

ROLE-BASED SIGNAL MONITORING DASHBOARDS FOR PROCESS PERFORMANCE MONITORING

A BIOVIA DISCOVERANT SOLUTION DATASHEET

The BIOVIA Signal Monitoring Dashboard (SMD) solution is a purpose-built validation-ready environment that satisfies requirements for Continued Process Verification (CPV), process robustness and process performance visibility needs across local operations and global manufacturing networks that include Contract Manufacturing Organizations (CMO's). Automated alerts driven by a sophisticated and flexible rules engine provide review-by-exception for efficient Process and Product Monitoring (PPM) that includes direct connections to process and quality databases as well as CFR 21 Part 11-compliant capture of paper based data.

PROCESS MONITORING AND CONTINUED PROCESS VERIFICATION CHALLENGES

Recent industry trends as well as updates to the regulatory guidelines have prompted pharmaceutical, biotechnology and medical device manufacturers to look more closely at process and product monitoring. Manufacturers want more robust and predictable processes to reduce business risks and improve process economics. They also want to satisfy regulatory expectations for routine monitoring of critical in-process and final product parameters for every batch to ensure that the process continues to operate in a validated state.

The goal is to be proactive rather than reactive, and to provide a high assurance of product safety with evidence from every manufactured batch, that all parameters are operated within their desired limits, not just the final product specifications. An efficient monitoring program is a cost-effective way to implement Stage 3 of the updated guidelines for process validation, namely Continued Process Verification. By providing operating staff and their support teams with alerts so they can take action before batches begin to fail, a monitoring by exception system can reduce production costs and delays. Managers and executives also need summarized visibility into process performance across processes and plants as appropriate for their roles, and with the ability to drill down into the details when needed.

Traditional process monitoring approaches often force highly-trained technical staff to rely on manual spreadsheet tasks when organizing the necessary data, which are usually spread across several databases and paper record systems. Traditional approaches also lack immediacy and flexibility, with significant data quality risks and substantial recurring costs due to error-prone, non-value-adding tasks like manual data manipulation and second-person verification. Another shortcoming of traditional approaches is that large quantities of time are needed to create and maintain the cumbersome manual monitoring systems needed for complex processes. This wastes

valuable staff resources on non-value-adding tasks. Traditional monitoring systems become even more complex when global manufacturing networks and CMO's are involved.

AUTOMATED PROCESS MONITORING WORKFLOWS AND ALERTS

The BIOVIA Discoverant SMD solution provides standard and unique CPV, PPM and process robustness functionality as well as valuable automation and alerting capabilities designed to help organizations develop, automate and maintain small local and large global monitoring-by-exception systems. For example, the capabilities of the BIOVIA Discoverant SMD solution include over 15 types of control charts (Figure 1), CUSUM charts, various process capability functions (Figure 2), pareto charts, batch summary reports, a variety of plotting capabilities, three different types of signal monitoring dashboard displays (Figure 3), and a large selection of easy-to-use data cleaning tools.

A valuable feature of the BIOVIA Discoverant SMD solution is its ability to further reduce the resource burden by automating workflows. Monitoring outputs can easily be configured to read new data on a regular basis, update the output charts and dashboards with new data, and generate e-mail alerts for 'out of trend' and 'out of specification' rule violations. Furthermore, all BIOVIA Discoverant outputs can easily be published to browser portals or sent to individuals and groups via email to increase process performance visibility across the organization. The data collection and automated analysis procedures are made available in an easy-to-use, point-and-click environment, eliminating the need to for IT resources and programming experts to configure outputs.

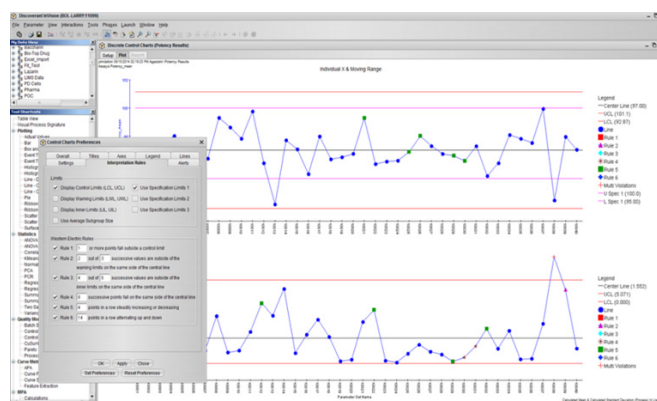


Figure 1: Control chart showing process trending with run rules and alerts for out-of-trend conditions

