OVERCOMING CHALLENGES OF RAPID GROWTH:

How to Conquer Four Major CQV Obstacles

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It's no secret that the past few years caused many biopharma and life sciences companies to experience some level of growing pains. The COVID-19 pandemic brought on a sharp increase in demand for new products and technologies and thrust the industry into a period of rapid growth.

While an uptick in demand is usually a good sign, overarching supply chain issues and strict regulations left many companies scrambling to keep up. These complications created the perfect storm that not only exacerbated existing issues but saw the rise of new obstacles.

The pandemic created a seismic shift within the day-to-day operations of organizations worldwide, and we're all still learning how to deal with the fallout.

This white paper outlines four challenges of rapid growth within the biopharma and life sciences industries—expanding within an existing facility, increasing quantity without sacrificing quality, scaling up the validation process, and hiring the right commissioning, qualification, and validation (CQV) talent—and how to navigate them.

Expanding Within Your Footprint

New facility construction isn't always in the cards for many biopharma and life sciences companies.

For one, finding the right real estate for a new build can be both time- and cost-prohibitive. And when demand for a product is high, and the market is waiting, time certainly isn't on your side.

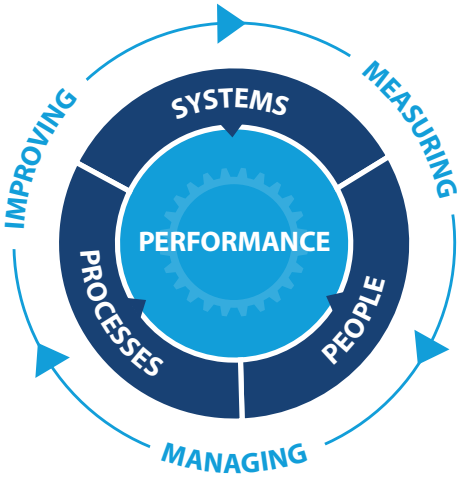
Repurposing an existing space to manufacture a new product or increase production efficiencies might make the most sense in these time-critical scenarios.

Consider these tips if you want to expand operations within your existing square footage.

Considerations for Expanding Manufacturing Operations Within an Existing Footprint

Take Stock of Your Existing Facilities, Utilities, Systems, and Equipment

What aspects of your expanded operation can your current space support? Start with a strategic gap assessment to determine which equipment and systems are suited for your new production goals and meet today's regulations and industry guidance and are suited for your new production goals. From there, you can prioritize upgrades and replacements as needed.



Taking inventory of your current setup can save you from unnecessarily replacing items that are still in good working condition. Additionally, a close inspection of these components can also prevent repurposing items that will later be identified as outdated or insufficient during qualification.

Save Space with Innovative Equipment and Technology

Even if some of your existing equipment could work in your updated space, is it the most efficient use of energy and space? Newer equipment will typically generate considerable utility cost savings, often making up for the initial investment over the long term.

On top of the financial benefits, a newer piece of equipment may also free up valuable floor space or allow you to reconfigure the layout to enable more production capacity.

Single-use systems (SUS) can save organizations time and money by decreasing energy, water, chemical, electrical, heating, and air conditioning usage; lower cleaning and sterilization expenditures; and a reduced physical footprint allowing companies to operate in smaller facilities.

For example, SUS and disposable technologies do not require the intensive cleaning and sanitation processes that materials such as stainless steel demand in addition to cleaning validation, which amounts to significant time and resource savings.

SUS come pre-sterilized and production-ready, eliminating clean in place (CIP) and steam in place (SIP) processes — saving money, time, water, chemicals, and complex plumbing components.

Evaluate Current Production Needs and Plan Accordingly

If your expansion goal is to increase the production of an existing drug or component, consider if you will need your facility to maintain an operational state during the renovations.

Do you have enough supply to meet market demand during the anticipated renovation downtime? If not, can you ramp up production ahead of the planned downtime to build an adequate supply?

If maintaining operations during construction is your only viable option, it can be done. However, much care must go into project planning and execution to ensure the working production lines are not contaminated or disrupted by the ongoing construction.

Increasing Quantity Without Sacrificing Quality

The past few years have shown that preparedness and the ability to meet high demand quickly without sacrificing quality are essential for biopharma and life sciences companies.

With this in mind, we've outlined some ways to keep your facility's manufacturing on track, meet client demands, and deliver the best quality product the first time, every time.

