

*Strategic  
measurement of  
product and  
process quality*

*Visibility of  
emerging quality  
issues and  
constraints to  
enable responsible  
management*

*Focused  
improvement of  
product and  
process quality*

Measure | Manage | Improve

*We offer a  
strategic  
solution for  
the measurement,  
management and  
improvement of  
product and  
process quality  
within the medical  
device industry*

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**Mgmt-Ctrl**



**Quality  
System(s)  
Management**

Measure | Manage | Improve

Mgmt-Ctrl is a Quality Management company offering a combination of enabling solutions for responsible quality management. The Quality System(s) Management (QSM) solution provides improved management control, in the focused pursuit of continuous improvement of product and process quality.

The strategic discipline of QSM is foundational to managing the quality of product and Quality Management System (QMS) processes, in support of the *quality* of operations.

The Quality System(s) Management (QSM) solution strategically measures product and process quality to identify constraint. The data that is resultant from the measurement solution provides the reporting visibility that enables responsible management to identify issues that can be addressed through targeted improvement initiatives to increase the level of product and process quality.

About Us

***Compliance  
does not  
equal  
'quality'***

***Compliant,  
Effective and  
Efficient  
processes  
create 'quality'***



Compliance ≠ Quality

### **Technology Offering**

The Quality System(s) Management (QSM) technology platform strategically measures product and process quality, inclusive of the cost of poor quality (COPQ).

### **Services Offering**

Support services facilitate the results stakeholders expect.

- Product (PMS) and Process (QMS) Quality Surveillance
- Product and Process Quality Reporting and Review
- Support of EU MDR Person Responsible for Regulatory Compliance (PRRC)
- EU MDR Technical Documentation Gap Assessment
- Program | Project Management
- CAPA Investigation
- FDA 483 Observation Response
- FDA 483 Observation & Warning Letter Remediation

Technology & Services