BIOVIA

3DEXPERIENCE®

INTEGRATED QUALITY MANAGEMENT SYSTEM

Use Case

DASSAULT SYSTEMES

Challenge:
A customer's siloed documentation, quality lab and quality management database, coupled with frequent manual entry errors, highlighted the need for a reliable data capture, tracking, and reporting solution.

Solution:
The **3D**EXPERIENCE® platform offers a suite of integrated solutions delivered as Software as a Service (SaaS). Biopharma Quality Management Analyst (BQM) delivers predefined, tested, and documented process models along with analysis tools. This approach offers a unified view of all captured data, effectively resolving quality concerns.

Results:
- Ensures a consistent link between processes, enhancing operational efficiency
- Eliminates need for re-entering data, saving time and minimizing risks
- Enables reuse of captured data, optimizing data management

CUSTOMER

BIOVIA's customer, an Ireland-based biopharma company, manufactures tablets globally for various markets. They have labs and manufacturing sites in Canada and India, as well as sales offices in the United States and South Africa, serving a multitude of businesses.

CHALLENGES

The company faced numerous quality management issues, including generating annual product quality reports, conducting audits, demonstrating continuous product improvement, reducing waste, and improving yield. A significant challenge was the effective utilization of their extensive recorded data and eliminating transcription errors.

They were in need of a solution that could provide reliable data capture and reporting on manufacturing activities, track incidents, and offer efficient data search capabilities. Given the numerous chemical assays the company performs, unexpected results often surface, leading to quality-led investigations and necessitating automated integration with their lab execution system (BIOVIA ONE Lab). In addition, the drive to prevent issue re-occurrence required an easy way to analyze.