Five Components to Meet Rapidly Growing Demand

Building a solid foundation into your manufacturing will set you up for success.

There are five components to consider when meeting this growing product demand:

1. Be Adaptable

Staying adaptable is vital to staying ahead and delivering life-saving treatments to patients. Create easily replicable processes so you can respond quickly as projects scale up or change.

2. Stay Communicative

Whether you're working with the manufacturer or a vendor, communicate challenges and needs for production. If something changes in the timeline, don't let it slip through the cracks.

3. Lean on Expertise

Having the right people in your corner can help your organization scale to meet demand while keeping quality at the top of mind. However, finding trusted, experienced staff for your projects can be difficult and time-consuming. Don't wait for the right people to support your commissioning, quality, and validation manufacturing processes.

4. Embrace Technology

New digital approaches in biopharma are enhancing compliance and process efficiency. You've heard of "Biopharma 4.0", better known as biopharma's industrial revolution. This is the dramatic transformation of business by utilizing automation, data, and analytics to increase efficiency in manufacturing, reduce errors, and increase quality.

Examples of up-and-coming technology used by pharma companies to reach Biopharma 4.0 include artificial intelligence (AI), digital twins, robotics, augmented reality (AR), virtual reality (VR), process analytical technology (PAT), and more.

Learning how these technology platforms can improve your processes will make adjusting to a quantity increase easier.

5. Collaborate with the Industry

In many instances, having consultants and partners during the manufacturing process can support faster production, allowing you to meet demand more quickly and improve speed to market.

While building a solid foundation can be an added advantage, it helps to be skeptical, too. Pharma Manufacturing suggests evaluating a potential partner's capabilities, utilities, and regulatory history, such as:

- Do they have the right infrastructure in place?
- Will they be able to mobilize quickly?
- Is the partnership likely to produce a safe, consistent product according to regulatory criteria?[1]

What Should Be Done to Ensure Supply Chains Are Not Interrupted?

Companies often use siloed improvement solutions and reactive fixes to address supply chain delays rather than committing to transforming business practices and prioritizing a patient-centric business model. Some would say this is a golden opportunity to address some bad habits.

Take action and build resilience in response to supply chain disruptions by doing the following:

- Add process agility with digital technology to improve collaboration and resilience
- Identify any weaknesses within your operations and combat them by implementing a quality improvement initiative
- Accept the opportunity to transform processes across all departments in the demand and supply network
- Prioritize responsiveness and compliance in the supply chain
- Aggregate and analyze demand data to forecast your supply needs
- Keep the patient at the center of your business

Scaling Validation Processes

Scaling up can often come with setbacks, but with thoughtful planning around validation, these setbacks can be reduced or even eliminated. There are many areas to consider that will keep your scale-up plan running smoothly. Remember, process validation is no longer a singular finite activity; it is a continuous activity that must be managed at every part of the scale-up phase.

Planning is the foundation to responding to all potential variables in your scaling up process – a key to delivering on time and within budget. Without thoughtful planning, it's impossible to predict which equipment or processes need to adjust to meet regulatory standards.

Our experts have four key considerations to maintain validation while scaling up your projects.

1. Planning

Starting with a plan is critical to determining how your scale-up will run and, ultimately, to ensuring success. A few pillars that you need to have in place during the planning process include:

- An agreed-upon project plan and scope
- Comprehension of the FDA's 2011 Process Validation: General Principles and Practices[2]
- A regulatory filing strategy
- A ready-to-respond, cross-functional team of experts

Proper planning also allows your company to facilitate a realistic approach to how and when the scale-up needs to happen and each validation process that needs to take place.

In addition to ensuring your project starts off strong with proper planning, a team of CQV experts will also be able to proactively predict and address potential process validation hurdles throughout your project.

2. Compliance and Regulatory Strategy

As part of the planning process, you'll need to layout a compliance and regulatory strategy, which should include:

- Internal controls
- A way to document to prove your processes (protocols, reports, and procedures)
- Risk assessments
- Identified hold times and processing times
- Repeat studies
- Documented regulatory requirements
- A validation strategy

Having a compliance and regulatory strategy can help you plan for process validation challenges that come with increasing capacity and output, often impacting things like:

- Fill/finish batch sizes
- Compounding, mixing, or homogenization capacity
- Processing times
- Bioreactor volume
- Flow rates

Documenting your compliance and regulatory strategy will show evidence of your facility moving from phase to phase during scale-up.

