Achieving Organization-Wide Integrated Commissioning, Qualification, and Validation Activities

Practical, Proven Strategies That Drive Efficiency

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Meeting Today's Regulatory Requirements: Challenges Abound

In recent years, it has become more critical than ever for biopharma and life sciences companies to drive efficiencies and lower costs while meeting regulatory requirements and achieving business objectives. However, today's biopharma leaders are encountering various challenges as they simultaneously seek efficiency and safety, including the following:

Changing Compliance Definitions

Constant guidance updates make it difficult for companies to stay ahead on compliance initiatives. In addition to the numerous updates to ASTM E2500, ICH Q8, Q9, Q10, and those from the FDA, the International Society for Pharmaceutical Engineering (ISPE) updated its paramount Baseline® Guide for commissioning and qualification in 2019.

In the new guide, ISPE defines the Baseline® approach for the commissioning and qualification of facilities, utilities, and equipment regulated by the FDA. While the goal was to provide the industry with simplified and efficient strategies to execute the integration of commissioning and qualification activities, industry-wide adoption has been slow as with any new guidance document.

Rising Operational Costs

Costs for biopharmaceutical contract manufacturing services have increased — a result of an improved balance between supply and demand, increased overhead and labor expenses, and high raw material costs.[1]

Most respondents to a 2019 HighTech Business Decisions study on biopharmaceutical contract manufacturing pricing reported higher prices over the previous two-year period, with about one-fifth reporting significant price increases of more than 10%.[1]

Blowing Through Budgets and Schedules

A 2021 report by construction consultant Turner & Townsend found that 70% of pharmaceutical construction projects go over budget by an average of 15% and over schedule by an average of four months[2] — another troubling sign for stakeholders looking for efficiency gains.

Evolving Landscape After COVID-19

The COVID-19 pandemic caused a profound shift in the biopharma and life sciences industries, with impacts that will persist for many years to come.

Despite the many challenges that COVID-19 introduced, there are also upsides. Sixty percent of pharma industry executives say that COVID-19 will greatly improve the business outlook in 2021 and beyond[3], in addition to 70% who expect more outsourcing as a result.[4]

Biopharma and life science companies face several barriers to integrating CQV activities across design, construction, and manufacturing phases, including cross-functional interdependencies, corporate regulations, and site-specific policies.

To overcome these barriers, some organizations — even those with an existing CQV program in place — have turned to integrated CQV strategies that can benefit all areas of an organization, including manufacturing, engineering, procurement, quality, and many others. An integrated approach requires cross-functional teams to collaborate and work towards a common goal — which can often be a challenge in and of itself.

The following sections aim to clarify some of the complex interdependencies at play and offer a simple, compliant, and effective approach that includes practical and proven strategies for biopharma and life sciences companies to achieve their regulatory and business objectives, all while staying ahead of schedule and within budget.

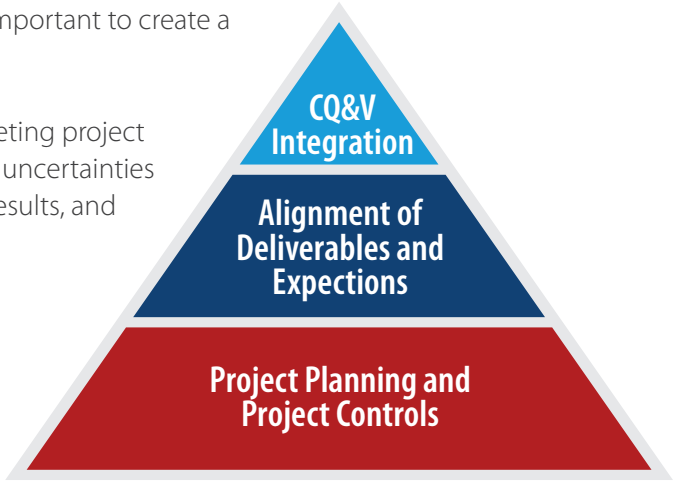
9 Strategies for Efficient CQV Integration

1. Address All Functions and Departments

Before integrating CQV deliverables, it's important to create a pragmatic, cross-functional strategy.

Recognize that there will be many competing project planning and control activities, as well as uncertainties around how the project will unfold, the results, and the benefits.

To achieve and maintain buy-in across departments, clarify the deliverables and expectations for all cross-functional teams and continually present the project specifics, updates, schedules, budget, and key metrics.



While total transparency is important, remember to present only the information that is meaningful to each group so you can maintain momentum and enthusiasm for the program.

