

Q&A - Adopting Agile for Medical Device Development

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(1) Why the fuss about Agile? What does it do for us?

Your productivity is ultimately your ability to compete. One medical devices client went from 14 releases a year to 14 releases in one month after a robust Agile transition program over approximately 2 years. More importantly, this is not an isolated instance; similar success stories are common. The “secret” of Agile methods is the higher level of *engagement* by a company’s technical delivery teams and its customers. Frequent releases comprise a feedback loop from customer through marketing and support to the engineers and designers. This keeps all engaged and focused on a unified vision.

Employee satisfaction (which ultimately means productivity) increases immensely when your move to Agile methods recognizes the true nature of “team autonomy”. When used appropriately, this practice supports the concepts promoted in Daniel Pink’s book *Drive*. Mastery is fostered by the learning that occurs in healthy teams, while the collaboration with the business side creates a higher purpose that’s far more effective than direct control over tasks and individuals’ time. The result is that as a team, your technical people exercise the autonomy necessary for handling the growing complexity inherent in modern product development. The *Drive* principles of Autonomy, Mastery, and Purpose are all in play.

(2) OK, so we can improve productivity. Won't that sacrifice quality?

The old adage used to be “We can do it fast, good, or cheap - pick any two.” Agile is a way to break the limits and achieve all three at the same time.

PROPER Agile methods address quality as an integral part of development, not by testing and reviewing after the fact.

Product safety risk mitigation comes in here as well. Product risks usually become apparent as the design emerges and customers get a chance to try it out - the regular re-evaluation inherent in Agile methods is flexible enough to address these. Agile teams are noted for their greater productivity - and this is not achieved at the expense of quality; quality invariably increases substantially when Agile technical practices are used correctly.

(3) What will the FDA, or the notified body inspectors, say to an Agile approach? My QA and RA folks tell me that FDA requires waterfall development.

Existing guidances, such as General Principles of Software Validation, the Design Control guidance, or IEC 62304, have always clearly said that they don’t dictate any specific lifecycle model. Now, AAMI’s Technical Information Report 45 points out how the Agile philosophy and good medical device quality processes can work together.

(4) We have hardware development going on in parallel. They have long lead times - so they can't be Agile, can they?

Prototyping is well known for getting rapid results on preliminary electronic and mechanical designs. Agile teams do not aim to do all a project’s design work before building anything. Instead they reduce risk by building the most important and / or most difficult features early. The activities of

design and build are interleaved throughout the project so that working features can be delivered every few weeks for real customers to try out and give feedback.

Yes, iteration cycles are longer in hardware than in software, but that fact doesn't impede Agile practices. Different teams in an Agile environment will "synch up" their activities from time to time, so that the software team can try out their design on the latest version of hardware or the latest circuit boards. Working closely and communicating often has another benefit – the groups often find ways to support each other's development, and finger-pointing over system glitches evaporates.

Lead-time constraints will always apply. The difference for Agile teams is they quickly learn their capacity, steer within it, and can deliver reliably to the commitments they make. This means that their managers are not blind-sided, as happens all too often to managers of waterfall teams.

(5) Agile sounds great. It's just for software, isn't it?

Actually, a flexible way of working and sharing information benefits ALL stakeholders in a product team. Software teams can speed up their delivery and improve their quality, but this will be useless if customer-facing functions (marketing, support, service) cannot work in an active and interactive way. Alignment within the organization is important, and is strained if one functional group moves much faster than the rest. A car with one wheel turning faster than the others is not a better car!

Agile practices were first developed for software development work, and equivalent practices have existed to some extent in hardware development for decades. More are being created all the time. Within any discipline, there can be practices that catch defects early, control complexity, and support the delivery of "thin, vertical slices" of product functionality.

(6) Isn't there some book we can read, or a course we can have everyone take, that would give us what we need to start working as Agile teams?

Yes, a company can take this approach. Just like learning to play a musical instrument or learning a new language, it's challenging and prone to false turns and blind alleys. You can actually save yourself time and money by engaging a coach to work with your team to build the mindset and habits needed for effective Agile work. We recommend using coaching, and starting that off with training that is customized to your company and your industry. Businesses vary far more than individual people do - a doctor who prescribes treatment without examining a patient would be guilty of malpractice. You don't need to become an Agile methodologist; you just need a guide to get your teams started on the right road for you.

(7) What we've heard about so-called "Agile" is that it's just an excuse to throw process and documentation out the window. What's the truth here?

Yes, there are companies who proclaim that they are "Agile" and indeed mean that they have discarded process, documentation, and all the other practices that support good development. This makes it difficult for non-Agile companies to understand how they can benefit and still deliver the quality and safety required quality in medical development, as well as comply with regulatory expectations. An Agile coaching firm which understands regulated medical work can guide you in developing processes that are flexible, compliant, and powerful. Indeed, properly implemented, an Agile approach is far better disciplined than past attempts to follow "waterfall" methodology.

(8) Are other companies using the Agile method?

Yes, a number of companies in regulated medical development are actively using Agile - and not just the startups. GE Healthcare and Siemens have been using Agile methods for some years now; we

have seen descriptions of Agile development at a number of other companies working in medical devices and clinical trial data management.

Leading companies such as Amazon, Ebay, Google, Apple, and Facebook all are using Agile practices to give them a level of speed-plus-quality that competitors simply cannot match.

(9) If we hire someone to help us with this transition, isn't that going to be a huge cost?

Actually, it doesn't need to be - and if you can increase your productivity, shorten your development time, and drastically reduce latent errors that go out into the field, you'll recoup your expense many times over.

The key is to have a long view. An Agile transition takes time: our client who reported the gains we cited in question 1 above, achieved that improvement after a two-year transition project.

The key is ROI. Schedule slips represent lost revenue. Lost revenue is never recoverable. Agile teams can deliver to their commitments. At the other end, defects result in higher support costs, which decrease profits. What does a week's schedule slip cost you? How much support cost would vanish if you could cut your defects by half? You are probably already paying a high price for not using Agile methods.