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Assured Construction Quality Saves Time and Money

by Jay Lad and Bruce Beck

This article demonstrates how Eli Lilly increased field efficiency and productivity, lowered costs, and improved overall build quality by implementing a proactive field quality assurance program and the latest technology.

Introduction

The global economic landscape has drastically changed, in recent years, resulting in a world of great uncertainty. The economies in the developing world are rapidly powering ahead, creating huge wealth and rising disposable incomes. In stark contrast, however, the western economies are stagnating, buried under huge mountains of debt with falling disposable incomes. If the western economies are to emerge from their current economic difficulties, they desperately need to focus their efforts on innovation, cost, and quality.

In the 1980s, Edward Deming's philosophies for quality management were introduced to American manufacturing and many companies began applying his statistical process control methods and quality management principles to production lines and business processes. Deming's work had begun in post-war Japan working with Japanese manufacturers and executives. His message to Japan's chief executives was:

> *"Improving quality will reduce expenses while increasing productivity and market share. By adopting appropriate principles of management, organizations can increase quality and simultaneously reduce costs by reducing waste, rework, staff attrition and litigation while increasing customer loyalty."*[1]

In today's market, "Less" is the new "More" and finding ways to drive up quality without increasing cost is the key focus.

In the highly technical and regulated world of biopharmaceutical manufacturing, life science companies are faced with falling revenues; largely due to loss of patent protection on their blockbuster drugs and a lack of pipeline for new medicines. As a result, the biopharmaceutical manufacturing world is focused on reducing costs, increasing efficiency and productivity, without lowering quality.

Similarly, from a capital projects perspective, there is also great urgency for controlling costs and assuring return on capital invested, especially for complex capital-intensive projects with long lead times such as in the biopharmaceutical industry.

Although companies cautiously continue to commit capital, there is more pressure today than ever, especially from a field execution perspective, to mitigate risks, accelerate schedule, manage cost, and drive up field quality performance. In addition, good operability, cost effective maintenance, and the entire "asset life" are becoming common key performance indicators for the value of the investment.

Large program delays, costly over-runs, and poor operability/reliability resulting from poor quality are no longer acceptable in today's market place.

For many years and with dramatic cost to our economy, the construction sector has been struggling with field quality issues resulting in commissioning/qualification delays and ultimately facilities with poor operability and reliability. However, this cost could potentially be reduced significantly if the industry were to embrace technology and apply Deming's philosophy of "quality" that has been used with great

success by the manufacturing sector of the economy.

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 analyze field quality performance.

The article, "Construction Quality: the Key to Successful Capital Projects Delivery," published in *Pharmaceutical Engineering*, November/December 2009 discussed how to manage construction quality. As a follow up, the two case studies below demonstrate how Eli Lilly and Company lowered costs and improved overall build quality for two new recently built facilities, one in the developed world and one in the developing world. The article also shares some of the field performance data, the challenges it encountered, as well as key learning points.

Background

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 rigorous testing and verification of system design, installed equipment and operation, and the documentation and rigor of testing requirements increased significantly. Lilly addressed these increased demands by developing and implementing a robust Commissioning and Qualification (C&Q) program, which significantly improved cost and schedule. However, as it improved its program, it began to realize that construction quality issues were having an adverse effect.

Therefore, in 2005, Lilly began to examine the impact of construction quality on the C&Q program 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 decided to develop a Construction Quality Assurance (CQA) program to avoid similar problems in the future.

Quality Program

The primary aim of Lilly's CQA program was to assure that construction contractors met design specifications, through a managed process, with the outcome resulting in a trouble-free C&Q program. The overall approach was to apply quality concepts and practices to the construction activities to ensure that the facility was delivered on time as specified, defect free, and in an operable state.

One of the objectives of our CQA program was to raise the importance of quality and self-inspections to the contractors in order to prevent deficiencies, minimize defective work, and strive toward 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.

Lilly modeled its CQA program on its "Contractor Safety Program," which had been highly successful for many years. The program comprises three primary elements, as seen in Figure 1.

