BIOVIA

3DEXPERIENCE®

CONTINUOUS IMPROVEMENT WITH QUALITY MANAGEMENT

BIOVIA'S BIOPHARMA QUALITY MANAGEMENT ANALYST SOLUTION

Whitepaper

The pharmaceutical supply chain continues to experience product recalls, drug shortages, and supply disruptions due to unsatisfactory quality in manufacturing, according to the FDA.[1] Since the COVID-19 pandemic, quality management issues in the pharma and biopharma spaces have suffered even more.

In fact, in 2022, the FDA issued more than 130 recalls attributed to temperature abuse, 100 recalls caused by products being stored outside the appropriate temperature conditions, and 51 recalls associated with manufacturing using a contaminated excipient that had already been recalled by its supplier.[2] These recalls—along with numerous smaller instances—come with a hefty price tag. The process of addressing these issues is time-consuming, expensive, and requires patience to correct the problem and prevent its recurrence. This does not even account for the wasted products and damage done to the company's reputation.

As biopharma companies embrace digital transformation, many are turning to quality management solutions. These platforms aid in managing product quality, ensuring they meet regulatory standards. But the advantages extend beyond just compliance. It's no surprise then, that the market valuation for pharma quality management systems will hit nearly $4 billion by 2030.[3]

DASSAULT SYSTEMES

QUALITY MANAGEMENT: A REGULATORY MANDATE

In the life sciences industry, and in biopharma especially, quality management procedures are mandatory. Regulatory bodies rigorously inspect that approved procedures are in place; staff are trained and usage is confirmed. Meeting regulatory requirements is crucial for companies to secure or maintain the license to manufacture and/or sell products.

For biopharma companies, regulatory organizations often demand documentation—detailing how product-related processes are carried out—and records, providing evidence of what was done, when, and by whom. Therefore, quality management becomes as much about ensuring product quality as it is about fulfilling requirements and checking regulatory boxes. McKinsey notes that many life sciences companies view quality management with a "policing mentality," shaping quality systems and processes with the primary goal of simply satisfying regulators.[4] Such systems can become a replacement for paper forms and filing cabinets – a complicated, time consuming way to store unusable data.

Regulators now seek to see evidence of continual product improvement:

- Regulators often look for a downward trend of issues and make note of changes specifically to solve problems for each product.
- Regulators expect evidence of analysis into quality investigations.
  - What are the risks?
  - What is the root cause?
  - Has this (issue) happened before?

As a product matures, the volume of data held increases – this in turn expands the time and effort required to analyze all product-related data and increases the risk of errors, which can be detrimental during regulatory inspections.

Clearly, there are regulatory and financial benefits to be gained when you prevent quality issues from reoccurring. Companies therefore seek to validate to regulatory bodies (and their shareholders) that they have rectified the issue and taken proactive measures to prevent future instances. Unfortunately, many quality management solutions fail to provide a comprehensive view from issue identification to resolution. Without end-to-end visibility, companies are not only risking the quality of their products, they're also risking regulatory penalties.

QUALITY MANAGEMENT: A CATALYST FOR BUSINESS IMPROVEMENT

Biopharma quality management is so much more than just regulatory compliance. It's also a business improvement process that increases a company's profitability. Here are some ways in which quality management financially benefits an organization:

- It continually reviews and seeks to improve product yield.
- It seeks to minimize mistakes and cut wasted time and materials.
- It avoids legal and regulatory consequences, saving time and money as well as preserving the company's reputation.
- The earlier in the process a problem is detected and resolved, the cheaper that resolution is.

The last point is especially relevant for biopharmaceutical companies hesitant about investing in an end-to-end quality management system. According to McKinsey, when companies proactively implemented quality management systems, the new framework cut regulatory complexity and effort associated with CAPA management by more than 50%. Companies can more easily fulfill regulatory requirements with quality management systems.[4]

As important as quality management is, a shocking 50% of life sciences companies are unaware of their cost of quality (COQ).[5] When companies don't know what their expenses, they miss out on opportunities to measure and improve their business efficiency. Quality management allows companies to improve product quality, track and review issues more efficiently, and analyze KPIs in real-time. This results in making business processes more efficient, leading to cost savings across multiple departments.

Additionally, Forbes reported that at life sciences companies, 61% of respondents lost at least a quarter of their working weeks to non-value-add manual admin and compliance upkeep tasks, with 25% losing at least half.[6] Quality management systems automate many of these manual tasks. Not only does this decrease the likelihood of human errors, it also frees up employees to focus on strategic, long-term projects that add more value to the company.

