PHARMACEUTICAL AND BIOTECHNOLOGY

Benefits

Achieve system validation with qualified cloud infrastructure

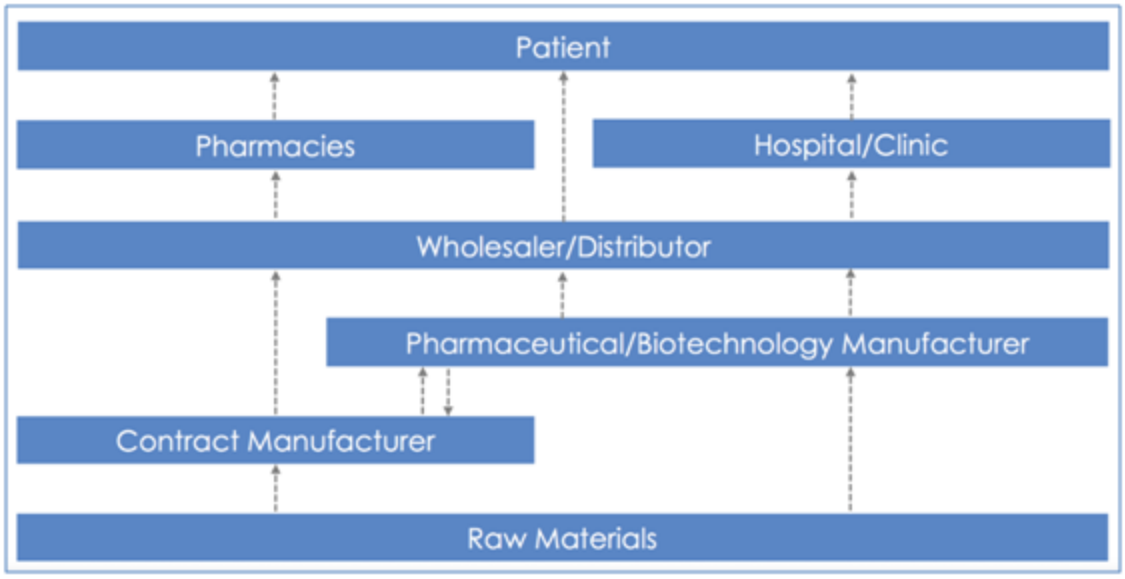
Integrate quality directly into core business processes

Improve supply chain governance and visibility

Establish consistent global processes

QAD offers a unique solution for pharmaceutical and biotechnology companies, including a world-class, full-featured ERP that delivers the agility needed to adapt to changing business and regulatory requirements. The solution provides the ability to forecast accurately to keep inventories at a minimum, drive greater operational efficiency and improve delivery in full on time (DIFOT) metrics, all while meeting GMP and serialization regulatory requirements. The solution improves overall operational performance and provides consistency in production planning, procurement and material visibility. It reduces duplication of purchased items and offers cold chain traceability and timeout of refrigeration (TOR) tracking, resulting in improved manufacturing cycle times and reduced scrap and rework.

Pharmaceutical and Biotechnology Value Chain



Key features include quality management, demand planning, supply chain execution and global financials. These and other capabilities help pharma and biotech companies control risk while improving operations that align with business strategy.

Reduce manual process costs and errors by 50% by automating complaint management and quality-related processes.

Increase inventory turns, reducing inventory by 10-25%, by using sophisticated forecasting methods and detecting demand forecast changes as they happen.

Improve DIFOT through better supply chain insight and accurate tracking of in-process inventory.

QAD Pharmaceutical and Biotechnology Solution Overview

The pharma and biotech industry has not traditionally focused on operational efficiency, meaning there is often an opportunity for significant operational improvement. For example, pharma and biotech companies are typically Make-to-Stock organizations. Excess inventory is frequently a challenge, but stock-outs are unacceptable, leading to high inventory levels and comparatively few inventory turns.

Pharmaceutical companies also often suffer from low capacity utilization. It is not uncommon to have 10 manufacturing suites with only five in use. Industry best practice points to 70 percent capacity utilization or higher, yet many companies report rates in the 40-50 percent range. Weak performance levels are usually attributed to idle equipment, lack of material or untrained personnel.

Pharmaceutical companies often have the opportunity to improve process flow and yields. They are required to calculate both theoretical and actual yield and often struggle to deliver performance improvements. In many cases, yields that fall outside of required specifications can be attributed to raw material lot variation, lack of inventory control or the relationship between process variables and raw material properties.

