LATISTA

ZERO DEFECTS
ZERO DELAYS
ZERO PAPER

Eli Lilly Finishes $400-Million Manufacturing Facility 2.5 Months Early, Reduces Rework by 46%

CURT National Conference Executive Briefing

Eli Lilly & Co. Director of Commissioning and Qualification Bruce Beck and LATISTA Executive Vice President Chris Ramsey publically conveyed the story below to the membership of the Construction Users Round Table (CURT) at the 2010 National Conference. Beck also presented these ideas with Jay Lad in an article from International Society of Pharmaceutical Engineers (ISPE) journal Pharmaceutical Engineering.

Summary

Eli Lilly & Co. implemented LATISTA quality management and field-automation software, in combination with a disciplined construction quality management program, on IE42, a $400-million, 158,000 sq. ft. manufacturing plant in Kinsale, Ireland.

On a previous project in 2005, Lilly suffered from poor quality of construction, a challenge that resulted in:

- delays in commissioning and qualification (C&Q)
- increased costs associated with facilities opening late
- risks associated with faulty systems

As a result, Lilly designed an extensive Construction Quality Management (CQM) program to meet their quality and documentation goals on IE42 and future projects. The process would reduce the number of QA/QC issues that would impact commissioning, which would, in turn, assure that the facility was delivered on-time and as-specified. LATISTA's mobile and web-based platform was the centerpiece of this program. It allowed users to conduct inspections and monitor quality on the jobsite while giving Lilly transparency from anywhere in the world. LATISTA unified Lilly's CQM process in one program for all stakeholders.

Improved Rework	Improved Schedule	Improved Budget	Improved Quality
Rework savings of 46%, an estimated $4.3 million	Project delivered 2.5 months ahead of schedule	Under budget on C&Q delivery	Only 54 of 10,000 identified issues (0.54%) affected C&Q
Rework addressed by contractors, not Lilly	Issues identified during construction, not operations	Under budget on overall project cost	Zero punchlist items open at final turnover

"CQM is not a given. It must be an expectation for the contractor.... Activities must be measured and reported on so that performance can be improved."

Bruce Beck
Eli Lilly & Co.
Director of Global Facilities, C&Q Group

BACKGROUND $400M Pharma Manufacturing

Eli Lilly & Co., the tenth-largest pharmaceutical manufacturer in the world, is constantly building facilities around the world for research, manufacturing, and administration, spending a billion dollars annually on construction. Lilly and other pharmaceutical companies share similar project drivers: quality, cost, risk management, and time to market. The pharmaceutical industry, in general, is very competent in the QA/QC of its manufacturing processes but has difficulty extending this competency to the delivery of capital projects.

In 2005, after a string of struggles qualifying new facilities, Lilly began to examine the impact of construction quality on commissioning and qualification (C&Q). They determined a solution was needed that would allow their project teams to control quality on projects during construction, rather than beginning the QA/QC process during the commissioning phase.

Web-based and mobile construction automation software, in combination with a disciplined construction quality management (CQM) program, was that solution. Lilly implemented LATISTA as a central part of the technology solution selected for IE42, a $400-million, 158,000 sq. ft. manufacturing plant in Kinsale, Ireland. The three-story facility not only produces drugs for Alzheimer's disease and diabetes, but also contains several laboratories for development and product engineering. A modular design allows IE42 to re-task and update processes quickly and easily. IE42 finished construction and was occupied in April 2010, two months earlier than its expected completion date.


IE42, Kinsale, Ireland

CHALLENGE Automating to Meet C&Q Needs

Bruce Beck, Eli Lilly Director of Global Facilities Delivery, Commissioning and Qualification Group, presented on CQM best practices and an IE42 case study to an audience at the Construction Users Roundtable (CURT) National Conference in 2010. According to Beck, pharmaceutical construction encounters and must overcome several challenges stemming from poor construction quality:

- Delays in commissioning C&Q
- Costs associated with opening facilities late
- Risks associated with faulty systems

Delaying a new facility's start-production date, or starting operations with faults that risk having to halt production to correct them, can measurably cost millions of dollars.

Demonstrating quality construction is critical for all stakeholders on pharmaceutical projects, so a transparent and documented process is important. Documenting progress and processes helps ensure that systems are commissioned properly and that the facility meets regulations. For Lilly project teams, this means that, "if activities have not been documented, they have not been performed," according to Beck.