QUALITY MANAGEMENT: A STRATEGY FOR PRODUCT IMPROVEMENT AND COMPETITIVE ADVANTAGE

Quality management systems in biopharma not only improve regulatory compliance and streamline business processes, but they also bring about significant improvements across the organization. When quality management is seen not just as a box to tick but as a chance to improve products, it allows a downstream benefit to be obtained from the data collection and investigation work – which gives the company a competitive edge. Sophisticated analysis and search functionality can be used to expose opportunities for improvement and facilitate 'before & after comparison' to establish the effectiveness of any change.

Quality management helps improve the consistency, quality, durability, and performance of a product, making quality a competitive differentiating factor.[7] As per an article published in *Drug Discovery Today*, the integration of machine learning and AI into quality management systems improves the quality of pharmaceutical products, leading to higher rates of customer satisfaction.[8] As companies improve their quality management, other areas of the business benefit too. *American Pharmaceutical Review* published an article that suggested that a higher degree of maturity in implementing quality management practices leads to improved operational performance.[9]

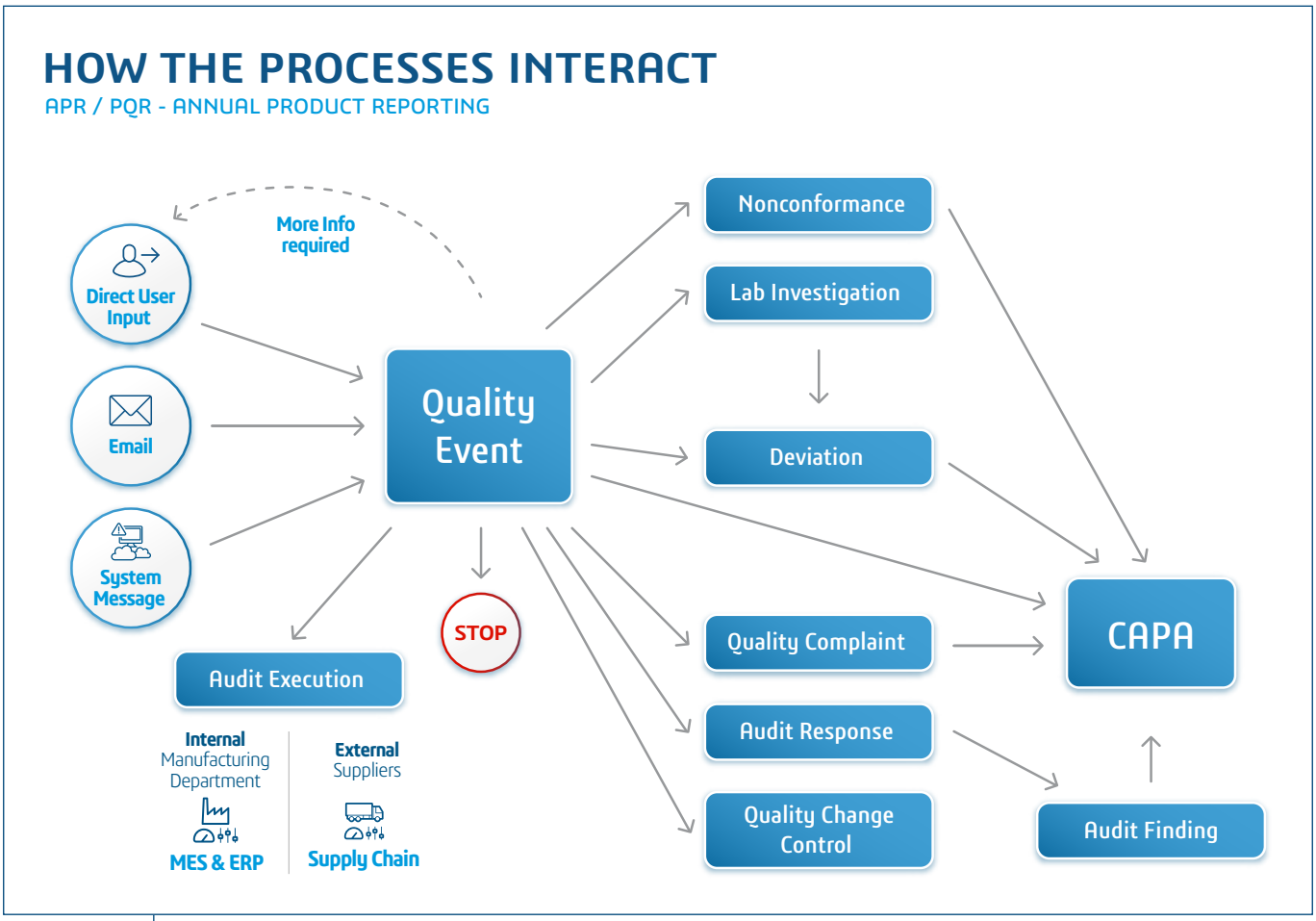

Fig 1. Documented and tested set of linked process models in biopharma

Even minor improvements in product quality can have large impacts on business, especially in today's market. PwC noted that recently, looking at the stock performance of the top 50 pharmaceutical companies, the divide between the leaders and laggards has been widening.[10] Staying competitive in this environment means companies can't take any chances on quality issues or sub-par products. Quality isn't just about meeting regulatory standards—it makes a statement about your company as a whole, and it could make or break your brand.

