

LIFE SCIENCES DIAGNOSTIC DEVICES

Benefits

Achieve system validation with qualified cloud infrastructure

Integrate quality directly into core business processes

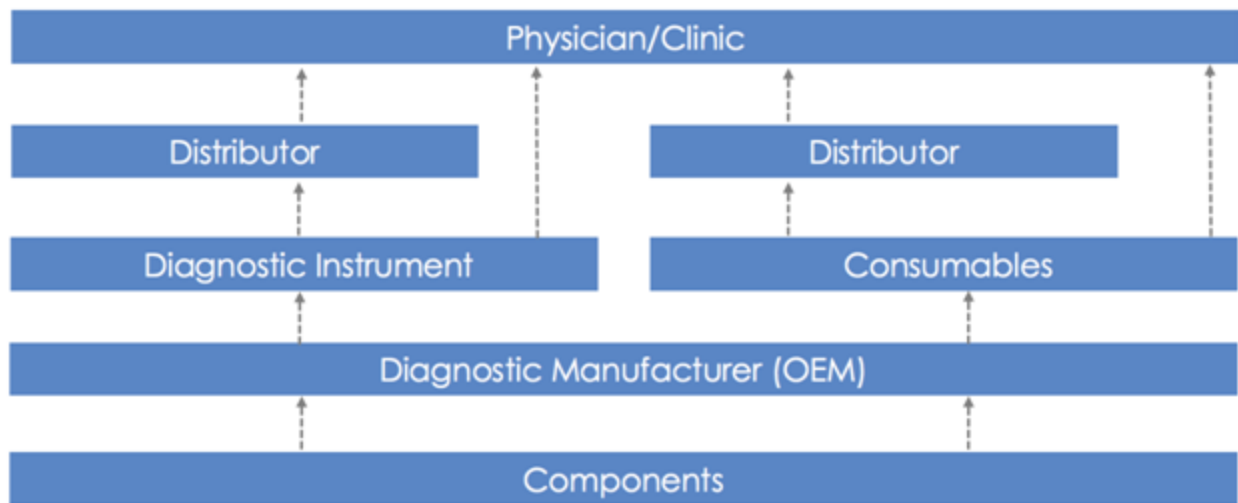
Improve supply chain governance and visibility

Establish consistent global processes

Control transaction costs, pricing and reconciliations in group buying scenarios

QAD offers a unique solution for diagnostic 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 diagnostic device manufacturers control of manufacturing processes while complying with global GMP regulations.

Diagnostics Manufacturer Value Chain



Key features 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.

Increase inventory turns, 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.

Reduce manual process costs and errors by automating quality-related processes.

QAD Diagnostic Devices Solution Overview

Diagnostics are tests that detect diseases, conditions or infections. Some tests are used in a laboratory or other health professional settings and other tests are for consumers to use at home. The overall market for diagnostic devices is growing briskly.

Diagnostics manufacturers make both instruments and reagents. The instruments are complex pieces of capital equipment used for the diagnosis of disease and range from scanners to molecular imaging to DNA analysis equipment. The equipment is sold or leased (and even given away) to providers. Reagent consumables, often in slide or cartridge form, are sold separately and used in the diagnosis of conditions.

Diagnostics manufacturers face a number challenges including pressure to develop new technology, produce innovative assays and keep pace with rapidly changing clinical trends. In particular, the molecular diagnostics segment values innovation as companies look to develop novel solutions that are simple to use and optimize testing efficiency. As companies look to differentiate themselves, launch new products and continue to support an existing installed base, M&A activity continues to be an important competitive strategy to access new technology, expand product offerings, enter emerging markets and increase market share.

Changing reimbursement dynamics pressure margins and many regulatory challenges, including new standards like ISO 13485:2016 and regulations like Unique Device Identification (UDI), make compliance an on-going challenge. Diagnostics manufacturers must adapt to point-of-care testing and deliver results faster than ever as consumer-based solutions are, in some cases, becoming viable alternatives to traditional diagnostic testing.