Pharma and biotech companies track DIFOT and Line Item Fill Rate metrics closely, but many are not able to meet the terms of an order. Poor upstream supply chain visibility and in-process inventory tracking, or lack of downstream assurance of appropriately handled batches, leads to missed delivery metrics that can result in costly penalties.

The highly-regulated nature of the industry results in significant quality assurance (QA) oversight, producing lengthy manufacturing cycle times which directly impact cash flow as finished goods wait for QA release. Lack of documentation, inventory control, process visibility or operator training are often sources of deviation that lead to delays and stand in the way of reducing QA cycle times.

Growth prospects for the industry remain promising but many challenges exist for pharma and biotech companies. The following are the key challenge areas facing the industry:

QAD QMS (Quality Management System)

Item Level Serialization

QAD DSCP (Demand and Supply Chain Planning)

Planning and Scheduling Workbenches

QAD TAM (Trade Activity Management)

Regulatory Compliance – Lot Traceability

Complex Formulation Handling

Supplier Management – Supplier Portal

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

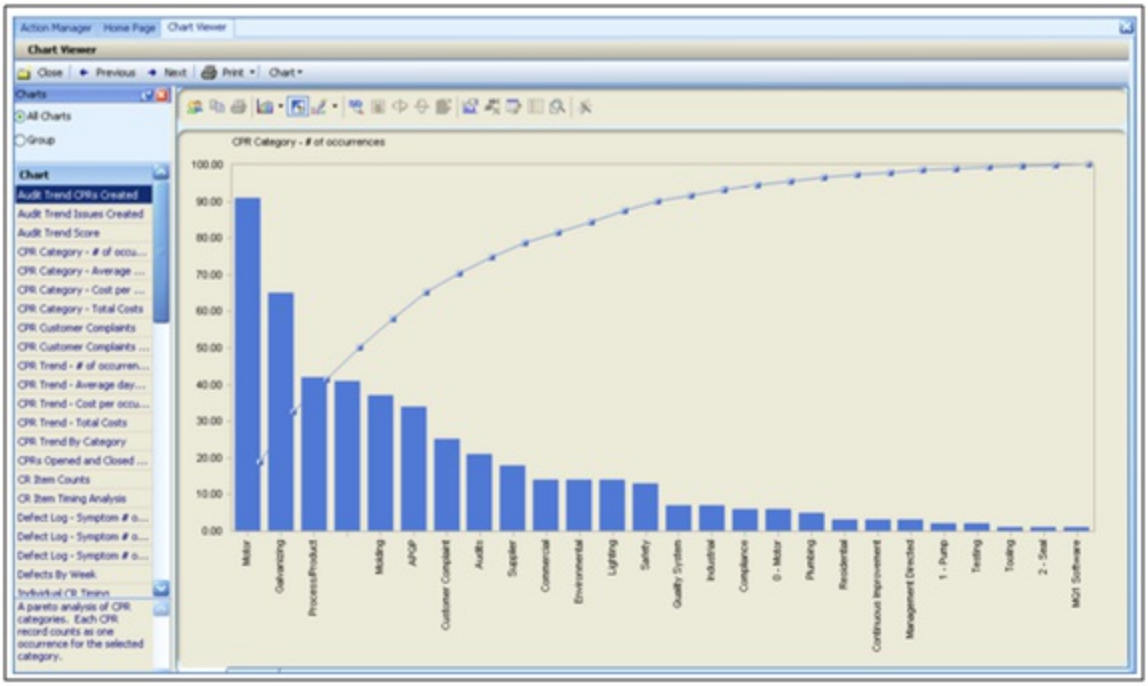
QAD QMS (Quality Management System)

QAD QMS offers advanced capabilities that can help pharma and biotech companies progress from manual quality processes to integrated quality control to fully integrated quality management across the value chain. The solution supports improvements in key life sciences metrics by helping pharma and biotech manufacturers integrate related process data, automate required business processes and comply with global GMP regulations. Built around a workflow engine with user-configurable processes, notifications and escalations, QAD QMS automates core business processes including:

- Document control for the central storage and management of controlled documents, including approval workflows, archiving and audit trails
- Complaint handling to comply with GMP regulations
- CAPA/NCR to provide an automated closed loop solution for problem resolution
- Employee training for the management and qualification of key personnel
- Reporting capability to support both internal and external audits

QAD QMS ensures complete synchronization of the quality management system, allowing documents to link to operator-training requirements and adjacent systems, ensuring subsequent changes to the document will synchronize throughout the system. Because of the integration, QAD QMS offers easy, fast access to key performance indicators and metrics, supporting well-informed decisions.

