# Building Assurance

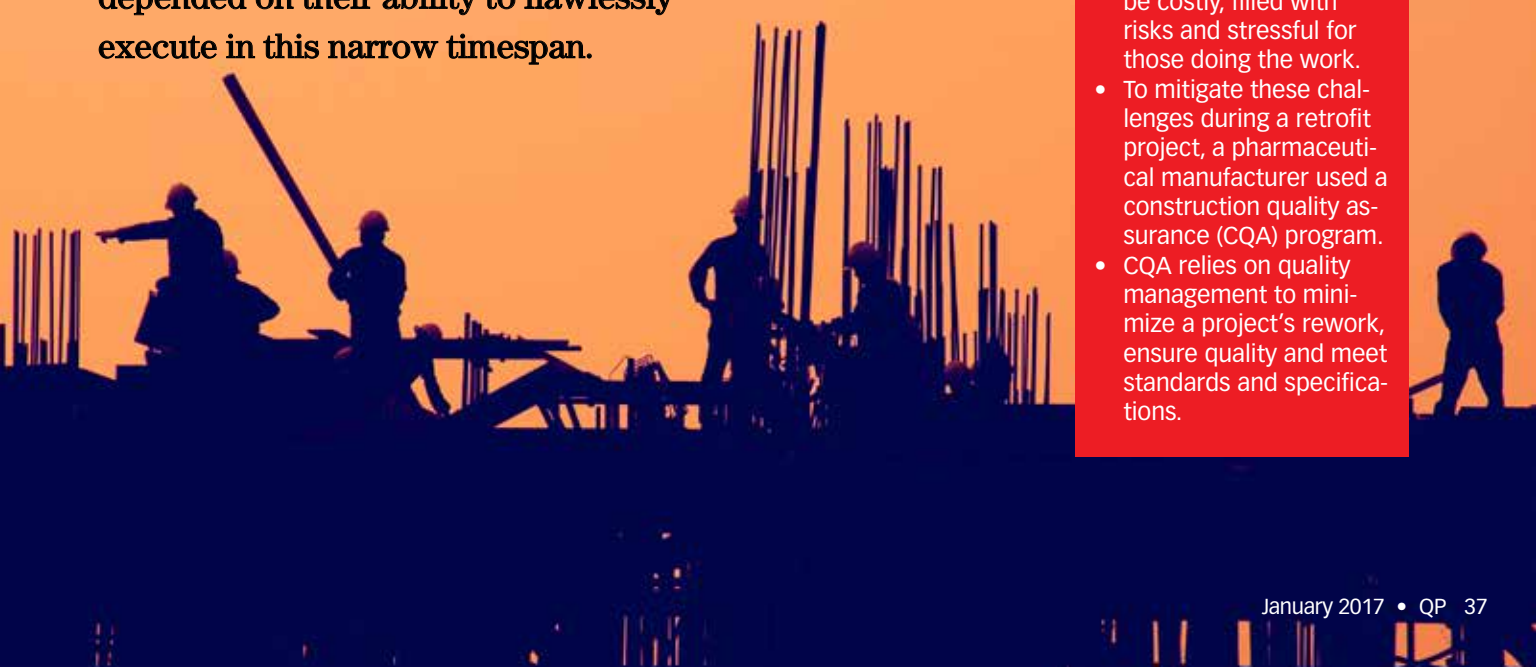
## Quality program **ensures success** in a **complex and time-constrained** construction project

by Bruce E. Beck and Tim Isle

**TWO YEARS AGO** during a major construction project at Eli Lilly and Co. in Indianapolis, a project manager walked into an office and sat down across from his construction manager. He knew their $90 million project to retrofit a pharmaceutical manufacturing facility was filled with challenges, including a tight shutdown window in which a massive amount of work had to be completed. The project's success depended on their ability to flawlessly execute in this narrow timespan.

### In 50 Words Or Less

- Upgrading facilities can be costly, filled with risks and stressful for those doing the work.
- To mitigate these challenges during a retrofit project, a pharmaceutical manufacturer used a construction quality assurance (CQA) program.
- CQA relies on quality management to minimize a project's rework, ensure quality and meet standards and specifications.



