LIFE SCIENCES
& HEALTHCARE

QUALITY & REGULATORY EXCELLENCE FOR BIOPHARMA

Achieve enterprise-wide data integrity
for total quality and compliance

THE PATIENT EXPERIENCE CHALLENGE

The biopharmaceutical industry is shifting. The business model for bringing a drug product to market is evolving, with innovation expected within areas of scientific discovery and from combination products. With the development of biotechnologies, new product discoveries will become increasingly complex. At the same time, biopharmaceutical companies are looking for therapeutic solutions that include not only drug products but also services based on technologies such as Internet of Things (IoT), drug delivery devices, companion diagnostics, big data and nanoparticles. These therapeutic solutions can create a better overall patient experience by improving patient adherence and treatment efficacy.

DASSAULT SYSTEMES

Key benefits:

- Ensure a single source of truth
- Enable change impact analysis, informed decision-making and full IP reuse
- Leverage regulatory and quality requirements as advantages rather than constraints
- Reduce time-to-market and cost of market expansion
- Secure consistency in quality, compliance and regulatory activities

Managing complexity in the pharmaceutical industry

Drug manufacturers work hard from concept to patient: they create and optimize formulated products, gain regulatory approvals and manage consumer medicine deliveries. The complexity of the drug lifecycle increases with frequent mergers, acquisitions and quality and regulatory compliance requirements (e.g., ISO IDMP and ICH Q12), presenting a challenging innovation environment for companies. More agile and integrated approaches to product development and commercialization are now necessary, especially when changes occur and assessing impact becomes exceptionally critical. With up to 1,000 medicinal products per substance or brand, the number of interconnected product-related changes per year in a company is crucial. Proactively managing this complexity is a key challenge Dassault Systèmes proposes to address.

Change control

Quality & Regulatory Excellence for Biopharma enables companies to perform impact analysis, support their decisions and improve traceability across all changes and variations at the substance, pharmaceutical product and medicinal product (country) levels. The solution helps companies streamline tech transfer, manufacturing and commercialization processes.

Quality & Regulatory Excellence for Biopharma provides a secure environment with a single source of truth enabling optimal improvement of product definition management, collaborations, visible change impacts and compliance as well as manufacturing quality and efficiency. Incorporating end-to-end change management in conjunction with visibility from the single source of truth can minimize risk and reduce non-value-added work throughout the process.

Reduce cost of quality (COQ)

Quality is often perceived as a costly burden while compliance is considered a non-value-adding aspect. However, companies can achieve quality and compliance simultaneously in a cost-effective way. An integrated, easy-to-use quality system contains compliance costs and efforts and enables more efficient and higher quality products and processes.

Quality & Regulatory Excellence for Biopharma allows organizations to automate and manage quality processes across all stakeholder access, ensure data integrity, reduce compliance risks and achieve quality excellence. In contrast to traditional document-centric solutions offering static, unstructured reports and documents, **Quality & Regulatory Excellence for Biopharma** is data-centric, allowing for easy access to documents and data supporting business use, audits and investigations.

Streamline regulatory filing

Chemistry, Manufacturing and Controls (CMC) are critical in ensuring the safety of a medicinal product and reproducibility between batches. To obtain marketing authorization for a medicinal product, companies must prepare and submit all data relevant to their application. The compilation of all appropriate data must be fastidious, thus necessitating several data verification steps.

Quality & Regulatory Excellence for Biopharma enables an automated and structured approach to data compilation that promotes stability data while ensuring data traceability. With the solution, companies can easily focus on dossier content instead of data transcription and data verification.

Using consistent sets of information throughout entire product lifecycles, **Quality & Regulatory Excellence for Biopharma** can significantly reduce non-value-added activities and enable stakeholders to collaborate in real time. The solution can integrate all product-related information and processes and connect people at any point throughout the product lifecycle.

Our 3DEXPERIENCE® platform powers our brand applications, serving 12 industries, and provides a rich portfolio of industry solution experiences.

Dassault Systèmes, the **3D**EXPERIENCE Company, is a catalyst for human progress. We provide business and people with collaborative virtual environments to imagine sustainable innovations. By creating virtual twin experiences of the real world with our **3D**EXPERIENCE platform and applications, our customers can redefine the creation, production and life-cycle-management processes of their offer and thus have a meaningful impact to make the world more sustainable. The beauty of the Experience Economy is that it is a human-centered economy for the benefit of all –consumers, patients and citizens. Dassault Systèmes brings value to more than 300,000 customers of all sizes, in all industries, in more than 150 countries. For more information, visit **www.3ds.com**.

3DEXPERIENCE®

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