HOW THE PROCESSES INTERACT

APR / PQR - ANNUAL PRODUCT REPORTING

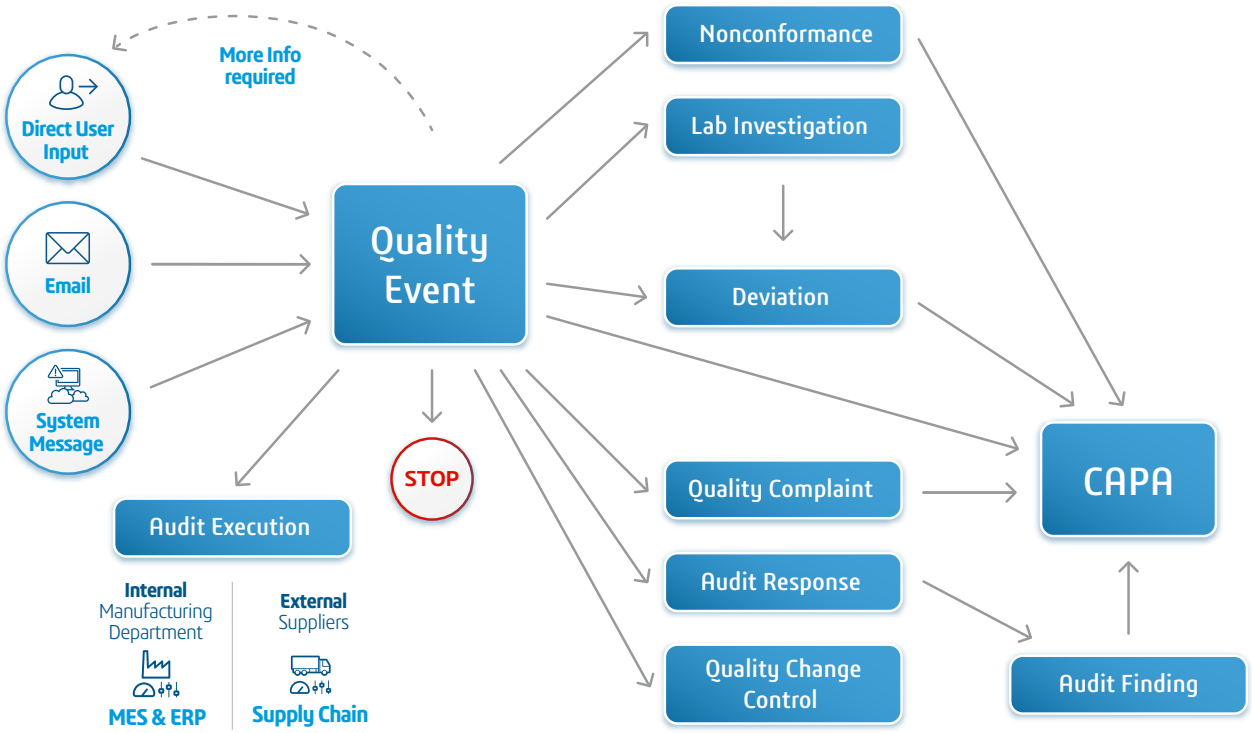


Fig 1. Documented and tested set of linked process models in biopharma

The company's Quality Lab System and Quality Management solution database existed independently, leading to disconnects such as an absence of direct links from Corrective and Preventive Actions (CAPA) to its root cause. In addition, manual data entry frequently led to transcription errors. The compilation of Annual Product Quality Review (APQR) reports, a regulatory requirement for pharma companies, was not only labor-intensive but also prone to omissions due to manual data lookup and transfer into spreadsheets for analysis. They had access to all the necessary data, including information on product batches made since launch, yield per batch, applicable deviations, lab analysis, change controls and CAPAs. However, this data was scattered across separate sources, making it difficult to access reliably.

SOLUTION

BIOVIA's Biopharma Quality Management Analyst solution provides a comprehensive set of quality process models for capturing, analyzing, and resolving quality issues. Users can access the system on fixed and mobile devices, and it is easily updated when regulations change.

Customers can also have bespoke process models designed to support other business processes, integrate multiple legacy data sources, and analyze records for recurring events.

Biopharma Quality Management Analyst uses the latest technology and fully integrates with other simulation, analysis, and manufacturing applications on **3D**EXPERIENCE®. It's a SaaS platform that is automatically updated, and the process models are based on current recommended practices. It is designed to integrate multiple sources of quality management data for unified search and analysis.

BIOVIA's Biopharma Quality Management Analyst (BQM) provides:

- Predefined process models (Figure 1) that are tested and documented based on industry practices, linking problem sources to resolutions with electronic signatures for authorization and closure. These models record any issue in detail, the steps taken to investigate and resolve it, and confirm its effectiveness. They also support internal and external audits.
- Most of the workflows are variations of the basic model (Figure 2). On each task – the user is presented with 'the information so far' – and a form to fill in for that task. eSignatures are used to authorize 'critical tasks' such as those approving changes to be made, or those closing the issue.
- Integration with other applications (in and out) is fully supported, for example;
  - Unexpected results in a BIOVIA ONE Lab experiment can be automatically used to create a quality event instance.
  - Risk Management analysis results can be attached to CAPAs and Change controls.
  - Problems encountered with suppliers (in an audit or from sub-standard assay results) can be passed to the Supplier Management application.
- Analysis tools that offer a unified view of all captured data (Figure 3), enabling users to assess items impacted by incidents and potential further impacts easily. A unique "similarity analysis" function identifies problems with similar textual descriptions by natural language processing, ranked by order of similarity. Additionally, analysis data and results from other **3D**EXPERIENCE® applications can be attached to provide evidence of the process. The BQM solution can identify and rank similar situations, establish usage history, and integrate analysis with legacy systems. It also supports analytics and reporting functions suitable for regulatory reporting.

