

PROCESS & PRODUCT MONITORING

A BIOVIA DISCOVERANT SOLUTION

DATASHEET

The Process and Product Monitoring (PPM) solution is a purpose-built, validated environment for PPM including CFR 21 Part 11-compliant data capture and enabling Continued Process Verification.

PROCESS AND PRODUCT MONITORING CHALLENGES

Due to federal guideline updates, companies are now expected to monitor in-process and final product parameters for every batch of materials produced. The goal is to be proactive rather than reactive and provide evidence of product safety with every batch. By providing operating staff and their support teams with warnings so they can take action before batches begin to fail, a monitoring by exception system can reduce production costs and delays.

Traditional PPM approaches often force highly-trained technical staff to rely on manual spreadsheets when organizing their data, which is usually spread across several databases and paper record systems. Traditional approaches also lack immediacy and flexibility, while involving significant data quality risks and substantial recurring costs resulting from error-prone, non-value adding tasks. Traditional monitoring systems become even more complex when global manufacturing networks and Contract Manufacturing Organizations are involved.

Process and Product Monitoring with Automated Alarms

BIOVIA Discoverant provides standard and unique PPM functionality as well as critical automation and alerting capabilities designed to help organizations develop, automate and maintain large scale monitoring-by-exception systems. A critical feature of the Discoverant PPM solution is the ability to

further reduce the resource burden by automating the system. Quality monitoring outputs can easily be configured to read new data on a regular basis, update the output charts with new data and generate e-mail alerts for 'out of trend' and 'out of spec' violations.

BIOVIA Discoverant is unique in its ability to account for genealogy when conducting upstream/downstream correlations or regression analysis, as well as its ability to account for group differences that provide critical information during investigations and process improvement initiatives.

The BIOVIA PPM solution provides a single software environment that can be easily upgraded to include additional capabilities supporting life science manufacturing data analytics including:

- Ad hoc cause-and-effect analytics and reporting to investigate adverse or favorable trends and identify process improvement opportunities
- Feature Extraction capabilities to include complex continuous process and quality parameters in a monitoring program along with their interactions
- Product stability monitoring and expiration dating capabilities that can be used to correlate stability outcomes with upstream process conditions
- A wide range of additional univariate and multivariate analytics and reporting capabilities

To get started meeting your PPM needs, please contact your BIOVIA Account Manager.

You can also email us at info@accelrys.com.

Our 3DEXPERIENCE Platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the 3DEXPERIENCE Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 170,000 customers of all sizes in more than 140 countries. For more information, visit www.3ds.com.



3DEXPERIENCE®