

# LIFE SCIENCES CONTRACT MANUFACTURING

## Benefits

**Achieve computer systems validation with qualified cloud infrastructure**

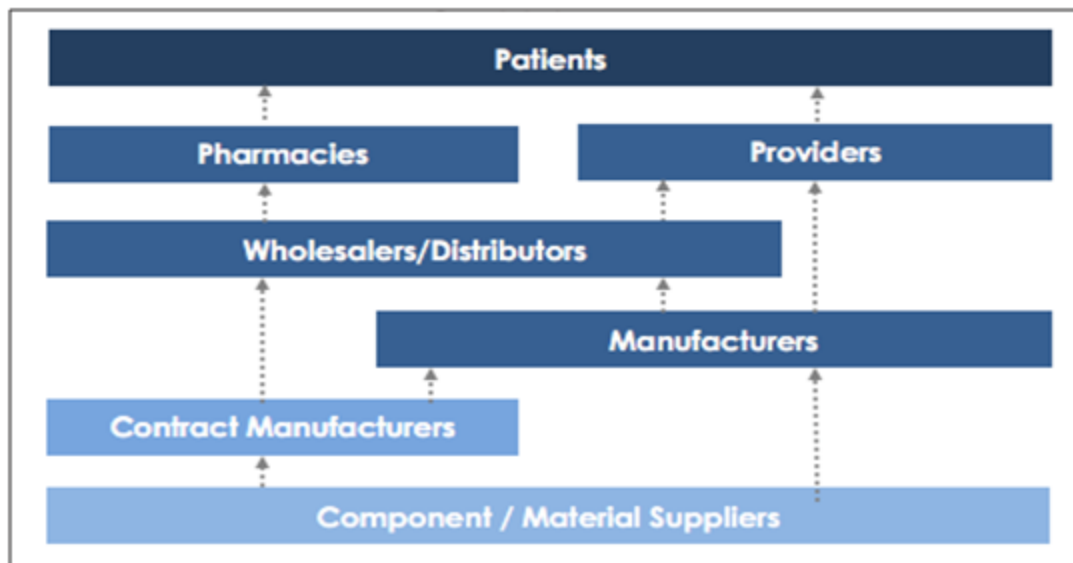
**Integrate quality directly into core business processes**

**Improve supply chain governance and visibility**

**Establish consistent global processes**

QAD offers a unique solution for Contract Manufacturing Organizations (CMOs) that serve the life sciences industry. The solution includes the full-featured QAD Cloud ERP and several related capabilities that help CMOs adapt to changing sponsor business requirements, improve forecast accuracy, drive operational efficiency and improve delivery in full on time (DIFOT) and meet Good Manufacturing Practice (GMP) and serialization regulatory requirements.

## Life Sciences Contract Manufacturing Value Chain



Key features include material traceability, demand planning, supply chain execution, quality management and global financials. These and other capabilities provide CMOs control of manufacturing processes while meeting compliance requirements, controlling risk and continuously improving operations that align with business strategy.

**Reduce manual 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 for your sponsors** through better supply chain insight and accurate tracking of in-process inventory.

**Double utilization** through better material planning and handling.

## **QAD Contract Manufacturing Solution Overview**

CMOs serving the pharmaceutical industry face a competitive and fragmented market. The hyper competitive market drives down prices and forces CMOs to evolve their offerings. CMOs constantly look for ways to differentiate themselves and deliver novel solutions to their sponsors.

CMOs need the ability to manage and meet simultaneous customer requirements that demand fast cycle times, reduced batch sizes, advanced capabilities like cold chain traceability and related information reporting, all while meeting complex and expanding global regulatory requirements. To address this business environment while controlling costs, CMO executives constantly look for efficiencies and flexibility.

Executives closely monitor specific operational metrics and expect differentiated performance. Metrics often include improving DIFOT, increasing capacity utilization, increasing inventory turns, reducing quality assurance cycle time, improving yield and decreasing manufacturing cycle times. In addition to improving operational metrics, the highly-regulated nature of the pharmaceutical industry requires CMO adherence to stringent GMP regulations throughout the manufacturing process.

While growth prospects for the industry are promising and capable CMOs have a bright future, challenges remain. The following are key processes provided by QAD's worldclass solution that helps CMOs successfully address their challenges and sustain growth.