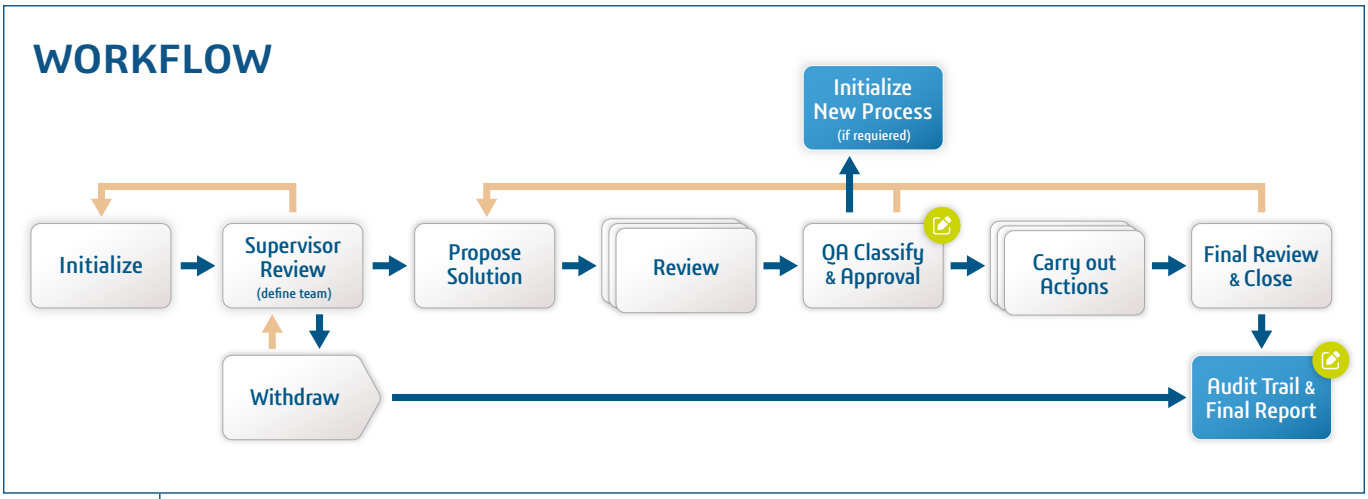


Fig 2. 'Generic workflow' indicative of those used in our process models

RESULTS

Upon deploying BIOVIA's Biopharma Quality Management Analyst, the customer was able to use the new process models to efficiently manage quality events. All users could now create new process instances to capture problem details, and events could trigger other process instances, such as Deviation or CAPA. Proposals now required approval before changes, with a review before closure. This ensures that all changes are properly documented and evaluated before being implemented. Historic instances could also be reviewed and similar ones displayed, helping users to learn from past experiences and identify potential risks. Additionally, the potential impact of other items by an issue could be discovered, enabling users to take proactive steps to mitigate any potential consequences.

Overall, BIOVIA's Biopharma Quality Management Analyst helped the customer to improve their quality management processes by making them more efficient, transparent, and data-driven.

In the near future, the customer's product development team plans to add more types of analysis, pre-defined reports, and new process models, especially for medical device usage and clinical studies.

