



What is the *Quality System(s) Management (QSM)* solution?

Product '*quality*' is an outcome of Quality Management System (QMS) process '*quality*' in conjunction with production process that are executed from within QMS control. The *Quality System(s) Management (QSM)* solution strategically provides the quality management necessary for control over the QMS, utilizing data technology, and enabling responsible decision makers to continually improve the '*quality*' of QMS processes, production processes, and the products produced.

1. The QSM solution is a **quality management tool**, providing a strategic and planful approach for management control over the quality of the products produced by a medical device company and the processes used to produce them. The QSM solution is comprised of three individual solution components that work together interactively:
 - measurement solution providing a strategic approach to actively measure product and process '*quality*';
 - management solution to interactively monitor, report and review what is measured to provide visibility of emerging issues and constraints;
 - improvement solution that provides a structured approach to managing the initiatives targeted.
2. The QSM solution is a **data technology tool**, a combination of process methodology and interactive programming, that enables the analytical processing and utilization of product and process data, transforming it to be useful for decision makers or '*responsible management*'... those who are typically held accountable by regulatory and business stakeholders alike for the results they are required to obtain.

Utilization of any large data set has an inherent degree of complexity. Data processing alone can be quite difficult and time-consuming. Critical insights are often obscured in stored data records that must be properly processed to become useful for analysis and consumption. Quality Management Systems are a combination of dissimilar processes that prove challenging to measure and aggregate. The QSM solution is designed to quantify and link the information that is crucial for statistically driven management control over the QMS.

3. The QSM solution is a **continuous improvement tool** that provides active measurement, interactive management, and structure for targeted improvement that must occur in support of EU MDR requirements, inclusive of Post-Market Surveillance (PMS) and QMS surveillance activities. Continual improvement of targeted constraint provides value through a return on investment (ROI) derived from compliant operations that are effective in obtaining the required results, and efficient in doing so.

Timely solution for *Quality System(s) Management (QSM)*

PMS & QMS surveillance is a significant requirement for EU MDR and FDA Case for Quality. The capability to extract useful information from data that can be utilized strategically for the management of product and process quality is essential. The European Union Medical Device Regulation¹ (EU MDR) PRRC responsibilities make it essential to conduct Post Market Surveillance (PMS) and Quality Management System (QMS) surveillance activities. Medical device companies have an obligation to ensure their PMS and QMS surveillance systems are state-of-the-art for regulatory and business stakeholders alike, and most importantly... for the patients and users they serve.

¹ (EU) 2017/745 of the European Parliament and of the Council, 117 Official Journal of the European Union 1 (Apr. 5, 2017) [hereinafter EU MDR]