The project manager explained his plan to add a small team of construction quality assurance (CQA) experts to his project. After listening for a while, the construction manager stopped him and voiced his vehement opposition by saying, "I don't want them. I don't need them. We have good people who will do a good job. They are a waste of money, and I don't want them looking over our shoulders!"

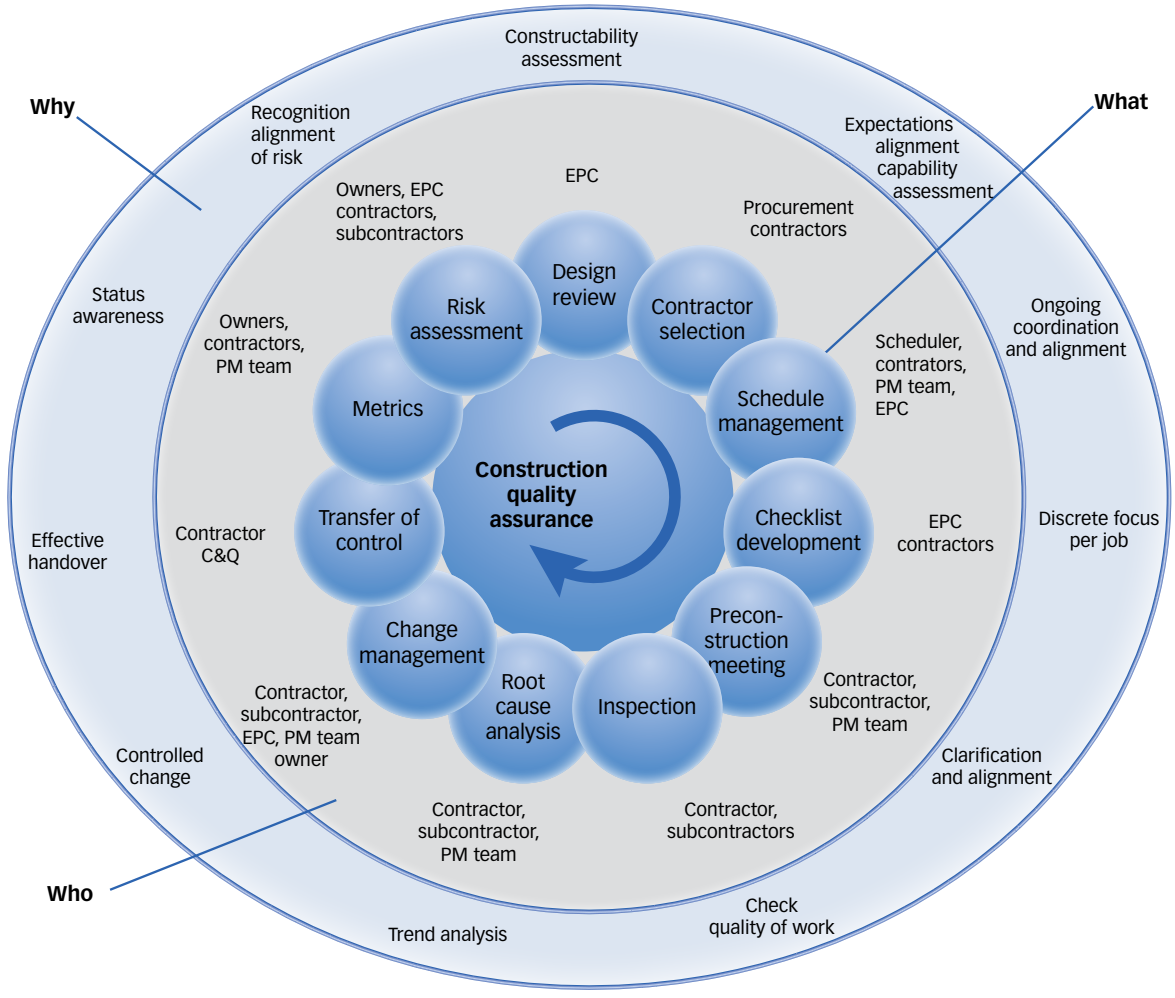
This was the beginning of a difficult conversation about their approach for ensuring quality and costs were controlled while adhering to a tight schedule. The project manager had used CQA teams on previous projects with significantly positive results and wanted to use these experts again. The construction manager, however, felt the team would be an intrusion and possibly a threat to his team's ability to complete the project.