With the goals of quality and documentation in mind, Lilly designed a rigorous process to meet these ends and wanted to ensure that project teams used them in the construction phase of IE42 and other projects. The process would reduce the number of quality issues that would impact commissioning, which would, in turn, assure that the facility was delivered on-time and as-specified.

"Construction Quality Management is not a given," said Beck, explaining the importance of a properly implemented CQM program. "It must be an expectation for the contractor. They must manage the process deliberately and demonstrate their capabilities. Activities must be measured and reported on so that performance can be improved."

SOLUTION LATISTA Unites All Stakeholders in CQM Processes

For IE42, Lilly enhanced their construction quality management (CQM) procedures with LATISTA web-based and mobile software. 163 end users accessed project information, includng several at Lilly's U.S. headquarters. On the jobsite, LATISTA unified Lilly's CQM process in one program for all stakeholders. Users could access information in the field using one of 15 mobile tablet PCs.

The five main categories for monitoring quality included:

- Contractor Quality System Auditing
- Inspections/Field Observations
- Testing for Conformance
- Training Records Review
- Documentation Review

Inspectors entered deficiencies into the LATISTA database using mobile tablet PCs and pre-loaded, standardized checklist and supporting documentation such as drawings and specs. Once synchronized, the system automatically created reports of issues and distributed them to defined recipients. Subcontractors received automatically emailed notifications of deficiencies, made corrections, and logged to the LATISTA web in to update statuses. Lilly representatives and quality managers could also log in to see a graphical dashboard of IE42's progress and quality statistics.

LATISTA was also used offsite to create quality inspections on the facility's system modules being constructed in Estonia, 1,500 miles from the jobsite in Ireland. Inspectors in Estonia checked modules in the factory, made corrections, and synchronized notes to LATISTA's web platform so that Lilly representatives could follow the process.

The solution allowed quality-conscious employees at every level and location to analyze the project, looking for possible areas of improvement, and to share responsibility for quality. When modules arrived for placement at the jobsite, many of the deficiencies had already been found and corrected, eliminating costly rework.

Automating the quality program allowed Lilly to bring their entire project team together on field observations and conformance tests. The LATISTA mobile and web-based platform, implemented on tablet PCs in the field, improved inspectors' accuracy and efficiency. As a result, Lilly had better data on performance and transparency to the subcontractor level.

"CQM can be a culture change. It must start with a fundamental commitment by leadership to instill quality principles into every aspect of the business."

Bruce Beck
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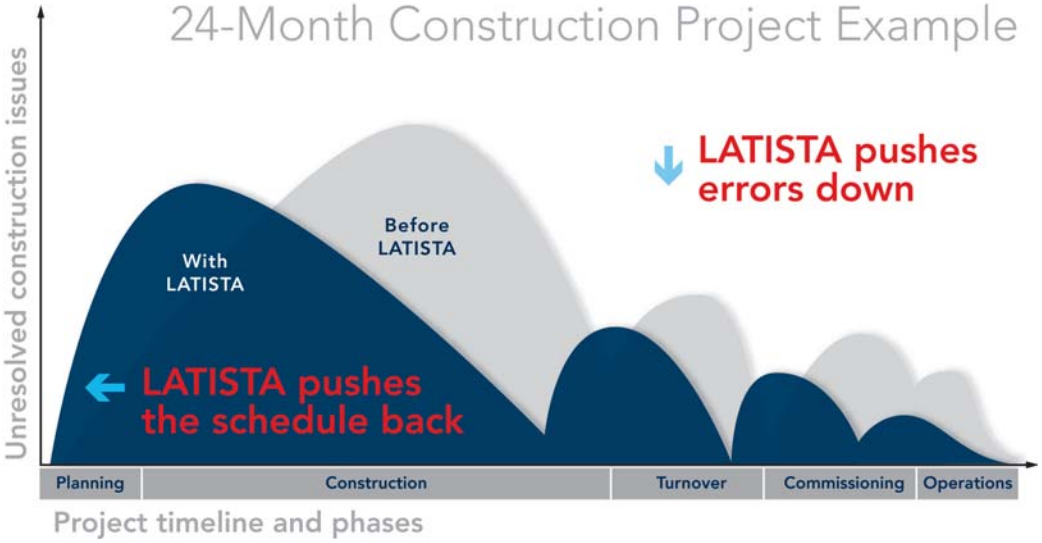
Automated CQM Results: Improve Quality and Schedule



Eli Lilly automated their CQM program in LATISTA to catch issues and deficiencies early so that the total number of outstanding issues was kept at a manageable level throughout the phases of the project. They were able to reduce their rework by 46%, which let them complete the project 2.5 months ahead of schedule.

