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The Down and Dirty on Scrum in Medical Device Development

Scrum. It's an interesting word, no doubt. While it conjures mental images of something removed from a clogged pipe, Scrum—actually derived from the word scrummage from the sport rugby—is an agile framework for completing complex projects. Scrum originally was formalized for software development projects, but works well for any complex, innovative scope of work. It's used to create a collaborative approach for compressing design and development timeframes.

Recently Pro-Dex, Inc., a development and manufacturing partner for medical device manufacturers, which also has been in the processes of integrating Scrum, hosted a dinner on the topic. Keynote speaker for the event was Bachan Anand, founder of Conscires Agile Practices, a training, coaching and consulting firm for Scrum methodologies. He discussed how Scrum could be applied to improve efficiency and effectiveness in medical device manufacturing.

Anand shared his insights with medical Product Outsourcing.

What's the origin of the term Scrum?

Anand: It actually comes from a rugby formation. If you've ever watched a rugby game, you've seen both teams bind together in a close-knit, shoulder-to-shoulder, three-rowed formation to restart the game after the ball has gone out of play. This formation is called a scrum. The team uses the scrum formation to work as a unit to try and win the ball. Then, in 1986, Hirotaka Takeuchi and Ikujiro Nonaka, two respected Japanese business professors, wrote a paper titled "The New New-Product Development Game" in which they compared rugby scrum to an innovative, agile approach for developing new products. So, now, it's referred to as Scrum.

What exactly is Scrum?

Anand: Scrum is a management framework. It's about how you keep things focused; how you build a collaborative work culture; how you deliver the highest value to clients; and how you build customer collaboration. It's also a mindset. Scrum emphasizes communication, cooperation, and learning between the people who are doing the work and the people who need the work done.

Can Scrum be integrated into any business or product development process?

Anand: Absolutely. Scrum's framework is adaptable based on a company's unique situation. In fact, integrating Scrum has completely transformed the productivity and morale in numerous companies, from Fortune 500 to small businesses, in industries as wide-ranging as software, publishing, and health-care. It's also improved the value they deliver to their clients and the marketplace.

What are some ways Scrum can help medical device companies streamline and compress the design and development of products?

Anand: One way is that the Scrum framework creates a much more collaborative work culture overall. Stakeholders are reenergized and workers gain more satisfaction from developing results they know are top priority for the client. People are working together more cohesively, not in silos. When this happens, there is better communication, increased productivity, and a smoother, more efficient workflow. Another is that with Scrum, results are created incrementally in short duration. In that duration, results and efficacy of the product are inspected. The feedback from these short iterations expose issues faster so companies can adapt more quickly. This accelerates the overall



Bachan Anand



Tricia Rodewald

design and development process and can also ensure safer, more reliable medical devices.

You’ve mentioned the Scrum “framework.” What does it look like and how is it applied to medtech manufacturing?

Anand: Like positions in scrum rugby, there are three main positions in Scrum product development: the Product Owner, the Team, and the Scrum Master. Altogether, they are known as the Scrum Team.

Let’s start first with the Product Owner. While Scrum has no project manager, the Product Owner role would be closest to that concept. The Product Owner represents the client and users of the product. They are responsible for maximum return on investment for the client and communicating what product features should be at the top of the priority list. There is one—and only one—person who serves in the role of Product Owner for the product being produced. In medical device manufacturing, this might be a product marketing manager or a product manager.

Then there’s the Team. In Scrum, the product Team is a small, self-organizing, cross-functional group of five to nine people— depending on the needs of the project. They are the ones most involved in the day to day work. In medical device manufacturing, the Team might be made up of mechanical, industrial, electrical, and software engineers, materials and planning, RA/QA, and operations.

Lastly, there’s the ever-important Scrum Master. The Scrum Master’s role is to protect the Team from outside interference; inform and guide the Team and Product Owner in the most effective use of Scrum; and help them resolve issues and remove roadblocks that stand in the way of the Team achieving their goals. The Scrum Master is not a project manager and does not tell people what to do or assign tasks—she or he facilitates the Scrum process. As with the Product Owner, there should be only one person in this role who, ideally, has completed Scrum Master training. In medical device manufacturing, Scrum Masters can come from any background or discipline: RA/QA, engineering, design, testing, operations, etc.

Can you describe how the Scrum Team engages in the Scrum process?

Anand: First, the Scrum process starts with a client wanting a product made. A simple example is a medical OEM that wants a surgical tool designed, developed and manufactured. The OEM decides to contract with ABC Company (contract engineering and manufacturing) to have this done.

Following the Scrum framework, a Product Owner is designated from ABC Company. This person communicates directly with the OEM client to gain clear insight as to what the client and stakeholders (device users, executives, patients, FDA) want done, how, why, where and when. The Product Owner must work closely with the client to put together a refined, prioritized list of all the features they want their surgical tool to incorporate, what it needs to do, etc.

This prioritized client and stakeholder “wish list” is called the Product Backlog. In Scrum, only one Product Backlog exists and it’s managed and continuously updated by the Product Owner.

An important thing to note is that, in Scrum, the Product Backlog adjusts to reflect changes in the needs of the client and stakeholders.