The conversation grew more intense, but a CQA team ultimately was established to provide quality oversight on the project because CQA is a proven method for ensuring quality, lowering costs and improving efficiency.

## Facilitating operations

Facilities are built to serve needs such as manufacturing, distribution, research or administration. A facility and its equipment serve a specific role for an organization. Financial models, business plans and revenue often de-

## Construction quality assurance program / FIGURE 1




C&Q = commissioning and qualification
EPC = engineering, procurement and construction
PM = project management

pend on intended availability and usage rates for these assets: Product is manufactured, the sales team sells and the distribution group delivers. This seemingly straightforward concept, however, is anything but simple.

A facility's sustained operation requires maintenance and the ability to make improvements. Interrupting a manufacturing process can be extremely costly. It was estimated that a 2012 shutdown of pharmaceutical manufacturer Novartis' Lincoln, NE, facility ultimately could cost about $1 billion in sales.[1] For any organization, this type of unplanned cost can be devastating to the bottom line.

Most manufacturing facilities require manufacturing shutdowns for maintenance at some point during their life spans—that is, unless redundancies were built into their designs so systems and equipment could be maintained without manufacturing interruption. If a shutdown is not needed for maintenance, however, it likely will be required for process improvements and expansion opportunities.

These shutdowns present an organization with opportunities to improve yield, throughput or new product capabilities. While these changes are positive, shutting down an important manufacturing asset and making significant changes can pose serious risks. There also might be significant pressure to successfully bring the operation back online before reducing supply chains and losing sales.

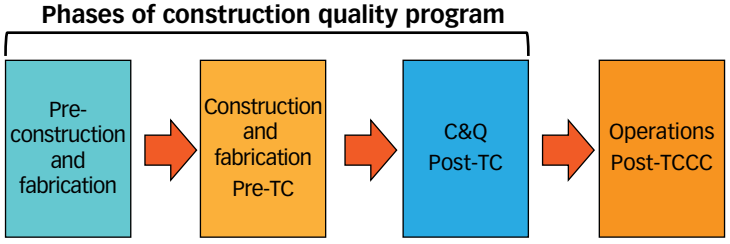
Shutting down a major manufacturing area can be stressful on an operations group and a project team performing the work. Unplanned issues can wreak havoc on an already tight schedule. Usually, a significant amount of planning takes place and many contractors are employed to perform work, but this doesn't guarantee unforeseen problems won't take place and create delays.

## Case study

Anova Technical Service—which specializes in construction quality assurance—collaborated with Eli Lilly to form a CQA team for its retrofit project. The CQA effort significantly reduced rework and costs. Most importantly, it was key in meeting the aggressive schedule. A CQA program that applies total quality management principles is an effective tool for ensuring a major project stays on schedule, minimizes rework and meets specifications (for an explanation of a CQA program, read the sidebar "Understanding Construction Quality Assurance," p. 41).

The retrofit project had demanding production requirements. The retrofit included making changes, and adding equipment and automation to several systems in an existing facility.

**Phases of construction quality program** / FIGURE 2




C&Q = commissioning and qualification
TC = transfer of control
TCCC = transfer of care, custody and control

These changes would provide a new, streamlined process for manufacturing that could save manufacturing cost, reduce cycle time, increase capacity and reduce the use of hazardous chemicals. The potential benefits were promising, but there were great risks in shutting down such a vital facility for several months to make major changes.

The project's leadership had a significant challenge because of a tight window allowed for a plant shutdown and the need to ensure the facility came back online in a qualified state—per U.S. Food and Drug Administration good manufacturing practices.

## Establishing the CQA program

It became apparent while developing the project delivery plan that errors and omissions by contractors during prefabrication work, and the shutdown would be devastating to the schedule. Rework had to be minimized to meet the aggressive schedule's deadlines, and missing them would be extremely costly. The CQA program addressed these risks and oversaw construction quality (see Figure 1).

