TOTAL QUALITY MANAGEMENT

From Reactive to Proactive Quality Management







A RAPIDLY EVOLVING LIFE SCIENCES ECOSYSTEM

Today the Life Sciences industry includes pharmaceutical companies, medical device manufacturers and health care stakeholders. The industry is highly competitive and regulated, requiring large investments in cutting edge technologies. The complexities associated with bringing new medicines or medical devices to market create a tremendous cost overhead, as well as serious challenges to quality and regulatory compliance. Quality, application functionality, usability and performance are essential Life Sciences company operations. Even more critical is to ensure that computerized systems provide secure, accessible and reliable data.

Data integrity lies at the heart of government regulations such as the US Food and Drug Administration (FDA) and the European Medicines Agency (EMA). Company policies around data security are also subject to local government rules, industry reviews and audits.

Minor inconsistencies in pharmaceutical data can skew the results of a clinical trial or other important events. More importantly, data errors can have a catastrophic impact on people's lives—such as patients not receiving the right treatment or causing personal harm in the worst-case scenario.



THE ROLE OF QUALITY ASSURANCE: ASSURING TRUST IN A GLOBALIZED LIFE SCIENCES ECOSYSTEM

A study conducted by The Everest Group, a leader in research and management consulting services, noted that for a variety of reasons, patients and consumers have a trust deficit issue with Life Sciences companies:



- Adverse events (AEs) and drug reactions: There has been a steady rise in AEs over the past six years. Over 100,000 people in the United States alone, die every year due to undisclosed/undiscovered pharmaceutical side effects.
- **Drug development efforts:** In parallel, the time (10-15 years) and cost (approximately US \$2.5 billion per drug) of drug development is creating significant time-to-value challenges, with the release of delayed and often expensive therapies.
- **Pharmaceutical pricing:** Drug pricing is a significant concern for consumers, particularly given high profile situations, such as the Turing Pharmaceuticals incident and the U.S. administration's posture forcing Pfizer and Novartis to temporarily suspend price hikes.
- Drug recalls: Although global Life Sciences companies have tripled their annual pharmacovigilance (PV) spend as a percentage of total sales—from 0.3% in 2003 to over 1% in 2017—drug recalls have not declined significantly.
- Poor GxP compliance: Poor adherence to good manufacturing practices have led to several trust-deficit situations. Wockhardt has seen three of its plants issued import bans by the FDA and a subsequent warning letter on similar issues. The FDA has frozen imports of Valsartan from ZHP, a Chinese API supplier. All these actions have led to significant financial and reputational losses.

Pharmaceutical companies paid a total of \$38.6 billion to federal and state governments from 1991 and 2017 resulting from 412 penalties.

To improve relations, Life Sciences is establishing a direct relationship with patients/consumers. This change places Quality Assurance (QA) in a valued position as the caretaker-in-chief.

The success of the revised QA role will be measured in new ways:

- Supporting the digital innovation agenda for life sciences
- Orchestrating the ecosystem to drive improvements in care
- Driving incremental and continual quality improvements
- Validating data to enable real-time insights
- Advancing a trust-based relationship with consumers

A 2017 McKinsey Report states that the costs associated with warranties and recalls for a single product can be as much as \$600 million.

 81% of 483 Warning Letters issued by the FDA are directly attributable to quality documentation issues. Companies can face up to a 10% drop in shares after a single major quality event such as a medical device recall. C The costs associated with warranties and recalls cost the medical device industry \$2.5 billion – \$5 billion annually.

BRINGING VALUE BACK INTO LIFE SCIENCES: DISRUPTING THE LIFE SCIENCES VALUE CHAIN

Technology represents a major opportunity to rethink business models, how to approach patients and transform a relatively "unchanged for decades" value chain. The use of data and analytics in R&D, the application of blockchain technology, the emergence of digital therapeutics and the various collaborations between life sciences and digital technologies serve as a benchmark for companies to check the progress of their respective digitalization journeys.



29%

of companies have digitized or plan to digitize their clinical trial processes. 34% have already applied of plan to apply big data in R&D, production, and distribution. However, there is an urgent call for action as this still leaves a vast number of companies that are not using digitalization in clinical trial processes.

Source: KPMG in Germany, 2017

CHARACTERISTICS OF A BEST-IN-CLASS QUALITY ASSURANCE (QA) PLATFORM

In 2019, the Everest Group highlighted trends in an analysis that recommended the QA engagement model must change as follows:



PLATFORM-LED

Streamline the solutions portfolio by adopting a platform-based model that can help scale the function.



CONSUMPTION-LINKED

Implement an as-a-service, platform-based QA operating model that offers secure and agile integration with a multitude of technology elements, including devices and the external ecosystem. A built-in repository of QA tools and solutions, made available through as-a-service catalogues, is critical to the easy consumption of services and offerings by ecosystem partner systems and consumption-linked commercial models.



END-TO-END

Focus on end-to-end process and data coverage for a patient care journey spanning the entire ecosystem.









LINKED TO BUSINESS OUTCOMES

Measure the efficacy of the QA function in terms of speed, agility and improvements in detection and accuracy of compliance reporting, not traditional cost metrics.

OPEN

Allow seamless integration through APIs and modularity as the platform stitches together both tools and services (e.g., crowdsourced QA) delivered through the ecosystem.

SECURE

Enable secured and compliant operations with several built-in security components as well as the ability to use best-of-breed, third-party security solutions.

AI-ENABLED

Build in intelligent components to learn QA activities as the platform produces data and eventually automates operations.