THE ROLE OF BIOVIA'S BIOPHARMA QUALITY MANAGEMENT ANALYST SOLUTION

BIOVIA helps companies move from seeing quality management as a hurdle to using it as a proactive approach to continuous improvement. Our Biopharma Quality Management Analyst product serves as a single application available to all key stakeholders. With easy access to all records, users can delve into insights detailing impacted items, contributors, change history, and full reports. By using natural language analysis of existing quality records, a single click allows users to filter and sort similar records, enabling quick access to required information. Issues are linked through all processes, making cause and effect easier to determine.

Addressing biopharma companies' challenges with the Biopharma Quality Management Analyst Solution

Biopharma Quality Management Analyst Solution is uniquely designed to solve the most common problems biopharma companies experience when it comes to quality management. The platform assists in organizing your documented and tested set of linked process models, which are designed in accordance with industry best practices and capture data for events, deviations, CAPA, change control, complaints, and audit activities. The BIOVIA team is also developing solutions for nonconformance, which is required for medical devices as well as integrations with Medidata to provide quality management functionality inside clinical studies.

Additionally, Biopharma Quality Management Analyst Solution provides built-in analysis of similar instances, with just a single click. This offers consistent, reportable insights of all records. Such visibility can demonstrate to regulators your downward trends in instances, proving that your company's commitment to continuous improvement.