### **Item Level Serialization**

[Planning and Scheduling Workbenches](#)

### **Temperature Controlled or Hazardous Substances Handling**

### **Regulatory Compliance**

[QAD QMS \(Quality Management System\)](#)

### **Supplier Management**

### **Complex Formulation Management**

[QAD TAM \(Trade Activity Management\)](#)

[QAD DSCP \(Demand and Supply Chain Planning\)](#)

## Lot Traceability

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

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

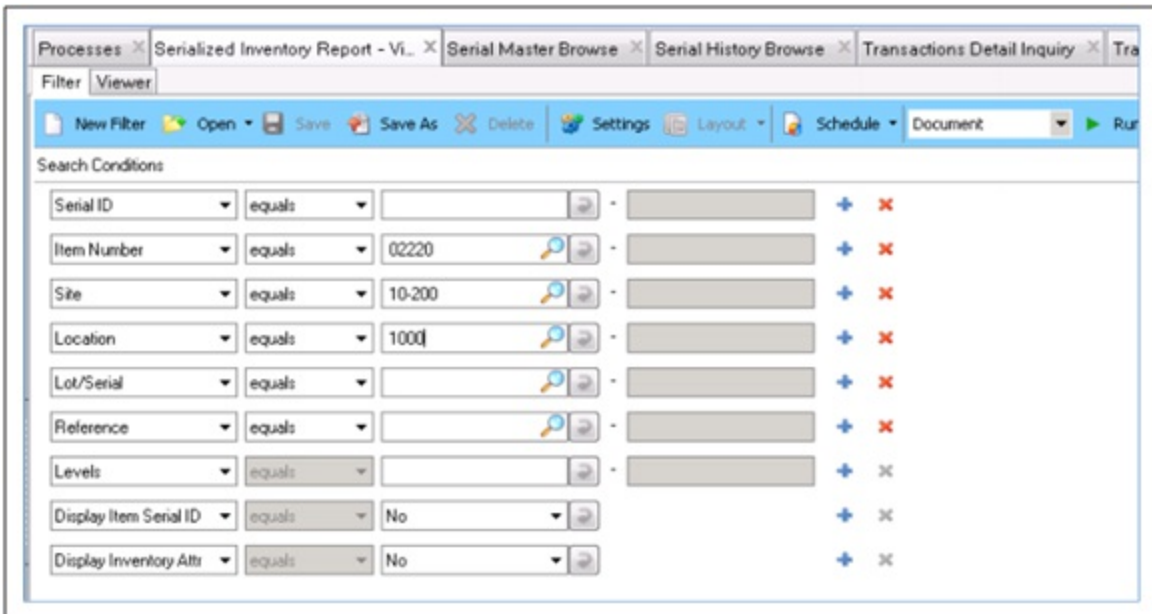
An overview of the first three processes follows. For information about the other processes, please visit [QAD.com](http://QAD.com).

## Item Level Serialization

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

The QAD Item Attributes and Serialization solution addresses the robust material traceability requirements of the DQSA and similar critical cGMP requirements. Traceability can extend to packaged inventory track and trace by identifying inventory with a unique License Plate Number (LPN), which helps to containerize inventory. Inventory can be packaged in a single-level or multilevel structure like cases on a pallet. Information about products stored in each of these logistic units are captured and accessible through a serial ID and inventory movements can be conducted by the serial number of the pallet or box.

### Serialized Inventory Report



Field	Operator	Value	Search Icon	Filter Icon
Serial ID	equals			
Item Number	equals	02220		
Site	equals	10-200		
Location	equals	1000		
Lot/Serial	equals			
Reference	equals			
Levels	equals			
Display Item Serial ID	equals	No		
Display Inventory Attr	equals	No		