LEARN MORE

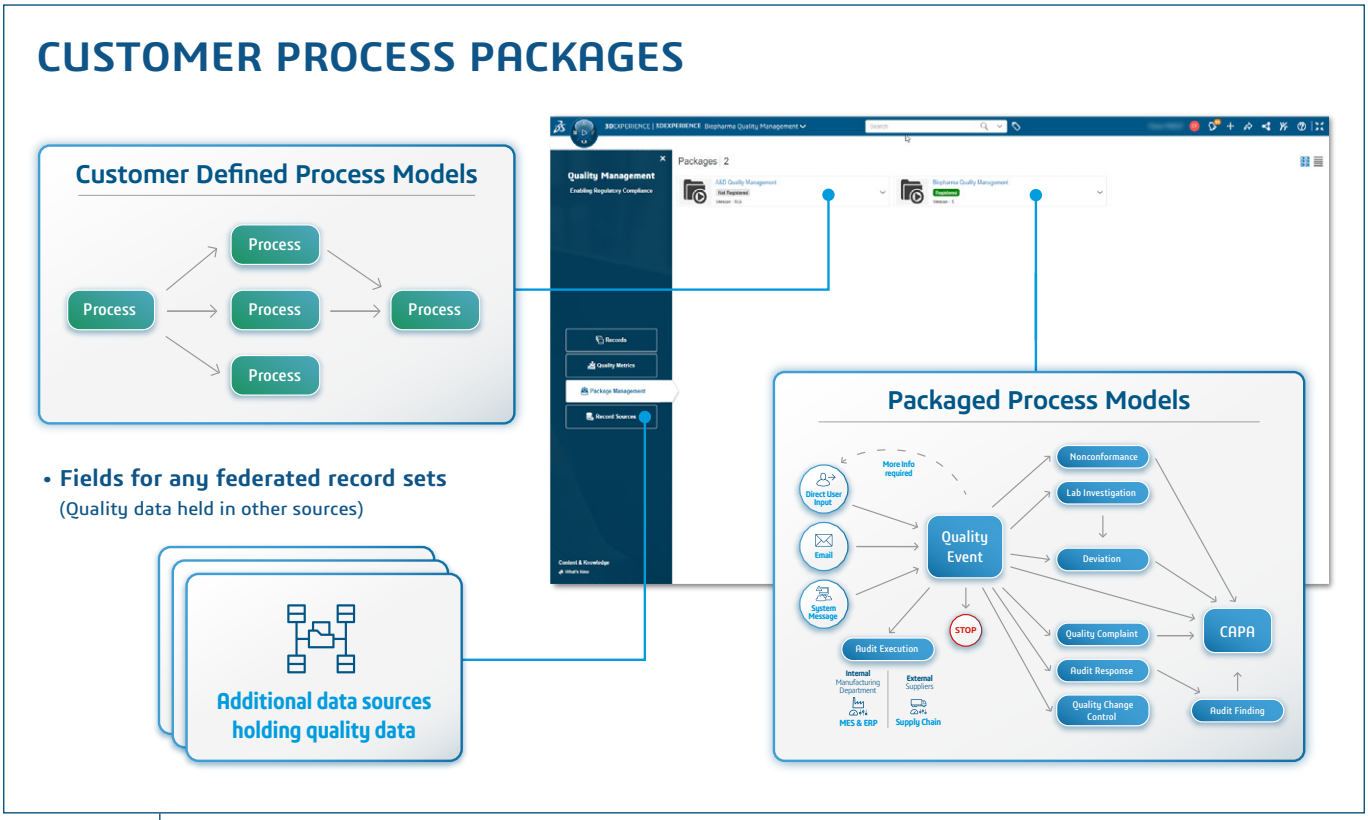
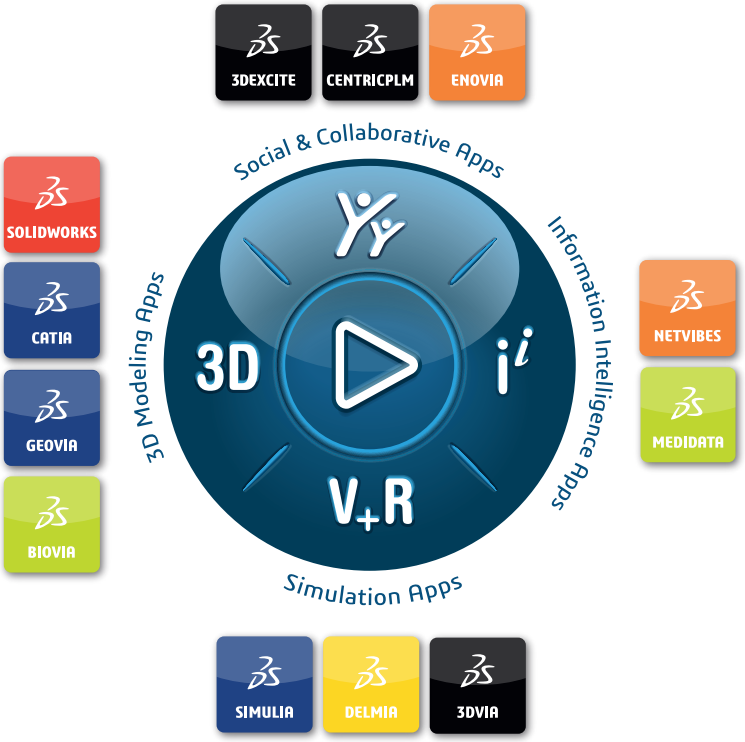


Fig 3. Process models are designed to support other customer specific processes, integrate multiple legacy data sources, and analyze records for recurring events



Our **3D**EXPERIENCE® platform powers our brand applications, serving 11 industries, and provides a rich portfolio of industry solution experiences.

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