QAD QMS



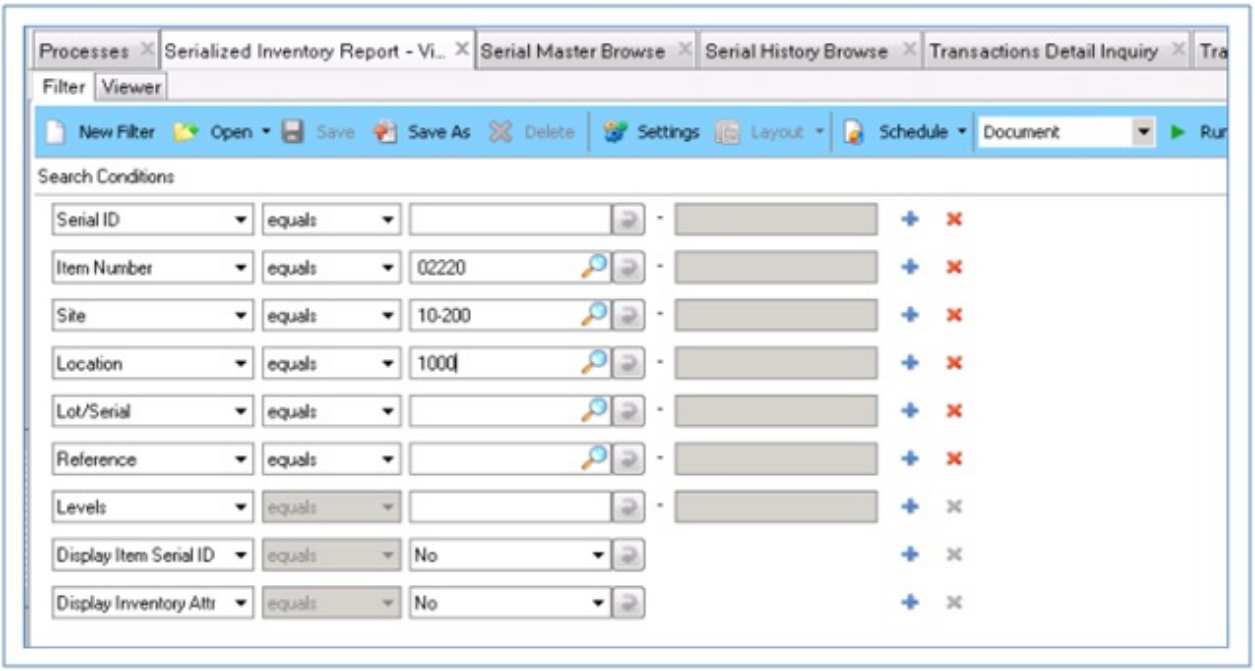
Item Level Serialization

With the passage of the Drug Quality and Security Act (DQSA) in 2013, pharmaceutical manufacturers and their contract partners are faced with a looming deadline in November 2017 for unit level, electronic serialization of their products. While most organizations are viewing the legislation through a compliance lens, several are looking at the business benefit that comes with better visibility and operational improvement.

While a complex and costly undertaking, serialized product increases supply chain visibility and integrity and guards against suspect product from entering the patient population. Other benefits include brand integrity, operational visibility and protection against false reimbursements.

QAD's Item Level Serialization and related item attributes address the material traceability requirements of DQSA, the Falsified Medicines Directive and critical cGMP requirements. Traceability can extend to packaged inventory by identifying items with a unique License Plate Number. Inventory can be packaged in a single-level or multilevel structure like cases on a pallet. Each packaging unit may require its own unique identifier and boxes or cases can be aggregated into a higher-level pack with its own unique ID or License Plate. Information about products stored in each of these logistic units such as pallets, cases, boxes and parts include site, location, item code, lot number and quantity which are captured and accessible through a serial ID. Inventory movements can be conducted by the serial number of the pallet or box.

