



BatchMaster helps Dong-A Socio Group streamline manufacturing operations & manage compliance regulations

Company Name:

Dong-A Socio Holdings, Dong-A ST, Dong-A Pharmaceutical and DM Bio

Location:

Headquartered in Seoul, South Korea

Industry:

Pharmaceuticals Manufacturing

Solution:

BatchMaster Manufacturing for SAP Business One

Company Overview

Dong-A Socio Holdings is acknowledged as a leading name in South Korea's Pharmaceutical industry with child companies as Dong-A ST, Dong-A Pharmaceutical and DM Bio. The business encompasses a broad range of activities related to the developing, manufacturing and distributing of ethical drugs, medical equipment, energy drinks, biopharmaceuticals and active pharmaceutical ingredients (API). Over the years, the company has built alliances with some of the biggest international companies to expand its market base. Its major products include Stillen tablet, Zyderna tablet, and widely-available Bacchus energy drink, among others, with the latter having gained unprecedented popularity across the country.

Strategically moving ahead, the company went in for a structural rejig to find new growth engine after 80 years of its successful existence, splitting into three companies through

stock split and asset carve-out - Dong-A Pharmaceutical, to solely focus on OTC business, Dong-A ST (Science & Technology) for the ethical drug business area, Dong-A Bio for Biopharmaceutical products in alliance with a Japanese Pharmaceuticals Mfg. Co. and the Dong-A Socio Holdings, the holding company, to focus on new investments such as biosimilar and other healthcare business, thus marking its foray into the biosimilar business.

Apart from having a strong base in the South Korean market, Dong-A Group has presence in approximately 40 countries in Europe, Latin America, and Asia where it markets its products, thus strengthening its foothold in the global pharmaceutical market. Dong-A also invests heavily in Research & Development (R&D), through its state-of-the-art Biotech Research Center. Based on its gene recombination, animal cell culture, and other futuristic technologies, the company aims to create patient-oriented innovative biomedicines.

The Need

Integration & Compliance

Dong-A had been operating on an in-house software which was struggling to meet its evolving business needs. Moreover, post the split, the Group wanted to deploy an ERP system which would act as an integrated solution to the needs of all the three businesses by bringing them on the same page. The pharma giant also grappled with a myriad of industry-specific regulations, including FDA's intense scrutiny, and meeting FDA 21 CFR Part 11 compliance needs, and complying with the requirements of good manufacturing practice (GMP) guidelines, among others.

A majority of the company's compliance-related struggles stemmed from the fact that the legacy system was not capable of managing the compliance needs of all the three businesses. This resulted in insufficient control over the compliance activities, and limited or no real-time compliance reporting, thus creating the need for a new system, which would be laden with a proficient compliance management functionality.



DONG-A PHARM

“We made the right choice with BatchMaster, and we are very happy and satisfied about it.”

**Mr. Minsung Kim,
Head, ERP System,
Dong-A Pharmaceutical**

As the Dong-A Group wanted to use the new ERP system for cGMP-critical operations, it also wanted that the prospective software should have got the third-party testing and subsequent validation done. This was a pre-requisite for the company, as any such validation would have testified that the product is in-line with FDA and global regulatory guidelines and meets all the FDA and cGMP standards. Another requirement from the software was third-party manufacturing capability.

Quality Control

Then there were other needs too, as Dong-A needed both formula (in-process) Quality Control (QC), as well as final product QC capability from their new software. By having the in-process QC functionality, the company wanted to ensure consistency in quality during all stages of production, apart from the ability to conduct temperature check and check the manufacturing process on other parameters during production. There was an inherent need for the new ERP to have a robust QC module, with strong Non Conformance (NC) and Corrective Action Preventive Action (CAPA) system.

The Solution

Robust yet Flexible

Keeping all the aforementioned needs in mind, the Dong-A management wanted an experienced, competent, and specialized ERP solution rich with the features specific to the pharmaceutical industry. After reviewing demonstrations from quite a few companies, Dong-A narrowed the list to BatchMaster Manufacturing for SAP Business One, and offering from another prominent ERP player. In late 2016, after an exhaustive on-site software selection process, Dong-A decided to go with BatchMaster, believing it was the best-fit for the scope of the project, its multi-divisional financial and manufacturing needs, and best value for price. “Our goal was to implement an ERP system that would be robust yet flexible,” said Mr. Minsung Kim, the head of the ERP implementation project at Dong-A. “We wanted to have a system that was robust in the sense that it had strong formulation, compliance, QC, and planning & scheduling modules, and flexible in the sense that it could adjust to the needs of our evolving business model, acting as one integrated solution.”

