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Agile leadership in GMP-compliant in-house software development

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Agile leadership in GMP-compliant in-house software development

This action research, commissioned by Bayer Oy, delves into the role of the product owner in an in-house software development project, ensuring Good Manufacturing Practice (GMP) compliance and implementation of Agile project management principles. The research was carried out from the product owner’s point of view. The primary objective was to clarify the key responsibilities and tasks of a product owner working in Agile software development project while ensuring GMP compliance and the delivery of high-quality software.

This research is based on a literature review and discussions with the stakeholders at Bayer. The aim was to adapt methods from theoretical sources of Agile software development processes to the requirements of the pharmaceutical software project. These methodologies were then applied in practice to improve the ongoing software development project.

The concrete aim of this thesis was to engage in the ongoing software development project to build a Minimum Viable Product (MVP) with Bayer’s Manufacturing Science and Technology (MSAT) department. During the project, the product owner ensured that the customer needs aligned with GMP requirements and project’s objectives. In addition, the product owner was involved in the implementation process of Agile principles, while carrying out other tasks related to the product owner’s role in Agile projects.

Keywords:

Agile, GMP, Product Owner, Software Development

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Ketterä johtajuus GMP-yhteensopivassa sisäisessä ohjelmistokehityksessä

Tämä Bayer Oy:n toimeksi antama toimintatutkimus tutkii tuoteomistajan (engl. Product owner) keskeistä roolia yrityksen sisäisessä ohjelmistokehitysprojektissa, jossa varmistetaan ketterän johtamisen ja hyvien tuotantotapojen (engl. Good Manufacturing Practice, GMP) yhdenmukaisuus. Tutkimus toteutettiin tuoteomistajan näkökulmasta. Tutkimuksen päätavoitteena oli tunnistaa ketterässä ohjelmistoprojektissa työskentelevän tuoteomistajan keskeiset tehtävät ja vastuualueet ja varmistaa samalla vaatimusten mukaisuus ja laadukas työskentely.

Tämä tutkimus pohjautuu aiempaan kirjallisuuteen sekä keskusteluihin Bayerin sidosryhmien kanssa. Tavoitteena oli soveltaa ketteriä ohjelmistokehitysmenetelmiä lääkealan ohjelmistoprojektin tarpeisiin. Näitä menetelmiä soveltamalla tuettiin sekä parannettiin käynnissä olevan ohjelmistokehitysprojektin toimintatapoja.

Tämän opinnäytetyön konkreettisena tavoitteena oli osallistua käynnissä olevaan ohjelmistokehitysprojektiin, jossa rakennettiin Bayerin Manufacturing Science and Technology (MSAT) -osaston kanssa MVP-tuote (engl. Minimum Viable Product, MVP). Tuoteomistaja varmisti, että MSAT-osaston tarpeet sovitettiin projektin tavoitteiden ja GMP-vaatimusten kanssa yhteen. Sen lisäksi, tuoteomistaja osallistui ketterien periaatteiden käyttöönottoprosessiin sekä työskenteli tuoteomistajalle ominaisien tehtävien parissa.

Asiasanat:

Ketterät menetelmät, Hyvät tuotantotavat, Tuoteomistaja, Ohjelmistokehitys

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Abbreviations and glossary

ADO	Azure DevOps (ADO) is a cloud-based project management tool provided by Microsoft.
Agile	Agile is a project management approach which emphasizes short development cycles, adaptability, and iteration (Coursera, 2023).
CI/CD	CI/CD is the combined practice of continuous integration (CI) and continuous delivery (CD) (Hakim, 2023).
DevOps	DevOps is the integration of development and operations aimed to enhance the efficiency, speed, and security of software development and delivery processes (Gitlab, n.d.).
EMA	European Medicines Agency (EMA) is a regulation agency which evaluates and supervises medicinal products in the European Union (EMA, n.d. a).
FDA	Food and Drug Administration (FDA) is a government agency located in the United States responsible for regulating the safety and efficacy of food and pharmaceuticals (FDA, n.d.).
GxP	GxP is a general abbreviation representing “good practice” quality standards and guidelines, where the “x” refers to their applicability across and within industries (Qualifyze, 2022).
GMP	The term GMP is derived from GxP, meaning “Good Manufacturing Practices”, used in the pharmaceutical industry (Qualifyze, 2022).
ISO	International Organization for Standardization (ISO) is a global organization establishing and promoting standards across various industries (ISO, n.d.).

