

LMS e-Learning Implementation Podcast Transcript #9 *Interview with Ben Schmitz*

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Mary Kay Lofurno: Welcome to the next edition of the [SyberWorks LMS e-Learning Implementation Podcast Series](#), where we take a look at actual learning management systems LMS implementations and e-Learning rollouts.

My name is Mary Kay Lofurno, and I'm the Marketing Director here at [SyberWorks](#) and your host today. In this edition we are [talking with Ben Schmitz, Technical Trainer for St. Jude Medical](#) about their use of the [SyberWorks Web-Based Learning Management System](#) to provide training for employees in the highly regulated medical device manufacturing industry.

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Mary Kay: Good afternoon Ben. Thanks for coming to talk with us today.

Ben Schmitz: Good afternoon, Mary Kay.

Mary Kay: Tell us about yourself and what you do for St. Jude Medical Incorporated.

Ben: OK. My name is Ben Schmitz. I'm a technical trainer for St. Jude Medical. I have been with St. Jude Medical for over a year. And my job is mostly focusing on operations employees but also on other employees in the atrial fibrillation division.

Mary Kay: OK, great. I understand that St. Jude Medical produces medical devices, but can you tell us a little bit more about your company and the products they make?

Ben: Yes. Our company is one of the third largest medical device manufacturing companies.

Mary Kay: Wow!

Ben: We make medical devices that go in the human body -- for our division specifically, for atrial fibrillation. These medical devices diagnose and treat atrial fibrillation, and they're mostly catheters; ablation catheters and EP catheters.

Mary Kay: OK, well that sounds great. You know, I know that the medical device industry is highly regulated by the Food and Drug Administration - the FDA. They can shut down a company in a New York minute if it's manufacturing regulations and procedures don't follow requirements.

Can you explain what [21 CFR Part 11 compliance](#) is, and why it's important to your training and tracking process?

Ben: OK. Well we're actually regulated by 21 CFR Part 820; that's quality system regulation. And in that, we - for training purposes - have a subpart B, which is quality system requirements. In there is 21 CFR 820 Part 25-- personnel. This really defines how we train our personnel.

With that, I'll just give you 820.25 Personnel is: Each manufacturer shall have sufficient personnel with the necessary education, background, [training](#) and experience to ensure that all activities required by this part are correctly performed. As specifically to training, each manufacturer shall establish procedures for identifying training needs, and ensure that all personnel are trained to adequately perform the assigned responsibilities. Most of all, [training](#) shall be documented.

A subpart to that is: As part of their training, personnel shall be made aware of device defects, which may occur from improper performance of specific jobs. Personnel who perform verification and validation activities shall be made aware of defects and errors that are encountered as part of their job function.

So the biggest aspect you just saw there was that personnel that perform verification and validation activities need to be aware of the defects and errors. Also, just general employees need to be aware of the defects and errors. And, that all training shall be documented.

The reason why [21 CFR 11 compliance](#) comes into existence is that now that we're using a [Learning Management System](#), we have gotten rid of our paper documents saying that, "Bob was trained to build a product under this specification."

Mary Kay: Right.

Ben: We have got rid of our paper document saying that Bob was trained to build the product under this specification. So now we have to document, we still have to document that training. And [21 CFR Part 11](#) defines that you have to make up for that ink signature that used to be there. How we do that is using Syberworks' unique user id and password combination along with our training record to show that Bob was the one who took the test. That's replaced the paper document.

Mary Kay: Well that makes a lot of sense and you know what, I really appreciate your explaining that all because it's pretty complicated stuff. So other than the compliant aspect that you had, what were some of the key business and system requirements that were important to your company's [online training](#) other than that?

Ben: OK. As far as, we have basically two types of employees and I hate to categorize it.

Mary Kay: That's OK.

Ben: We have production employees who build products and we need to train and track their development and that's a huge piece of the pie. And then, if you look at a company that's around 60% of its employee base. Then we have the other percentage of the employee base which is the exempt workforce, the people who are not dealing with production or support it only.

So the requirements we are looking for them is to be able to track and train professional with [courses](#) such as mini tab or software or also other [off the shelf](#) performance management type training. And so we looked at trying to balance the two. We had a need to be really compliant but we also had a need to be able to deliver online content to a large group people very easily and almost automated.

Mary Kay: OK. Well that sounds good. It makes a lot of sense. [Why did you choose the Syberworks Learning Management System](#) to manage all of your training with both of those aspects?

Ben: We went through a process. We looked at the big players and little players. [Syberworks](#) is pretty much right in the middle. One of the biggest reasons is cost. But the other reason was that Syberworks gave us everything the big players had.

And so with that, we are able to get a [Learning Management System](#) for our division for 1000 employees under \$20,000. That allowed us to function as if we were buying a million dollar implementation. So for us it made sense as a business case.

And also dealing with [SyberWorks](#), every time I called, someone was there to answer. For me, getting back and going through all the demos and stuff, other companies didn't have that type of . [So that's why working with John Donaghue and the SyberWorks Group was very easy and fluid and so that's why we went with them.](#)

Mary Kay: All right. Let's talk about some of the important elements of your configuration process. I am told you are using the SyberWorks Competency Management Module to manage skills training, can you tell me a little bit more about that?

Ben: Ah Yes. Being a department of myself and my boss for the training department for about 600 employees.

Mary Kay: Yes.

Ben: Being very limited amount of time to interact with the system, what the competency and see management module allows us to do create generic [competencies](#) for production floor workers and for the professionals.

We will shoot through two examples. We will use the production folks. If I am a production employee and I have seven tasks that I do and we have four different product lines that all build roughly the same product but it has different uses. But those tasks are relatively the same.

