Assured quality saves money

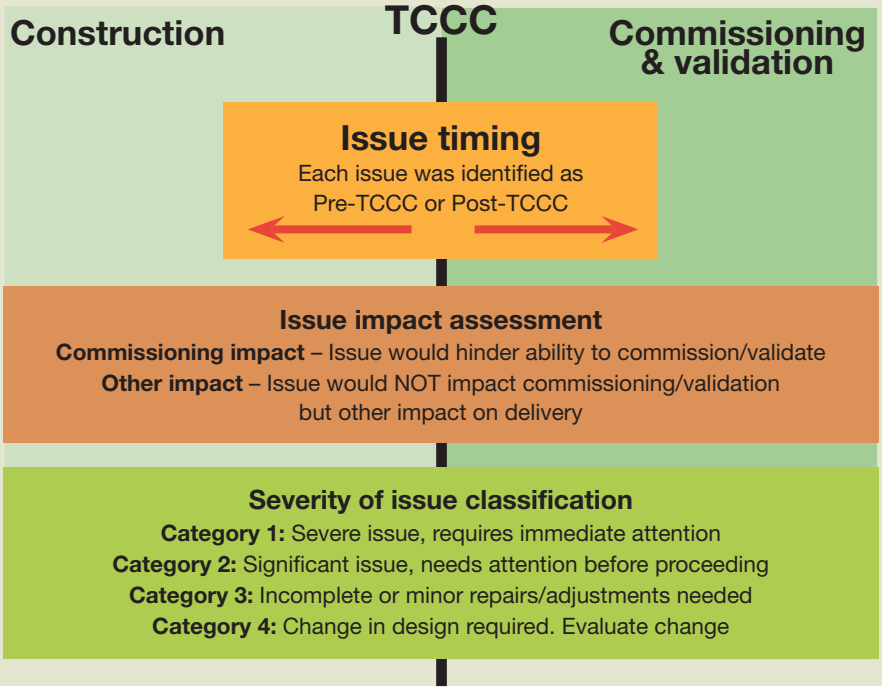
In harsh economic times, quality assurance is all the more important, say **Bruce Beck** and **Jay Lad**

CURRENT economic difficulties make it all the more important that businesses are efficient and productive in their operations, and this is no different in the construction industry where there's a constant dynamic balance of cost, schedule and quality. Obviously, the desire is always to have optimal performance in all three areas, but often quality is compromised at the expense of cost and schedule.

In recent years, significant work has gone into studying construction quality and specifically, how to reduce rework. Unfortunately, it's often been difficult to gather data and effectively analyse field quality performance.

We discussed how to manage construction quality in our article *Can we build it?* published in ***tce*** 841 (July 2011). We follow this with a case study, showing how Eli Lilly and Company successfully used a construction quality assurance (CQA) programme to manage a major capital project in Europe.

Figure 1: Issue timing and impact assessment



the world of pharma

The pharmaceutical industry is highly regulated and requires that manufacturers demonstrate that their processes are under control, capable of consistently producing quality medicines and above all are validated. In general, the world of pharmaceutical manufacturing is *precise*, heavily scrutinised and operates under strict QA/QC (quality assurance/quality control) rules. It can be characterised by its 'batch sheet' mentality.

In stark contrast, however, pharmaceutical facility design/construction is an evolving and *imprecise* world. It's a world where ideas, concepts and designs are developed by engineers and scientists, which constructors attempt to bring to reality. Project design often starts while the products are still in development and are yet to be fully characterised and understood. As a result, aspects of the facility often evolve and change during design and construction, leading – in extreme cases – to a complete redesign midway through a project.

For a long time, engineers have been trying to apply the batch sheet mindset of the manufacturing world to the changing world of engineering and construction, often resulting in escalating costs as well as large programme overruns and delays.

The challenge has been to merge these two worlds and bring a level of QA/QC competency to field execution.

Eli Lilly

In 2001, Eli Lilly found itself in an intense period of capital expansion worldwide. At the same time the industry was going through increased regulatory scrutiny of manufacturing practices and validation of new facilities. This resulted in more rigourous testing and verification of system design, installed equipment and operation, and the documentation and rigour of testing requirements increased significantly.

Lilly addressed these increased demands by developing and implementing a robust commissioning/validation programme, which significantly improved cost, time and quality. However, as it improved its programme it began to realise that field quality issues were having an adverse effect.

Therefore, in 2005, Lilly began to examine the impact of construction quality on the programme and soon concluded that construction deficiencies and poor field quality management were a significant hindrance. Each time a construction issue was found, the company had to halt commissioning and re-engage the construction team to rectify the issue – costing time, money and more importantly compromising schedule.

