



Get Reliable, Quality Product—With No Delays

The goal of PAT is to enhance understanding and control the manufacturing process, which is consistent with our current drug quality system: Quality cannot be tested into products; it should be built-in or should be by design.

“PAT—Framework for Innovative Pharmaceutical Development, Manufacturing, and Quality Assurance,” U.S. Food and Drug Administration, September 2004.

What if...

- You could predict final quality at any point during production?
- Your operators knew which factors were most likely to push your process from its ideal path?
- You could control critical quality attributes in real time, without depending on a quality-control laboratory?

To stay competitive, you have to reliably make high-quality products within tight schedules. But even when things are going well, laboratory tests and process documentation make this a demanding task. And when process variability interferes, your job gets more complicated—while your choices become severely constrained.

If you compensate for that variability by making cumbersome process changes, regulatory compliance becomes even more complex, and the time you spend investigating batch records can jeopardize your time-to-release. When variability is especially bad, you might even need to re-work or discard a batch.

Unless you break free of these constraints, your company’s long-term competitiveness is in doubt.

In pharmaceutical and biotech manufacturing, it’s no longer enough to stick with the old way of doing things. Staying ahead means sustaining high production while managing process variability—all while maintaining regulatory compliance.

EASILY FULFILL PRODUCTION COMMITMENTS

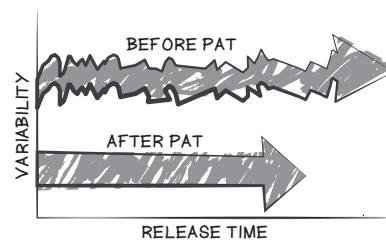
Meeting your company’s production goals is one of your major responsibilities. So you and your company both lose when you have batch-release delays, process and business bottlenecks, quarantines, or discarded batches. And when you don’t produce quality product on a timely schedule, you’re breaking a commitment to management and customers.

ALWAYS STAY WITHIN QUALITY SPECIFICATIONS

Either you produce a high-quality product from every batch, or you’ve wasted a great deal of effort and money. But when variability enters your process through variable equipment function, raw materials, or staff performance, you need to find it and counteract it as soon as possible. After all, staying the course is bad for your batches, it’s bad for you, and it’s bad for your company.

MAKE REGULATORY COMPLIANCE PAINLESS

It’s not easy to maintain efficient regulatory compliance and production at the same time. Every deviation means a great deal of extra work and cost from added investigations and potential quarantines. It can even draw the attention of regulators. But regulatory compliance and product quality are both mandatory. So if your job calls for you to make process changes to preserve quality, that’s what you do—even though it adds complexity to an already expensive and risky enterprise.



Using Emerson solutions with PAT-based manufacturing can reduce process variability and shorten product release times while promoting smoother regulatory compliance.

PROCESS ANALYTICAL TECHNOLOGY (PAT)

With Emerson consultants and solutions, you'll use Process Analytical Technology (PAT) to get short release times and product that's consistently within specification. You'll be able to keep deviations to a minimum and otherwise simplify regulatory compliance while attacking the root of your process problems.

MASTER YOUR PROCESS PARAMETERS

With Emerson, you'll reduce bottlenecks and deviations, shrink batch-record review times, and improve overall process control. When you can take advantage of our consultants' expertise, you'll be able to make lasting production and business-process changes to smooth your overall operation. With Emerson's Batch Analytics solution, you'll have the ability to quickly intercept any threats to production using early alerts about process issues, as well as model-based analysis and prediction.

You'll also use that process knowledge to remove bottlenecks. With end-point quality estimates and final product-quality prediction, you'll be able to move your batches quickly through every stage and completely eliminate some laboratory tests for faster overall release. And when you're armed with closed-loop control and a full understanding of your critical process parameters, you'll even be able to prevent batch quarantines.

