

## With our new SPC system, a pharmaceutical manufacturer now solves production problems quickly while improving regulatory compliance.

**Background:** The manufacturing of pharmaceuticals is complex and drugs must be rigorously tested and quality controlled before entering the supply chain. Ensuring regulatory compliance is another important factor that complicates operations management.

### The Problem

The pharmaceutical company required an improved system of alerts in order to reduce the time involved in correcting problems and meeting compliance requirements. It took analysts a significant amount of time to compile data for analysis because it was so disorganized. Alerts were not being generated quickly enough and even once they were generated, because the data was so disorganized, it took analysts a significant amount of time to compile data for analysis.



### The Solution

Predictum team developed an SPC system that monitored the process and generated alerts informing the appropriate technician and supervisor. Once the email was received, the analyst simply launched an attached script to automatically draw relevant information and produce a set of pre-determined analyses. Analysts are immediately in problem solving mode – no time lost trying to figure out what is needed, getting the needed data via any number of SQL queries then joining the data together. The system did all of that in an instant.

The system also facilitates change management including recommended changes and supervisor approvals.

Throughout this whole process of alerting, analyzing and approving the application is recording events using our *Compliance as a Consequence™* (CAC) database. A CAC database automatically records all data, analysis, comments-entered, approvals sought and granted or declined. Each of these events are time-stamped and all of the compliance work happens automatically – without additional cost, time and effort. The benefit is that staff can remain ones in focused on their primary task. If they are ever audited they need only point the auditors to the CAC database.

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Through a process control strategy, facilitated by an SPC system, productivity has increased, fewer mistakes are made and it is easier to investigate problems before they become excursions.

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### The Benefit

Now that the manufacturer had the new SPC in place alerts were reduced to real time and with the accelerated corrective action time to resolution was cut by 49%. Adoption of the *Compliance as a Consequence™* (CAC) database provided automatic records keeping and compliance was automated, this enabled staff able to work undistracted on production with increased productivity.

 **The Problem**  
Responding to problems and staying compliant was difficult

 **The Solution**  
A process control strategy facilitated by an SPC system

 **The Benefit**  
Real time alerts with action to resolution time cut by 49%

Learn how Predictum® analytical data solutions can make your operations more productive and reduce costs.

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