MSAT	Manufacturing Science and Technology (MSAT) is a department within Bayer's organization.
PO	Product Owner (PO) is a member of the Agile project team (Simplilearn, 2024).
UAT	User Acceptance Testing (UAT) is testing done by end-users to ensure that the software solution works as intended and meets the user's needs before it is deployed (Gillis, 2022).

1 Introduction

In in-house software development projects, various leadership roles play a key role in driving projects forward. Among these roles, the product owner (PO) stands out as a cornerstone. The PO is responsible for facilitating effective collaboration among stakeholders and ensuring value is being generated. This bachelor's thesis explores the adaptation process of implementing Agile project management in a software development project, benefitting methods such as DevOps, while adhering to the compliance requirements inherent in the pharmaceutical industry.

The selection of this topic arises from a recognition of its high importance and relevance in today's competitive landscape of pharmaceutical companies. Particularly, this topic is important in the context of established industry leader companies like Bayer, where Agile in-house projects for innovative technology solutions are crucial for staying ahead and keeping up with the revolution of technology. When compared to off-the-shelf software, in-house software development offers many benefits such as a superior user experience tailored to the specific needs of the organization and the possibility to create something unique and innovative. These factors enable the creation of enduring competitive advantage.

As pharmaceutical companies aim for innovation and operational efficiency, the adoption of Agile methodologies presents both opportunities and challenges. By embracing Agile principles, organizations aim to streamline their internal software development processes, improve collaboration across teams, and speed time-to-market. However, in an industry governed by regulatory frameworks and standards, such as Good Manufacturing Practice (GMP), the integration of Agile practices requires expertise and adherence to compliance requirements.

In this context, the PO plays an important role in Agile projects, connecting the ideas and forces between development teams, internal customers, stakeholders, and regulatory bodies. The PO is responsible for guiding the Agile

project team towards successful project outcomes. The PO's ability to effectively prioritize requirements, align customer and stakeholder needs with project objectives, and ensure compliance with regulatory standards is essential to the success of the project.

This thesis aims to clarify the role of the PO within the pharmaceutical context, highlighting the challenges, best practices, and opportunities for improvement. The research of this topic benefits theoretical principles to understand practical insights derived from real-world experiences in the pharmaceutical company's in-house software development project. Leveraging insight from discussions and existing literature, the aim of this thesis is to construct a comprehensive understanding of product owner's role in software development in pharmaceutical domain.

By examining existing practices and principles, and identifying areas for enhancement, the aspiration is to contribute to the ongoing evolution of Agile methodologies in software development in a regulated industry. Through this exploration, valuable insights will inform industry practice, drive innovation, and enhance the efficiency of software development processes using Agile principles within pharmaceutical organizations like Bayer.

2 Operating in the pharmaceutical industry: Stringent requirements

2.1 Understanding the regulatory framework in pharmaceutical industry

In the pharmaceutical industry, a thorough understanding of regulatory guidelines is essential for companies operating within this sector. Companies are given various stringent regulations that govern their activities. These guidelines govern every aspect of the pharmaceutical sector, including research, development, manufacturing, and distribution. As each step of pharmaceutical manufacturing is under strict supervision to ensure safety, the process for many medical products to reach the market can span several years. (Investopedia, 2021)

The paramount objective of existing regulatory guidelines is to safeguard public health by ensuring that pharmaceutical products meet standards for safety, efficacy, and quality. The usage of poor-quality medical products can cause severe consequences for patients (Wood, 2019), ranging from health issues and prolonged illnesses to the worst-case scenario, death. Taking these aspects into consideration, a comprehensive understanding of the regulatory landscape is crucial for professionals in different management roles to work within the pharmaceutical domain.

