

Chameleon CMS Case Study

The Background: Large multinational pharmaceutical seeks better method of tracking inventory

Actavis is one of the world's leading developers of first class generic pharmaceuticals. The company has locations in over 30 countries and has over 11,000 employees. The company was founded in Iceland in 1956, where its head office is still located.



Actavis has an aggressive growth program and has acquired more than 20 companies in the last seven years. One of the acquired companies is located in Elizabeth, New Jersey. After completing the purchase, Actavis reviewed the Elizabeth location's inventory and manufacturing control practices and decided that an upgrade was necessary.

The goal was to introduce a system that would provide end-to-end electronic tracking of raw materials from receipt through consumption in pre-weigh. The selection criteria was as follows: the system must be able to create an environment that eliminated any holes in the process; the system must be able to be validated; and the system must provide a justifiable return on investment (ROI).

The ROI should come from three main areas: allow for the re-allocation of unnecessary personnel brought on by the introduction of electronic signatures, eliminate costly time spent investigating inventory discrepancies and increase overall work flow efficiencies.

The Problem: Manual data recording has potential for error

Actavis used a complicated system of manually produced paper documents to identify its inventory location / quantities and to track inventory movement and consumption. This information was stored primarily on paper cards and subsequently transferred to their ERP. Unfortunately, the information on the cards was not always as accurate as was required. This in turn caused their ERP to have inaccurate information, causing issues with production planning as well as the FDA.

These inventory cards could also be easily misplaced, causing everything to stop while the card was located.

In addition to having paper cards as the primary inventory control system, all production (pre-weigh) records were manually produced and recorded. This manual system required duplicate work and the re-entering of information into various systems.

The information produced by the manual system was time consuming to produce, collect and verify. The potential for error was large.

The Solution: Go electronic

Actavis decided to purchase a best of breed real time paperless inventory and manufacturing control system that would eliminate most of their paperwork, while meeting regulatory requirements including FDA CFR 21 Part 11.

The system they needed had to interface to and work with their existing MFG Pro Enterprise Resource Planning (ERP) software to improve its accuracy, efficiency and value.

The company developed a comprehensive systems requirement and requested a number of companies to present them with system proposals. After a review of the various companies' solutions, Actavis selected Valdata Systems, a Fairfield New Jersey based systems integrator.

The Supplier

Valdata Systems, a member of The Winter Group (www.thewintergroup.org), specializes in providing turn-key manufacturing automation systems. Valdata's primary product line is a Chemical Management System (CMS) developed by Mar-Kov Computer Systems out of Toronto Canada.

Turn-key systems include software, hardware, interfaces to existing host ERP systems and training.

Valdata Systems has been installing electronic / paperless systems since 1997, and has systems in a wide variety of industries including Flavor & Fragrance, Pharmaceutical, Cosmetic and Vitamin.

The System

The Chemical Management System (CMS) is a client / server application that bolts onto existing host ERP systems through thoroughly tested interfaces. It can be installed thick (installed on a local PC) or can be run thin through Citrix or Microsoft Remote Desktop. At Actavis, the application runs on a variety of networked IBM personal computers, Motion Computing wireless tablets, Pro-Tech harsh environment computers and Symbol wireless hand held terminals, all of which communicate with a centralized database server. The CMS system is integrated with the Actavis host ERP, MFG Pro.

The system communicates extensively with peripheral equipment such as bar code scanners, bar code printers and directly interfaces to scales.

CMS was developed using the Delphi programming language from Borland. The system uses standard Windows APIs and runs on any 32bit operating system from Microsoft.

Warehouse Operation

When raw materials arrive at the Actavis receiving dock, the receiver enters the purchase order number into the Chemical Management System. Through its host ERP interface, CMS retrieves from MFG Pro all pertinent information about the PO.

The receiver verifies that the correct materials and quantities are being received and enters this data into the CMS. CMS also verifies that the correct items / qtys are being received.



Once the receipt is complete, CMS posts the receipt information back to MFG Pro. After a successful post, CMS commits the transaction locally and then produces individual license plated bar code labels for each container, including labels for sample containers. These containers are marked as HOLD for testing within the system and cannot be utilized in any pre-weigh operation until they are released through the LIMS portion of CMS.

As an added step, CMS can also produce small MSDS and CofA labels that can be affixed to the MSDS / CofA documents that came with that shipment. These documents can then be scanned on a flat bed image scanner and ‘electronically’ attached to the received containers. These images can be viewed at any time within CMS via right clicking on a container and selecting the ‘view MSDS / CofA’ option.