- Pre-Qualification: contractor quality program assessment.
- Job Quality Plans: establish an expectation of having defined job specific quality plans that are developed and managed by contractors.
- Monitoring Program: a rigorous project quality monitoring program with immediate feedback to contractors.

It was important to Lilly that its CQA program was scalable and only implemented on projects that were deemed to be high risk. As a result, Lilly developed a quantitative approach to assessing risks, based on complexity and size of the project as seen in Figure 2.

Technology

Although significant work has gone into studying construction quality and specifically, how to reduce rework, it has often been difficult to gather data and effectively analyze field quality performance, as historically methods for collecting data have often relied on manual/paper-based systems.

However, recent advances in technology have made the capture and sharing of field information much easier than in the past. Today there are several web-based software applications that will allow you to easily assimilate, systemize, categorize, prioritize, and disseminate field performance information, including the capture of digital pictures. Therefore, when Lilly developed its field quality program, it decided to take advantage of the latest construction field

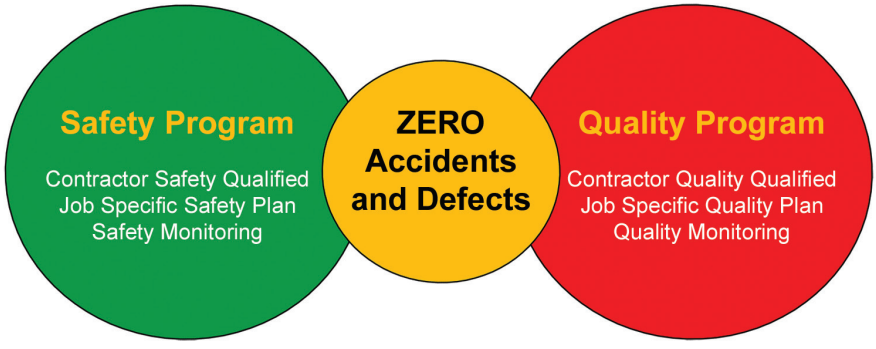
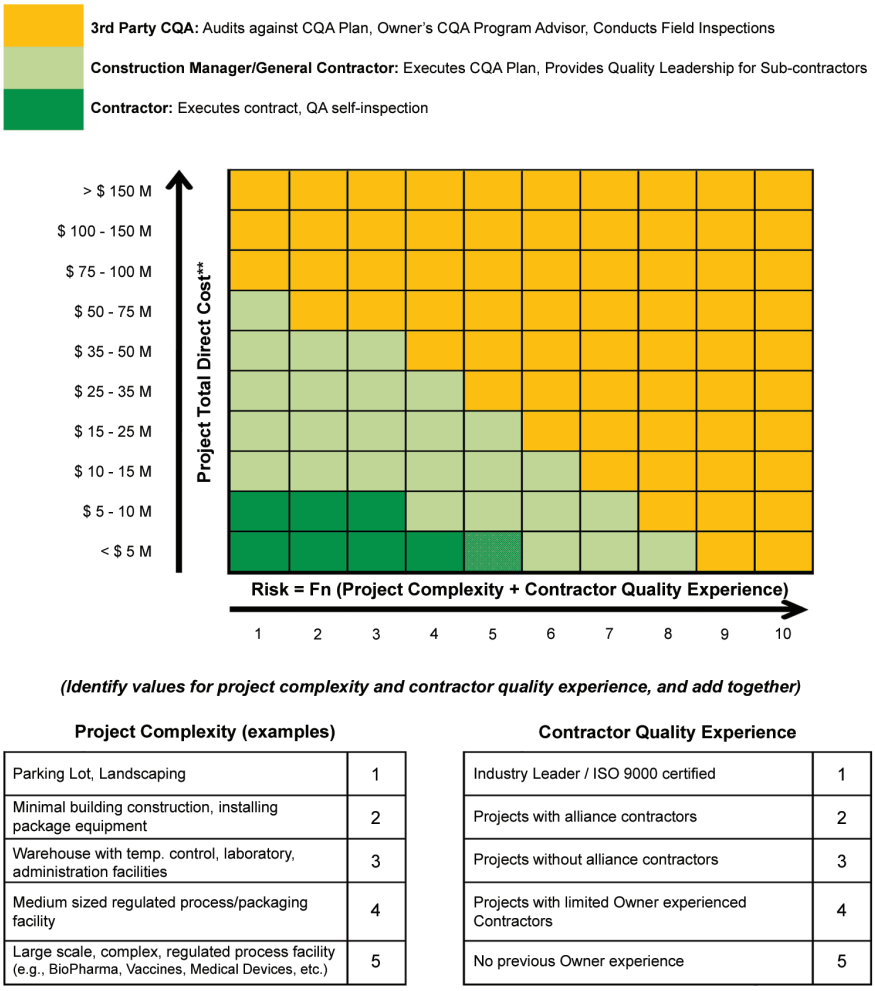


