

IBM Podcast

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MATHENY: Welcome to this IBM podcast, building better medical devices with model-driven development. Medical device manufacturers are faced with challenges to bring innovative products to market quickly while meeting functional, safety and regulatory requirements.

Discovering a defect late in the development -- or even worse, one that forces a product recall -- can be devastating to a medical device manufacturer.

Today, Paul Urban, Senior Medical Device Marketing Manager, joins us to discuss how using model-driven development helps to accelerate the development, validation and verification of medical devices by assisting in team collaboration through graphical modeling, validating requirements through rapid prototyping, and automating the software development and test process. Hi, Paul. Welcome to the podcast. Thanks for joining us.

URBAN: Hi, thank you for inviting me and letting me join the podcast.

MATHENY: Paul, let's start with this. So what are the challenges medical device manufacturers companies are

facing?

URBAN: Well, medical device manufacturers, they're facing many of the same challenges that all embedded systems and device manufacturers are facing with rising complexity, challenges of geographically distributed design teams and just trying to get products to market faster.

But they also have another challenge, which is meeting the regulatory guidelines set forth by such as the FDA, and that's a bigger challenge that they have to face that other companies don't need to face in the regular marketplace.

And as medical device products become more and more complicated, they end up having more and more software in them. So the software that was in the device maybe 20 years ago is much smaller than what was there before.

And today, they need even more complex software to really differentiate their products. This is where using tools like MDD, which stands for Model-Driven Development, provided by Rational can really help a medical device company.

MATHENY: So what is MDD?

URBAN: MDD -- or, Model-Driven Development -- is a way

of representing in design using models which are based on a standard language such as a UML or the Unified Modeling Language.

And these diagrams are not just pictures. The diagrams are interconnected together such that you can represent the design with multiple views or abstraction levels.

In this way someone that may not be a technical expert can still understand what you're trying to build. And because these diagrams are all interconnected, make change in one part propagates that change to other parts of the design. So this is a really powerful capability because it helps improve the productivity as you're developing.

So when you make one change -- and there's always going to be changes in your design -- you can really respond to that change quickly by doing the change and then having that change propagate into all your different diagrams down to the deepest level.

And, also being able to communicate more effectively to your domain experts using domain terms that they might understand much better than if you were just working, for example, if someone was just developing code in a traditional fashion, the code is not something that you can show to a doctor or a nurse. So it's really much more effective to communicate

using MDD.

MATHENY: And how can MDD help medical device companies?

URBAN: Well, one of the really big reasons is just as the communication that can be gained by it. But in addition you can have your requirements tied into your modeling environment. And for medical companies meeting FDA approvals is very important.

So what you need to be able to do is show traceability from the design to the actual requirements and prove to the FDA that your design is going to meet those requirements. Last year, in 2008, there was actually a bill put forth to the Congress that was going to have medical device manufacturers and CEOs actually responsible for ensuring that their devices were meeting requirements.

Now, that bill didn't go through last Congress, but it might be coming up in the next Congress. But it's just an indication of how the FDA is really putting a lot of increasing standards on to the medical device manufacturers to prove that they're actually meeting their requirements.

MATHENY: So how can a medical company effectively adopt MDD with their existing processes?

URBAN: Well, one thing that they can do, and one thing that's very important for the medical device manufacturers, is that they have legacy code. And this legacy code has already gone through certification standards.

And it's very important for them to be able to leverage that existing code. And one way that we can do this with MDD is be able to reverse engineer that code and bring it into the modeling environment. And when it's brought in, it can be visualized, so diagrams can be created from the code.

And in some cases, the medical or even all the customers that have done this not just in medical, but they might find that the code, they'll be very surprised at what they see because the actual representation of the code individual format will show many of the different problems that they may have in their code...

And, how the code might be interconnected, perhaps poorly, because you don't get to visualize how your actual code is connected when you just code alone. And it's not clear how it's tied together. And using MDD, they're able to pull that in and then also move from there and start doing subsequent development.

So they'll start to build their actual design using MDD while still leveraging their existing code base. So they

may have an existing code base that they built previously that was certified and FDA approved, they can continue to use that existing code base untouched but develop new features of their products using MDD, so tying those two together.

And this is especially important. This is one of the key technologies that Rhapsody provides, is being able to take existing code and bring it into the modeling environment and then visualize that code and then perform forward engineering where you can continue to do further development of your actual design.

And once you have it in your modeling environment, you can continue to use all of your existing tools and processes. So, for example, you may be using doors for requirements traceability. Those can be brought into that modeling environment and your requirements can be modeled in the Rhapsody environment, and then Rhapsody lets you go further and start to execute the actual code.

So you'll start to actually be able to simulate your code to see where your code might be. For example, Rhapsody provides a state diagram which is highlighted as you're actually executing the design. So as the design is running, you're able to see what state you're going in, and move from state to state and do high-level debugging.

And then that's going to help your system engineering capabilities in that you'll be able to test your design early on, validate your requirements. And this is very important for a medical company: instead of finding a defect late in the development lifecycle, they can find that defect early in the development cycle...

...where maybe in the system engineering phase before going through all kinds of certification they can validate that the design they're building is correct, is going to meet requirements, is going to actually meet the requirements of not just design technical requirements but also the requirements set forth by the end user.

So they may be able to show the end user such as a doctor or nurse, here's how this is going to behave using some prototyping capabilities. They'll be able to see the design action in a mockup of the design, and the doctor or nurse can say, no I think you've got it wrong. This is not the way the functionality should work.

And then you can go and correct it early before they've actually spent a lot of money creating prototypes or first cut at something. So when they come out of market they're better able to ensure that they're going to be building the correct product that is ready for the market.

So those are some of the capabilities that MDD will provide, and the capabilities that allow Rhapsody to be incorporated into the existing development process. Besides just DOORS or requirements traceability which I talked about, there's other aspects such as moving into collaboration and configuration management.

And the same modeling environment can use the existing tools that are in place for the customer, such as if they're using a ClearCase or Rational Team Concert, they're able to leverage those tools with Rhapsody and plug Rhapsody into the existing development environment to ensure that they're going to be meeting the quality standards that the FDA requires of their system and their process and deliver their product to market in a much faster time.

MATHENY: Well, I can really see how MDD would be beneficial to these medical device manufacturers in a very fast way. Paul, thanks so much for sharing your time and expertise with us on building better medical devices with model-driven development. This was very informative and we really appreciate it.

URBAN: Thank you.

MATHENY: That was Rational's Paul Urban, Senior Medical Device Marketing Manager. If you'd like to listen to this

podcast again or others just like it, you'll find more podcasts like this one on the Rational Talks to You podcast page at www.ibm.com/rational/podcasts. This has been an IBM Rational podcast. I'm Angelique Matheny. Thanks for listening. Keep tuning in as Rational Talks to You.

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