-added method of ensuring the ultimate safety of the product for the end patient. Compliance is built into the design from concept onwards and is appropriately documented using good engineering practice, where applicable.

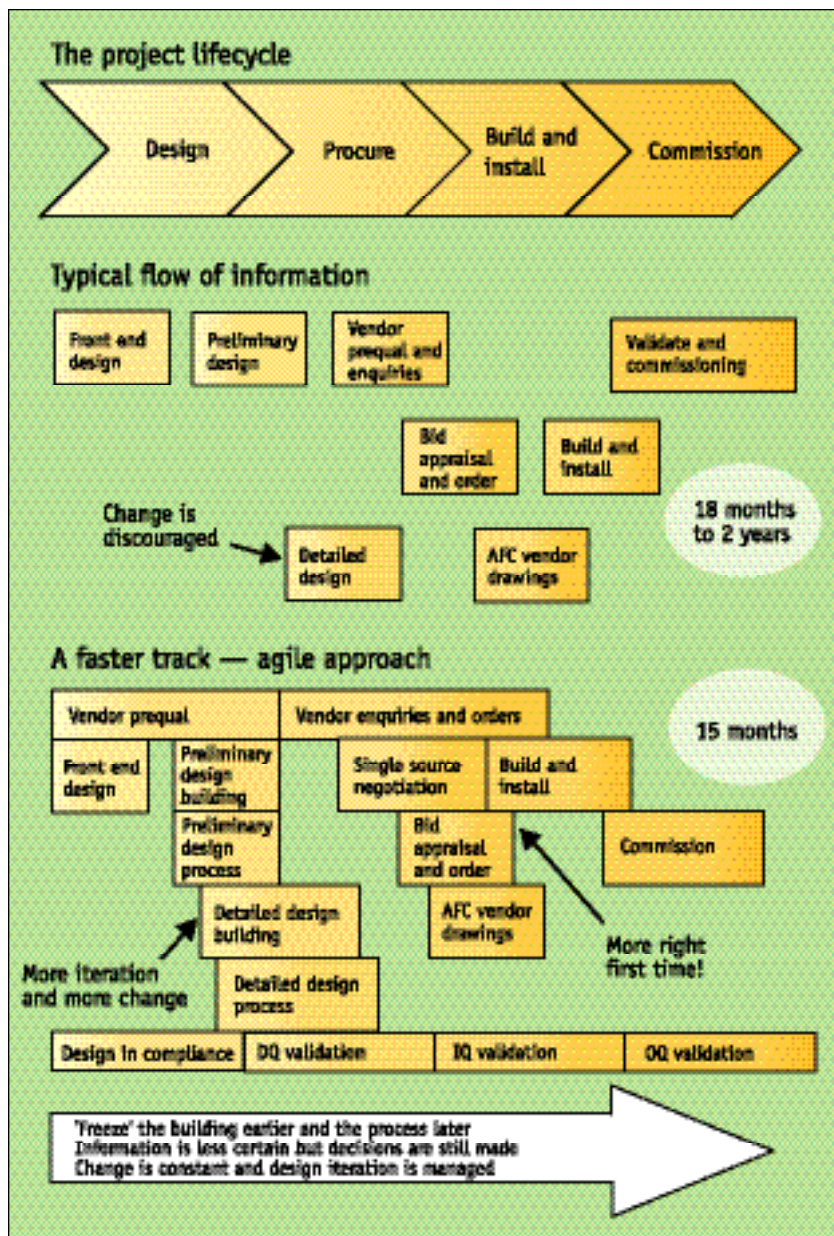


Figure 2: Project information flow

best practice

By pulling together a novel set of strategies the project management needed to be truly 'best practice'. In other words, it had to ensure that the right facility was built which was completely value added for the client. The development of a delivery strategy prior to project implementation addressed the client's critical success factors. Equally important was the need to review the traditional critical path – and then take out all the waste.

As a result earned value progress measurement provided data on the success of the strategies, and constant stakeholder management at all levels within the client organisation. A key delivery strategy was to move the lead for the project between different disciplines as required by the project phase – an architect-led front-end to

building freeze, a chemical engineering-led design as the process developed, a project engineering-led procurement (supported by the qualification team), a construction project management-led site construction, and client-led commissioning. This was achieved without compromising the overall project management control strategy.

So, to sum up, what makes 'faster track' really agile? It assures an understanding of the client's business drivers. It means truly working with the client, so that technical and project management capability really is the sum of all the capable parts of both organisations. It recognises that experts' help can speed a path through the process. And finally, it dares to be innovative and to do things differently – and that means both clients and contractors. ■

Trish Melton, who recently moved from GSK, is head of the PharmaChem division at Atkins Process and founder chair of IChemE's project management subject group