The CQA plan also established staffing needs and contractor expectations for performing work, and reporting and addressing quality issues. It also established software tools for inspecting, recording and tracking quality issues in the field. These tools became instrumental in generating CQA metrics that were routinely reviewed by management.

Root cause expectations and a classification system

for rating quality issues also were defined in the plan. The CQA program provided oversight of the contractor's efforts to manage quality with a goal of minimizing issues or field rework that could affect the schedule, and contractors were always expected to own the quality of their work.

## The CQA strategy

The CQA strategy for this project consisted of three major phases (see Figure 2, p. 39):

**Phase one—Preconstruction and fabrication.** This effort was intended to identify errors or omissions in specifications and drawings being issued to contractors and vendors by the design firm. The project was heavily relying on prefabrication in the mechanical contractors' shops to minimize the amount of field welding. The review was intended to be proactive in ensuring correct information was provided to the shops.

Incorrect drawings and specifications would result in incorrect prefabricated piping that could lead to field modifications or shop returns. This would make an already tight schedule even more challenging and raise the risk for project failure.

**Phase two—Construction and fabrication.** In this phase, the CQA staff reviewed in-process and completed work from the shop and field. Reviews were conducted with a contractor to ensure work was understood and craftsmanship met standards and specifications. The findings were recorded as quality observations reports (QOR) and recorded using a tablet.

This enabled the inspectors and contractors to record observations in the field, identify ownership of an issue, prioritize the issue, take photos for documentation and email findings to an appropriate contact person to resolve the issue.

This tool also allowed the team to:

- Track an issue to resolution and follow-up.
- Gather metrics to understand trends, status and readiness for transfer of control (TC) from construction to commissioning and qualification (C&Q), and transfer of care, custody and control (TCCC) from C&Q to operations.

**Phase three—C&Q post-TC.** This phase primarily involved CQA team support of the C&Q team. Finding construction issues during C&Q wasn't ideal, but issues uncovered during this phase would have minimal impact if the CQA program was effective. The CQA staff recorded issues identified during this phase and coordinated rapid follow-ups and resolutions by contractors.

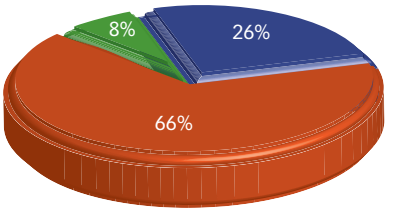
These phases were intended to:

- Prevent quality problems by clearly communicating expectations and clearing up misunderstandings before commencing work.
- Proactively find and address construction quality issues quickly and early during the construction phase.
- Minimize construction issues found during C&Q.

## Results and data

An effective CQA program not only prevents quality issues, but also identifies them as early as possible. Early detection can reduce or eliminate costly rework and create less stress on the project. Reviewing data from the

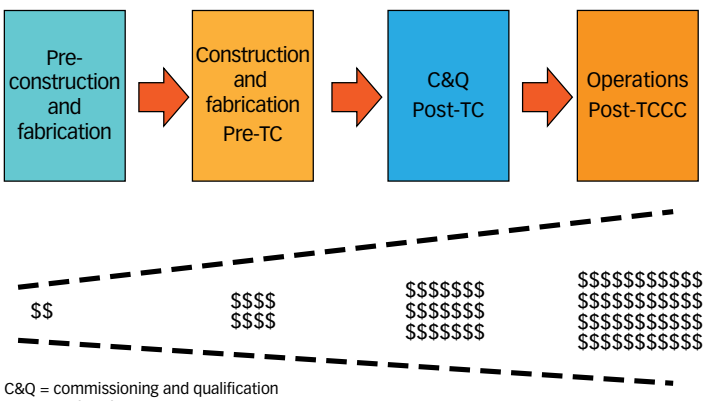
### Distribution of quality observations reports / FIGURE 3




Levels one and two = critical or serious.
Level three = minor.
Level four = design issue.