RESULTS LATISTA Improves Quality and Schedule

Data collected from inspections in LATISTA gave Lilly insight into IE42's construction, since they could view quality and correction trends. "Data allowed us to track issues by discipline type and focused on key areas," said Beck. "It provided a deeper assessment of performance and allowed us to drive improvement." Comparing subcontractor performances helped assess strong and weak parties and changed the nature of feedback with more attentive subcontractor management. Moreover, data helped identify new cause and effect relationships, helping Lilly improve its internal practices, strengthening their CQM for future projects.

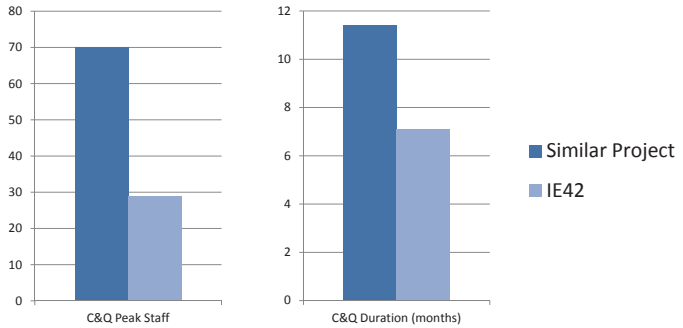
The success of this CQM effort demonstrated the effectiveness of Lilly's learning, as the vast majority of quality issues were identified earlier, when they were still the contractor's responsibility and long before they could affect the facility's operations. The project team could identify and correct problems as they occurred, preventing rework and eliminating deficiencies long before the C&Q process started.
Eli Lilly recognized and recorded several significant benefits from implementing a strong, automated CQM process:

Improved Rework	Improved Schedule	Improved Budget	Improved Quality
Rework savings of 46%, an estimated $4.3 million Rework addressed by contractors, not Lilly	Project delivered 2.5 months ahead of schedule Issues identified during construction, not operations	Under budget on C&Q delivery Under budget on overall project cost	Only 0.49% of 10,000 identified issues affected C&Q Zero punchlist items open at final turnover

As part of the automated CQM process on the IE42 project, Lilly kept detailed issue information in LATISTA, including severity information and the expected impact of the issue on C&Q. As a result, they were able to identify and resolve 78% of deficiencies—66% of which would have impacted commissioning—before transferring the facility's care, custody, and control from the project team to Lilly.

Compared to a similar project completed in 2006 with no defined CQM program, IE42 showed several benefits:

	Similar Project	IE42
CQM Program	None	LATISTA based
C&Q Peak Staff	70	29
C&Q Cost (as % of Total Installed Cost)	10%	< 4%
C&Q Duration (months)	11.4	7.1
Final Result	Over budget	Under budget



Overall, automating the CQM processes and documentation allowed Lilly to finish IE42 faster and at a lower cost. This prompted a long-term commitment by Lilly to a dedicated CQM program: "Construction Quality Management can be a culture change," said Beck. "It must start with a fundamental commitment by leadership to instill quality principles into every aspect of the business."

"We see a construction quality management program as the cornerstone for any successful LATISTA implementation," said Chris Ramsey, Executive Vice President of LATISTA. "Lilly demonstrated that investing in the software and implementation services necessary to automate quality management has immediate return-on-investment for capital project owners. They further demonstrated that CQM, in combination with a technology solution, has long-term positive effects operations and profitability of new facilities. Lilly is leading the industry in construction quality and we are proud to be associated with their efforts."

References

Bruce Beck, presentation. Construction Users Round Table National Conference 2010. November 10, 2010. http://www.curt.org/FileDetails.aspx?id=118&title=Construction+Quality%3a+The+Key+to+Successful+Capital+Projects+Delivery.

Bruce Beck and Jay Lad. "Construction Quality: The Key to Capital Projects Delivery." *Pharmaceutical Engineering*. November/December 2009. Vol 29. No. 6. http://www.spgl.eu/pdfs/09ND-Lad_noads2_nosecurity.pdf.