Government agencies and regulatory bodies around the world establish a broad range of regulations that formulate the regulatory framework in the pharmaceuticals industry. In the United States, the Food and Drug Administration (FDA) is responsible for ensuring pharmaceutical safety as one of their responsibility sectors along with food safety (FDA, n.d.). Similarly, in Europe, the European Medicines Agency (EMA) is responsible for authorizing and supervising medical products in member states of European Union, as well as in Iceland, Norway, and Liechtenstein (EMA, n.d. a). In Finland, the safety of pharmaceuticals is monitored by a Finnish Medical Agency Fimea (Fimea, n.d.). Each of these regulatory bodies aims to prioritize patients' safety by ensuring

compliance with standards in medical products. Collaboration among various agencies is essential to ensure consistent compliance of manufactured products, despite minor differences in management principles, for instance in risk management procedures agencies perform. (Biomapas, n.d.)

As stated in, the regulatory guidelines are established to affect every phase of the medical product's lifecycle. Even if the activities performed by a pharmaceutical company are not directly linked to the product itself, for instance IT (Information Technology) software supporting product's usage, the guidelines still need to be obtained. Nowadays, software is recognized as a crucial part of the medical device which needs to be safe for its user and function effectively. (Health Sciences Authority, 2022) Consequently, regulatory guidelines also apply to software development.

2.2 GMP compliance in a regulated industry

One of the cornerstones of pharmaceutical regulations is Good Manufacturing Practice (GMP). The term "GMP" originates from the broader concept of "GxP" which encompasses the good practices associated with various aspects of pharmaceutical operations. (Symmetric, n.d.) GMP guidelines the basic requirements that pharmaceutical manufacturers must adhere to during production processes. GMP requires that products manufactured in pharmaceutical industry are high quality, appropriate for their intended use and meet requirements of the clinical trial authorization as well as marketing authorization. GMP can be seen as a minimum standard which the manufacturer is required to fulfill when operating in the pharmaceutical environment. (EMA, n.d. b)

Adherence to GMP enables companies to establish optimal processes for the safe and high-quality manufacturing of products. Pharmout states that GMP requirements consist of the following principles. (Pharmout, n.d.) GMP requires written procedures and instructions. Documented procedures, or so called standard operating procedures (SOPs), are crucial for every step of the

manufacturing process that has an influence on the quality of a final product. It is imperative to maintain written documents as evidence demonstrating that accurate procedures are uniformly executed at each stage of the manufacturing process.

In addition, GMP requires maintenance of facilities and equipment. To ensure product quality, it is essential to have proper design, maintenance, and cleanliness of facilities and equipment. Additionally, consistent operations require processes such as validation and calibration. It is also important to have and use qualified materials. In a manufacturing process, it is important that all materials meet quality standards, are easily traceable, and are clearly labeled by the means of identification. This requirement encompasses not only the product's ingredients, but also other production supplies used in different production phases.

GMP principles also require accurate production phases. To uphold consistency and compliance, manufacturing processes must undergo precise definition, control, and validation. Validation of critical processes ensures consistent high-quality of manufactured products. Quality control must also be considered. Testing products at various stages of manufacturing is crucial to ensure high and integrative quality. Due to these tests, overall quality will be guaranteed.

Comprehensive documentation is also a characteristic of GMP principles. Records, raw data, and documentation concerning production and distribution must be maintained and accessible for review purposes. The documents provided should be clear, comprehensive, and accurate. In addition, qualified personnel performing the work is also important. Having employees who are qualified and sufficiently educated is paramount. Each personnel engaged in manufacturing should require the necessary education, training, and expertise to perform their work.

According to Pharmout, GMP also requires validation and change control. Any changes made to the manufacturing process require examination, validation, and documentation to ensure the quality integrity of the product. Any complaints

or recalls must be processed correctly. Establishing procedures to manage complaints and product recalls is essential. These procedures include taking appropriate corrective actions when necessary.

As a final principle, Pharmout emphasizes auditing which consists of self-inspection and quality audits. Conducting regular audits is paramount to verify adherence to GMP requirements. These audits provide a comprehensive review of needed improvements and guarantee the implementation of possible corrective measures.