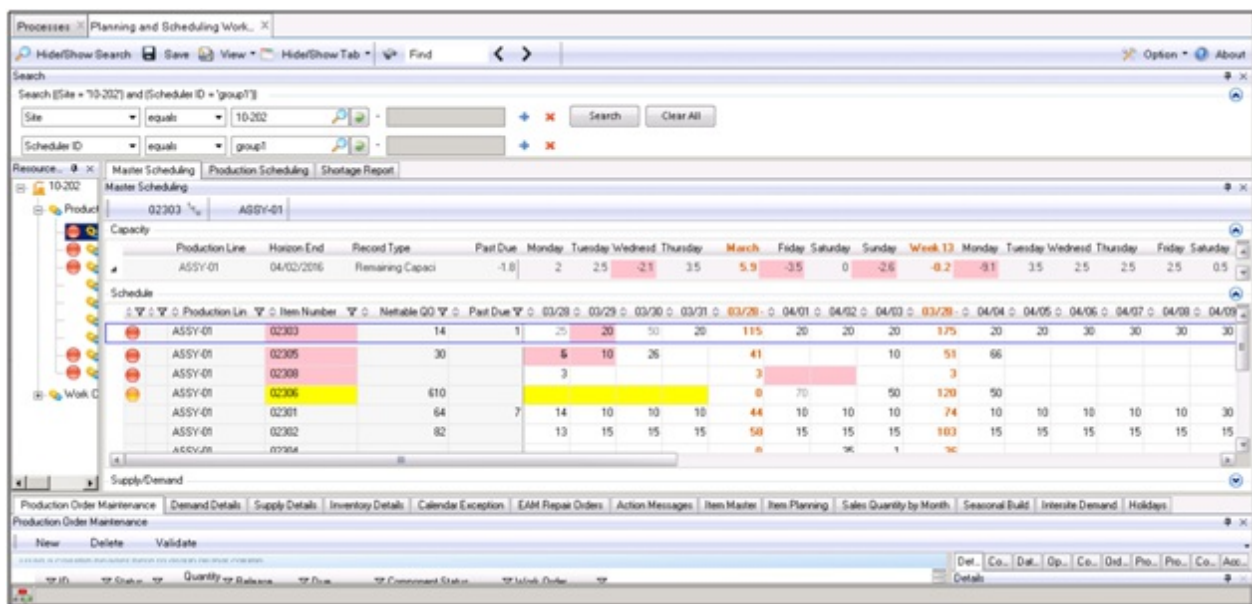
## Planning and Scheduling Workbenches

Planning and Scheduling Workbenches generate more reliable production plans, manage

exceptions proactively and respond to changing conditions. This improves the quality of production plans with a direct, positive impact on manufacturing schedules, manufacturing efficiency, asset utilization and inventory effectiveness.

Planning and Scheduling Workbenches provide schedulers total visibility of demand, supply, inventory, capacity and production, all displayed in an intuitive spreadsheet-like workbench. Planned production, alternative resources, changes in customer demand, inventory levels, safety stock, forecast, capacity and planned maintenance schedules are centralized and managed. Schedulers interact directly with the schedule using color-coded alerts that focus attention on potential issues.

### View of all production lines including capacity, schedules and supply/demand data



### Temperature Controlled or Hazardous Substances

Life Sciences companies place strict controls over the handling, storage and movement of material and products used in the manufacture of drug substances. GMP regulations deal specifically with inventory and require that all handling of materials and products, such as receipt and quarantine, sampling, storage, labeling, dispensing, processing, packaging and distribution should be done only by authorized personnel and in accordance with written procedures. Many CMOs also need expanded capability like cold chain traceability and timeout of refrigeration tracking.

QAD Automation Solutions improves manufacturers' material transactional effectiveness and efficiency by aligning ERP with material processes. Data Collection captures material and production data through simplified ERP transactions using a mobile device such as a radio frequency scanner, tablet or a stationary shop floor personal computer or terminal. Label Printing Services routes and prints labels associated with material and production transactions based on manufacturer, supplier and customer specified formats and rules.

### Serial History Browse

The screenshot shows the QAD Serial History Browse window. At the top, there is a menu bar with 'File', 'Edit', 'Tools', 'Workspace', 'Window', and 'Help'. Below the menu bar are several tabs: 'Serialized Inventory Report - VL...', 'Serial Master Browse', 'Serial History Browse', 'Transactions Detail Inquiry', 'Transactions by Item Browse', and 'Lot Trace Workbench'. A search bar is present with the text 'Search (Item = 102207)'. Below the search bar, there are navigation buttons: 'Actions', 'Setup', 'Cancel', and 'Add to Favorites'. The main area displays a table with the following columns: Serial Hist Nbr, Serial Hist Type, Serial ID, Pack Code, Parent Serial ID, Master Serial ID, Transaction Number, Transaction Type, Site, Location, and Item. The table contains 15 rows of data, with the first row highlighted in blue.

Serial Hist Nbr	Serial Hist Type	Serial ID	Pack Code	Parent Serial ID	Master Serial ID	Transaction Number	Transaction Type	Site	Location	Item
1051	PKI-RCT	10200C00005	FL02		10200C00005	1003781	RCT w/O	10-200	1000	02220
1050	PKI-CHS	10200C00002	B>02	10200C00005	10200C00005			10-200	1000	02220
1049	PKI-BLD	10200C00002	FL02	10200C00005	10200C00005			10-200	1000	02220
1048	PKI-BLD	10200C00002	B>02		10200C00002			10-200	1000	02220
1047	PKI-CHS	10200C00002	B>02		10200C00002			10-200	1000	02220
1046	PKI-CHS	10200C00001	B>02	10200C00005	10200C00005			10-200	1000	02220
1045	PKI-BLD	10200C00001	FL02	10200C00005	10200C00005			10-200	1000	02220
1044	PKI-BLD	10200C00001	B>02		10200C00001			10-200	1000	02220
1043	PKI-CHS	10200C00001	B>02		10200C00001			10-200	1000	02220
1042	PKI-COM	10200C00006	FL02		10200C00006			10-200		02220
1041	PKI-COM	10200C00005	FL02		10200C00005			10-200		02220
1040	PKI-COM	10200C00004	B>02		10200C00004			10-200		02220
1039	PKI-COM	10200C00003	B>02		10200C00003			10-200		02220
1038	PKI-COM	10200C00002	B>02		10200C00002			10-200		02220
1037	PKI-COM	10200C00001	B>02		10200C00001			10-200		02220

For more information on how the QAD Contract Manufacturing for the life sciences solution can help your company, please contact QAD at +1-805-566-6100 or email [info@qad.com](mailto:info@qad.com).