3. Facility Fit

Without a doubt, equipment is the costliest consideration when scaling up. Many things will need to be modified as you transition from small batch to commercial production or ramp your commercial efforts to a larger scale.

You will certainly have to modify or bring in new equipment to meet your needs, but also consider facility fit. Is your facility large enough to accommodate the new equipment? Are structural adjustments required? Do you also need to scale up your utilities?

A seamless validation process that addresses all equipment and utilities associated with sterilization, cross-contamination prevention, processing times, fill/finish, modifications, and safety can reduce rework, save time, and keep production on track.

4. Quality-by-Design (QbD)

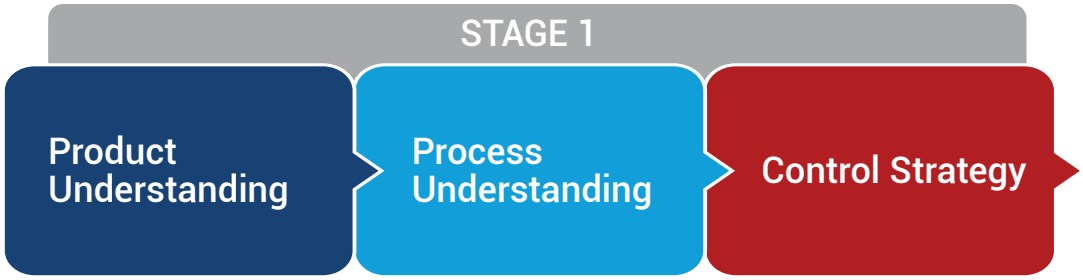
The QbD concept is a systematic approach to development that begins with predefined objectives and emphasizes product and process understanding and process control, based on sound science and quality risk management [ICH Q8 (R2)].

Because QbD is in place from the start of a project, it can give you a leg up in terms of validation. This means using a process development plan, an engineering plan, and a strong data integrity process as the roadmap to your scale-up's success.

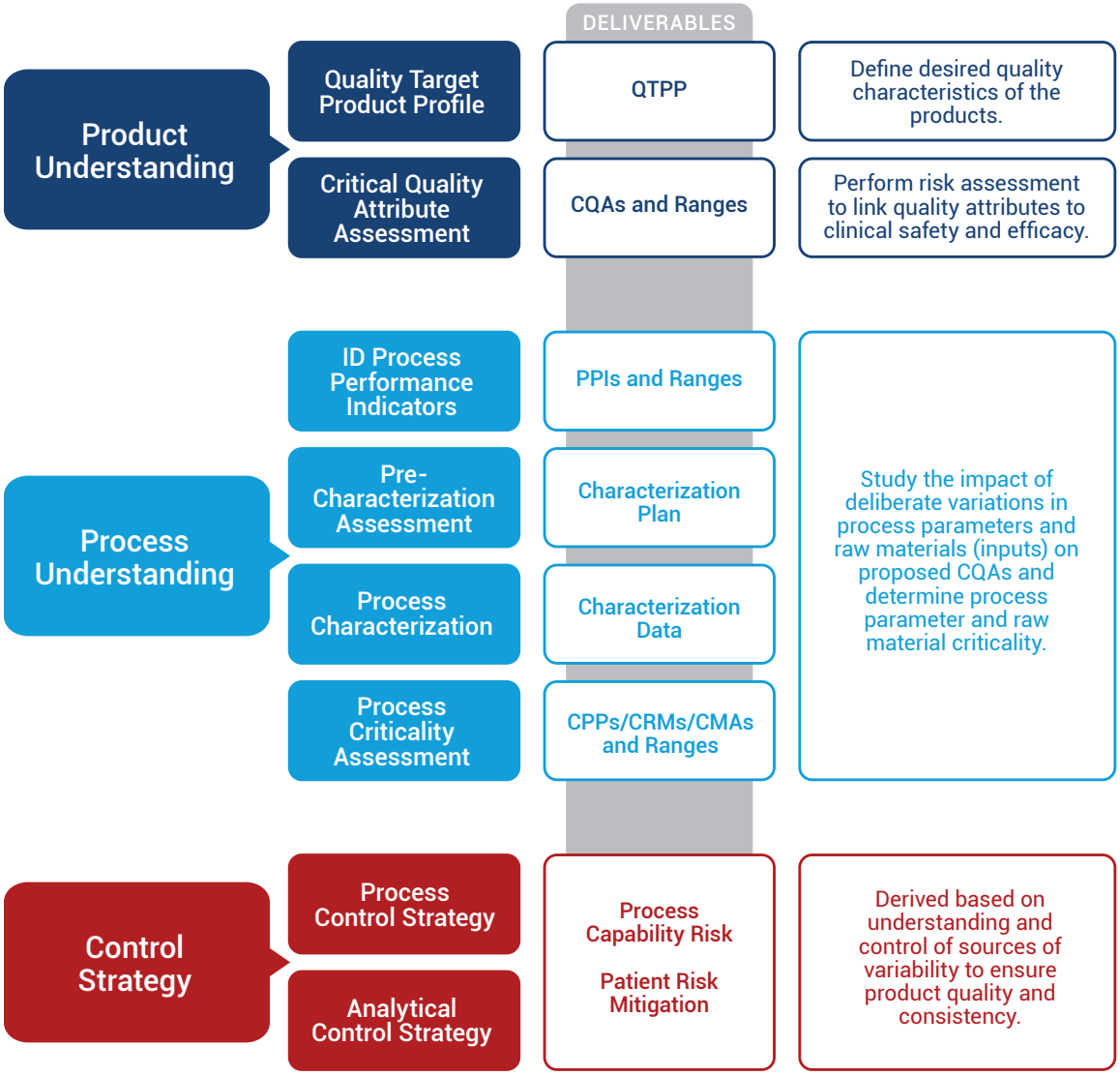
With QbD, quality is controlled not by simply testing the product but rather by building quality into the manufacturing process by design. This is achieved by a control strategy based on product and process understanding.

