

## LIFE SCIENCES LICENSE FOR QUALITY

Integrated close-loop quality system, from non-conformance reports to corrective and preventive actions



### LICENSE FOR QUALITY

**License for Quality** is a comprehensive quality management solution that directly embeds quality and compliance directly into the product development process. It enables organizations to take control of their global operations, while continuously improving operational performance.

### INDUSTRY CHALLENGES

Organizations are consistently struggling to deal with quality issues efficiently and effectively. As the complexity of products and processes increases, this predicament only promises to worsen. By removing departmental silos with the **3DEXPERIENCE®** platform it is possible to enforce common quality processes, while adapting to local regulatory requirements and improving communication.

### SOLUTION HIGHLIGHTS

**License for Quality** manages the entire event lifecycle from customer event intake through investigation, root cause analysis and closure. This comprehensive solution is designed to help manufacturers expand programs to best capture a wide scope of operations intelligence, which can drive continuous improvement and streamline their quality processes. It provides ease of use at all levels of the organization for managing quality events, corrective and preventive actions (CAPA), product nonconformance, and audits. It is all about collecting the right data, and making it available to the right person, at the right time. This very powerful combination, if done right, can have a profound impact on performance and a pathway to becoming best-in-class.

The challenges of implementing and sustaining an effective CAPA process can vary. There are often too many quality data silos with difficult to view data that hinders access to real time information resulting in poor decisions. A common enterprise-wide quality solution like **License for Quality** helps companies avoid compliance risk, reduce waste, and improve quality and decision making by improving the interconnection of team members and business processes.

**License for Quality** is also an effective, consolidated, global approach to managing customer complaints. It improves the management of the complaint handling lifecycle from identification; valuation to closure. **License for Quality** improves visibility throughout the organization to help reduce delays in identifying, evaluating, and communicating serious events. It automates the control and disposition process of non-conforming products and processes by identifying the nonconformance, tracking its review, and monitoring and reporting the follow-up actions.

For a complete and systematic QMS approach, audits are conducted. After audits are planned, findings are classified and follow-up is assigned to the responsible person. Upon completion of follow-up actions, a final report is issued and routed for complete closure. **License for Quality** links all artifacts, records, analysis, documentation, and validation results. These artifacts are easily traceable and retrievable for internal or external audits providing added value for engineering, manufacturing and quality teams working on new product programs.

## SOLUTION VALUES

- Standardize the development of a closed-loop, holistic approach to CAPA activities and management.
- Manage complaint handling processes from identification and product evaluation, to closure.
- Manage deviation/nonconformance identification, reporting, disposition and resolution with explicit documentation to ensure quality standards and compliance.
- Manage audit activities and processes from scheduling to execution to ensure quality assurance and quality systems are working as defined and approved.

## LICENSE TO CURE FOR MEDICAL DEVICES

High consumer expectations for better healthcare and advances in technology that improve quality of life are creating favorable market conditions for medical device companies. *License for Quality* is part of *License to Cure for Medical Device* a Dassault Systèmes Industry Solution Experience based on the **3DEXPERIENCE®** platform that allows companies to eliminate scattered processes and data and to “embed” regulations as an asset, optimizing quality and compliance and reducing cost and time to market.

This end-to-end solution supports all aspects of a medical device company’s quality system and regulatory compliance ISO-regulated design controls.

---

### Our **3DEXPERIENCE®** platform powers our brand applications, serving 12 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 190,000 customers of all sizes in all industries in more than 140 countries. For more information, visit [www.3ds.com](http://www.3ds.com).



**Americas**  
Dassault Systèmes  
175 Wyman Street  
Waltham, Massachusetts  
02451-1223  
USA

**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