2. Simplify the Complex

Consider all the quality systems across departments and processes at the beginning of any project — whether embarking on a greenfield or brownfield capital build or streamlining ongoing operations with change management or validation maintenance. Then, look for opportunities to simplify.

For example, some companies apply system- and component-level assessments with a vast degree of complexity, but it's not usually necessary to list every component for every system.

Instead, look at the unit class level and separate the critical components from those that are not. With this simplification, you'll be able to execute the component impact assessments more efficiently.

3. Conduct Basic Process Mapping

You can accomplish a simplified approach when you first understand the project deliverables and the relationship between all interdependent activities. Basic process mapping helps identify areas in your quality system processes that can be streamlined when applying the new ISPE Baseline® Guide or other guidance.

Map out your scheduling dynamics, including inputs, outputs, and schedule logic inter-relationships so you can understand how they interact. Your cross-functional teams from QA, QC, manufacturing, and other areas should then provide feedback on the process map and suggest process improvements.

For example, when developing the schedule and schedule logic, analyze all touchpoints where activities change hands. You might consider modifying your CQV strategy and activities based on the number of transitions that occur among your cross-functional teams.

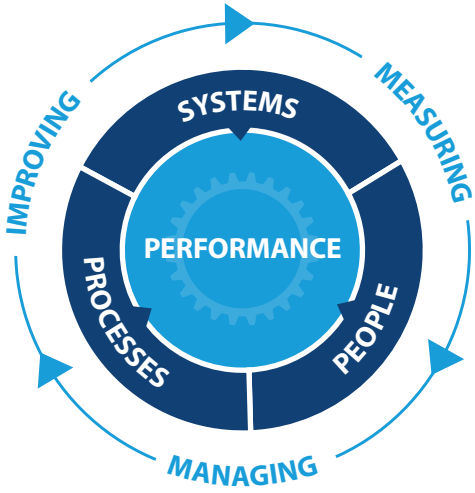
When you adequately map out expectations for all teams, breakdowns occur far less frequently.

4. Code the Metrics

Metrics and reporting are often an afterthought but are a necessary step for any CQV project.

Once you have developed a baseline schedule, be proactive about measuring and reporting progress. Identify what needs to be reported and to whom. Then, code the metrics and statuses as you go since they are so often susceptible to change.

With a clear plan and consistent measurement, it's far easier to look ahead, anticipate changes, and identify resource gaps — all to prevent bottlenecks from impacting other departments, teams, and projects.



5. Create Test Plan Templates

A test plan template that includes ideal formatting and a basic structure for how the document should flow will reduce inefficiencies and variability, and as a result, limit errors in the CQV process. Once the template is approved, simply enter the data to be verified in each field.

Streamlining documentation ensures that it's easy to track, review, and approve. Documentation is also an important step to identifying the critical and non-critical aspects of the installation and operation of mechanical and automated systems.

In addition to test plan templates, also create a template for the objective and acceptance criteria guidelines. Identify the pre-defined specifications that meet your acceptance criteria that are verified in the field or that you've integrated from your commissioning to your qualification.

It's also important to consider that a mature change management process supports this template-based approach. For example, suppose you go through the engineering change process and identify a non-critical aspect of a non-critical system. In that case, it's not necessary to go through change control.

6. Decide What Needs to Be Integrated and How

While process mapping and advanced planning are critical to CQV integration, it's not always necessary or feasible to plan for every detail.

Some companies find it challenging to identify which aspects of the equipment and systems should be tested and at what stage in the lifecycle. As a general guide, this decision should be based on the component impact assessment, which determines the truly critical aspects and where and when they should be tested.

One critical aspect of CQV integration is ensuring efficient quality oversight during the early stages of Factory Acceptance Testing (FAT) and Site Acceptance Testing (SAT), so the work can be integrated into the overall project.

Whether it's buy-in for new procedures or policies around CQV integration or the specifics of the integration itself, it's vital to involve the quality team early in the process.

7. Align All Lifecycle Documents

Review your lifecycle documents carefully to ensure alignment with your CQV procedures and practices. Look at your current CQV processes to determine if you have business systems that interact with your quality systems, regardless of how critical they may be.

For example, if you determine that a change is non-critical, a work order process may be sufficient instead of a complete change control process — a move that takes less time and doesn't require as much quality oversight.

Skimping on alignment review can incur project delays and costly rework down the line.

8. Consider a Hybrid Approach

Every company is unique, so a plug-and-play approach to CQV integration won't apply across the board.

