

## Case Study of Corporate Account

# Elegant Manufacturing: A Life Science Case Study

In the midst of a difficult economy, a company might prescribe a strong dose of creativity into the main corporate vein. As the saying goes, “Necessity is the mother of invention,” and for those fortunate companies who do manage to conjure up less expensive—yet unusually creative—solutions the financial benefits are sure to follow.

### **A Schiff Solution: Thinking Outside the Box**

Schiff Nutrition International, Inc., a dietary supplements company, develops, manufactures, markets and distributes branded and private label vitamins, nutritional supplements and nutrition bars in the United States and throughout the world. Like other life science manufacturers (e.g, pharmaceutical, biologics) Schiff Nutrition utilizes batch records when manufacturing their products. An average batch record at Schiff might run anywhere from 28-35 pages and some batch records found within the life science industries can reach the very considerable size of up to 2,000 pages.

Knowing this, it's easy to imagine how quickly batch record documentation management becomes a weighty issue in any FDA regulated company. For example one work order at Schiff, resulted in the creation of a batch record printed for the manufacturing floor without altering the original batch record template. That second version of the record then had to be routed to appropriate manufacturing personnel and stored for possible reprinting in the event that it was damaged during the manufacturing process. The process, when conducted manually, was obviously inefficient—not to mention, non-compliant with the new regulations--and Schiff professionals knew it.

### **Resolution Begins**

Schiff professionals wanted to address these deficiencies by further developing a homegrown solution that had been--and still was--used to manage the former batch record forms/documents but realized that would be impossible when the FDA announced it would be regulating dietary supplement companies (like Schiff) according to 21 CFR Part 111 and Part 11 (for electronic systems) standards.

This was a serious problem for Schiff since their homegrown solution didn't provide audit trails, version controls, electronic signature approvals or the electronic securities required in the Part 11 regulations and also failed to provide some of the electronic process capabilities that would be valuable in complying with Part 111.

Security for example was an especially difficult issue and would have cost Schiff programmers months or even years of additional programming time which simply wasn't an option since Schiff had only one year to comply with Part 111 and Part 11 requirements.

The homegrown solution also resulted in batch records that were essentially

“static,” or in other words, harder for regulatory professionals to edit. In fact, with the homegrown system, it required a visit to the programmers’ office to get the simplest of changes made to batch record documents.

In order to resolve these issues Schiff decided to start with the documentation itself. They wanted to develop a batch record that could be edited more easily by batch record creators and editors (R&D and Quality). This solution was fairly easy to implement after a Schiff employee performed a little leg work and met with a GMP documentation redesign consultant, Chuck Krumwiede, at a trade show. The company Mr. Krumwiede works for, Malcom Associates, specializes in business process improvement and redesign solutions for the Life Sciences, Nutraceuticals, Health Care and Food & Beverage industries. Their solutions reduce human error and redundancies and improve workflows, regulatory compliance, document and procedural practices. During the meeting, Mr. Krumwiede mentioned there were opportunities for many life science companies to include their Word-based batch record documentation within their document control management systems and to generate these documents with pre-printed header information instead of entering the information manually. At the time, Schiff was currently using the MasterControl document management system and knew the solution worked well but wondered how to convert their current batch record documents to more flexible Word-based batch record documentation that could be managed within the MasterControl EDMS.

It was at this time that Schiff decided to hire George Benevento, a consultant and batch records documentation expert, to provide his expertise regarding system processes and Word-based batch record documentation. Tom Gosse, Document Control Manager and System Administrator and Fred Priwo, Business Analyst remember that Schiff requested Mr. Benevento and Mr. Krumwiede to conduct a gap analysis. “We had them come in since we were concerned about being compliant with the new CFR Part 111 regulations for dietary supplements. We had them do a gap evaluation on our processes and batch record documents. They put together a proposal of what they could do to handle the batch record documentation problems while using the MasterControl system as one of our control options. Gosse also stated of Benevento: “He understood the FDA regulations and requirements. These documents are serious business. Some of our batch record documents are around 30 pages long...they are good-sized documents and cover all parts of the manufacturing process.”

Benevento adds: “Schiff’s culture and the knowledge and experience of the professionals and manufacturing personnel who participated in designing and creating the batch record documents made it possible for Schiff to meet FDA’s timeline for implementation of Part 111.”

Benevento and his expertise proved to be a sound decision for Schiff. Benevento met with Schiff professionals and manufacturing personnel and helped Schiff design and create a batch record document that could be created and edited within Word and controlled completely within the MasterControl EDMS. The initial problem was resolved. However, Schiff was left to contemplate another--more complex—issue.

## Second Resolution

The more complex issue had its roots in ‘a *disconnect*’ between Schiff’s ERP system JD Edwards (JDE) and the MasterControl EDMS. For example, a work order was initially created from the ERP system but the ERP system had no way of connecting with the MasterControl system to access the “recipes” or batch record documentation which contained information necessary for the work order and the actual batch manufacturing process itself. This created a disjointed process. The work order would be created but the recipe could not be accessed. This was a serious problem and at first Schiff programmers considered the creation of homegrown code to integrate the two solutions and even considered asking MasterControl programmers to participate in some configuration that would be unique to Schiff. However, Gosse was also adamant: “We didn’t want to deal with custom code if at all possible.”