As a result, Lilly sought to develop a QA/QC programme in the field to avoid similar problems in future.

task at hand

In 2007 Eli Lilly committed to build a new US$400m biotech facility in Kinsale, Ireland which was critical to its long-term strategy in biotechnology. With almost US$0.5b at stake, Lilly was keen to ensure that the facility was delivered on time, within budget and provided a return on invested capital.

From previous experience, the company recognised that good construction quality was key to ensuring the quality of the finished facility and avoiding any negative impact on cost, schedule and knock-on effects on the overall performance of the facility post hand-over. As a result, a construction quality team was created within the overall construction management team to implement a construction quality assurance (CQA) programme for the project.

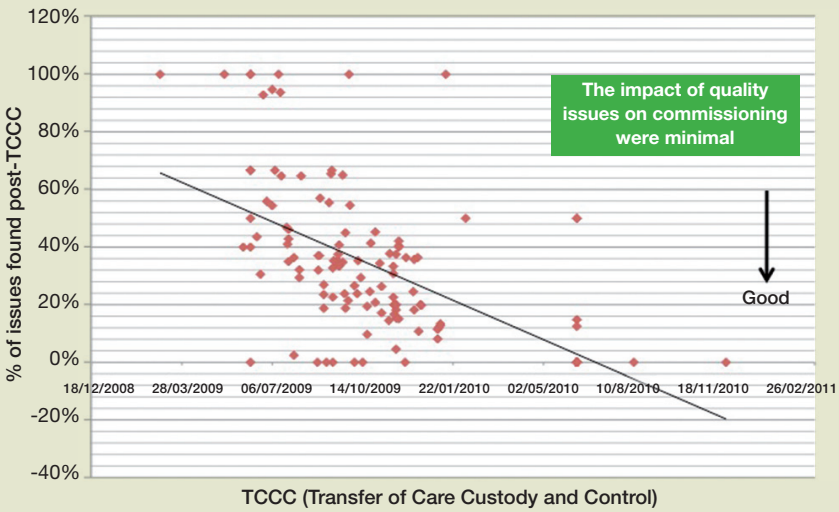
The primary aim of Lilly's CQA programme was to raise the importance of quality and self-inspections to the contractors in order to prevent deficiencies, minimise defective work and strive towards a zero critical items punch list. It was critical that field issues were identified early during construction and resolved quickly in order to prevent them from surfacing late in the project. As a result the CQA team conducted inspections, tracked issues and worked closely with contractors to assure quality of work and timely resolution of issues.

CQA programme

Lilly's CQA programme was a mirror image of its successful contractor safety programme. It comprised of three pillars:

Lilly had recognised that good construction quality was key to ensuring the quality of the finished facility and avoiding any negative impact on cost, schedule and knock-on effects on the overall operation produced

Figure 2: % of issues found post-TCCC that impact on commissioning



- pre-qualification of the contractor's quality programme;
- implementation of job specific quality plans; and
- the quality monitoring programme.

The CQA team took advantage of the latest construction field software, tablet PC and the internet to help implement its CQA programme. This allowed field inspectors to document, communicate and track issues throughout the project in one web-hosted database as opposed to historical approaches of notebooks, spreadsheets and emails. This not only improved the ability to record and track issues, but also provided valuable data for analysing effectiveness of the overall CQA programme.

issues in the field

Each issue identified by a contractor, inspector or other member of the construction management team was given a unique identifying number. There were several attributes assigned to each issue to properly assess and characterise the issue, such as description of issue, system the issue belonged to, priority of issue, commissioning impacting potential, and contractor responsibility.

Having this type of information in a database, accessible from anywhere in the world, gave much better and timely information on quality issues and status.

For the CQA programme to be successful it was crucial that at transfer of care, custody and control (TCCC) of each system (from the construction team to the commissioning/validation team) there were minimal quality issues that could impact on the commissioning/validation team's ability to proceed with its work. The intent was to have all or the majority of issues identified pre-TCCC and to track whether any issues could impact commissioning and validation. The team also classified each issue by severity. This classification identified the nature of the issue and urgency for resolution (see Figure 1).

the findings

Lilly recorded 10,990 quality issues during the Kinsale Biotech project, all of which were recorded, tracked with a unique identification number and often included a digital picture for ease of communication. These issues ranged from structural errors to instruments missing or not properly installed. Of the 10,990 issues identified, 78.8% of them were identified pre-TCCC, during the construction phase of the system. This meant that 21.2% of issues were identified post-TCCC during commissioning. While that was a disappointingly high proportion and raised initial concerns over the general effectiveness of the programme, closer scrutiny showed that only 0.49% of all issues were of severity level 1 or 2 *and identified* post-TCCC – showing that CQA was actually quite effective in preventing severe issues from impacting commissioning/validation.

The majority of the post-TCCC identified issues were severity level 3 and included items such as missing tags, labels, insulation and so on.