The industry outlook remains strong and capable 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 diagnostics 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 Trace Workbench

[QAD EAM \(Enterprise Asset Management\)](#)

[QAD BI \(Business Intelligence\)](#)

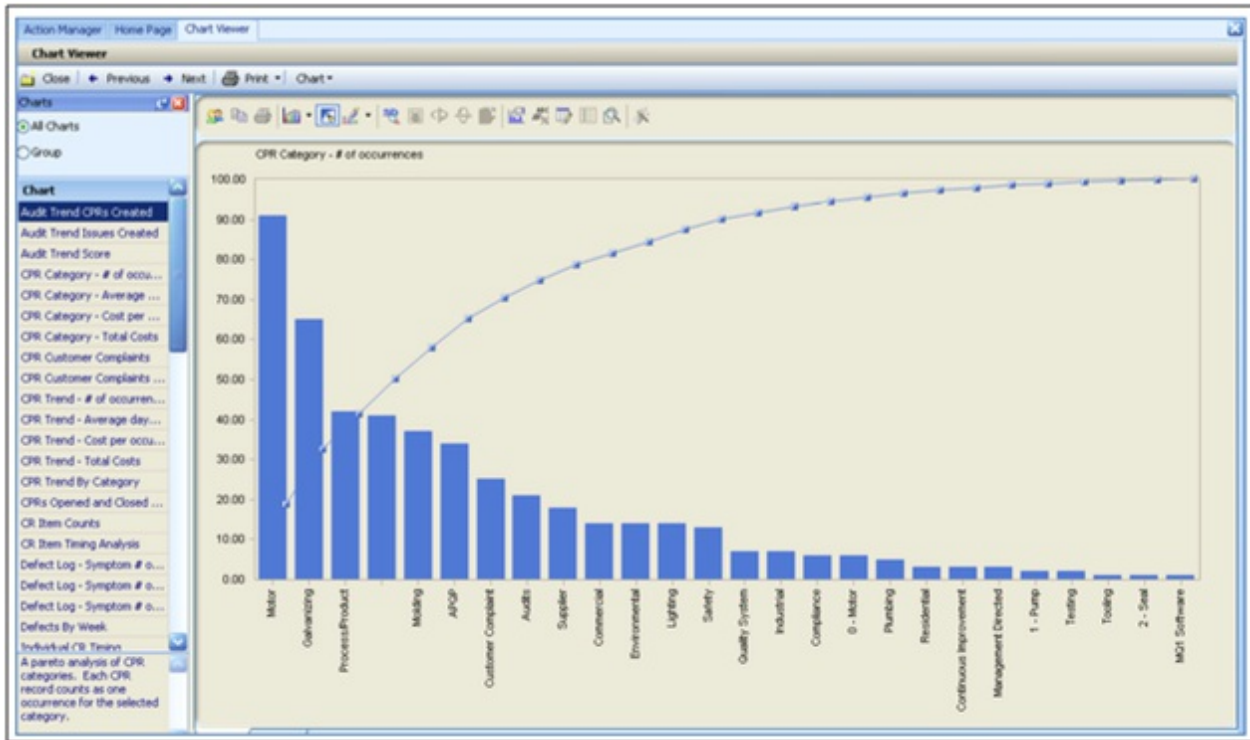
An overview of the first three critical processes follows. For information about the other processes, please visit QAD.com.

QAD QMS (Quality Management System)

QAD QMS offers advanced quality management capabilities. It 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 diagnostic manufacturers the option to integrate quality management capabilities into their core ERP functions to develop an enterprise 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