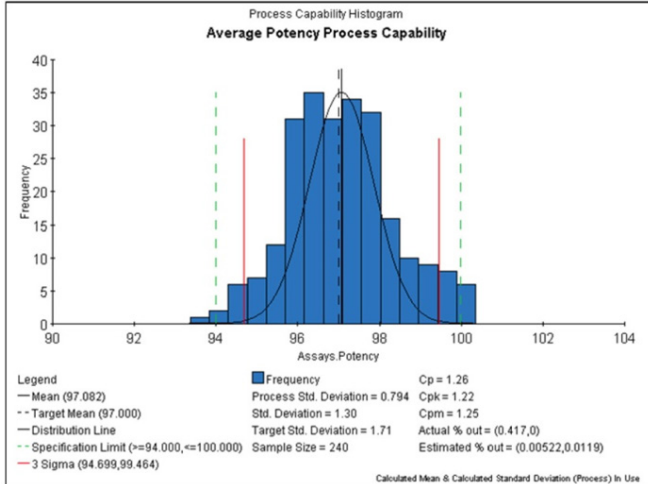


Figure 2: Process capability analysis for quantifying the current and future ability of a process to operate within desired limits

BIOVIA Discoverant's role-based signal monitoring dashboards show the current status of individual parameters, or any weighted combination of summarized process and quality parameters (Figure 4). This gives users maximum visibility into those aspects of the process most useful to them in their specific roles. Point-and-click drill-down capabilities enable users to see the current status of all the process and quality parameters contributing to any signal indicator, as well as the current trend chart for any parameter in the summarization.

The BIOVIA Discoverant SMD solution provides warnings when a process may be going out of control which may also trigger the need for limited or full scale investigations to understand the cause of the problem using additional BIOVIA Discoverant capabilities. BIOVIA Discoverant is unique in its ability to also account for process genealogy when conducting upstream/downstream correlations or regression analysis, as well as its ability to account for differences between groups of batches that provide critical insights during investigations and process improvement initiatives. The state-of-the-art BIOVIA Discoverant SMD solution can be easily upgraded to include

additional powerful data analysis and visualization capabilities in the same working environment to help locate the sources of process variability and deepen process understanding:

- Ad hoc cause-and-effect analytics and reporting to investigate adverse or favorable trends and identify process improvement opportunities
- Feature Extraction capabilities to enable inclusion of complex on-line, continuous parameters in monitoring programs 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 plotting and data visualization capabilities, as well as univariate and multivariate analytics and reporting capabilities

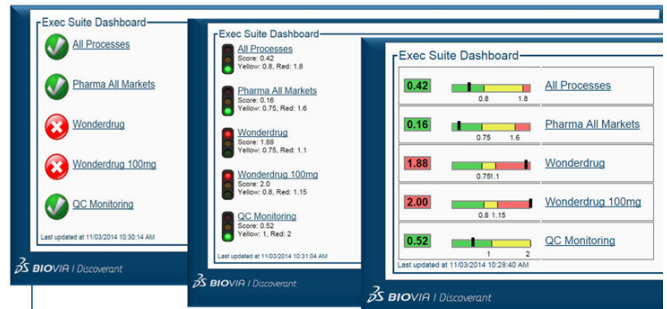


Figure 3: Three different types of signal monitoring display symbols are available with increasing levels of information content