### Effect of quality issues / FIGURE 4

**Quality issues become more expensives as a project progresses**




C&Q = commissioning and qualification
TC = transfer of control
TCCC = transfer of care, custody and control

Eli Lilly project revealed the following:

**Phase one—Preconstruction and fabrication.** There were 262 issues identified by the CQA inspector. About 81% were related to information correction, meaning that piping and instrument drawings, isometrics or specifications sent to contractors or vendors needed to be corrected.

**Phase two—Construction and fabrication field observations.** A total of 2,792 QOR issues were identified during field construction and C&Q. Each issue was classified by severity as follows:

- **Level one (critical)—**Deficiencies that pose risks of imminent danger or have incomplete scopes that inhibit the ability to use a system or completely review it.
- **Level two (serious)—**A deficiency that inhibits the ability to execute a system's C&Q.
- **Level three (minor)—**A deficiency that's minor and will not impede a system's C&Q.
- **Level four (design issue)—**An issue that's determined to be constructed or installed per the approved drawings and specifications but was later recognized as potentially problematic and justified a consideration for a change.

Figure 3 illustrates the distribution of issues found during Eli Lilly's project. About 66% were level-three issues compared with 26% of the issues that were level

## Phase distribution of quality observations reports / TABLE 1

| Phase | Levels one and two | Level three | Level four | Total | Percentage |
|---|---|---|---|---|---|
| Pre-TC construction | 688 | 1,269 | 199 | 2,156 | 77.2% |
| Post-TC C&Q | 53 | 561 | 22 | 636 | 22.8% |
| Total issues | 741 | 1,830 | 221 | 2,792 | 100.0% |

C&Q = commissioning and qualification
TC = Pretransfer of control

## UNDERSTANDING CONSTRUCTION QUALITY ASSURANCE

Construction quality assurance (CQA) is the process of ensuring defined specifications and standards are followed, sound construction and fabrication techniques are implemented, and appropriate suppliers are used in the construction and fabrication of facilities, processes and systems. These efforts help:

- Prevent quality issues by clearly communicating expectations and resolving misunderstandings before work begins.
- Minimize negative consequences of noncompliance to project requirements by proactively finding and addressing issues in a timely manner.
- Minimize construction issues found during commissioning and qualification, which prevents delays in transfer of care, custody and control.
- Save contractors time and money caused by rework of nonconforming installations.
- Keep a project construction on schedule.
- Ensure an organization that a facility has been built to standards, specifications and drawings.

A CQA program does not take quality responsibilities away from contractors and subcontractors. They are still ultimately responsible for the quality of their work, just as they're responsible for safety. The CQA program focuses on ensuring quality programs are in place and functioning as intended.

An effective CQA program gives an organization a team in the field that's looking out for an organization's interests on the project. Contractors are motivated by factors such as cost savings and schedules and, too often, organizations are forced to trust that a contractor will do the right thing.

Many total quality management principles are applicable in CQA implementation. A successful implementation includes key elements such as:

- Front-end CQA planning to define a project's methods and staffing needs. The plan also assesses and identifies potential quality risks based on complexity, project demands, and skills and experience of the workforce. A variety of tools, such as failure mode and effects analysis and process hazard reviews, can help assess risk.
- Prescreening contractors' capabilities to consistently deliver high-quality services and products. The goal is to understand their strengths and weaknesses.
- Establishing a defined process for managing incoming materials and equipment to ensure quality and adherence to standards and specifications.
- Ensuring that contractors use deliberate, managed plans to coordinate the inspection, testing and resolution of issues.
- Holding preconstruction meetings that focus on ensuring there's alignment with requirements, specifications and standards.
- Using a database to track and monitor construction quality issues and provide metrics for trend analysis and improvement measurement.
- Performing root cause analysis to identify quality issues and provide timely responses to identified quality trends.
- Holding periodic field audits and CQA status meetings that are conducted by an organization's CQA advisor. These meetings assess compliance to a contractor's CQA program and help monitor resolutions of construction quality issues.

*—B.E.B. and T.I.*

one or two. We combined levels one and two because it was deemed unacceptable to transfer control to C&Q if a level one or two issue existed on a system.

The distribution of the 2,792 QOR issues between the pre-TC construction phase and the post-TC C&Q phase is important to understand because a key goal of the CQA program was to identify QOR issues as early as possible and prevent significant effects on the C&Q effort. Table 1 (p. 41) shows the phase in which QOR issues were identified.

