Medical Devices

MedicaMetrix Uses Synergis Adept to Run Through Brick Walls Headfirst

CUSTOMER: MedicalMetrix

Profile: Medical device company

Headquarters: Wayland, MA

Challenges:

- Domestic and international regulatory and compliance
- Managing CAD, General Office, and BOM files
- Creating an FDA history file

Solutions:

- Automate processes to facilitate compliance
- Cooperate and collaborate more efficiently
- Improved access to documents

Christopher LaFarge, CEO and President of MedicaMetrix

Christopher LaFarge, CEO and President of MedicaMetrix, Inc., a medical device company in Wayland, Massachusetts, is not a man who takes “No” for an answer very often. He is not quick to compromise his vision.

When the funding for his startup, MedicaMetrix, fell through just as the great recession was starting, he regrouped, self-funded, and bootstrapped his way through the hard times until he could raise a Series “A” round. Now he is poised to launch a revolutionary medical device that could save the US healthcare industry more than $1.4 billion a year.

He is not a big fan of clever ideas if they do not come with people who get things done…

Says LaFarge, a serial entrepreneur, “What investors are really looking for is people who will run through brick walls head first. . .who will redesign something if it is not working to make sure they have a product that goes to market…who may end up redefining the product, or changing the strategy. Somehow, these entrepreneurs are going to end up in the market with something that makes money. In addition, they have the flexibility, drive and spirit to make it happen. That is really, what investors are looking for in entrepreneurs. They are not just looking for a clever idea.”

So, when he went looking for an engineering document management (EDM) system that would enable him to bust through the prodigious engineering, manufacturing, and regulatory obstacles involved in his market…let’s just say he was not in the mood to compromise.

Sipping & Sifting the Alphanumeric Soup

First, LaFarge needed a way to cut through all the “alphanumeric soup” of the domestic and international regulatory and compliance bodies he has to satisfy including the tangle of FDA 21 CFR Part 11.

One of these requirements is an “EU Technical File” for the European Union’s equivalent of the FDA design history file. This file contains the schematics, design layout of the circuit board, and the SOLIDWORKS CAD files for the product itself. It also contains Word documents, Excel documents for the BOMS, PDF files, and on and on.

LaFarge’s solution? A three-ring binder.

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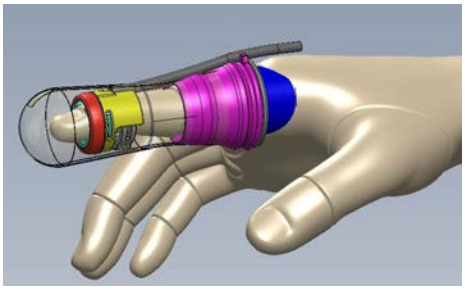

The company's "ProtaMetric" finger is modeled in SOLIDWORKS. Its version history and related documentation are managed throughout the design cycle by Adept PDM.

> "Adept is one of the few solutions out there that does a good job of managing both SOLIDWORKS and general office files."
>
> *- Christopher LaFarge, CEO and President*

But of course, LaFarge wasn't satisfied with this solution – too hard to keep updated. He found and implemented Synergis Adept.

"Now we use Adept's unlinked records feature to create an FDA design history file and its EU equivalent, the Technical File. I also have another unlinked record called Design Specs – analogous to a tab in a three-ring binder. Then, linked underneath that record, are all the documents for the design specs. So, I have a hierarchical set of children-to-parent files which make up a complete virtual Technical File and Design History File."

Explains LaFarge, "If we get audited by either the EU CE Marking authorities or by the FDA, and they say 'I need to see the technical file.' Or 'Let me see the Verification & Validation ("V&V") testing results.' Or 'Let me see the report on that clinical trial', it is all right there, complete with an audit trail, a version history, and, for controlled documents, an approval."

Compromise and Run Two Systems…or One?

Had it not been for Synergis Adept, LaFarge would have had to run two parallel systems to replace his 3-ring binder system. And that is more than a regulatory issue…it also impacts manufacturing downstream.

"Almost all of our design work is done in SOLIDWORKS and most companies say they end up with two systems," says LaFarge. "They end up with something that is compatible with SOLIDWORKS' own Parent/child like system -- assembly and part files. Then they have another system that works well for MS Word and Excel but isn't able to handle SOLIDWORKS files and their interrelationships."

LaFarge explains, "An assembly has two or more part files each of which may be used by multiple assembly files. But if you update the part, somehow that has to get put into the version history/audit trail as an updated version without messing up the other assemblies that call on that part file."

Version control is the hobgoblin of a secondary system--- an issue MedicaMetrix cannot tolerate.

And when you're racing to get a hot, delicate, new product to market, the last thing you need is your engineering document management system delivering the wrong, or unapproved, parts, assemblies, and versions to your people.

"Adept is one of the few solutions out there that does a good job of managing both SOLIDWORKS and general office files," says LaFarge. "All the version control going forward is maintained by Adept." Versions created prior to the installation of Adept were "versioned" by adding time/date to their title and are now located in an "Archive" library as children of the most current version (as of the launch of Adept) – a Library to which only LaFarge has access. Thus, only the current/approved version of files are available to the Company.

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The PROSTAGLOVE is a revolutionary medical device that could save the US healthcare industry more than $1.4 billion a year.

And What about ROI?

While it's hard to determine ROI for a company that is "pre-revenue," LaFarge is convinced that Adept has more than paid for itself already.

Complying with all the requirements is now a snap. "If I go in and type 'ISO 14971', all the documents that are related to that set of analyses pop up," states LaFarge. "If I type in 'ISO 13485', all the 13485 quality control system documents for every part of the system can come up as a search result. I can say 'within ISO 13485, I need to see a SOP for returns from customers.' It has made the whole process much more effective and more efficient."

MedicaMetrix also has been able to cooperate and collaborate more efficiently even though few of the employees work at the same location. "Everybody has access to the documents; we can review things very easily," says LaFarge. "Multiple people can touch the same document but we can keep track of who has touched it, and when."

In addition, regulatory workflows have been fully automated and paper has almost disappeared from MedicaMetrix's office. "I'm down to one box, mostly of paid invoices."

To paraphrase LaFarge's statement about what investors want, Adept is the kind of solution that runs through brick walls headfirst. It helps companies redefine the market; it helps companies optimize their strategies. And, it is flexible enough to automate processes to facilitate the way a company works.

"When push comes to shove, Adept has a captive market in medical device, pharmaceuticals, and biotech because these companies have to have a system like Adept. In my opinion, Adept has the market cornered for medical device companies using SOLIDWORKS."

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