3 REASONS FOR INTRODUCING AGILE PRODUCT DEVELOPMENT IN MEDICAL TECHNOLOGY

Medical technology has never lacked revolutionary ideas. Yet, cost pressure and new international competitors in the healthcare sector make shorter development cycles inevitable, even for this highly innovative industry. Many companies have to ask themselves, how, under current regulatory frameworks, product development can be faster, less cost intensive while still providing premium quality products? Agile development frameworks, like Scrum, provide answers to these questions.

European Patent Office [1]
http://bit.ly/1fEz54M

See DIHK-report [2]
"Gesundheitswirtschaft"
autumn 2013

See „Medizintechnik in [3]
Deutschland", study by
HWWI on behalf of HSH
Nordbank AG, March 2013

Medical technology is by far the most innovative industry in Europe: Out of a total of 94.060 submitted patents, the European Patent Office registered 10.412 patents from the medical technology sector, making the top spot yet again.[1] Despite the longlasting economic crises, the medical technology sector, which is mainly characterized by small- and medium sized businesses, was able to produce growth rates on a regular basis, because product innovation is regarded as the most important motive for investing.[2] Approximately nine percent of the total revenue is going directly into research and development. Products that have been on the market for three years or less make up 30% of the turnover.[3] And when these companies talk about innovation, they mean fundamental innovation, not mere product updates or further developments.

Nevertheless, this industry is facing bigger challenges than ever before:

❯ **Rising costs for healthcare**
The healthcare system is one of the major budgetary items for every European State. Some argue that high tech medicine is a cost driver. But that would be one sided. Still, it is hard to tell how much direct or indirect costs are being saved by innovative medical technology – for instance by treating patients faster and more effectively. Ironically, in medical technology, ongoing innovation is necessary in order to yield saving potential.

❯ **Budget cuts**
Budget cutshave a direct impact on purchasing behavior in the healthcare sector. The decision of whether or not to acquire a device is increasingly made by the procurement departments, and less frequently by the actual operators, like doctors, nurses or lab personnel. Cost effectiveness is a strong argument – still, it should not come at the expense of user friendliness.

❯ **Integrated product development**
In most parts of medical device development, hard and software are becoming more and more inseparable. Nowadays, innovative product development in medical technology is synonymous to integrated product development.

❯ **Regulations**
The enormous amount of innovation energy becomes even more impressive in light of the fact, that there are only a few other industries that are as highly regulated as medical technology. In order to "survive" the long path from product development to FDA approval, a medical device has to pass a series of national and international admission procedures that pursue but one goal: the patient's safety. Necessary clinical studies are a heavy additional financial burden. Medical technology companies have therefore implemented substantial quality and risk management systems, in order to cope with these regulations. And this is exactly where the conflict between process conformity, necessary documentation and a quick market entry arises.

Faster, cheaper and 100% compliant – all at the same time. These are the main challenges of medical technology in a nutshell. But how can medical technology companies launch their innovative products faster despite these challenges? How can product development be user oriented and cost efficient at the same time?

A Déjà-vu: Software development before the agility leap

About 20 years ago, the software industry was confronted with similar problems to those the medical technology is facing today. Development was characterized by a cumbersome, sequential waterfall project management method. Procedures and standards that were meant to serve as improvements, such as CMMI and ISO 9001, extended the development cycles and made them even more expensive. Despite these standards, user friendliness and customer needs have often been ignored and product quality was not necessarily better. In the end, it turned out to be the dissatisfaction of the software developers that lead to the uprising of agile development methods. Looking closer, it was a re-discovery of a method that had been primarily used for the development of highly complex hardware, like military jets, the Mercury Program of NASA and later on for the space shuttle – by definition an industry with rigid regulations.[4] What was called "iterative and incremental development (IID)" back then is now experiencing a huge comeback under the name of "Scrum". To sum it up, Scrum is not primarily an agile software development method. Rather should it be seen as a framework that reduces the complexity of a product into comprehensible cycles – whether you are working on hardware, software or a combination of both.

Hence, agile frameworks like Scrum are especially strong where it is all about real product development – where new solutions have to be found for old problems. Therefore, implementing Scrum in Medical Technology almost seems logical because of its focus on the development of new products. Especially in the early stages of a product development project, there are a lot of unknowns. The available information on feasibility and risks change from day to day. Whether they are promising or a deadlock, can often only be determined in later stages of a project. With its transparent and highly adaptive nature, Scrum creates a continuous alignment of planning and delivering. What's mostly keeping Medical Device Companies from implementing Scrum are two questions:

❯ Is agility a laissez-faire approach, where everyone does whatever they like to do?
❯ Is agile product development compatible with regulations for Medical Devices?