The labels produced by CMS (raw material and sample containers) include a bar code. This bar code is a unique license plate for each container. This ‘license plate’ allows the system to perform individual container tracking and tracing, which has numerous advantages over item / lot / location tracking.



Once the receipt is complete, containers are moved to ‘legal’ locations via hand held wireless scanners. CMS enforces the placement of containers to specific locations based on attributes of the item. To move a container, warehouse personnel scan the bar code on the container and then the bar code at the destination location. Additionally, because all items are marked electronically as quarantined until approved, containers need not be segregated in a quarantined location, although Actavis elected to continue this practice.

Warehouse functionality within CMS extends well beyond material receipt and placement. Actavis uses other functions including inventory cycle counting. Cycle counting is carried out at any time on any number of locations using the hand held data terminals. Not only is the counting process simplified but it can also be performed

without disrupting any other ongoing operations. Once a history is built up of successful cycle counts, Actavis expects to eliminate annual physicals.

The methods employed by Actavis for warehouse operations have eliminated the manually updated 'cards' and eliminated the redundant data entry back into MFG Pro. The warehouse operations have greatly increased in efficiency since installing the system.

LIMS

Once containers have been received in WMS and sample container labels (collectively know as the test set) are automatically generated, CMS sends electronic notifications to the QC department letting them know that samples must be taken.

CMS produces the appropriate number of sample container labels based on the material. These samples can include, but are not limited to, analytical, micro and retain. CMS randomly chooses the containers to be sampled when statistical sampling is in effect.

Once sampling is completed, depending on the material type (DEA / API / etc.), the sample weight must be determined via placing the sample container on a scale. DEA regulations require that all material be accounted for. Determining the weight of the sample enforces this requirement. The sample quantity is equally and automatically deducted from the random list of containers from which the sample was taken. CMS supports multiple sampling methods including square root plus 1.

Once the samples are delivered to the QA department, they are scanned into that location. As a 'leave no open holes' approach, samples can only be approved from within an area designated as being able to approve such samples.

The software has the ability to specify the testing requirements for each material. Items can have ranges set for such attributes as potency, particle size, etc. QA test results can be entered and verified against these acceptable ranges prior to material release.

In Actavis' case, QA test results are recorded in another manual system and CMS is utilized for the purpose of sample approval only.

The process of material release is straight forward and requires a number of steps to be completed prior to the release ... or rejection of material. Some of those steps are mentioned above but an additional required step is that retains be placed into a special retain warehouse. This retain warehouse is a logical warehouse within CMS and emphasizes the concept of enforcing SOPs.

In order to approve a sample, all sample containers belonging to that sample set must be approved. To approve each sample, the sample container bar code is scanned and the container is marked as 1st quality. This continues for each sample in the set until a final approval is given. The final approval involves approving the test set and assigning a re-test date as well as a destruct date.

Once approved, electronic notification is automatically sent to the person who initiated the creation of those sample labels. Generally speaking, this is the warehouse operator. Upon receiving such notification, the warehouse operator is then free to move materials to another ‘legal’ location.

Pre-weigh

Once production requirements have been scheduled in the MFG Pro ERP system, it produces the required work orders and ingredient Bill-Of-Materials. This information is automatically downloaded to CMS, which then takes full responsibility for controlling the pre-weigh manufacturing process and collecting, recording and validating all manufacturing data.

Prior to pre-weighing items, operators utilize a staging function within CMS warehousing. Tow motor operators access this screen on the wireless tablet computers affixed to their fork trucks.

This function lists all items that are required for pre-weigh in order of priority. Although some customers stage material for multiple orders at one time, Actavis only stages material for one order at a time.

The staging process is extremely helpful in that once an item is selected\ the system shows all available containers in FEFO (first expired first out) order. As a design element in CMS, by displaying items in FEFO order rather than FIFO order, the amount of container re-testing is reduced substantially.

Once containers have been staged (i.e. moved) to the pre-weigh area, weighing can begin.



Instead of paper batch sheets pre-weigh operators are assigned electronic work orders that contain the required formula and Bill of Materials. Through carefully designed system prompts, the system prompts and then polices the operators through the pre-weigh process, following Actavis’ standard operating procedures. If there is an error performed at any time, the system stops and will not allow the operator to proceed further until the problem has been corrected.

To begin weighing an order, the order is selected and made ‘current’. Operators are then prompted to scan the bar code license plate label on the raw material ingredient container to verify that the correct ingredient and lot have been selected. Once scanned, if the item is incorrect, the system outright rejects the selection and will not allow the operator to continue, hence the policing. If the item is correct but there is a raw material lot that has a FEFO date closer than the one selected, the system will not allow the ‘newer’ container

to be used without authorization. If the container is past expiration or if the quality code is incorrect, the system will also outright reject that container.