This project had 112 systems which were formally managed and turned over individually from construction to commissioning/validation. The percentage of issues found post-TCCC that impacted commissioning was graphed out (see Figure 2) and demonstrates that as systems were turned over throughout the project, the

Figure 3: Final project performance comparison

Categories	2010	2006
Facility type	Biotech manufacturing	Biotech manufacturing
Capital project cost	US$400m	US$400m
Project location	Kinsale, Ireland	Indianopolis, Indiana, US
Defined CQA programme?	Yes	No
Commissioning/validation peak staff	20 people	70 people
Commissioning/validation costs	<4% TIC (Total installed cost)	~10% TIC (Total installed cost)
Performance against budgets	Under budget	Over budget
Total commissioning/ validation duration	7.1 months	11.4 months

Conclusion: Kinsale facility delivered faster and cheaper!

number of issues identified post-TCCC decreased steadily, indicating continuous improvement in inspection and construction.

splitting the cost

Lilly's CQA programme cost around US$2m, split between labour and software. In addition around US$5m was spent on rework (i.e. 2.2% of direct cost). Studies by the Construction Industry Institute indicates that rework for projects of this type can typically run to 4–7% of direct cost, demonstrating that the CQA programme saved US$4.3–11.2m.

It's also worth noting that rework was largely addressed and paid for by the contractor rather than Lilly; contractors realised that Lilly's CQA programme meant field defects could be identified much earlier in the project, allowing faster resolution and quicker payment. Lilly realised that issues identified by the CQA programme may not have been discovered until much later after handover.

comparing projects

A comparison between Kinsale and a similar biotech facility built in 2006 in Indianapolis, US, which didn't use a formal construction quality assurance programme showed that the Kinsale project used less than half the number of people in commissioning and validation, which resulted in significant savings (see Figure 3). Kinsale came in under budget and completed commissioning and validation four months earlier than the Indianapolis project.

keys to success

Lilly identified several fundamental keys to success for the Kinsale project:

step 1: cultural change must be managed

CQA is not natural to many contractors and often requires a fundamental change in behaviour. Training must be deliberate, reinforced and verified to ensure changes in behaviour are taking place. It's important that the CQA team checks status routinely and maintains a positive emphasis. It's not negative to find issues, just like it's not negative to report an unsafe condition on a site. This was a challenge at Kinsale and we realise we should have put more emphasis on understanding and buy-in up front.

step 2: develop CQA plan for project

It's worth having a structured CQA plan for the project which defines expectations, process and roles and responsibilities for managing and assuring quality. This establishes a foundation for the programme and expectations.

step 3: engage contractors in the process

The more you engage the contractor in the process, the better. They must still own the quality of their work, so engaging them in the programme and creating a positive atmosphere is important. Reinforce that this programme is as much for them as it is for the owner. Key tactics included pre-work meetings with contractors to review specifications, drawings and approaches.

step 4: field inspection and reporting programme

Field inspection by well-trained and knowledgeable experts provided vital assessment of contractor performance throughout the project and adherence to quality commitments.

step 5: routine management of quality issues

It was very important to have real-time management of quality findings. This included identifying, assigning and resolving issues. On the Kinsale biotech project there were weekly (and eventually daily) quality review meetings with the contractors to review issues and make sure they were being resolved in a timely manner.

step 6: embrace technology

The technology used at Kinsale was extremely valuable in managing the CQA programme. There are a number of technologies available on the markets today which are very useful in recording, tracking and communicating quality issues. When selecting technology tools it's recommended that they should be user- and field-friendly, use digital cameras to capture issues easily, capable of extracting data for learning, and easily accessible from anywhere in world via the web.

summary

The Kinsale biotech project was a success in that it not only came in under budget and delivered ahead of schedule, but also the end users were able to start the processes in a timely, successful and sustainable manner.

The CQA programme was critical to the overall success of the project as it allowed early detection of field issues and faster resolution. This proactive approach to field quality resulted in fewer issues impacting the back end of the project. As a result, the commissioning/validation team was able to focus its attention and efforts on functional performance rather than construction rework.

conclusion

Good construction quality is a prerequisite for successful commissioning/validation. This case study shows that a relatively small investment upfront (ie 0.5% of total installed cost) in construction quality can bring huge benefits at the end of the project and beyond, reducing cost/schedule and ultimately helping speed products to market.

In reality, the true cost of failing to get your facility up and running on time is missing a launch date for a product, losing a race to market or not being able to maximise your revenue by not meeting market demand for a product.

Selecting a good constructor is obviously very important. However, deciding to implement a CQA programme early on in the project will have significant benefits in helping you deliver a facility on time, to budget, great quality, zero defects and accidents, good operability and maintainability, as well as high availability and reliability. Moreover, it should help guarantee a return on investment and value for money! **tce**

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