BatchMaster – The Best-fit

What the company also liked about BatchMaster's offering was the fact that it provided efficient processing capabilities without compromising with Dong-A's existing business-critical functionalities. “The brilliant combo of BatchMaster Manufacturing and proven capabilities of SAP Business One offered us the best solution in terms of industry-specific functionality, technology, implementation methodology, along with the scalability to match our expanding business, among all the systems we evaluated. Hence it was a no-brainer for us,” added Mr. Kim.

BatchMaster Manufacturing for SAP Business One is a process manufacturing add-on for SAP Business One. BatchMaster Manufacturing is not integrated, but built-in SAP Business One- rendering its process manufacturing capabilities and making it a complete solution handling all of Dong-A's distribution, manufacturing, finance, quality & compliance needs.

The Implementation

Getting rid of the antiquated legacy software to bring in a new ERP system so as to manage all the three businesses was not easy to begin with. The different group businesses had different and unique business processes, and bringing all of them under the scope of one ERP software was always going to be challenging during the implementation phase. However, the Dong-A management saw it as an opportunity to standardize and improve processes across all the businesses.

Seamless Transition

BatchMaster Manufacturing for SAP Business One provided the desired flexibility and scalability to support all the unique business processes of Dong-A's different businesses. The solution seamlessly integrated into the processes and adapted to meet the specific business needs. Initially, the company did not require much customization, as the solution was an as-it-is fit to their business needs. But gradually, it did opt for customizations at its own end for a few customized processes.

All through the implementation project, the team of consultants at BatchMaster was extremely supportive to Dong-A's needs. It ensured that the transition from the legacy system to BatchMaster Manufacturing for SAP Business One for all the users at Dong-A's different companies was a seamless one. The pilot exercises post implementation made sure the users were completely at peace with the new system, and ready to make the big switch.

The Results

BatchMaster Manufacturing for SAP Business One streamlined and automated Dong-A's critical business processes, proving as the ideal solution for all its three businesses by bringing them together. The fact that BatchMaster's offerings have third-party validation helped, as the company didn't have to think much before selecting it.

Meeting GMP Guidelines Made Easier

It is easier now for Dong-A to meet GMP guidelines by using backwards and forward traceability for the raw materials/Finished goods inward/outward transactions. GMP demand that each process should be documented properly to establish evidence that the produced drug meets its pre-determined specifications and quality attributes. It is thus important for the process manufacturers to create and maintain Batch Manufacturing Records (BMR), something Dong-A was missing with its legacy software & managing with hand-written BMR & MBR.

But with BatchMaster Manufacturing for SAP Business One, the company can now create and maintain BMRs/MBRs, listing vital details such as batch records, Bill of material, equipment cleaning

record, yield, and general instructions for manufacturing, in process QC, Check lists & Finished Goods QC. Defining QC tests as per the GMP norms like quarantine, release and reject is also possible now for Dong-A. With the in-process QC functionality, the company is now assured of quality during all stages of production.

Fulfilling a Myriad of Needs

Software's other modules have enabled Dong-A to manage its inventory, planning & advanced scheduling, NC & CAPA, formulation, production batches- running both SuperBatch as well as normal batch, etc. in an efficient manner.

Compliance Simplified

Last but certainly not the least, the solution has acted as panacea to all of Dong-A's compliance needs. The company is now managing its complicated compliance processes with confidence, as the solution is FDA 21 CFR part 11 compliant, thus fulfilling one of Dong-A's most important compliance requirements.

In a nutshell, Dong-A is extremely satisfied with its ERP choice, and has readily agreed to become BatchMaster's reference customer.

About BatchMaster Software

BatchMaster Software (an ISO 9001:2015 certified company) is a leading provider of ERP solutions that help formula-based process manufacturers streamline their operations and scale production, while reducing costs and complying with changing customer demands and ever more stringent regulatory mandates. The company delivers industry-specific solutions for Food & Beverages, Nutraceuticals, Life Sciences, Cosmetic & Personal Care, Chemicals, Paint & Coatings, and other process industries. BatchMaster ERP is seamlessly integrated with SAP Business One, Tally, and Sage 100 & 300 ERP, and is available on both - on premise and on cloud.

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