Serialized Inventory Report



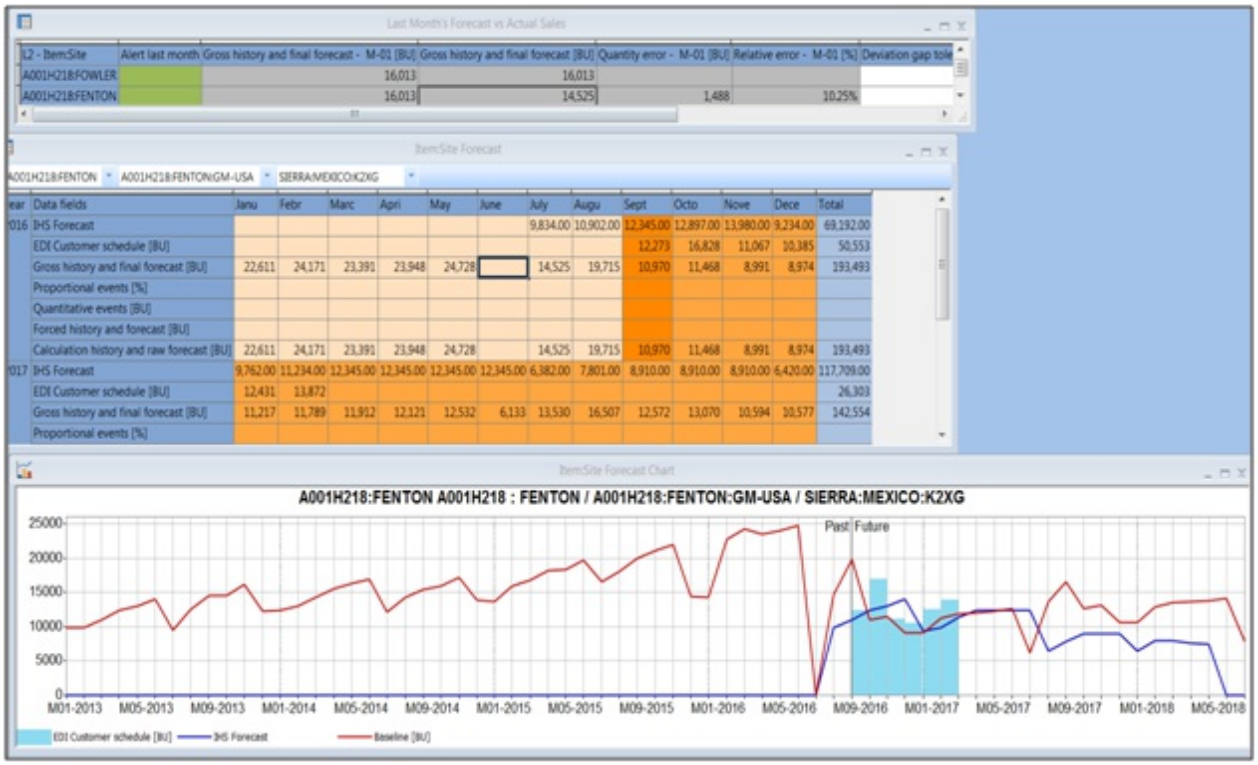
QAD DSCP (Demand and Supply Chain Planning)

Demand Planning generates more reliable forecasts and helps better manage product life cycle events, directly impacting inventory effectiveness and customer service. Typical measurements related to these KPIs include DIFOT, Forecast Accuracy, Line Item Fill Rate and Inventory Accuracy. The result: bottom line improvements to cost of sales, margin and revenue.

QAD DSCP provides a sophisticated tool to build and manage forecasts, improving reliability and accuracy by collaborating with all the players involved in the forecasting process. Organizations can manage forecasts at any level – customer, item, group or family – with input from a variety of sources – sales representatives, customers, marketing and finance. This enables true collaboration, one of the keys to improving forecast accuracy. It creates sales forecasts based on historical data, market analysis data and customer production data.

QAD DSCP uses sophisticated statistical modeling to pinpoint statistical anomalies that can skew demand, smooth historical data if applicable, determine the effect of exceptional events, and generate a forecast for each individual item, automatically selecting the best-fit statistical model.

Two-year production plan based on multiple sources



For more information on how QAD's Pharmaceutical and Biotechnology solutions can help your company, please contact QAD at +1-805-566-6100 or email info@qad.com.