While 22.8% of the issues were identified during post-TC and after being transferred to C&Q, only 53 issues were level one or two. Compared with the total number of QOR issues identified across the project (2,792) these data (53) indicate 1.9% of the total issues identified were rated level one or two and made it through to the C&Q phase. The early QOR identification resulted in minimal interruption of the C&Q work by critical or serious construction issues, which led to less costly rework.

## Financial impact

The premise of a CQA effort is that issues must be prevented and identified as early as possible. Early identification can prevent recurring construction errors, costly rework and schedule delays to C&Q and operational start-up. Figure 4 (p. 40) illustrates the financial impact of CQA and finding issues as early as possible.

When a quality issue is found, resources and time are used to mitigate it, but historically, it has been difficult to characterize and quantify the effect of construction-quality issues. Over the past several years, however, software has been developed to record, track and communicate field-quality observations.

This has made issues much more visible in the field, and consequently creates a mechanism for tracking and ensuring resolutions occurred in a timely manner. This software also presents an opportunity to assess the cost impact.

To evaluate the effect of the CQA program on Eli Lilly's project, an activity-based cost model was developed. This quantified the impact of QORs found at various phases of the project. These models were further refined for the preconstruction phase, fabrication/construction phase and C&Q phase. Each model looked at the resources required to deal with a QOR at that phase of the project.

## Effects and calculation

The financial model provided a mechanism for evaluating QORs' effects on costs at various phases of the project. Precise data, including classification and when it was discovered during the project, were recorded for each QOR. From these data, costs were estimated for resolving QORs.

The overall effect of the CQA program also was determined by calculating the impact of not having a CQA program on the project. The cost calculated from the QOR data and models was compared with a calculation that assumed the absence of a CQA program.

The comparison showed the absence of a CQA program would lead to 75% of the construction QOR issues not being identified until the project's C&Q phase. This assumed that even without a CQA program, 25% of the QORs eventually would be identified and resolved by construction prior to the transfer of control to C&Q. By applying this approach, the total projected impact of the CQA program was determined to be $2 million.

## CQA program cost

The cost of the CQA program for the entire project only was $200,000. Interestingly, the 262 issues identified in phase one alone created a savings totaling $226,200.

This meant that the CQA program had paid for itself during just the phase-one effort. The total savings for the project was $2 million, which represents a 10-to-1 return for every dollar spent on the program.

After the project was completed, the construction manager who had said "I don't need them!" when originally asked to use CQA experts admitted he had been wrong.

"The CQA inspector was a vital part of our team and provided incredible insight," he said during a project-review meeting. "He saved us incredible costs by identifying issues early in the project. We would have fabricated based on incorrect isometrics and had a real mess in the field. We would not have made our schedule."

## CQA success

There several keys to implement a successful CQA program in a capital project:

- **Be invested in helping contractors understand the CQA program—**Explain the program to contractors. They might be resistant to CQA if they don't understand its intent.
- **Use CQA experts—**Bring in experts who specialize in this service. They offer technical expertise to provide appropriate oversight of specific work.
- **Have engaged project managers—**A project man-

ager must be highly committed to a CQA program's importance and implementation, and CQA team members should report to him or her.

- **Use software**—Available software packages are robust and useful for recording, tracking and communicating issues.
- **Integrate metrics for CQA into project reporting processes**—Define metrics and identify who will routinely receive and review these data.
- **Engage CQA, a CQA manager and knowledgeable, capable resources during the planning stage of a project**—Make sure this happens early enough to influence design and field construction activities.

## Ally to success

A CQA program's approach must be planned and disciplined, and emphasize contractor acceptance and engagement. Strong project management and CQA leadership are integral for success.

Every organization executing capital projects should ask, "How is the project team implementing quality principles to ensure quality output?" A well-run CQA program can ultimately become an ally to everyone involved in the project and become a valuable tool for organizations. QP

**REFERENCE**

1. Ed Silverman, "The Novartis Shutdown Could Cost How Much?" *Forbes*, Jan. 10, 2012.

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