Real-Time data analytics to predict and manage risky process deviations

02 September 2020 | Features

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Out of control processes in pharma manufacturing are not something to take lightly. If your production runs are seeing frequent deviations, leading to expensive batch losses or frequent rework, it's time to take a look at ways to correct any process deviations in a more expedient manner. Uncorrected deviations or processes that vary from approved process parameters can lead to costly and dangerous mistakes.

You don't want to wait until you have regulatory warnings or face fines before taking steps to avoid risking a patient's health and safeguarding your processes and company's reputation. One of the most effective ways to ensure your processes stay within their approved critical quality attributes is with real-time process monitoring

It's not enough to hope that training and operator experience will do the trick, or that your team will be able to handle the most common types of process deviations quickly. You need a more reliable and quantifiable method that ensures patients' health, and your compliance with FDA and regulatory guidelines.

Multivariate Monitoring in Real-Time

Using advanced data analytics models in real time gives your team more confidence in your process performance. A real-time analytics tool such as SIMCA®-online allows you to know when a process is performing optimally or to see immediately when a deviation occurs. This early warning allows you take the necessary steps right away to correct any issues that might cause a batch to be rendered unusable or to stop contamination of a downstream process.

Why a Multivariate Data Analytics Tool?

A real-time multivariate analytics solution utilizes regression models to summarize all of the individual data points from various operations into multivariate models that can be monitored in real time. This becomes very efficient in the control room

because instead of looking at a large number of individual parameters or signals, your operators have a small set of summary parameters that let them monitor all the variables at the same time. This makes it easier to notice changes in the process as they happen.

What Can SIMCA®-online Do?

SIMCA®-online is the real-time data analytics tool from Sartorius that lets you use data from all your processes in a proactive way. With SIMCA®-online you can:

- **Monitor in real time.** You can create an ideal model of your process and then compare your actual data for the process to the model in real time.

- **Predict with confidence.** The multivariate analysis model provides a basis for predicting quality parameters over time using regression analysis. Using this tool, you can predict the final critical quality attributes with a high degree of confidence.

- **Control at a glance**. SIMCA-online with its real-time drill downs let you pinpoint issues and detect problems with equipment as they happen.

SIMCA®-online gives you:

- Remote golden batch monitoring
- Multivariate predictive monitoring
- Fault detection
- Root cause analysis
- Automatic corrective recommendation

Predicting the Future

Effective process monitoring using data analytics doesn't have to stop at monitoring what's happening right now. The right data analytics tools can also help predict the future for a process given the parameters of the current production state.

A great feature of SIMCA®-online is the module called Control Advisor. Control Advisor is a supervisory type of control tool that advises you how you should run your process to avoid problems before they arise and to get optimal final results.

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Visit www.umetrics.com to download a 30 day free trial of SIMCA®-online and Control Advisor.