Agility – misunderstood

Most concerns when thinking about the introduction of Scrum in a Medical Device environment emerge from the false interpretation of the Agile Manifesto, which summarizes the essence of agile development practices. So what do the following phrases mean?

Through this work we have come to value:

❯ **Individuals and interactions** over processes and tools
❯ **Working software** over comprehensive documentation
❯ **Customer collaboration** over contract negotiation
❯ **Responding to change** over following a plan

That is, while there is value in the items on the right, we value the items on the left more.

See Craig Larman & [4] Victor R. Basili: Iterative and Incremental Development: A brief history. In: IEEE Computer, Volume 36, Issue 6, June 2003, p 47–56.

The salient point in this regard is: it's not a distinction between good and evil. It's an evaluation, in order to speed up development processes. You could just as well write the following:

❯ **Self responsibility**
The value of processes and tools is highly dependent on the people that utilize them. People can only create a successful product, if they talk with each other and, in a given setting, are allowed to make decisions by themselves in order to create a better product. This does not mean that employees may use Scrum as an excuse to do whatever they want.

❯ **Documentation**
Does everyone just stop documenting in Scrum? This part of the Agile Manifesto is often deliberately misinterpreted, because no one likes to document. But in Scrum you also document what has to be documented and what's reasonable (but no documentation for the documentation's sake) – either by the Scrum Team itself or the respective support. Whether it's for legal reasons, the presentation to public authority or simply to make the work of others easier. Primarily, a Scrum Team should focus on product development, therefore the key has to be efficient documentation.

❯ **Collaboration**
In Scrum, clients and users are included into the product development from the getgo – for example by taking part in reviews at the end of each sprint. The user's benefit is at the heart of agile product development and it can only be achieved through close and steady contact with customers and users. Capturing the rules of collaboration in a contract is sensible but a contract should not be an instrument that makes it easier to cheat on each other.

❯ **Continuous Planning**
One accusation that is often being made is that with agile methods there is no planning. That is just wrong. In reality, there is permanent planning. However it's true that in the beginning of a project not every potential detail is being specified – simply because it's just not possible, especially if the product is innovative and has never been built before. You create a rough outline in order to be able to start. Then, after each sprint, you update the planning documents according to newly collected information. Therefore: new insights (e.g. a requirement changes) are immediately being taken into consideration and you can act on changes directly instead of deferring these changes to the end of the project where they become insurmountable.

Scrum

Scrum is a framework for iterative and incremental – agile – development, where a product, based on a vision, is being refined step by step, from one cycle to the next. There is no attempt to specify everything right down to the last detail, because not all the eventualities are predictable. To be able to reduce complexity, a Scrum Team works in single steps, called "Sprints", that are no longer than four weeks. Essential functionalities are being determined in the beginning. After each sprint, customer and/or user feedback helps to decide whether a functionality is going to be developed further or if it's going to be discarded because it turns out to have lost its value. In contrast to classic project management, the customer doesn't have to wait until the end of the entire development project, but is included into every step along the way. These are the organizational principles of Scrum:

❯ **Small, self organized- and self responsible, cross functional teams** – consisting of Scrum Master, Product Owner and Development Team

❯ **Pull Principle:** The Development Team decides on the amount of functionalities (prioritized by the Product Owner according to the business value of each feature) it is going to develop in one sprint. The team also decides on how it is going to develop these functionalities.

❯ **Clearly determined time intervals (timebox):** the goal is to really develop the chosen functionalities within the sprint.

❯ **Usable business functionality:** at the end of each sprint, the team has to provide a deliverable, that meets the standards, policies and specifications of the project.

These principles alone are not everything there is in order for Scrum to be successful. One essential factor is the intense communication: the members of the team synchronise each other's work in short daily meetings (Daily Scrum). The Estimation Meetings help the team members to develop a mutual understanding of the features that are to be developed and the Sprint Plannings 1 and 2 determine which feature is developed when and how. At the end of each Sprint, the team talks to the customer about the developed product increment and during the Retrospective the team challenges its own course of action, adapting where necessary.

Regulations in Medical Technology and Agile Product Development

Does regulation per se mean, that agile product development isn't possible or even forbidden? The answer has to be a clear "No". Neither the FDA nor European directives and standards for manufacturing medical devices dictate, which development method has to be applied.