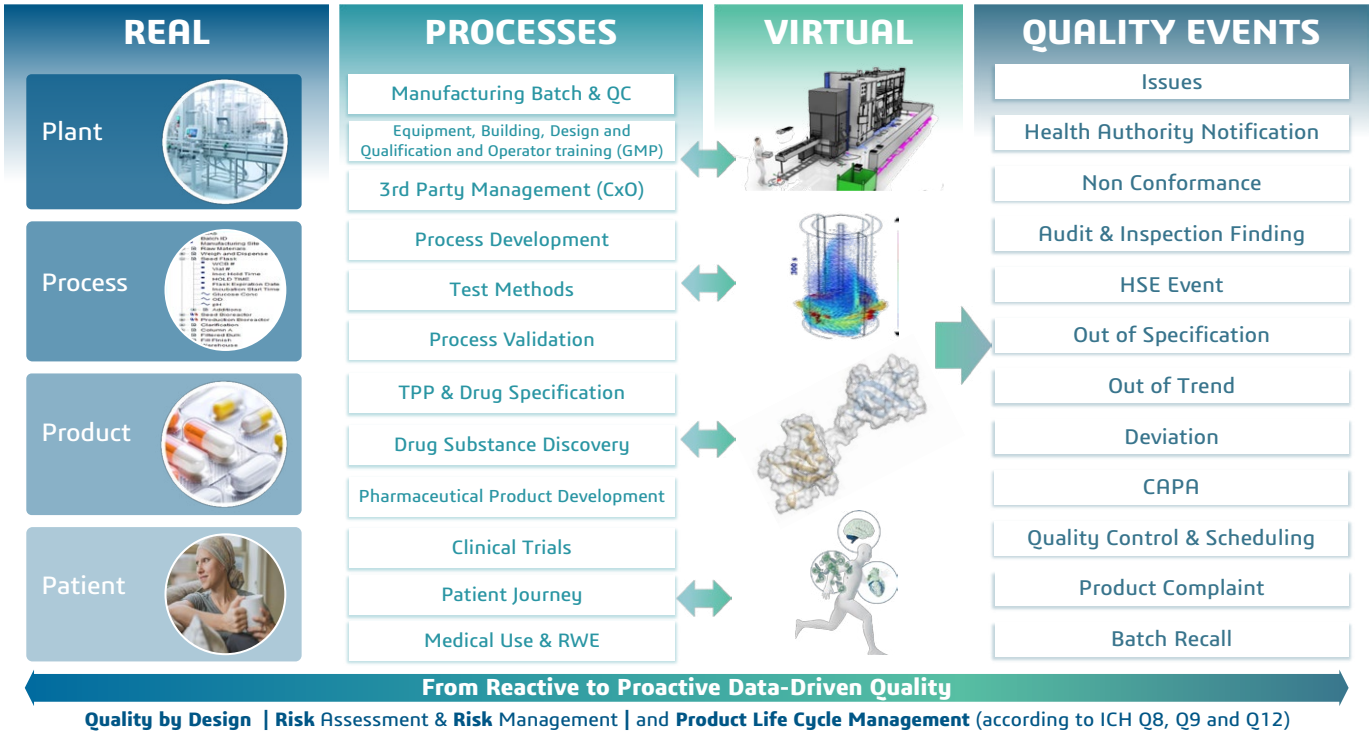

Fig 2. From Reactive to Proactive Data-Driven Quality

USING AI/ML TO ENVISION THE FUTURE

Artificial intelligence and machine learning (AI/ML) are the newest tools to make your quality management faster and more efficient. BIOVIA's Biopharma Quality Management Analyst Solution adopts a model-based approach to AI to leverage current and legacy quality records to predict and prevent potential issues. This platform can enrich your company's quality department decisions with AI-driven insights.

You can even envision the future with Biopharma Quality Management Analyst's Virtual Twin capabilities. The quality-focused insights derived from virtual simulations provide you with AI-enhanced analytics for forecasting, preventing instances, and assessing condition similarities.

WHY THE BIOPHARMA QUALITY MANAGEMENT ANALYST SOLUTION IS WELL-SUITED TO BIOPHARMA

Biovia's Biopharma Quality Management Analyst's unique capabilities empower biopharma companies to:

- Integrate industry-standard best practice processes with a workflow engine and analysis capabilities for comprehensive quality management.
- Adopt, manage, and integrate custom processes with BIOVIA's own out-of-the-box design.
- Incorporate legacy data for analytics and AI/ML, treating legacy system data as a valuable resource.
- Analyze quality process records, particularly impacted items, change history, contributing users, and view-final reporting.
- Identify similar instances for comparison and learning.
- Display and export regulatory metrics analysis for transparency and compliance.
- Install or upgrade sets of tested and documented business process models that support common biopharma quality processes.
- Record electronic signatures on change approval and issue closure workflow tasks
- Integrate with lab analysis systems (for example: ONELab for QC or Development Lab)
- Connect quality management to the line-of-business data and applications
- Fit the needs of various life sciences industries, with enterprise QMS covering QA, manufacturing, clinical, and medical device needs
- Combine industry best practices with your customers' unique needs with world-class process designs