Figure 1. Construction quality modeled on safety program.



(Identify values for project complexity and contractor quality experience, and add together)

Project Complexity (examples)

Parking Lot, Landscaping	1
Minimal building construction, installing package equipment	2
Warehouse with temp. control, laboratory, administration facilities	3
Medium sized regulated process/packaging facility	4
Large scale, complex, regulated process facility (e.g., BioPharma, Vaccines, Medical Devices, etc.)	5

Contractor Quality Experience

Industry Leader / ISO 9000 certified	1
Projects with alliance contractors	2
Projects without alliance contractors	3
Projects with limited Owner experienced Contractors	4
No previous Owner experience	5

Figure 2. Project scaling.

software, tablet PCs, and the internet to help implement its program.

By implementing web-based tools, field inspectors would be able to document, communicate, and track field issues throughout the project in one web-hosted database as opposed to historical approaches of notebooks, spreadsheets, and emails.

Field Issue Management

Each issue identified in the field by Lilly was entered into a web-based field quality system and given a unique identifying number. Several attributes also could be assigned to each issue to properly assess and characterize the issue, including items such as:

- Description of issue
- System that issue belonged to
- Contractor responsible for issue
- Date identified
- Expected resolution date
- Priority of issue rating
- Commissioning impacting potential
- Root cause

The issue also could be classified by severity. This classification identified the nature of the issue and urgency for resolution as seen in Figure 3.

Having these tools not only improved Lilly's ability to record and track issues, but also provided valuable data for analyzing the overall effectiveness of our CQA program. The data allowed field inspectors to assess a variety of important factors for managing the CQA program such as:

- Time to resolve issues
- Number of open and closed issues
- Contractor and subcontractor performance over time
- Issues identified prior to TCCC and post TCCC
- Root cause assessment and patterns

For Lilly's CQA program 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/qualification team) there were minimal quality issues that could impact on the commissioning/qualification 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 qualification.

Case Study 1: Biotech Facility, Kinsale, Ireland

In 2007, Eli Lilly committed to build a new $400 million biotech facility in Kinsale, Ireland, which was critical to its long-term strategy in biotechnology. With almost half a billion dollars at stake, Lilly was keen to ensure that the facility was delivered on time, within budget, and defect free. As a result, it was decided to implement a CQA program on the project, utilizing the latest web-based construction field software and tablet PCs.

The Findings

The data generated from the CQA program was insightful and helpful in identifying future improvements. In all, Lilly recorded 10,990 issues during the Kinsale biotech project,

