

INTERACTIVE GRAPHICAL PROCESS GENEALOGY MAPPING

A BIOVIA DISCOVERANT SOLUTION DATASHEET

BIOVIA DISCOVERANT FEATURES INTERACTIVE GRAPHICAL GENEALOGY MAPPING AND AUTOMATED FRACTIONAL CONTRIBUTION CALCULATIONS

The BIOVIA Interactive Process Genealogy Mapping solution is a purpose-built, validation-ready capability for visualizing all the points where splitting and pooling occur in the process stream during production operations. By clicking on the map, users can easily see all the input and output relationships in the process stream from the start to the end of the process as they relate to any unit operation. Automated calculations of the fractional contributions of upstream operations into downstream operations are also available. This enables users to do meaningful upstream/downstream correlation analysis for Quality by Design (QbD).

PROCESS GENEALOGY CHALLENGES

Splitting and pooling of process streams is common in both Process Development (PD) and full scale commercial manufacturing operations. In manufacturing, process lots are often split and pooled to match upstream processing capacity with downstream operations. In PD, batches are typically split into subsequent unit operations where sub-batches are run through different sets of experimental conditions and then recombined into downstream steps where the downstream equipment has higher capacity compared to the upstream equipment. The complexity of lot genealogy in the PD environment rapidly increases with the number of unit operations and the number experimental conditions.

To minimize the risk to patients from quality-compromised products, it is important to be able to quickly visualize upstream/downstream relationships clearly in the process stream for lot traceability, batch dispositioning, and recall management. As QbD initiatives gain acceptance across life sciences process development and manufacturing organizations, there is an increasing need to also understand the relationships between critical portions of the process stream more fully. For example, detailed accounting of the fractional contributions of upstream process steps to downstream process steps is required at points of splitting and pooling in the process stream so that statistical correlations between upstream process parameters and downstream process outcomes can be calculated. These fractional contributions are compounded in processes that have multiple points of splitting and pooling.

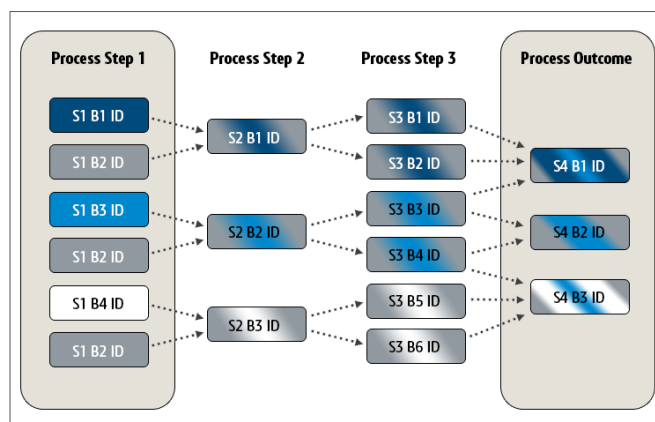


Figure 1: Diagram showing a process with splitting and pooling of the process stream where users would like to correlate variation in Process Step 1 with the Process outcome

Un-validated spreadsheets are sometimes pressed into service to visualize process genealogies and help calculate compounded fractional contributions across multiple process steps, but they are error-prone and hard to manage and they become impractical very rapidly as the number of splitting and pooling points in a process grows. Better automated and flexible tools are needed to visualize process genealogies and perform these calculations so that useful process models can be built to link upstream Critical Process Parameters (CPPs) to downstream Critical Quality Attributes (CQAs) in processes where splitting and pooling occurs.

BIOVIA PROCESS GENEALOGY MAPPING AND AUTOMATED FRACTIONAL CONTRIBUTION CALCULATIONS

The manual spreadsheet approach to viewing process genealogies and calculating the fractional contributions from upstream to downstream process steps is labor-intensive, complex, time consuming and error-prone. The BIOVIA Interactive Process Genealogy Mapping solution provides freedom from errors, simplicity of use, and the ability to easily perform upstream / downstream correlations in complex manufacturing processes with multiple points of splitting and pooling in the process stream.