Once an appropriate container has been selected, the system prompts the user to scan the scale to be used for the weighment. Upon scanning the scale, the system automatically zeros the scale through its direct scale <> PC interface.

The operator is then instructed to place the empty container on the scale and press OK. This action causes the system to automatically record and execute a tare. If by chance the scale is empty during this step (i.e. the tare is ZERO), the system will warn the operator that the tare is incorrect.

After the tare is established, the system prompts the user to begin weighing the item. As product is added to the empty target container sitting on the scale, the system displays a bar graph indicating the pour completion percentage. This is possible because the scale is connected directly to the system via Serial <> Ethernet interface. The goal is to reach 100% ... exactly. If the pour is under weight, the system will accept the weighment and show that there is a balance that still needs to be weighed into another container. The system will not allow for an item to be over-weighed, under ANY circumstance.

Upon completion of the pour, the system prints another bar code label similar to the ones produced in receiving. The difference is that this container is allocated to the order for which it was weighed and cannot be used for anything else.

CMS continues to prompt and police users through each item in the order until the order is completely weighed out.

Out of the many functions available within the Manufacturing Execution System, there are a few notable features utilized by Actavis that have assisted them considerably with investigations:

Purity Adjustment

CMS automatically adjusts the quantity required of active ingredients based on their purity. It also adjusts the filler to compensate.

Adjust Container

When a source container is emptied, the user has the ability to ZERO the container. For example, although CMS may show a very small amount of material left in the container, the container is empty. Without ZEROING out that container, these small amounts would continue to reside in CMS until a full physical is performed. Note that the amount that can be adjusted out is policed as a percentage of the original container amount. So without authorization, users could not ZERO large amounts of material.

Correcting for Tare

Actavis has a requirement that the tare be verified for DEA Products. CMS enforces this by requiring that Gross Weight and Tare be entered at the time of Receipt, and that when

the empty container be reweighed when empty. Any difference between the empty weight of the container and the tare weight originally received becomes an adjustment to quantity received. This adjustment appears in their lot reconciliation report, as well as other reports.

The Results: Actavis achieves what it set out to do

CMS has eliminated the need for employees to record data manually. The system has eliminated most of the paperwork, with its potential for recording and transcription errors. The time that has been saved by eliminating the paperwork allows the employees to increase the number of transactions they produce each day.

CMS produces a validated electronic audit trail record of all transactions to prove how it knows the data is accurate. This audit trail helps to ensure that the data exchanged with MFG Pro is accurate.

CMS has eliminated the operator's ability to make a bad batch that is caused by the operator selecting an incorrect ingredient, the operator selecting an incorrect lot or the operator weighing an incorrect amount.

CMS ensures that Actavis constantly produces the highest quality product possible. It protects the company's reputation while reducing its risk for legal actions based on bad product.

The fully integrated system has been validated to meet the CFR 21 Part 11 requirements and has allowed Actavis to dramatically increase its production output with the same number of overall personnel.

Actavis plans on rolling out CMS into all aspects of its Elizabeth plant within the next 12-18 months.

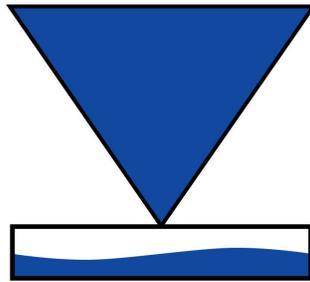
Danny Allis, Manager - Supply Chain at Actavis had this to say about the system:

CMS has been a great improvement to our Receiving, Sampling, and Dispensing processes thus far. The system has improved efficiency, accuracy, and control. Furthermore, there is a lot of anxiousness to move forward and utilize CMS in additional processes, as well as controls. Besides actually getting raw materials to the facility, it's a comfortable feeling, knowing your inventory is accurate and being policed.

Our Mission

Our mission is to create, develop and implement integrated software systems, which will increase our customer's ability to produce more product in less time, without errors, while using fewer resources. We will continue to use leading edge technology to ensure the accuracy and validity of the inventory and production data that our systems collect. We will develop software and hardware solutions, which meet and enforce industry and regulatory requirements. We will continually adapt our thinking to better meet the ever-changing operational and regulatory environment. We will conduct ourselves ethically and support the needs of our customers, employees and shareholders as our top priority.

Providing solutions for Pharmaceutical, Cosmetic, Flavor / Fragrance, Vitamin and specialty chemical industries.



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