AAMI TIR45:2012: [5] Guidance on the use of AGILE practices in the development of medical device software

In its Technical Information Report TIR 45:2012[5], the Association for the Advancement of Medical Instrumentation explicitly states that, along other life cycle models, agile methods are just as eligible for developing software for medical devices. It goes without saying that regulations impose demands on quality assurance throughout the entire development process, because after all, the patient's wellbeing is at the center of everything. However, it is left to each company, with which method it wants to meet the demands of validation – depending on how the development of a product can best be managed. According to the AAMI TIR 45:2012 the FDA does not determine a certain method. Sole premise is, that all quality assurance measures are being satisfied. Regarding documentation, the FDA only wants to ensure, that what is being done and how it is being done is recorded. It does, however, not tell a Medical Device Company how to develop its products:

"Based on the intended use of the safety risk associated with the software to be developed, the software developer should determine the specific approach, the combination of techniques to be used, and the level of effort to be applied. While this guidance does not recommend any specific life cycle model or any specific technique or method, it does recommend that software validation and verification activities be conducted throughout the entire software lifecycle." (General Principles of Software Validation; Final guidance for industry and FDA staff)

"The quality system requirements do not dictate the types of design process that a manufacturer must use. Manufacturer's should use processes best suited to their needs. However, whatever the processes may be, it is important that the design controls are applied in an appropriate manner." (Design Control Guidance for Medical Device Manufacturers)

The Process Norm IEC 62304 allows for the same liberties. It lists different life cycle models, like Waterfall, incremental (for product development) and evolutionary (corresponding to agile models) and indicates possible advantages and disadvantages, but it doesn't dictate a model:

"This standard does not specify an organizational structure for the manufacturer or which part of the organization is to perform which process, activity, or task. This standard requires only that the process, activity, or task be completed to establish compliance with this standard. This standard does not prescribe the name, format, or explicit content of the documentation to be produced. This standard requires documentation of tasks, but the decision of how to package this documentation is left to the user of the standard.

This standard does not prescribe a specific life cycle model. The users of this standard are responsible for selecting a life cycle model for the software project and for mapping the processes, activities, and task in this standard onto that model."

The most important finding is: from a regulatory point of view, agile development is "allowed". What could that look like in practice?