ANALYZE AND SUPPRESS VARIABILITY

By using Emerson's products and services to do PAT-based manufacturing, you'll have the chance to vanquish process variability by quickly recognizing it and counteracting its effects—all while improving staff effectiveness. With multivariate data and the real-time process models of Batch Analytics, you can detect variability early and take advantage of fault alerts to understand how urgent that variability is.

You'll be able to intercept variability before it affects production—whether it stems from equipment degradation, raw-material variations, or differences in staff performance—and you'll know how to best ensure product quality. To further enhance operator effectiveness, you'll take advantage of easy-to-understand process models, closed-loop control, and web-based interfaces.

ENHANCE YOUR PROCESS UNDERSTANDING, CONTROL, AND DOCUMENTATION

Reduce the cost and effort involved in regulatory compliance, even when you need to adjust your process. You'll be able to use the highly accurate process models of Batch Analytics to understand your critical process parameters on a deep level, and you'll have the ability to detect developing process issues—and even reveal their causes. With Emerson solutions, you'll also have the opportunity to use closed-loop control to make automatic, effective, and defensible process changes.

And by integrating several of our solutions, such as the DeltaV™ digital automation system and Syncade™ operations management solution, you'll have centralized access to the documents you need, and you'll more easily meet change-control requirements and other regulatory mandates. Add the ability to defend process changes with Batch Analytics's real-time process models, and you'll be able to cut cost and risk for easier compliance.

“PATs are systems for design, analysis, and control of manufacturing processes. They aim to assure high quality through timely measurements of critical quality and performance attributes of raw materials, in-process materials, and final products.”

Ajaz Hussain, former deputy director of the U.S. FDA CDER Office of Pharmaceutical Science, *et. al*, in *Advanced Drug Delivery Reviews*, February 2004.

PROCESS ANALYTICAL TECHNOLOGY (PAT)

Start improving your process and your production now. With Emerson's solutions for PAT-based manufacturing, you can revolutionize your approach to important process areas.

BLENDING
<ul style="list-style-type: none"> • Content uniformity • Percent active ingredient
BIOREACTOR
<ul style="list-style-type: none"> • Cell density • Impurities
CHROMATOGRAPHY
<ul style="list-style-type: none"> • Eluent composition • Column integrity/performance
COATING
<ul style="list-style-type: none"> • Dissolution/coating thickness
CRYSTALLIZER
<ul style="list-style-type: none"> • Polymorphic state • Component concentrations • Crystal formation • Turbidity
DRYING
<ul style="list-style-type: none"> • Particle size • Moisture • Solvent content
FORMULATION
<ul style="list-style-type: none"> • Purity • Particles
GRANULATION
<ul style="list-style-type: none"> • Particle size distribution • Moisture • Solvent content
REACTOR
<ul style="list-style-type: none"> • Reaction end-point detection • Purity • Yield
TABLETING
<ul style="list-style-type: none"> • Potency • Content uniformity • Hardness

EMERSON CUSTOMERS ACHIEVE REAL COST SAVINGS

IMPROVED PROCESS PERFORMANCE



Real-Time Measurement of Critical Quality Attributes

Using Emerson's PAT solutions for real-time moisture measurement and closed-loop control, a global generic pharmaceutical manufacturer drastically reduced dryer cycle time and improved product consistency.

A FLEXIBLE PROCESS IN A DEFINED DESIGN SPACE



PAT in Quality-by-Design

As part of its Quality-by-Design (QbD) program, a global pharmaceutical company is using Emerson's PAT solutions in process development to create a design space and a multivariate process model useful in large-scale manufacturing. To achieve that goal, the company is developing the detailed process knowledge necessary for identifying critical process parameters (CPPs) and understanding their effects on critical quality attributes (CQAs).

PRODUCT THAT'S ALWAYS WITHIN SPECIFICATION



End-Point Quality Prediction

One major biologics company used Emerson solutions to predict CQAs in its fermentation process. With that greater process understanding, the manufacturer gained the ability to control final protein concentrations and to detect faults related to CPPs early in the process.



www.EmersonProcess.com/PAT

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