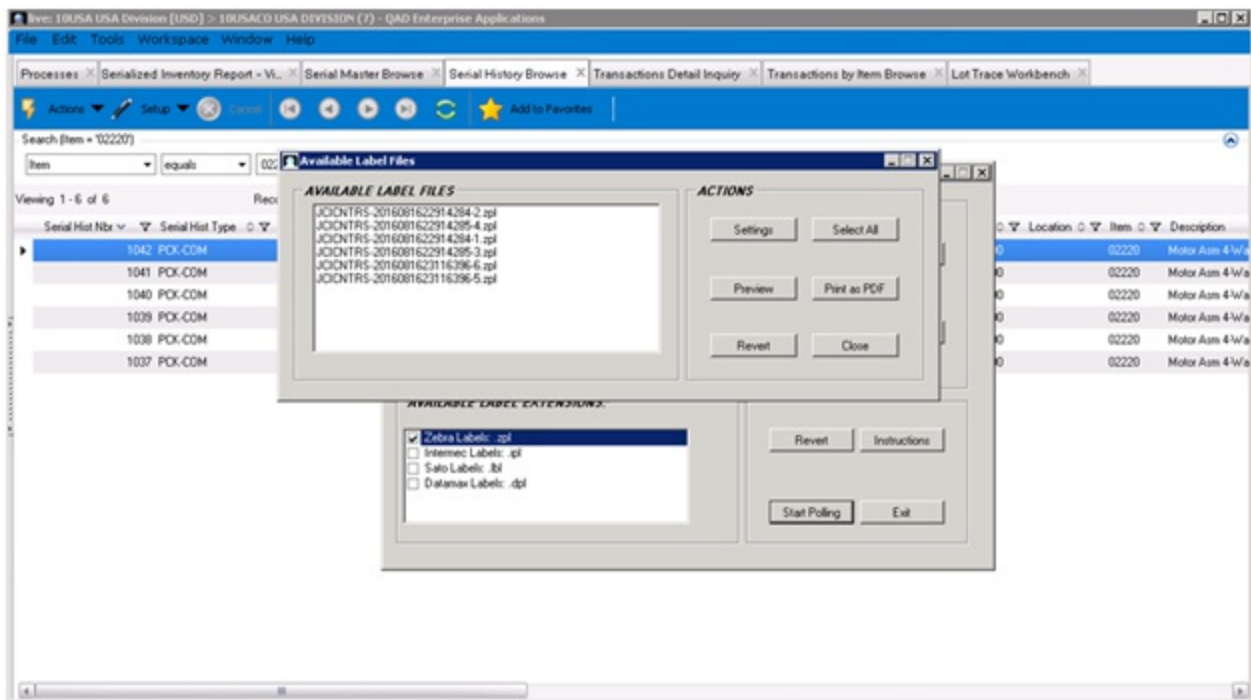


QAD Automation Solutions – Shop Floor Data Collection and Label Printing

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.

Serialization combined with QAD Automation Solutions, which provides label printing and data collection functions, allows **greater visibility and faster and more accurate transaction processing**. In addition, the QAD 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. It provides serialization and data collection for inventory tracking and included enhanced label printing services for the creation of compliant labels.

Serialized Inventory Report with Label Printing Options



QAD TMS (Trade Activity Management)

Diagnostic manufacturers often face significant challenges managing EDI transactions and reconciliations. Large wholesalers and distributors transact a huge amount of data with manufacturers that requires reconciliation, and the corresponding 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 address these requirements, but that often results in significant loss of revenue due to short payments, double payments and incorrect contract terms.

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

Trade Contract Activity Center

TAM Contract Activity Center

Contracts Contracts by Customer Contracts by Buying Group Contracts by Member Contracts by Item

Search

Customer starts at Search Clear All

Viewing 1 - 72 of 72 Records per page 100

Customer	Sort Name	Active	Bill To	Class	List Type	Business Relation	Type	Site	Country Code	Region
10C1003	Pacific Health Care Systems	yes	DIST	customer	10-C1003	DIST	10-100	USA		
10C1004	Price Chopper	yes	WHSL	supplier	10-C1004	WHSL	10-100	USA		

Customer Pricing Contracts Indirect Sales Browse Customer Resale Contracts

Viewing 1 - 100 of 130 Records per page 100

Contract Code	Description	Contract Type	Status	Buying Group	Customer	Buy Start	Buy End
CR-00250	Return Distributor Contract	Distributor Contract	Closed	10C1003	11/28/2014	11/28/20	
CR-00248	Test Generate and Review Claims	Distributor Contract	Closed	10C1003	11/28/2014	11/28/20	

Contract Deal Contract Earned Discount Total Browse TAM Contract History Browse TAM Deduction Claim Browse

Viewing 1 - 3 of 3 Records per page 100

Contract	Deal	Description	Deal Start Date	Deal End Date	Deal Category	Entity	Deal Effects	Combination Type
CR-00250	Dist Service Fee	Distributor Service Fee	11/28/2014	11/28/2014	Deferred Discount	None		
CR-00250	Distributor Contract	Distributor Contract Pricing	11/28/2014	11/28/2014	Contract Pricing			Exclusive
CR-00250	One-Off Deferred	One-Off Deferred Incentive deal	11/28/2014	11/28/2014	Deferred Discount	None		

For more information on how the QAD diagnostic device solution can help your company, please contact QAD at +1-805-566-6100 or email info@qad.com.