Tunnell
STRONGER PERFORMANCE AHEAD®

Realize the Full Value of Continued Process Verification

From Compliance to Science to Reliability

With the 2011 guidance "Process Validation: General Principles and Practices" the FDA articulated the product lifecycle approach to process validation that it expects manufacturers to implement. To the first two stages of process validation — process design and process qualification—the agency added a third, continued process verification (CPV). As manufacturers work to implement this new requirement they have a choice. They can aim for compliance alone, or they can aim higher – at a fully mature program that integrates quality and compliance with science and technology to extract the full operating and business benefits of CPV.

Tunnell Consulting can help—at whatever stage your organization finds itself on the journey to full lifecycle management. Our highly experienced statisticians, scientists, and regulatory and process experts can assist with the design and implementation of an entire CPV system, help move an already established program forward, fill critical gaps in resources and skills at any level of maturity, and provide ongoing support, as necessary.

Why Adopt An Integrated Approach to CPV?

Approaches that focus narrowly on statistics and compliance fail to extract the full benefits of CPV and can, potentially, increase risk. And those narrow approaches may ultimately fail to deliver the level of reliable supply the FDA now expects. Tunnell's approach, integrating quality and compliance with science and technology, helps you deepen scientific process understanding while achieving compliance. With a strong science-based foundation for compliance you can more easily demonstrate process control, deliver reliable supply, and achieve multiple benefits, including:

- Enhanced inspection readiness, with lower risk of observations or actions
- Avoidance of costly re-validations
- Avoidance of delays in the manufacturing and launch of pipeline products
- Reduced out-of-specification results, deviations, and discards
- Fewer investigations and associated costs
- Increased productivity and throughput
- Many-fold return on investment through cost savings and increased revenue

The result: **the reliability of supply that will be the market differentiator of the future.**

Guidance Defines Three Stages of Process Validation

Stage 1:
Process Design

Commercial manufacturing process is defined.

Based on knowledge gained through development and scale-up.

Stage 2: PPQ
Process Performance Qualification

Process design is evaluated – test control strategy.

Determine if capable of reproducible commercial manufacturing.

Stage 3: CPV
Continued Process Verification

Stage 3a

Initial batches, heightened monitoring.

Stage 3b

Ongoing, routine monitoring.

Ongoing assurance that the process remains in a state of control.

Choose the Solution that Fits Your Needs

Drawing on our extensive capabilities, we create solutions that are both comprehensive and customized to your product history, state of process knowledge, and level of internal resources. Our capabilities include the capacity to:

- Deploy the right mix of statisticians, process experts, and scientists to complement your team
- Provide a product lifecycle management framework that is appropriate for your needs
- Develop policies and SOPs for CPV that are optimally integrated within your QMS
- Provide a uniquely efficient method for trending and handling data
- Establish and document links to the design and PPQ stages of validation
- Calculate process capability (Ppk and Cpk) baselines and updates, and develop risk mitigation strategies across your portfolio
- Provide basic and advanced training in SPC
- Coach and mentor personnel
- Align CPV with annual product reviews in order to avoid duplication of effort
- Offer expertise in online, real-time monitoring

Guided by a clear understanding of regulatory requirements and partnering with your internal resources, this comprehensive approach ensures efficient progress from compliance to science to reliability—and the operating and competitive advantages of CPV maturity.

Leverage Tunnell's Extensive Industry Experience

Our sole focus is on the life sciences industry. For more than 50 years we have helped life sciences organizations extract the business value from regulatory and quality imperatives. Our multi–disciplinary team includes life science process experts, engineers, statisticians, and business consultants. Their collaborative approach to implementation and knowledge transfer leaves your organization with the core competencies it needs to ensure a sustainable solution and unparalleled maturity in CPV.

Find Out Where You Stand

Where does your organization stand on the path to CPV? We can help you answer that critical question. Through our unique CPV diagnostic, we can rapidly help you:

- Determine the current level of CPV maturity in your organization
- Identify areas of operational and regulatory vulnerability
- Develop the business case for CPV within your organization – how to enlist the support of senior executive sponsors for the proactive investment required
- Scope the staffing and other resources required to implement CPV
- Benchmark your organization's CPV progress against peer companies
- Determine how best to connect CPV monitoring to current Operations and Quality review programs, such as Annual Product Review and tier boards or meetings
- Identify efficient approaches for CPV monitoring of high-risk parameters such as raw material attributes and assay performance
- Build on CPV to gain relief on inspection frequency through the FDA's Quality Metrics initiative
- Create a statistically-based rationale for prioritizing the initial parameters and attributes selected for CPV monitoring

The results will not only tell you where you are and how far you have to go, but also what you will need to take you forward. Give us a call to learn more.

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Founded in 1962 and serving many of the world's leading life sciences firms, Tunnell Consulting integrates strategic, technical, process, and organizational skills to design and implement sustainable solutions that exactly meet client needs. With deep industry knowledge, extensive scientific cedentials, and superior measurable results, we consistently boost the operating performance of each unique client we serve.

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