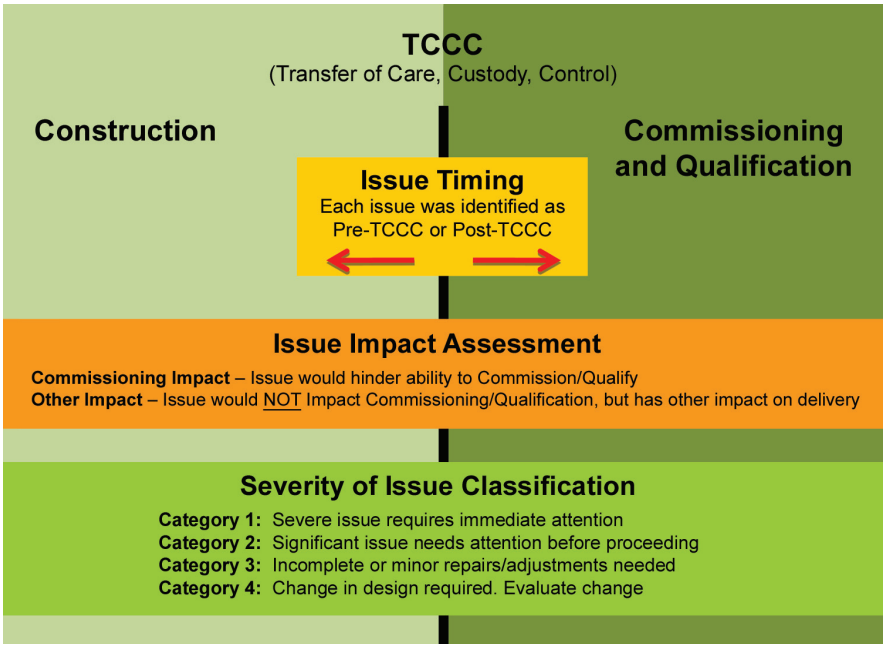


Figure 3. Issue timing and impact assessment.

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 this number, nearly 80% were identified prior to transfer to the C&Q team. This was important to understand since a key measure of success was understanding how many issues were being captured prior to transfer and not being identified by the C&Q team. Initially, this was very discouraging as more than 20% of all issues were identified after transfer to C&Q; certainly not what was expected and raised concerns regarding the effectiveness of the program. However, upon closer examination, the team discovered a very important distinction when they looked at the priority of the type of issues identified and when they were identified.

Lilly discovered that only 3.6% of the post-TCCC issues were severity level 1 or 2 (issues were ranked by severity 1 to 4 with 1 highest).

This was 54 total issues or 0.49% of the total (10,990) issues that were of severity level 1 or 2 and found Post –TCCC.

The program actually was quite effective in preventing severe issues from impacting commissioning/validation as seen in Figure 4.

It turned out that the majority of the post-TCCC identified issues were severity level 3 issues that included known and agreed omissions, such as permanent tags, labels, and insulation installation. The majority of the post-TCCC issues were conscious, deliberate decisions to delay completion, but tracked in the system to assure completion. Only 54 issues out of 10,990 issues were severity level 1 or 2 and identified post-TCCC.

Cost and Savings

Lilly's CQA program cost around $2 million, split between labor and software. In addition, around $5 million 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 to 7% of direct cost, demonstrating that the CQA program saved $4.3 to $11.2 million.[2] It's also worth noting that rework was largely addressed and paid for by the contractor rather than Lilly. In addition, contractors realized that Lilly's CQA program meant field defects could be identified much earlier in the project, allowing faster resolution and ultimately quicker payment.

Finally, Lilly also realized that some issues identified by the CQA program might not have been discovered until