Especially in larger organizations with increased complexities, competing priorities, and multiple levels of decision makes, a hybrid approach to CQV integration may be more impactful than full integration.

When assessing a hybrid approach, it's important to consider the touchpoints, supporting systems, and programs that could benefit the most from integrated CQV and those in the purview of leaders who are bought into the process.

Take engineering change management, for example. When deciding if the change management log can be integrated into the qualification package, you may want to physically verify the piece of equipment, component, instrument, or device in question.

If nothing found in the inspection or the engineering change management log has changed from the commissioning activities, you can continue integrating it into the qualification package.

In this example, if you don't have a mature engineering change management program, a hybrid approach to CQV integration allows you to develop that program before leaping into full integration.

9. Determine the Engineering Deliverables

When you're moving from commissioning to qualification or if you're executing within the commissioning activity itself, there are going to be several groups involved, each comprised of several individuals with many layered responsibilities and objectives.

To avoid overwhelming your current staff, determine the engineering prerequisites, timing, duration, and necessary resources upfront. This critical planning step lets you identify the type of CQV resources you need on staff and when you'll need them.

How to Deal with Resistance to Change

In the past, quality systems were either non-existent, immature, or lacked an adequate level of detail. There was a lot of variability, both in approaches and expectations.

Although companies have more recently started to adapt and make changes to their programs and policies, many are still reluctant to embrace change and only see it as a disruption.

To address resistance to change at your organization, consider the following tips:

1. Set Expectations

Be transparent to help your team understand that change is inevitable — especially in the biopharma and life sciences sector — and that the long-term benefits of CQV integration will result in improved efficiencies and compliance.

Have an open discussion about which team members will be impacted by the proposed process changes, how their roles will change or improve, and what work will be necessary to achieve the goals.

CASE STUDY:

Realizing the Benefits of Integrated CQV

Problem: A leading biotechnology company was looking for more efficient and compliant processes for a rebuild.

Project: $30MM project for start-up, commissioning, and qualification of a fourth process train and utility improvements in an existing 59,000 square-foot cell culture facility using a hybrid integrated approach.

Results:

- **Installation and startup:** Complete in 7 weeks
- **Qualification:** Complete 4 weeks later
- **Protocols written, approved, executed, and closed:** 237
- **Schedule impact:** Completed 1-month early
- **Budget impact:** $20MM recovery of the project cost (2/3 of the total project capital cost)

2. Identify Gaps

Look at your current programs to identify where there is room for improvement and how you can enhance quality while also increasing efficiency.

Ask questions to determine where your team is experiencing challenges and where your organization lacks the structure necessary to improve consistency, efficiency, and compliance. Also, determine if your work will be sustainable with your current team or if you'll need more staff or partners.

3. Collaborate with Your Team

In discussions with your team, listen to all their ideas and consider their input seriously. The best solution may not always be what you initially had in mind, so be patient and let the process unfold.

Driving Efficiency with an Integrated or Hybrid Approach

With a quality-first approach and streamlined processes, biopharma and life sciences companies that integrate CQV activities across departments are more efficient and more likely to achieve their regulatory and business objectives. Contact biopharma's CQV experts to get it done right the first time.

ICQconsultants.com

References

1. Biopharma Contract Manufacturing Pricing Analysis. Contract Pharma. January 2020. https://www.contractpharma.com/issues/2020-01-01/view_features/biopharma-contract-manufacturing-pricing-analysis/

2. Big Pharma Urged to Share Plant Construction Data Because Projects Are Late And Over Budget. Global Construction Review. January 2021. https://www.globalconstructionreview.com/big-pharma-urged-share-plant-construction-data-bec/

3. Outlook for Pharma Manufacturing Looks Bullish. Contract Pharma. April 2021. https://www.contractpharma.com/contents/view_breaking-news/2021-04-27/the-outlook-for-pharma-manufacturing-looks-bullish/

4. Top Trends in Biomanufacturing. BioProcess International. February 2021. https://bioprocessintl.com/business/economics/top-trends-in-biopharmaceutical-manufacturing-2020/

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About ICQ

ICQ (Integrated Commissioning & Qualification Corporation) partners with the world's largest biopharmaceutical manufacturers and emerging life sciences companies to provide comprehensive commissioning, qualification, and validation services that accelerate the delivery of medications and therapies to patients in need.

ICQ's biopharma focus, 75+ years of combined industry leadership, and deep bench strength of qualified CQV professionals ensure strict adherence to industry regulations, internal quality standards, and mission-critical project schedules and budgets.

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