And what does that mean for medical device development?
Just as in any other environment, Scrum as a management framework in medical device development first and foremost means one thing: Collaboration in cross functional teams. These are given total responsibility for the delivery of a solution. Prerequisite for this responsibility is, that the teams know all the constraints inside of which the solution has to be created. Therefore they have to completely understand the functional and technical requirements. They have to master the technology and know the quality management guidelines. This team ideally is working co-located in one room and has to be given a clear picture of what is to be delivered in one iteration. The team in collaboration with the product management, works out the first functional requirements of the product, based on a product vision and clear framework conditions (for example the FDA regulations, technology or security aspects). Those functional requirements are collected in the so-called Product Backlog. Whenever they have collected enough features, they start working on the first feature. While the Development Team is working on that feature, another part of the team starts working on functional prototypes that show, how the next functional requirements could be fitted into the following iterations. The results are then shown to the customer/user after one to four weeks. Newly gained insights are being integrated into the development process.
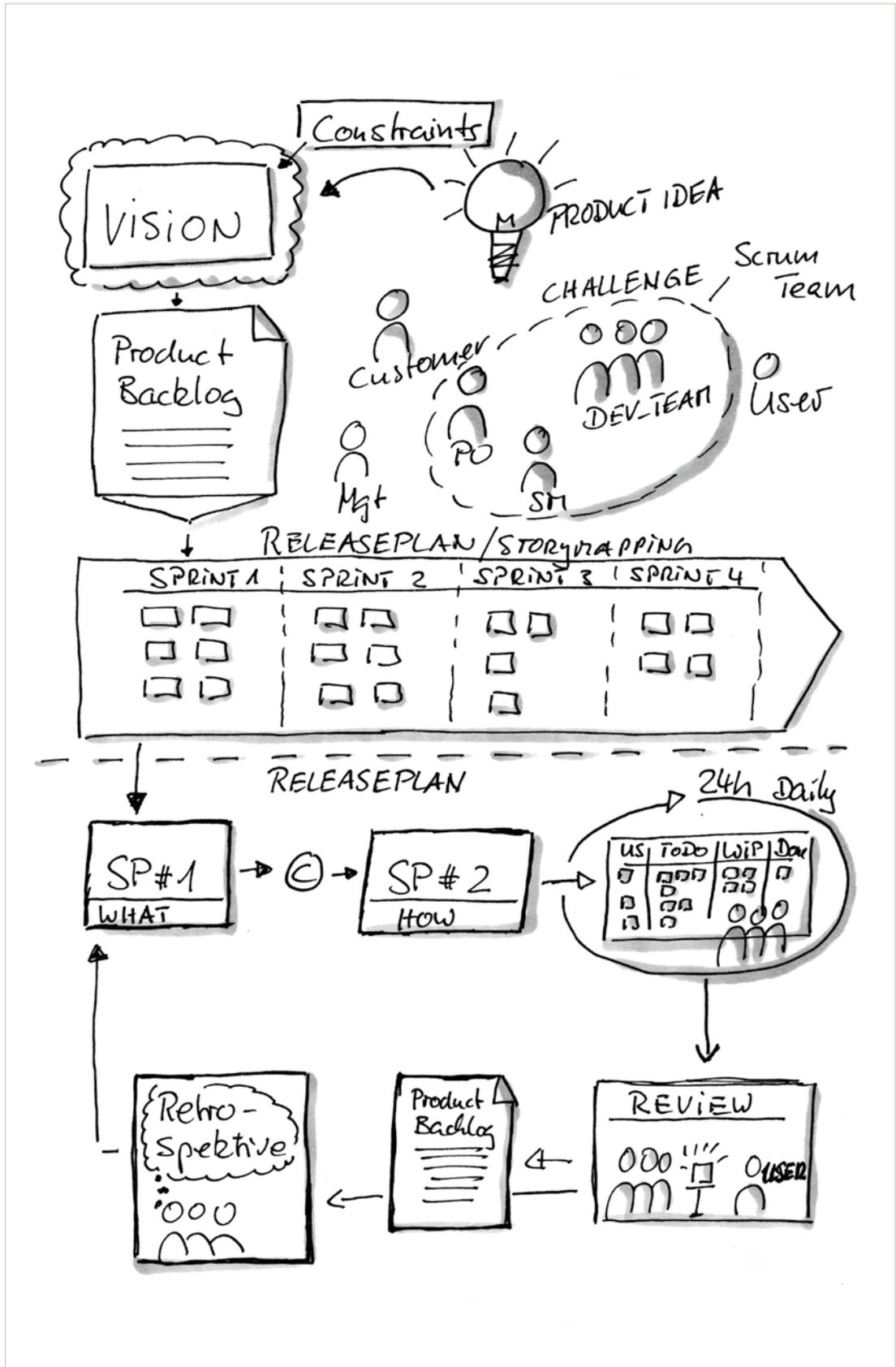
Example: Risk Management with FMEA
Before delivering a medical device, a list of analyses and plans has to be conducted, that serve the reliability and safety of the product. The FMEA (Failure Mode and Effect Analysis) which identifies and evaluates potential malfunctions of the system as well as measures for risk reduction is part of this category. If you read current books on Scrum you are not going to find the typical instruments of risk management. Still, there is not a single approach with which the detection of impediments and risks in product development and project management can be pursued as consequently as it is the case with Scrum.

Only done is done. Let's take the example of the Definition of Done (DoD): This artifact determines obligatory quality requirements and the level of completion of functionality. The Definition of Done is a K.O. criterion at the end of each sprint: only stories that meet the requirements may be marked and accepted as done. Complying with the DoD, for example, prevents the buildup of technical debt: whoever waits for integration testing to be done at the end of the project will still have to do a lot of cleaning up after the development.

FMEA can be integrated superbly into a DoD. In a current borisgloger consulting project devices for laboratory automation are being developed. In its DoD, the development team has constituted that every alteration of a construction plan is not finished without the documentation of potential risks as well as possible countermeasures. Since the team is working in two-week iterations, where alterations of construction plans are being completed in small steps, it has become a routine task for members of this Scrum team to conclude every significant development stage with a corresponding risk evaluation and control. In conventional projects, risk management hasn't been tackled until the development phase was concluded. Therefore risks were only kept in check marginally. Now it is possible to assess possible risks from the very beginning of a project and at the end of the development phase, risk management has already been dealt with. After all the Scrum team has been attending to it the entire time.

And what about quality assurance? If the team imposes the DoD on themselves and if it also controls itself: where, in this scenario do we find quality assurance departments? Very simple: An employee from quality assurance is integrated into the Scrum team. He or she will be responsible for implementing legal requirements as part of the development process. She will do so not with a wagging finger on the left and the checklist on the right, but by actively participating and by showing the other team embers how risk management is done. That is an adjustment, but over time supervisory bodies become redundant. The detection of risks will happen in real time – from sprint to sprint.

3 good reasons for Scum in medical device development

1. Permanent checking for compliance

Scrum is basically a validation instrument. Not only does the Review Meeting unearth insights on the product itself on a regular basis, but it also constantly asks the question, whether all quality standards have been met. As the person responsible for the product and the outcome, you immediately see, if your project has been going in the wrong direction and you are able to counteract. You realize right away, whether requirements are clear, whether the development team is implementing these requirements, whether necessary documentation has been delivered and whether the device is doing what it's supposed to be doing, according to the requirements. Scrum creates the certainty for you, to always know, where you are.