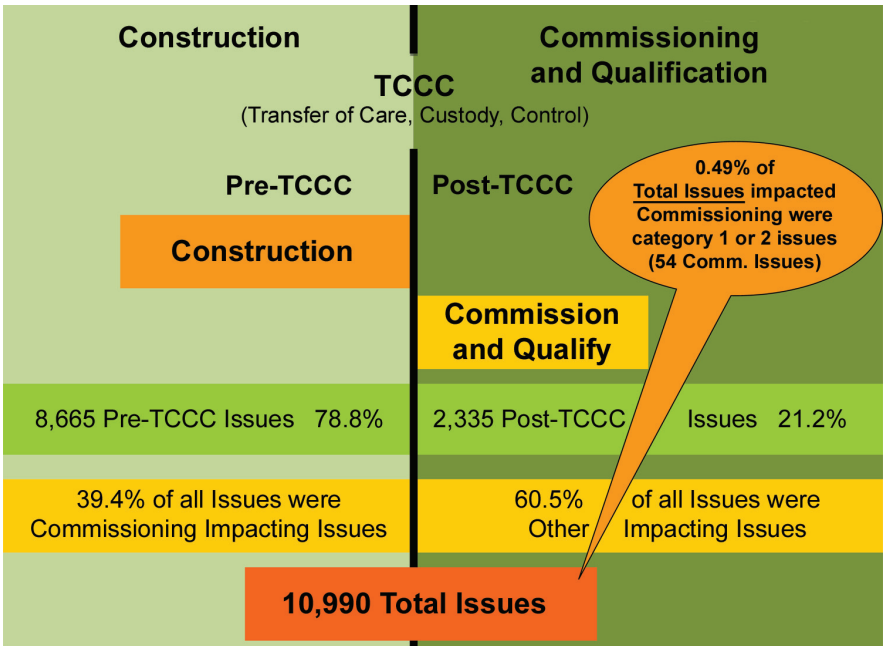


Figure 4. Impact of CQA program.

Categories	2010	2006
Facility Type:	Biotech Manufacturing	Biotech Manufacturing
Capital Project Cost:	$400 M	$400 M
Project Location:	Kinsale, Ireland	Indianapolis, Indiana, USA
Defined CQA Program:	Yes	No
Commissioning/Validation Peak Staff:	20 People	70 People
Commissioning/Qualification Costs:	< 4% TIC (Total Installed Cost)	~ 10% TIC (Total Installed Cost)
Performance Against Budget:	Under Budget	Over Budget
Total Commissioning/Validation Duration:	7.1 Months	11.4 Months

Table A. Final project performance comparison – Kinsale facility delivered faster and cheaper.

much later after handover to operations, and this could have potentially resulted in costly repairs.

Comparing Projects

A comparison between Kinsale and a similar biotech facility built in 2006 in Indianapolis, USA, which didn't use a formal construction quality assurance program, showed that the Kinsale project used less than half the number of people in commissioning and qualification, which resulted in significant savings. Kinsale came in under budget and completed commissioning and qualification four months earlier than the Indianapolis project - *Table A*).

Case Study 2: Packaging Facility, Suzhou, China

In early 2012, Lilly completed the construction of a packaging and storage facility in Suzhou, China. This was the first capital project in China by Lilly of any size in a number of years (~$70 million) and Lilly was on a steep learning curve to understand current China building practices, skills, and capabilities. A decision was made to apply the CQA program on this project as we had successfully done on other projects throughout the world. The CQA team was assembled and trained on the intent and elements of the program. The actual implementation, though, became an adventure in learning culture, capabilities, and the need for absolute persistence.

Challenges to CQA Program

The general contractor on the Suzhou project struggled to adhere to specifications and it became evident that the most important goals for the contractor were speed and cost since they were doing much of the work on fixed bid contract. Quality was only a consideration if it impacted the first two goals of speed and cost. Quality of work was often left for inspectors to evaluate and discover deficiencies. This meant inspectors had to be very diligent in their inspections and timely in identifying, tracking, and communicating issues. After a slow start to the CQA program, it gained momentum and regular quality meetings were being held with contractors to assess system status and open issues.

The impact of the months of tracking issues became clearer to the contractors and construction management team as we got closer to TCCC of specific systems. The database allowed the team to sort the issues list by systems and clearly understand what issues were still open and must be addressed prior to TCCC for each system. This focused the energy of the contractor and construction management team to meet the defined TCCC dates.

Though we had a slow start to the CQA program and have many opportunities to improve on future projects, Lilly did see a benefit in using the CQA program. Many issues were identified by inspectors and resolved by the contractor at the contractor's expense. Transfer of systems was often delayed as we had identified issues the contractor was required to address, but in the end only 1% of the issues identified post TCCC were classified as a severity level 1 or 2. All other issues identified post TCCC were of a minor level of severity. As a result, once system TCCC occurred, the C&Q program proceeded smoothly and with minimal disruption.

