SURGICAL DEVICES

Benefits

Achieve system validation with qualified cloud infrastructure
Integrate quality directly into core business processes
Improve supply chain governance and visibility
Establish consistent global processes
Control transaction costs, pricing and reconciliations in group buying scenarios

QAD offers a unique solution for surgical device manufacturers that includes a full featured ERP to help deliver the agility needed to adapt to changing business and regulatory requirements. QAD Cloud ERP Life Sciences edition is the core of the solution that incorporates demand planning, supply chain execution, quality management and global financial capabilities. The solution provides surgical device manufacturers control of manufacturing processes while complying with global GMP regulations.

Surgical Device Manufacturer Value Chain

Key capabilities include material traceability, demand planning, supply chain execution, quality management and global financials. These and other capabilities help device manufacturers control risk and support continuous improvement of operations that align with business strategy.

Reduce manual process costs and errors by automating complaint management and quality-related processes.
**Increase inventory turns and reduce inventory** by using sophisticated forecasting methods and detecting demand forecast changes as they happen.

**Improve Delivery In Full On Time (DIFOT)** through better supply chain insight and accurate tracking of in-process inventory.

**QAD Surgical Device Solution Overview**

The surgical device market continues to expand rapidly and sub-segments of the industry, such as devices used in support of interventional cardiac surgery, are growing particularly fast. The aging of the global population, chronic conditions like heart disease, rise in demand for minimally invasive procedures and technological advancements leading to innovative products all continue to fuel growth in the industry. The advent of novel devices and procedures are enhancing the lives of an increasingly elderly population and patients with poor cardiac function.

To take advantage of the growth, however, surgical device manufacturers face constant pressure to innovate. Hospitals and physicians view device manufacturers today as full solution providers, not simply product suppliers. They expect manufacturers to provide a variety of kitting and solutions options that shorten surgery times, increase operating room efficiency and improve patient outcomes — many of which are tied to reimbursement. Manufacturers often work directly with physicians to devise comprehensive surgical solutions to complex clinical problems.

Regulators globally have increased focus on patient safety. New standards like ISO 13485:2016 and regulations like Unique Device Identification (UDI) require manufacturers to invest in operational changes and systems to comply.

The surgical device industry outlook remains strong and capable device manufacturers have a promising future, yet challenges remain. The following are critical business and manufacturing processes addressed by QAD's world-class solution that helps surgical device manufacturers successfully address their challenges and sustain growth.

- **QAD QMS (Quality Management System)**
- **QAD Automation Solutions:** Shop Floor Data Collection and Label Printing
- **QAD TAM (Trade Activity Management)**
- Item Level Serialization
- Regulatory Compliance
- **QAD DSCP (Demand and Supply Chain Planning)**
- Lot Traceability
- **QAD EAM (Enterprise Asset Management)**
QAD BI (Business Intelligence)

An overview of the first three critical processes follows. For information about the other processes, please visit QAD.com.

QAD QMS (Quality Management System)

QAD QMS offers advanced capabilities and supports improvements in key medical device metrics by helping device manufacturers integrate critical production and quality data and automate required business processes.

QAD QMS provides global medical device manufacturers an option to integrate quality management capabilities into their core ERP functions to develop an enterprise-wide quality culture. By choosing an ERP solution that integrates quality management functionality and current good manufacturing practices (cGMP), companies can more effectively meet global regulations.

QAD QMS Defect Tracking

QAD Automation Solutions: Shop Floor Data Collection and Label Printing

Increased regulatory scrutiny is creating compliance challenges for device manufacturers. ISO 13485:2016, the new standard for medical device quality systems, and regulations like Unique Device Identification (UDI) are placing greater emphasis on supply chain governance and material traceability.

QAD's Serialization capability combined with QAD Automation Solutions, which provides
label printing and data collection functions, allows greater visibility and faster and more accurate processing of transactions. In addition, QAD's UDI solution automates the aggregation of required UDI attribute data from sources across the enterprise and maintains a single and secure system of record for regulatory submissions. The solution enforces access control, preserves data integrity and manages changes throughout the product lifecycle, and provides serialization and data collection for inventory tracking, as well as enhanced label printing services for the creation of regulatory compliant labels.

Serialized Inventory Report with Label Printing Options

QAD TAM (Trade Activity Management)

Surgical device manufacturers often have significant challenges managing EDI transactions and reconciliations. Large wholesalers and distributors transact a huge amount of data with manufacturers that requires reconciliation, and GPO contracts are dynamic and intricate. In addition, constantly changing prices, contract terms and complex chargebacks add to the management burden. Many manufacturers use manual processes and rely on spreadsheets to manage this complexity, but that often results in significant loss of revenue due to short payments, double payments and incorrect contract terms.

QAD TAM (Trade Activity Management) enables the automation of the complex transactional environment, reducing errors, lowering costs and adding efficiencies.

Trade Contract Activity Center
For more information on how the QAD Surgical Devices solution can help your company, please contact QAD at +1-805-566-6100 or email info@qad.com.