2. Fast Delivery

Only agile development frameworks allow for fast delivery while at the same time assuring conformity with standards and regulations. The project becomes totally transparent in all its deliverables for all involved parties – the development team and management. Changes can be implemented easily in the course of the project.

3. Motivated employees

Cross functional teams – all employees who are involved in the product development work hand in hand. Electronic engineers, mechanics and design engineers, software developers and medical personnel; they are all part of one team and want to be successful together. The common goal unites the team and encourages collaboration. Handovers are being reduced and a lot time is saved.

Starting with Scrum: What you should consider when choosing a consultant.
The market for organizational and product development with Scrum is still very young, yet also very attractive because the advantages have spread beyond the borders of software development. There are only a few providers that are truly specialized, that can show more than five years of profound Scrum expertise, not only on team level, but also in a scaled environment. Naturally there is even less experience in the development of medical devices with Scrum, because Medical Device Manufactures have only recently discovered this process for themselves.

Many providers concentrate on the mere implementation of the Scrum "handicraft". However, it is the responsibility of a prescient change management to make the Scrum implementation permanently successful and sustainable. Scrum not only has an impact on the collaboration inside the respective teams, but it also has to be refined at the interfaces of each team. Along come questions on leadership and self-responsibility that require experience with social dynamics.

Hence, Scrum is not just a mere add-on to classic project- and requirements management, but an independent discipline.

Your consultant, not only should be firm in Scrum and the necessary development practices and bring along experiences from other projects, but should also be innovative and agile in his own approach when tackling a problem. Here is a checklist for the selection of your consultant:

1. Has the provider advised clients from different industries?
2. How much experience do the individual consultants have?
3. What role does the provider play in the agile community?
4. Do the individual consultants have experience in cross-company collaboration in an agile context – for example with suppliers?
5. Can your consultant produce successful projects in a scaled environment with more than 60 – maybe even distributed – team members?
6. Is consistency ensured, because all consultants of the provider work according to the same principles?
7. Does the provider tell you, what you want to hear, or does the diagnosis sometimes hurt?
8. Do you find the provider on conferences, together with his clients?
9. Do you find the provider on conferences, together with his clients?
10. Are your provider's consultants individual personalities, who feel responsible for your company's success, who want to and are able to participate actively in you're the project?

How does borisgloger consulting work?
Your organization is already unique. Agile product development preserves this uniqueness while at the same time equipping you for the increasing dynamics of the medical device market. Therefore, our goal is to make ourselves expendable: it is you and your employees that have to live agility – we can not divest you of that. But, we can build the necessary foundation: From the very beginning we create a common understanding of what Scrum means for the organization – with all involved parties, development teams or managers. Building upon this foundation we establish pilot teams with members of all involved domains and departments, that decide for themselves, how they want to tackle the assignments that are necessary for the implementation. Creating a very first Scrum Team is also part of this assignment: This team goes through a couple of sprints and collects information on where we can still improve in the next step.

The management is also involved from the very first steps and is playing an active role. It makes necessary decisions and can see for themselves, what it means to work with Scrum. This involvement is especially important to us, because trust in the new method has to be build on all levels. In the course of a Scrum implementation you will come to realize, that fields of activities of your employees might change – yet not in predefined directions. Employees create their new roles by themselves. Step by step, we include corresponding development practices, like Continuous Delivery. We integrate suppliers and the entire organization starts to engage in the new way of working.

That is an example on how it could be implemented but, according to your situation and goals we will develop the right framework together. We are there for you during the entire change process.

Let's talk about your challenge!
Mutual trust is the unconditional requirement when taking a step as important as the transformation into an agile company. We would love to visit you for an unbinding interview, to show you who we are, how we work and what we can do for you. Contact us, we are looking forward to hearing from you!

borisgloger consulting GmbH
Lichtentaler Straße 7
D-76530 Baden-Baden
T +49 (0) 72 21.398 737-0
F +49 (0) 72 21.398 737-10
office@borisgloger.com
www.borisgloger.com

About borisgloger consulting
borisgloger consulting, located in Baden-Baden and Vienna, is one of the leading management consulting agencies in the DACH region when it comes to agile change management and agile product development. Its emphasis lies on the management framework Scrum. The founder and managing director, Boris Gloger, is the first Certified Scrum Trainer worldwide and has trained more than 5000 managers and project teams in this iterative process model.
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