



Advancing Process Analysis, Tech Transfer & CPV

In-depth process analysis is typically daunting for pharmaceutical companies and other process manufacturers. After a batch is completed, scientists and engineers must track down production data and assign context manually. Comparisons across batches and campaigns are even more resource-intensive, and process changes over time only compound the challenge.

Neo Analysis simplifies batch reviews like never before. Through unprecedented interconnectivity, the module automatically collects and contextualizes production data against a detailed process design. You gain robust analytical capabilities to optimize processes and product quality—and a powerful tool for continuous process verification (CPV). Your scientists gain the freedom to focus on innovation rather than data extraction, cleaning and transformation.



Seamlessly Synchronizing Design & Production Data

Some technology providers claim to offer “smart” analysis and CPV capabilities based on machine learning. However, these applications attempt to build on-the-fly process models based solely on batch history data—an error-prone approach that requires substantial maintenance as processes evolve.

Neo Analysis integrates with your current systems and Neo Design—the core module of our Product Lifecycle Management (PLM) suite—to seamlessly synchronize design data with actual process data.

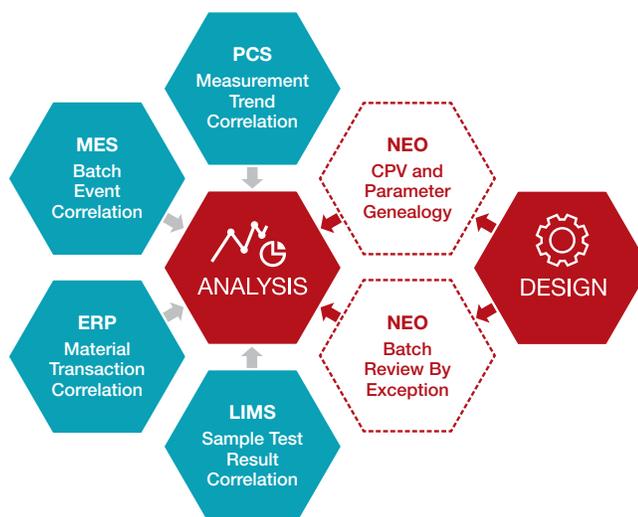
The Neo Analysis module:

- Confirms each batch ran according to the recipe, within predefined parameters
- Enables near-real-time batch review by all plant personnel
- Simplifies process investigations and other in-depth analysis
- Effectively automates your (CPV) program

1 As a batch executes on the shop floor, Neo Analysis continuously collects production data from your Data Historian, Laboratory Information Management System (LIMS), Electronic Batch Records (EBR) and Enterprise Resource Planning (ERP) system.

2 Production data is automatically assigned to the appropriate process action, as defined in Neo Design. This rich context is maintained as a design evolves during the product lifecycle, or production moves from one plant to another.

3 Once a batch has run, Neo Analysis provides point-and-click access to contextualized production data. The module enables you to easily chart data trends and compare them across batches and designs, and dramatically accelerates process investigations and root cause analyses.





Providing the Ultimate in CPV Capabilities

In batch review, Neo Analysis automatically evaluates:

- **Process Limits** – including CPV parameters, and flags them if their range is violated.
- **Batch Events** – including out-of-sequence tasks, extra tasks and missing tasks
- **Mass Balance** – including unexpected materials, volume or mass
- **Time Cycle** – including unexpectedly short or long task durations

Action is required only to review exceptions before a batch can be approved. Users may choose to view instrument tag data related to the violated limits and provide comments and reasoning.

Enhancing Tech Transfer

Neo Analysis considerably improves the accuracy and efficiency of tech transfer by empowering the receiving site with actual process data from the sending site. In fact, the module can electronically “replay” a complete batch execution for the receiving site, including:

- Automated and manual actions carried out during the batch
- Trending capabilities for all parameters across equipment

The ability to see how a process actually ran at another site greatly enhances process understanding at the receiving site.

Start streamlining batch reviews, automating CPV and improving tech transfer with the first digital design-based process PLM solution.

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