A FUTURE-PROOF LIFE SCIENCES QA PLATFORM SHOULD EXHIBIT THESE CHARACTERISTICS TO HELP ENTERPRISES MEET EVOLVING DEMANDS.

These changes will also lead to an evolution of QA's role in the enterprise ecosystem.

Who do you see as the drivers and initiators of digital transformation in life sciences? (multiple choice, in %)

85 Tech companies **Biotech companies** 69 Medtech companies 67 66 Regulators 62 Start-ups 61 Pharma companies Healthcare professionals 42 Insurers 37 Patients 20 40 60 80 100 0

Source: KPMG in Germany, 2017

THE 3DEXPERIENCE PLATFORM: TOTAL QUALITY BY DIGITALLY CONNECTING THE DOTS

The **3DEXPERIENCE**[®] platform provides the applications, collaborative processes and single data source to embed quality throughout the product development process. The platform enables control, visibility and traceability to help ensure that quality challenges are not only met but also transformed into advantages.

Contributors across the extended enterprise can anticipate and mitigate errors, rather than react to them, creating a learning organization that doesn't repeat quality issues. This delivers an authentic Total Quality Management (TQM) experience.





PLM AND THE 3DEXPERIENCE PLATFORM

The platform supports and helps Life Sciences organizations comply with a myriad of regulations and industry standards such as:

- Current Good Manufacturing Practices (cGMP)
- EU Annexe 11
- FDA 21 CFR Part 11
- FDA 21 CFR Part 211
- FDA 21 CFR Part 820
- ISO 13485
- ISO 15378

The **3D**EXPERIENCE platform offers the following capabilities to help ensure that TQM is embedded from end to end:

A Lean Approach

Digitalized Lean practices offer intuitive tools that leverage Lean methodologies to reduce or eliminate nonvalue added work and help ensure efficient processes.

Project Management Methodology

Quality methods are governed as projects with automated and event-driven tasks, change orders and actions, and a model-based enterprise approach for requirements and functions.

Risk-based Thinking

As part of quality management (e.g. ISO9001/ ISO 13485) risks are managed, controlled and synchronized with controlling tasks throughout all design, manufacturing and services processes.

Fully Embedded

Embedded CAPA and non-conformance tools are linked to complaints, deviations and non-conformance management. Customer complaints and nonconformances are managed and directly linked to the product definitions, reusing past experiences either for efficient resolution or to enrich the know-how database.

Audits for Compliance

A fully traced process — from ideation to go-to-market — with audit and inspection tools allows for continual and seamless compliance with regulations and internal requirements.

Analysis and Reporting

Organizations can reveal and analyze quality and compliance data to improve quality processes and gain a competitive advantage. With digital analysis, future quality issues can be predicted and prevented before they reveal themselves.

The **3DEXPERIENCE** platform enables traceability from initial requirements to product delivery to ensure consistency and completeness of all quality tests and verifications.

Experience Total Quality, Not Just Manage It

Today, Life Sciences organizations are pushing away from "managing quality" to embedding a "culture of quality" that promotes a proactive approach to "total quality."

The best Quality Management Systems (QMS) are data and content-centric, enabling easy access to relevant information, such as enterprise level quality metrics to provide to the FDA.

Apps for intelligent, federated searches and predictive analytics allow organizations to leverage information for deeper insight into their processes. These actions result in better knowledge-based decisions that can impact product quality, process, brand reputation, sustainability and competitiveness.



CASE STUDY **OSSTEM IMPLANT**

Dental implant and medical device manufacturer Osstem Implant wants to become the world's number one implant provider by 2023. To achieve this, it first needed to automate its business processes related to Unique Device Identification (UDI).

The company adopted the **3DEXPERIENCE** platform and its License to Cure for Medical Device industry solution experience to accelerate the delivery of innovative, safe, and fully compliant medical devices.

The **3DEXPERIENCE** platform's integrated business framework helps Osstem Implant eliminate traditionally disconnected processes and data and increase the efficiency and accuracy of its product quality control.

Read the full case study...



"With Dassault Systèmes' **3D**EXPERIENCE platform, we enhance business efficiency and develop higher-quality medical device products that comply with international regulations."

-Kim Tae-yong Head of the information system management team, Osstem Implant

LEARN MORE:

The **3DEXPERIENCE** platform provides the applications to enhance and advance the early detection of quality issues. The platform offers a unique combination of modeling, simulation, collaborative innovation, data science and artificial intelligence for end-to-end research and discovery, development, clinical testing, manufacturing and commercialization, with full visibility and collaboration across a company's internal and external ecosystems.

Learn how the **3DEXPERIENCE** platform and ENOVIA Quality Management helps Life Sciences manufacturers transform quality challenges into a competitive advantage.

HTTPS://IFWE.3DS.COM/LIFE-SCIENCES/TOTAL-QUALITY

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

Dassault Systèmes, the **3DEXPERIENCE**® Company, provides business and people with virtual universes to imagine sustainable innovations. Its world-leading solutions transform the way products are designed, produced, and supported. Dassault Systèmes' collaborative solutions foster social innovation, expanding possibilities for the virtual world to improve the real world. The group brings value to over 250,000 customers of all sizes in all industries in more than 140 countries. For more information, visit **www.3ds.com**.





Europe/Middle East/Africa Dassault Systèmes 10, rue Marcel Dassault CS 40501 78946 Vélizy-Villacoublay Cedex France Asia-Pacific Dassault Systèmes K.K. ThinkPark Tower 2-1-1 Osaki, Shinagawa-ku, Tokyo 141-6020 Japan Americas Dassault Systèmes 175 Wyman Street Waltham, Massachusetts 02451-1223 USA CATIA, BIOVIA, # B 322 306 44

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