Produce Quality Drugs Faster Than the Competition

"In general, most generic [pharmaceutical manufacturing] companies estimate that 60% to 80% of their potential profit for any one product is made during this [180 day] exclusivity period" for being the first to file.

Daniel F. Coughlin & Rochelle A. Dede Hatch—Waxman Game—Playing from a Generic Manufacturer Perspective, 25 Biotech. L. Rep. 525, 525-26 (2006).

What if...

...you could shorten your time to product launch?

...you could ensure consistency in documentation, supplies, and production?

...you could prevent costly process and personnel interruptions?

The generics market is evolving rapidly. More drugs are coming off patent protection while demand keeps rising. Bringing new generic drugs to market—and doing so first—can be fraught with difficulties, requiring years of research and development and millions of dollars.

You cannot compromise quality, compliance, or audit readiness at any stage, but unplanned deviations, difficulties inherent in managing multiple products, the crunch of resources, and maintenance issues all threaten to hold you back.

MEETING YOUR PRODUCT LAUNCH DATE IS A STRUGGLE

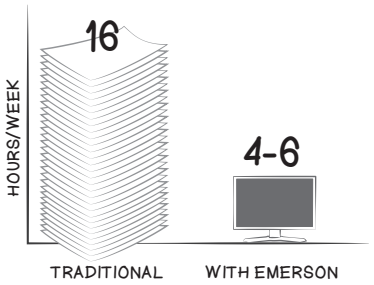
Everything you do is aimed at meeting your product's launch date. The failure to do so almost always means the loss of millions of dollars and a massive advantage for your competition. You simply cannot afford to miss that date.

But no matter how many resources you put into meeting that date, the nature of the business makes that task challenging. Between the audit and validation process, issues with information integration, and securing the right resources, there are always roadblocks to meeting your deadline.

IT IS DRAINING TO MAINTAIN QUALITY AND MEET COMPLIANCE REGULATIONS

Creating a new generics product or production facility can often leave you feeling pinched from multiple angles.

Yet you can't sacrifice quality or compliance at any stage. You must put out a quality product while complying with regulations from multiple agencies. Managing it all within a given timeframe with limited resources, however, is easier said than done.



Repligen Corporation shortened its quality assurance time from 16 hours per week to just 4-6 hours by switching from paper documentation to Emerson's Syncade Smart Operation Management Suite.

HITTING PRODUCTIVITY GOALS IS DIFFICULT UNDER EVEN THE BEST CIRCUMSTANCES

When production ramps up, it's vital that you hit your productivity goals—especially in the first six months— to justify all of the upfront costs.

You've seen other projects stumble right from the start, and you know the consequences can be dire. You want to build solutions into your process, but the difficulty obtaining and retaining skilled workers, the complexity of your operation, and potential maintenance issues all threaten to slow you down. Not hitting your goals can mean a significant financial burden on your project—a prospect you cannot abide.

EMERSON™
Process Management

GENERICS

Working with Emerson, you can produce a higher quantity of safe drugs sooner than the competition by utilizing a full slate of solutions tailored to your needs.

SHORTEN YOUR TIME TO PRODUCT LAUNCH

Missing your launch date is simply unacceptable. Getting to market on time—and often getting there first—is one of the most important things you do.

With Emerson's array of integrated solutions, removing or circumventing those roadblocks to product launch has never been easier. By implementing any number of automated, electronic solutions, you can greatly reduce information integration efforts, ease the burden of any time readiness (ATR), and find, track, and prepare the right resources when you need them—all without sacrificing an ounce of quality.

ENSURE CONSISTENCY IN DOCUMENTATION, SUPPLIES, AND PRODUCTION

With the advantage of Emerson's expertise, you can better spot unavoidable errors and take corrective action sooner, removing the trouble spots that previously would have thrown your operation out of balance. You'll automate time consuming validation tasks, predict and plan for deviations in your process, and precisely track and monitor your supplies in real time.

By peering into your process, your supplies, and your data with Emerson's electronic tracking, change control, and analytical systems, you can gain more control over your process and ensure your operators have the tools they need to produce a quality product in a compliant environment.

PREVENT COSTLY PROCESS AND PERSONNEL INTERRUPTIONS

Your plant has to hit the ground running with as few interruptions to production as possible—or risk failure.

Thankfully, that failure is avoidable. With Emerson's integrated solutions, you'll better manage your process with a single system, speed up training and reduce turnover, and predict equipment failure before it affects the process. In no time you'll stop looking at productivity goals as minimums and start wondering by how much you can exceed them.

> ***"Our work practices have certainly changed. We have been able to shift our focus to prevent from correct, and the documented savings are significant. We intend to keep exploiting the predictive maintenance environment and avoiding unexpected stoppages. The more we can plan and schedule our work, the more efficient we will be, and that is our ultimate goal."***
>
> **Wade Howarth**
> Automation Manager
> Cargill Vitamin E Plant

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