



BIOVIA Compose – A dedicated system based on industry standards for comprehensive and efficient Procedure Management, enabling an organization to remove process inefficiencies and reduce cycle times while improving product and process quality.

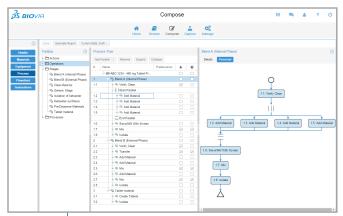
CHALLENGES

The challenge in the process industries today is the need to more quickly and efficiently transform new product development processes and analytical methods into reliable and repeatable procedures. It can take many years to bring a product from ideation to full commercialization, the point in the product lifecycle in which a company can begin to recoup the research and development investment. For example, pharma companies spend on average more than \$1 Billion over a 12- to 15-year period to bring a new drug product to market. Ultimately, any reduction in the product commercialization process not only reduces investment cost, but shortens the time to which a return on investment is realized.

One manner in which to directly influence this challenge is by implementation of a standards-based approach to product development and scale up, by driving utilization of a recipe/method framework into the early stages of development. In the context of BIOVIA Compose, consider that a procedure could represent any number of processes, such as a synthetic chemistry or formulation recipe, an analytical method, a standard operating procedure, or a protocol.

SOLUTION

A standards-based approach to procedure authoring enables the right content to be input into processes from the beginning and enables carrying out production in similar ways globally. The standards put in place will give the production system a common language and a shared way of working. The ANSI/ISA-88 structure, standards, and framework can guide the definition of the content and the execution, as well as the generation and visualization of the data. Specifying the critical steps, the parameters that need to be controlled, and data to be monitored and evaluated. Planning and execution under S88 is the key to being able to expose the context needed for process understanding.



BIOVIA Compose with procedure and process flow view of the recipe/method

CAPABILITIES

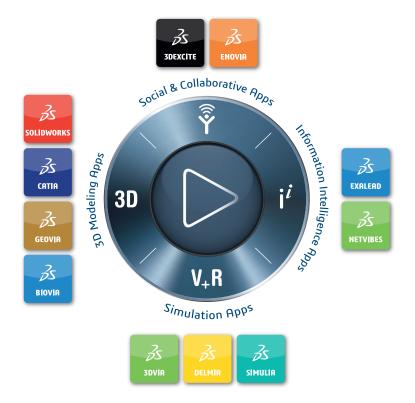
- Enterprise procedure authoring system using built-in libraries of operations and actions
- Dynamic web-based user experience on desktop, laptop and mobile devices
- Integrate with material and equipment management systems
- Define parallel operations and dependencies
- View Process Instructions and Process Flow
- Externalize and transfer procedures via S88 standard

BENEFITS

Organizations equipped with BIOVIA Compose will benefit from:

- An integrated solution from laboratory procedure development to execution on the manufacturing plant floor
- Streamlined global tech transfer from bench to pilot plant
- Strengthened adherence to regulatory, safety and QA requirements
- Transparency across functional lines on past, current and future development projects
- Systematic re-use of organizational knowledge, experiences and best practices

Capabilities Benefits • Consistent procedures and terminology via a standard framework Assured process completeness and reduction of rework · Easy planning and managing processes and testing, • Easy transfer and adaption of general recipes to site and Improved process efficiency master recipes · Contextualization of data, Increased product and process quality, Easy retrieval and reuse of data Faster and more informed decision making Automated data transfer Improved compliance · Efficient management and approval of recipes and Reduced cycle times methods



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