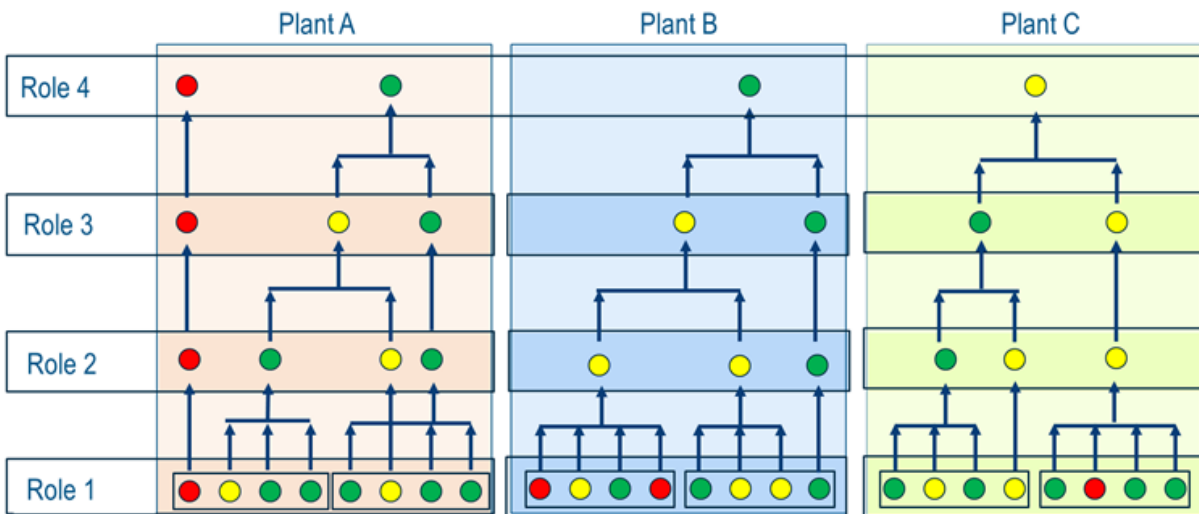


Figure 4: Diagram showing an example of weighted summarizations for role-based signal monitoring across three manufacturing plants each operating multiple processes.

GET STARTED TODAY

BIOVIA consultants can work with you to leverage the BIOVIA Discoverant SMD solution for developing and deploying a statistically sound, automated process monitoring system to achieve the goals for process performance visibility and CPV. This includes determining the appropriate data aggregation and organizational structure for small and large volume monitoring-by-exception systems. No matter where your organization is on the journey towards process monitoring excellence (Figure 5), the BIOVIA Discoverant SMD solution can match your current needs and provide an appropriate path forward. Please contact your BIOVIA Account Manager for more information, or email us at us at discoverant@accelrys.com

To view a short video of the BIOVIA Discoverant SMD capabilities visit accelrys.com/DiscoverantSMD

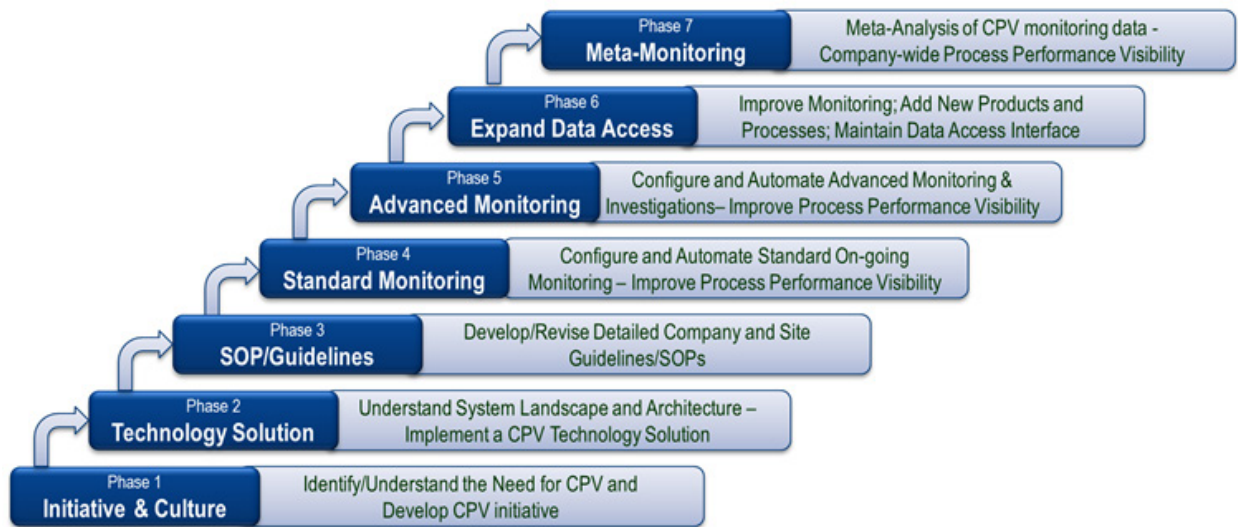


Figure 5: The BIOVIA CPV Maturity Model identifies the progression of phases an organization goes through on the path to achieving process monitoring excellence

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