> We needed an ERP system that would support our compliance needs. After evaluating more than 20 providers, we implemented QAD Enterprise Applications for life science manufacturers and quickly realized many benefits.

Melissa Rosness, Senior Director of Operational Excellence, Ajinomoto Althea

CUSTOMER CASE STUDY

ALTHEA

HIGHLIGHTS	
Company	Ajinomoto Althea, Inc.
Location	San Diego, California, USA
Sector / Industry	Pharmaceuticals/ Biotechnology
Products	Contract development and manufacturing
Solutions Utilized	QAD Enterprise Applications

QAD ERP SYSTEM ELEVATES cGMP PRACTICES FOR HIGHLY REGULATED PHARMA CORP

THE COMPANY: AJINOMOTO ALTHEA

Ajinomoto Althea Inc. (Althea) is a fully integrated contract development and manufacturing organization providing clinical drug process development and manufacturing services to global biotechnology and pharmaceutical companies. Althea has the capacity to support early-stage clinical requirements through commercial manufacturing and is an expert in executing drug formulation and aseptic fill finish for vials and syringes.

Althea has an excellent track record with global regulatory agencies, including the FDA, EMA (Europe), PMDA (Japan), and RP (Germany). Their processes and procedures are in compliance with European cGMP (current good manufacturing practices) standards and FDA guidelines. Their expertise in aseptic filling and extensive knowledge of international requirements help their clients' products meet the highest possible quality standards.

Althea is committed to the success of their clients for process development, drug substance and drug product manufacturing.

THE CHALLENGE: CRITICAL REGULATORY REQUIREMENTS AND cGMP DEMAND BETTER PERFORMING ERP SYSTEM

Althea was using two ERP systems that didn't communicate efficiently with each other, as well as a number of paper-based and manual systems. As a rapidly growing company, Althea needed to find an ERP system that would integrate all of their key business processes, ensure their ability to meet changing and increasing government reporting requirements and be able to scale with the growth of the company.

Three of the biggest driving factors behind implementing a new ERP solution were:

- Compliance — Althea has to comply with a wide variety of regulations and requirements for both the drug formulas they develop and produce and the vials and syringes they fill for their various contracted clients. They also need to be ready to meet the rapidly approaching deadlines of the new Drug Quality and Security Act (DQSA) requirements.
- Outdated Systems — Althea's existing ERP systems didn't "talk" to each other and there were many inefficient paper-based systems.
- Project Cost Management/Reporting — There was no central database, only silos of information in a multitude of spreadsheets.

"We had everything we needed but no way to effectively make it all work together," comments Melissa Rosness, Senior Director of Operational Excellence, Ajinomoto Althea. "We needed a new system that could accommodate all the existing information and processes — that could also provide lot level transaction information, transaction history and transaction statement of all shipments as required by the new DQSA going into effect."

THE SOLUTION: CHOOSING AND IMPLEMENTING THE RIGHT ERP SYSTEM

Althea put together an ERP evaluation team that reviewed over 20 different ERP systems using a predefined list of selection criteria. They narrowed it down to the top three who then provided system demos. QAD was selected as the system of choice.

The key reasons for choosing QAD were:

- Low risk and total cost of ownership
- Full-featured ERP system
- All-in-one system/database
- Scalable to thousands of users
- Cloud solution
- Expertise in life sciences manufacturing
- Complete support for FDA and cGMP regulations
- Rapid deployment using process maps based on industry best practices
- System validation as part of the implementation

Althea also implemented QAD Item Attributes, Quality Control and Automation Solutions.

"Althea had a completely paper-based process for its QC Testing and QA Release of GMP Raw Materials, Intermediates, and Final Product. When we saw QAD's Item Attributes/Quality Order Module demo, we knew we could use the module to move to an electronic system, comments Rosness. "It's flexible enough to fit our business processes and reduces paper work, streamlines data capture, and brings visibility to the material and product testing and the release process."

Althea runs a cGMP warehouse where they are receiving, testing, releasing and issuing materials for various contracted companies on a daily basis. Barcoding and label printing services are a critical part of this process and have to meet DQSA requirements. QAD had built-in processes that streamlined the current system and introduced much more automation.

Althea hoped to avoid the need to integrate a third-party label solution. They were able to work with QAD's development group to put in place label printing that met the GMP and regulatory guidelines for inventory control and labeling, all within a single QAD solution.

"Right out of the box our new QAD system addressed and resolved the vast majority of our current needs and the new requirements that are coming soon," notes Rosness. When we needed personalized solutions, the QAD development team worked with us using their expertise and life sciences sector knowledge to design what we needed."

THE BENEFITS: COHESIVE ERP SYSTEM RESULTS IN NEW FUNCTIONALITY AND TIME SAVINGS

Using a now fully integrated ERP system, Althea has all critical business processes under one system with data visibility. They will continue to realize even more benefits as more and more data is tracked and reported on from the system.

QAD's Automation Solutions product now allows Althea to more efficiently:

- Receive inventory
- Perform cycle counts
- Move inventory
- Issue inventory to work orders

This has greatly reduced the overall data entry time in the warehouse. Chris Dorio, Senior Manager of Materials Management, notes, "I did receiving today and it only took a few minutes, whereas with the old system it would have taken me hours."

The Item Attributes and Quality Control solution moved the previously paper-based process of QC testing and QA release of all raw materials and final products prior to use or shipment to an electronic format, which:

- Creates more visibility to the entire testing and release process
- Generates reports for customers
- Prints CofA for final products in real time

QAD's Automation Solutions product streamlines the processes for:

- Incoming receipt
- Work order component issue
- Cycle counting
- Inventory transfer
- Required tracking abilities

Now having the capability to use handheld devices, users have the flexibility to perform these tasks on the warehouse floor by scanning the item barcode and/or entering minimal data. Being able to perform these tasks on the floor greatly increases warehouse efficiency.

Printing the release label and dispense labels allows the Materials Management team to accurately track the items from receipt to issuance, minimizing key strokes. Scanning is more accurate and efficient in the release and kitting process.

In conjunction with the QAD implementation, Althea also went live with a new larger warehouse. Improving these efficiencies has allowed Althea to maintain the same staff while supporting a greater increase in material and product flow within the new warehouse, thus minimizing overall costs.

> "QAD Enterprise Applications has been a great success for us. We are now ready to meet future challenges including the new DQSA requirements.

Melissa Rosness, Senior Director of Operational Excellence, Ajinomoto Althea

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