A Pragmatic Approach to Biopharma Commissioning, Qualification, and Validation

Biopharmaceutical commissioning, qualification, and validation (CQV) activities are a high-impact, high-reward endeavor, with mission-critical schedules and budgets on the line. For quality teams looking to hire expert CQV resources, the high stakes make for a difficult and complex decision.

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Initial vetting of CQV vendors will leave you with a few qualified partners from which to choose, but it's the next phase of consideration that will set your facility on the path to manufacturing readiness ahead of schedule and under budget. Look for a partner with a proven track record of proactive delivery in these three critical areas.

3 Hallmarks of Pragmatic CQV Delivery

1. Streamlined Schedules

Your CQV vendor should take full accountability of your budget and schedule and look for opportunities to cut costs and time while maintaining compliance. An integrated plan that conducts CQV initiatives in parallel with other construction activities will streamline your schedule and can reduce the number of resources required to complete the project.

As an internal quality manager, you don't have time to track down documentation and keep tabs on the minute details of the project. Ask your prospective CQV vendor about their documentation processes and how they keep clients updated on progress. Finding a CQV partner that can seamlessly become an extension of your team can knock months off of your schedule and lead to major cost savings.

2. Comprehensive Project Controls

A proactive, hands-on approach to CQV project controls will help you discover and prevent potential issues before they have a negative impact on your project. With a CQV partner that takes comprehensive accountability of your project, you can focus your attention on other critical internal initiatives.

Look for CQV experts who have experience successfully conducting CQV projects in similar biopharma, biotech, or medical device facilities with a proven track record of knowing what works and what doesn't. CQV partners that already know the latest procedures, regulations, and trends that apply to your industry and facility — including ISPE and PDA guidelines — can give you a jump start to quality while customizing their proven templates to your project.

When considering potential vendors, be sure to seek a partner who can give you 24/7 access to a custom dashboard that tracks documentation, budgets, and all important project milestones.

3. Proof of Minimized Execution Time and Cost

Your project team should take pride in their ability to minimize execution time and lower costs. Ask for proof that they can:

- Follow appropriate industry standards outlined by the FDA, EMA, ICH, WHO, ISPE, PDA, and ISO and apply them to your project to avoid regulatory slowdowns.
- Plan for all direct impact and not direct impact systems needed and ensure the engineering designs are accurate and meet cGMP requirements.
- Utilize a pragmatic CQV approach with proactive planning methods and apply it to their daily work, helping you complete the project ahead of schedule.
- Rely on extensive biopharma validation experience to navigate continually changing regulatory requirements.
- Routinely provide savings in overhead costs to help pay for a majority of the capital project.
- Staff your team from a database of experts, allowing you to choose from accomplished construction managers, project managers, C&Q technical leads, C&Q consultants, C&Q engineers, documentation specialists, and more.
- Lead you toward 100% right-first-time performance.

The CQV Process that Leads to Profitability

Search for a biopharma CQV partner that can prove their ability to streamline your schedule and use fewer resources with a proactive, customized, and transparent approach to project controls. Minimize execution timelines and costs with CQV experts who can get it done right the first time.

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About ICQ Consultants

ICQ partners with biopharma and life sciences companies to help engineering and quality teams proactively solve complex commissioning, qualification, and validation challenges to facilitate safe, timely medication delivery.

Our transparent, data-first communication and project management philosophy ensures strict adherence to continually evolving industry regulations, site-specific requirements, schedules, and budgets.

Get it done right. Contact ICQ to get started.
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