Here's what we mean:

QbD implementation is facilitated in Stage 1 (Process Design) of the Process Validation Lifecycle.



Your organization should meet the multiple risk assessments and deliverables outlined in the workflow below to develop a robust process and analytical control strategy:



These deliverables and risk assessments:

- Form the basis of the design of the product
- Establish critical quality attributes (CQAs) and process performance indicators (PPIs)
- Identify process parameters, material attributes, and raw materials with potential impact on CQAs and PPIs
- Ultimately classify process parameters, material attributes, and raw materials as critical or non-critical

Together, these items merge to create a comprehensive control strategy for a product's lifecycle. A comprehensive control strategy derived from current product and process understanding makes it easier to scale projects and assures process performance and consistent, quality production.

Hiring the Right CQV Talent at the Right Time

When a project grows rapidly, so does the need to hire more CQV talent.

However, the great resignation, a phenomenon brought on by COVID-19, has affected industries across the board, making finding and retaining the right talent increasingly difficult.

Another factor to consider is the speed at which biopharma and life sciences companies usually need to hire people, especially when growing quickly. Many roles within the industry are niche and require a certain level of experience, meaning hiring managers can't always hire the first person they find.

We recognize that every team has different needs, and when companies need additional staff on-site, there's no time to waste. CQV staff augmentation helps reduce the risk of projects going over schedule or budget.

Source Vetted CQV Staff Quickly

ICQ's Applicant Sourcing Platform (ASP) helps companies overcome the challenge of adequate staffing during periods of rapid growth.

Our proprietary ASP offers access to hundreds of skilled engineers, consultants, and project managers, provides complete transparency about every candidate's qualifications, and displays reliable, up-to-date resource availability to ensure pharma teams get the help they need.

- **Access 500+ CQV Professionals**
- **Receive Full Transparency**
- **Experience Constant Availability**

Conquer Major Obstacles While Growing Rapidly

While periods of rapid growth can be challenging, they can also be the catalyst for increased efficiency, productivity, and innovation.

Conquering the aforementioned obstacles may seem daunting, but with the right planning, strategies, and expertise, companies can set themselves up for success.

To overcome these challenges, biopharma and life sciences companies should consider partnering with a CQV firm that tackles these problems every day. Allying with a company that uses a quality-first approach and streamlined processes for CQV activities will help your company get it done right the first time.

ICQconsultants.com

References

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2. Process Validation: General Principles and Practices. U.S. Food and Drug Administration. January 2011. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/process-validation-general-principles-and-practices

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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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