As an example, if you're putting together a pen, you're always going to put the cap on the same way. Then you're going to slide on the other parts; the spring and everything else, in different stages. Well if you build a pen that's two inches long and a pen that's four inches long you're still doing the same task. However, it's a different product.

So what we did is, we took putting on the cap, as an example, as a [competency](#). The [learning events](#) building up to the competency were reading the manufacturing process, going through and watching videos of the cap assembly, and going through different stages of system certification where I took a test.

I had to take a test and I had 20 samples of pens that were put together. And pen caps that were put together. And I had to pick out the ones that were bad and pick out the ones that were good.

I took a test on that, and then I had somebody review and say, "You're certified in that learning event or that competency." Once you get to that competency then it's very easy to move you to other areas.

Maybe you'll go work on the four-inch pens for a while because you know how to put a cap on the two-inch pen. If you're competent on that, all you have to do is go and read the manufacturing process under the two-inch cap. And then you're able to perform that job.

And so, that's how we're kind of using the competencies for the production employees. Also, once they reach where they have all of the competencies, then you have the job skill in that building with those four product lines. You're able to float and work wherever you want.

As far as the professional level employee or exempt level employee, we have taken engineer one for product development and made that a job skill. From that job skill it's going to build up several [competencies](#). One may be your software; one may be your design of experimentation analysis. The others may be your time management and project management.

You go through and the [LMS](#) automatically pushes out those learning events to that employee. We don't really have to manage the system; it does it itself. That's why we have configured the [competency management](#) to work for us.

Mary Kay: OK, well that sounds good. How were you able to configure the [SyberWorks Web-Based Learning Management System](#) for 21 CFR Part 820 compliance?

Ben: Well we were able to configure it for that compliance using the competency management and showing how people are trained. We set it up where - like with the [competency modules](#) I just explained - we were able to set up job skills for specific job types. And underneath that job type we're able to set up learning events.

Those [learning events](#) can be anything up to, I think, seven different types of things. So we can send out a reading assignment of the manufacturing process as one of the learning events. We can send out a video of the event taking place as one of those learning events, and we can do observation as one of the learning events.

So we're really falling into what 21 CFR 820.25 personnel really requires: employees should be aware of the defects they create. And that [training](#) should be documented. That's how we have configured it to work with that.

Mary Kay: That's great. It's super; it's really a good thing when the [functionality](#) is already built into the system and it's just a matter of running a report.

Given what you've already told us about your company, the medical device industry and the [21 CFR Part 11](#), 21 and 820 compliance, it sounds like your company really had to validate each part of the system's functionality. I know you worked a lot on that process. Can you tell me about your validation?

Ben: Yes. Well with software validation you basically start at a ground level and you work your way up. It's a risk assessment based process the whole way through. So as you go through and what you first want to do is you want to do, you want to create your criteria basically. What are you looking for, for your learning management systems? We did that and we said "these are the specific requirements that we need to meet."

I don't have the list in front of me but one was that we need a unique identifier and password for an employee. We need to be able to store all records of [test](#) results. We need the ability to archive the data. We need the ability to pull off a report that shows all the training that employee has had. We need the ability to push out training to multiple levels of the organization. We need the ability to so and so.

You just keep going through. And it is really what are your specific requirements. From there, we took those requirements and we did a risk assessment on those requirements against the code, the quality system regulation.

We took, we need to have a unique identifier, password and user name and that needs to stay with the employee. So we took that chunk of information and said, "OK what risks would happen if that failed, that piece of the software failed?" And so the risk would be that someone's information would be lost. Someone could access the system, all those risks.

And then what we did is we created a test against those risks. That test was a user interface, a common user interface and also on the admin administrator interfaces. We tested it against every single one of those requirements to make sure that the [SyberWorks Learning Management System](#) met those requirements and met the regulation's requirements.

So we made it our requirements with the [21 CFR 820](#) regulations or its intent. That is how we created our validation testing. Then we did a couple of rounds of validation testing. And walked through all those requirements and made sure they passed. And then we had a sign off at the end saying this has met the intents and other requirements and the intent of 21 CFR 820 and 21 CFR Part 11.

Mary Kay: Well that sounds great. That was a lot of work. It sounds like it to me, anyway. Is there anything more that you would like to tell us about your [customer experience](#) or interaction with SyberWorks that you would like to share?

Ben: Yes. During the testing process, I was able to get a hold of [SyberWorks](#) if I had any issues or concerns. It was very easy. But one of the greatest things I found out about the [SyberWorks Learning Management System](#) is that a lot of the [functionality](#) is built in. It's there.

And a lot of the [customization](#) can be done by, not even customization but the customization of the look and feel can be done by the average person. I don't have any HTML background and do not know coding. I was able to take away functions that I didn't want people to see using their page group features.

The average employee does not have the ability to go in there and change any of their information. As any admin level in the system doesn't have the ability delete a user. I was able to go into the code and simply change that. So the ability to change those functions. It was very easy.

The ability to change the hard coding is a lot harder but it doesn't need to be done because there is so much functionality in the system already. One case in point was the report. We asked [SyberWorks](#) if we can have a report that showed ever incident of someone's training.

If I took a test four times, I want to see those results and the time and the date and the actual time bound to them minute seconds when they actually passed that. We were able to get a report that shows all that information. A lot of that is built in there and needs to be requested or utilized.

Mary Kay: Thank you so much. This is a tremendous amount of information. I really, really appreciate it. Thanks so much for joining us today Ben.

Ben: Thank you.

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