Next, the Product Owner meets with the Team in a Sprint Planning Meeting, which is facilitated by the Scrum Master. At this meeting, the Product Owner reviews the Product Backlog with the Team, communicating what the OEM client wants and what the high-priority items are.

The Team then focuses on estimating how long it will take to complete the highest priority items on the Product Backlog and creates their own list, called a Sprint Backlog. The Sprint Backlog is made up of the highest priority items the Team has committed to complete.

For example, the Product Backlog may have 40 items on it that the client would like their surgical tool to include. The Sprint Backlog might include the top three, four, five or six items from the Product Backlog.

Once the Sprint Backlog items are selected, the Team plans out short duration milestones called Sprints, to get the Sprint Backlog items done. Sprints allow

the Team to tackle the highest priority items in manageable, “time-boxed” chunks—usually one week to 30 days.

The Team then breaks down the items on their Sprint Backlog into detailed tasks for how the Team members will complete the high-priority items.

For Example: Sprint Length—Two Weeks

Sprint Backlog Item	Sprint Task	Team Member
Add button to top of device	Create circuit board	Tonia
	Design interface to motor control board	Sam
	Protect device electronics	Vita
	Design button system	Alex

This process is vital in Scrum because asking the Team what it realistically can achieve in two weeks on the Product Backlog’s list of priorities allows the Team to take ownership of the work and stay focused on completing the project at hand.

So the Team has their Sprint Backlog, their list of tasks, and their time-boxed Sprint. How do they know the work is actually getting done?

Anand: Once the Sprint has begun, the Team meets every day for a short meeting called the Daily Scrum to synchronize their work and report on challenges. The Daily Scrum is held at the same time, same place every day for 15 minutes or less.

Then, there are actually a few productive and rewarding ways the Team can manage their progress. In my opinion, the Task Board is the best tool for this. The Task Board consists of different columns: To Do, Work in Progress, and Done. It can also be good to add a History column (for completed projects) and a column for the full Product Backlog to give an overall picture of the work planned for the Sprint and full completion of the project.

Once the Team members are ready to take on their specific task, this visual display makes it easier for the cross functional Team to self organize and stay focused.



Is there an opportunity for the Team to reflect on what may not have worked to improve for the future?

Anand: Definitely. In Scrum, this is called the Sprint Retrospective. This takes place at the end of each Sprint when challenges and triumphs are at the top of the mind. Retrospectives are a key part of making changes and creating improvements. Basically, in a Sprint Retrospective, the Team answers three questions: What worked this Sprint/iteration? What didn't? What could we do better next time? And then goals for improvement are made by the Team.

That, in itself, provides great potential to transform the way we approach work.

As the Team makes progress with the Sprint, the Task Board offers a transparent view of the work that is completed by the whole Team and gives them get a better picture of what needs to be completed to meet the Sprint commitment.

Another approach is that the Team members update their estimate of the amount of time remaining to complete their current Sprint Backlog tasks. Someone then adds up the hours remaining for the Team as a whole and plots it on the Sprint Burndown Chart. The Sprint Burndown Chart also can be a helpful visual to see how close the team is to achieving goals and if adjustment is needed.

What happens after a Sprint time-box ends?

Anand: Then it's time for the Sprint Review, which is an opportunity for the Team to show the Product Owner, the client, management, users, and other stakeholders what's been created during the Sprint. It creates better ownership because the Team proudly presents what it has completed.

For example, for a two-week Sprint for a surgical tool, Teams most likely wouldn't deliver a full prototype. But they can show parts of that prototype at the Sprint Review. The most important element to a Sprint Review is the dialogue that occurs at the review between the Team, the Product Owner, and other stakeholders. This focused conversation is what supports a collaborative, engaged company culture. After the Sprint Review, the Product Owner may update the Product Backlog to reflect any new changes, insights, and priorities. The Team then moves on to the next Sprint, starting the process over again (Sprint Planning Meeting, Sprint Backlog, time-boxed Sprint, Daily Scrum, Sprint Burndown Chart, Sprint Review).

What are some of the challenges with a sequential product development strategy?

Anand: First, stakeholders are not involved until late in the process. If changes are needed, they can be very disruptive and difficult to implement, sometimes even causing the project to be scrapped or significantly delayed. Another is that re-visiting a phase once it is completed is rarely done. This often fosters an adversarial relationship between the people handing work off from one phase to the next. Also, people simply can't predict the future—regulations change, competition brings a new, similar product to market first, financing changes, etc. Planning, designing, and documenting everything up front leaves little room to respond to these changes if necessary.

What are some noteworthy solutions Scrum offers to medical device manufacturers?

Anand: Though Scrum can be a significant shift in the way medical device manufacturing is done, the reality is that Scrum leads to happier clients, as they are now part of the process. Employees are also more satisfied as they are no longer just working for the sake of working. There's also less waste because Teams are focused on what the client wants. In turn, better products are developed that improve healthcare and save lives.

Final thoughts?

Anand: Change is hard, but change is inevitable. The real question is: Do you want to change for the better? Scrum is a framework in which to do that.

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