It was during and between discussions for other possible solutions that Gosse remembered hearing about a MasterControl product, the API toolkit, which allowed MasterControl users to easily integrate the MasterControl EDMS system with a variety of ERP systems including JDE. The API toolkit was simple and elegant. Schiff purchased the MasterControl API toolkit and then Doug Hansen a Schiff programmer integrated the two systems using their own .NET program and the API toolkit. The process (see Figure 1) was then easily streamlined as work orders were planned, ordered, split into batch quantities, parts lists printed, work order types assigned and work order(s) information passed to the ERP’s data queue, where the Schiff-created .NET application then transferred the information to the MasterControl API toolkit which extracted the batch record stored in MasterControl. Once the appropriate batch record had been identified for a specified work order request the batch record was automatically duplicated and via the Microsoft ‘find and replace’ function, the program would then apply the work order number and quantity to the document header. The original batch record would remain untouched—unscathed as it were—but the new copy version would be printed for use on the manufacturing floor and then stored in another MasterControl vault where it would be saved for six months and then automatically deleted. This ensured that a copy of the original print-out would be available for reprinting during the manufacturing process should any part of the document become damaged or if additional process monitoring pages are required. This completely electronic process allowed Schiff employees to process work orders without worrying about uncontrolled/unofficial documents, compliance issues, information errors and extra training required for users.

## Reaping the Benefits

This creative solution was beneficial to Schiff end-users of both the ERP and MasterControl EDMS systems. End users didn’t have to change the way they worked in either system because the creative solution simply involved connecting solutions—and effectively—connecting both sets of end users. The process bespeaks a “touch of genius.”

Gosse states: “The unique thing about the way that we handled this problem was that our solution was seamless from the end user’s standpoint. Everybody knows these programs. We didn’t have to retrain anyone. We didn’t have to train the planners because they do it the exact way they have always done it in the ERP system.



Work Order Print Process

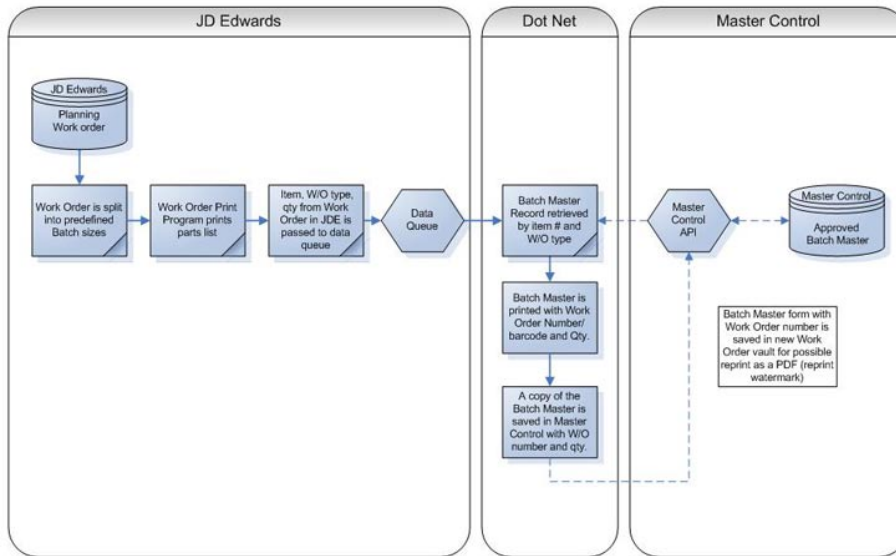


Figure 1

It is a pretty amazing and I think...a pretty creative solution,” says Gosse.

Krumwiede adds: “Schiff was willing to think outside of the box when we proposed this solution to leverage and utilize the MasterControl EDMS. This solution systemically helped Schiff meet the new regulatory requirements for nutritionals and greatly improved their batch documentation management process.”

**More**

Many life science companies, like Schiff, are looking for creative solutions that won't cost them excessive time or money. Schiff did what they needed to do with a minimal amount of resources and manpower. If you would like to learn more about Schiff, Malcom Associates (GMP documentation consultants) or MasterControl, Inc. please contact their respective representatives:

- [Contact a Schiff Representative](#)
- [Contact a Malcom Associates Representative](#)
- [Contact a MasterControl Representative](#)

**About MasterControl**

MasterControl produces software solutions that enable regulated companies to get their products to market faster, while reducing overall costs and increasing internal efficiency. MasterControl securely manages a company's critical information throughout the entire product lifecycle. Our software is known for being easy to implement, easy to validate and easy to use. MasterControl QMS and QEM solutions include quality management, document management/document control, product lifecycle management, audit management, training management, bill of materials, supplier management, submissions management, and more. Supported by a comprehensive array of services based on industry best practices, MasterControl provides our customers with a complete information management solution across the entire enterprise. For more information about MasterControl, visit [www.mastercontrol.com](http://www.mastercontrol.com), or call: 1.800.825.9117 (U.S.); +44 (0) 1256 325 949 (Europe); or +81 (03) 6801 6147 (Japan).