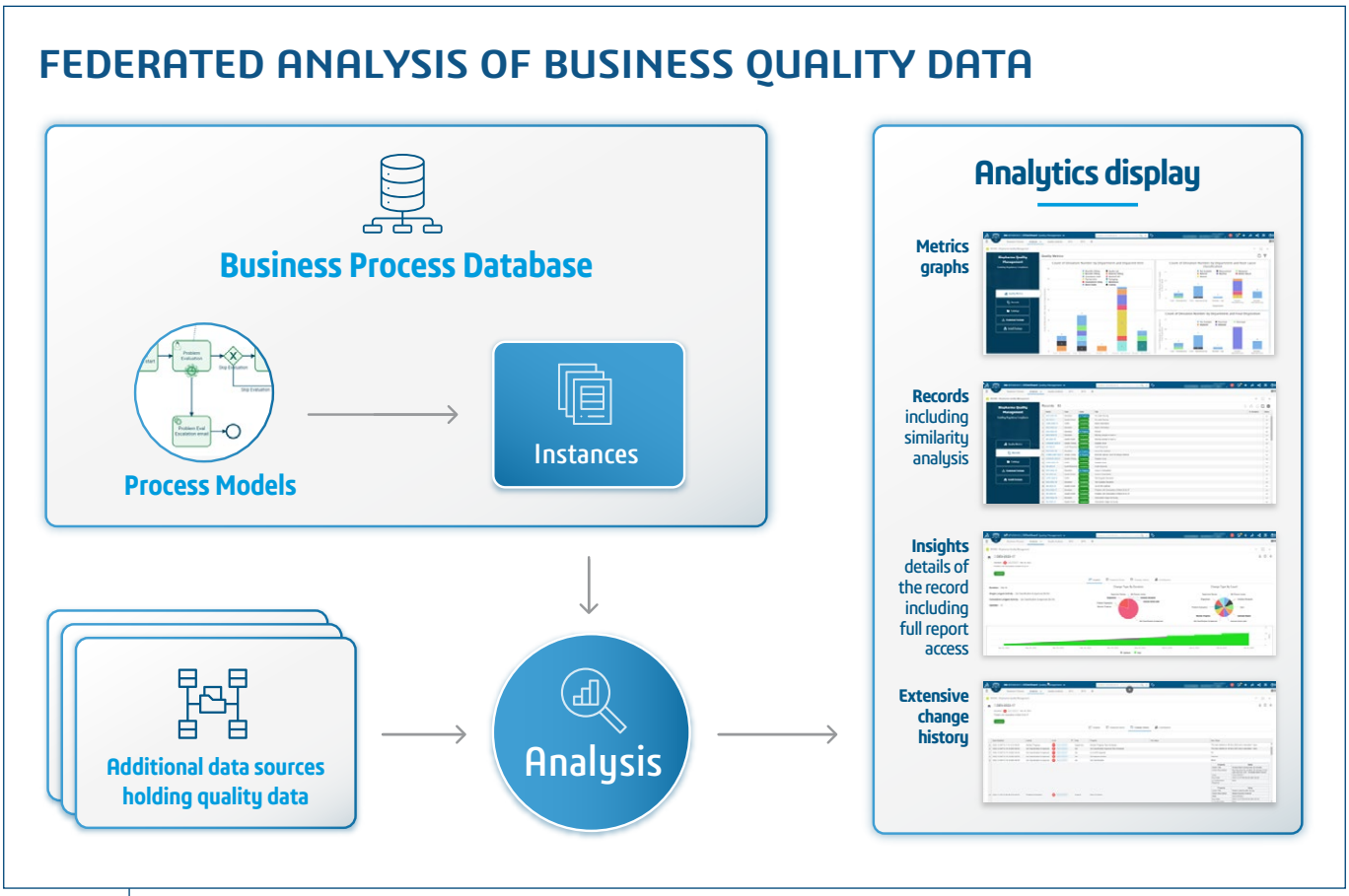

Fig 3. Data to be displayed and analyzed comes from many sources

CONCLUSION

Digital transformation is empowering biopharma companies to perceive quality management as more than a set of challenging constraints. As life science companies embrace AI and machine learning, they are discovering the transformative potential of quality management.

Quality management, when used as a proactive approach, helps companies:

- Be more compliant with regulations
- Save money by resolving issues faster
- Save time by having fewer CAPA events
- Improve overall business processes
- Become more efficient by automating mundane quality procedures
- Free up employees to focus on more strategic decisions
- Increase customer satisfaction and boost company reputation
- Differentiate your company from similar biopharma companies
- Improve product quality to give your company a competitive edge

By leveraging the functionality of our **3D**EXPERIENCE® platform, Biopharma Quality Management Analyst Solution helps biopharma companies improve more than just the quality of their products—we help you elevate the quality of your entire company.

LEARN MORE

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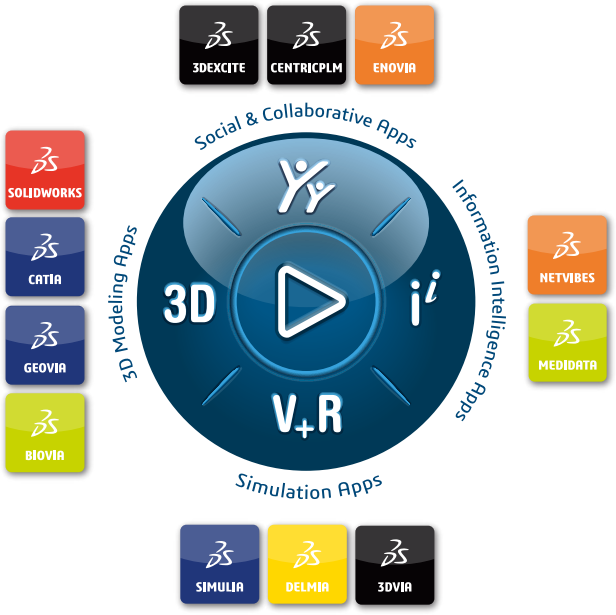

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