The Findings

The project has identified and tracked more than 2,200 quality issues. Initially, uptake of the program was difficult. The discipline of recording issues in a timely manner was not valued by members of the construction management team or the contractors. In fact, there was a strong belief that recording issues was a negative and should be avoided. This was compounded by individuals struggling to see the long-term value of recording each issue in a central web-based tool and database. The desire was either to not record at all or keep records in individual notebooks, computers, etc. After significant coaching and training, we began to

make traction and the impact of having items in a central database became clearer over time. As we approached system TCCC to C&Q, it was very powerful to sort data by system and understand clearly open issues requiring attention.

The data indicates that 92% of all issues were identified prior to TCCC to the C&Q team. The C&Q team worked very closely with the construction management team to identify issues and address prior to TCCC. This resulted in systems being transferred to C&Q in good shape with minimal to few issues after TCCC. There were significant construction quality issues and challenges on the project, but the CQA program acted as a filter to assure these issues were addressed prior to transfer to C&Q.

Key Learning Points

These projects shared the following common learning points:

- **Upfront CQA training and oversight is essential for success** – investing energy and effort into training the contractors, Construction Management Team, and inspectors on the program and tools is extremely important. It is very important to create understanding of the program, tools, and metrics to engage as many people as possible.
- **Job Specific Construction Quality Plans surface issues and misalignment** – insisting that contractors and subcontractors create Job Specific Quality Plans is extremely valuable in highlighting misunderstandings regarding specifications and expectations.
- **There must be an established CQA leader who is passionate about Quality** – leadership of the CQA program is critical for success. The individual must be passionate about quality and highly credible with the construction team contractors. In addition, they must be disciplined in following the process.
- **Subject Matter Experts must be used in inspections** – it is important to have inspectors who are subject matter experts for the discipline they are inspecting. Besides knowledge they add credibility to the contractor and findings.
- **Routine and regular quality meetings must be held with contractors** – quality should be a regular meeting between the CQA Team Contractors and Construction Management team.
- **Tools to record issues and manage data are essential** – the technology now available is essential for tracking of issues in a CQA program. They allow timely tracking and provide meaningful metrics of performance and status.

Technology Considerations

When selecting CQA tools, it is recommended that the following should be considered:

- User and field friendly for construction environment – the tool should be simple to use by the user with minimal key strokes or actions to input or retrieve data. It should take a minimal time to learn the tool and how to use it.
- Utilize digital cameras to capture issues – most tools today take advantage of internally mounted cameras and capture digital photographs and insert them within the database tool automatically.
- Document download – determine if the tool will allow unique check-list, drawings, etc., to be down loaded into the tool to assist inspectors.
- Metrics and reporting – assess the tool's ability to create metrics and reports that are applicable and useful to your project. Determine if these are configurable by the users.
- Capable of extracting data for learning – the tool should allow users to access data for analysis and exporting to other databases if desired.
- Web-based – easy access from anywhere in world – a web-based tool allows people to easily access the database. This improves communication of issues since essentially all contractors have access to the internet.
- Hardware requirements – determine what type of equipment is needed to effectively utilize software. Many systems now can use iPads as well as tablets in the field.
- Ease of configuration – when choosing a system, it will be necessary to configure the system for your specific project. Understand the effort required by your staff to configure the tool. Understand the level of help the provider will provide for configuring.
- Robust and supported system – the provider must demonstrate a stable, robust system with adequate technical support and training.

Conclusion

In summary, the CQA program together with technology was critical to the overall success of the projects 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/qualification team was able to focus its attention and efforts on functional performance rather than construction rework.

Today's technology has made CQA programs more practical and easier to implement. It has also allowed them to be more effectively managed and facilitated the collection/assessment of large quantities of field data in a more useful way. Lilly's experience has shown that a relatively small investment upfront (i.e., 0.5% of total installed cost) in a field quality program and technology can increase field efficiency and productivity, improve quality, accelerate schedule, reduce costs, and ultimately help speed medicines to market.

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