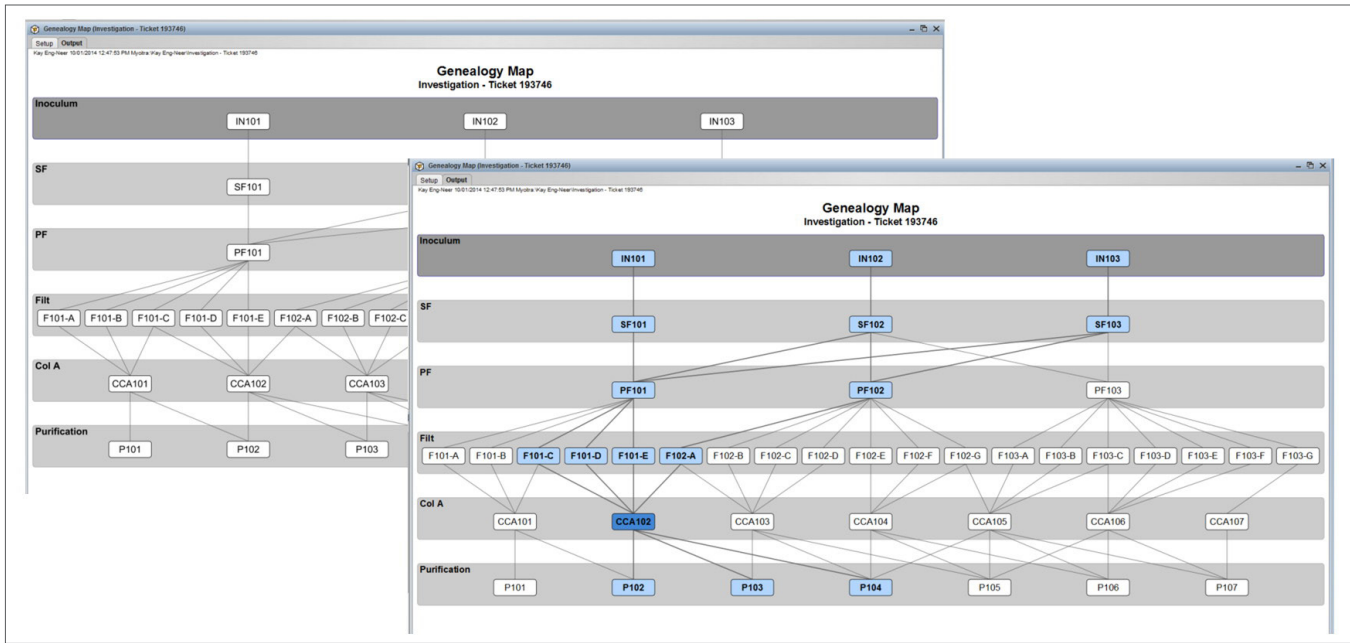


Figure 2: Interactive graphical process genealogy map showing all the ancestors and successors of a step late in the process

An important benefit of being able to easily perform upstream / downstream correlations in complex manufacturing processes, is that significant barriers are removed from identifying potential cause-and-effect relationships between upstream process conditions and downstream process outcomes. Such relationships drive the formation of hypotheses that can be confirmed, extended or refuted using mechanistic knowledge and/or experimentation. The information thus gained about the relationships between upstream process parameters and downstream process outcomes helps to make processes better understood and outcomes more predictable by linking CPPs with CQAs to shape useful process models that meet the goals of QbD.

The state-of-the-art BIOVIA Interactive Process Genealogy Mapping solution provides a single software environment that includes 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 for on-line data that enable inclusion of 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

For more information, visit accelrys.com/DiscoverantGenealogy to access the article titled, "Traditional Lot Traceability Approaches are Not Sufficient to Enable Upstream/Downstream Correlation Analysis for Quality by Design (QbD)."

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