Non-compliance with GMP guidelines in the pharmaceutical industry can cause severe consequences that extend beyond regulatory breaches. GMP breaches endanger patient safety, impact on the company's reputation, and cause stringent regulatory audits and legal burden. These breaches can lead to medical product recalls spanning several production batches. In addition, breaches can lead to license cancellations, accusations of fraud, and criminal prosecution, damaging the financial and operational viability of affected corporation. Furthermore, GMP non-compliance reduces public confidence in medical products, undermining industry credibility and has an influence on patient care and wellbeing. (Swift Systems, n.d.)

2.3 Harmonizing GMP compliance with standards

GMP and quality standards are linked in pharmaceutical regulations (Škufca, 2022). This means that GxP regulatory compliance, particularly in this case GMP, can align with ISO certifications to assist pharmaceutical companies manage their quality compliant operations effectively. ISO certifications are granted after certification audits conducted by certification bodies. Certifications of international standards indicate that the product or service in use is safe, reliable, and high-quality. (ISO, n.d.) By following standards, companies are ensuring the compliance of their actions. For instance, quality standard ISO 9001 (ISO 9001:2015) furnishes companies with a comprehensive framework of quality and guiding principles for effective organizational management. ISO

9001 and other standards relevant for pharmaceutical operators possess pivotal roles in ensuring regulatory compliance, quality management and operational efficiency within the pharmaceutical sector. (Nqa, n.d.)

ISO standards encompass a various range of quality and safety related aspects, whereas GMP are tailored specifically for the pharmaceutical landscape. GMP guidelines concentrate on maintaining consistent production and control in accordance with quality standards. ISO standards reinforce GMP by offering a structure for quality management systems, making them both necessary for pharmaceutical companies. (Blok, 2023)

As mentioned, maintaining GMP guidelines and considering standards is paramount for pharmaceutical companies to prioritize safety, quality, and compliance, to secure public health and to uphold industry integrity. By holding to GMP principles, companies address their commitment to ethical practices, ensuring that the well-being of patients remains during each phase of pharmaceutical manufacturing processes (Swift Systems, n.d.).

3 Agile project management

3.1 Agile methodologies in software development

Agile, in a concept, exemplifies the ability to adapt and respond to unexpected change swiftly and effectively. It represents a mindset and methodology to manage uncertainties and complexities in work and projects. Agile favors iterative and incremental development emphasizes collaboration and flexibility, and continuous improvement. Rather than sticking tightly to predefined project plans, Agile emphasizes an adaptive and changing approach. Agile methodologies prioritize individuals and interactions over processes and tools, valuing customer collaboration, and adopting change as a part of the development process. (Agile Alliance, n.d.)

In software development, Agile principles and methodologies are applied to streamline development processes and reinforce outcomes of the projects. Agile software development contains a set of frameworks and policies arising from the values and principles articulated in the Manifesto for Agile Software Development (Agile Manifesto, 2001). It contains iterative cycles of planning, execution, and review, implementing the focus on delivering working software solution incrementally and frequently. (Microsoft, 2022) The Agile Manifesto consists of four core values (Agile Manifesto, 2001):

1. More individuals and interaction than processes and tools
2. More working software than comprehensive documentation
3. More customer collaboration than contract negotiation
4. More responding to change than following to plan

Agile encompasses various branches known as frameworks. Commonly utilized Agile frameworks and principles in software development include, for instance, Scrum, Extreme Programming (XP), and Kanban. Each Agile framework differs from others, including variations of key principles and practices. Various

organizations use many of these frameworks, often modifying principles to suit their needs and iterating on their own Agile processes. (ProductPlan, n.d.)

In Agile framework, iterative approach to workflow is divided into periods called sprints. Sprints are defined time periods, typically lasting from one week to one month. Within these periods, Agile project team members cooperate to implement continuous cycles of development. Throughout Agile sprints, efforts are directed towards developing new functionalities in alignment with User Stories and backlog items. After each sprint, a new sprint promptly begins without a delay. (Scrum.org, n.d.) Each sprint is divided into the following main phases: design, build, test review, and launch (Image 1).

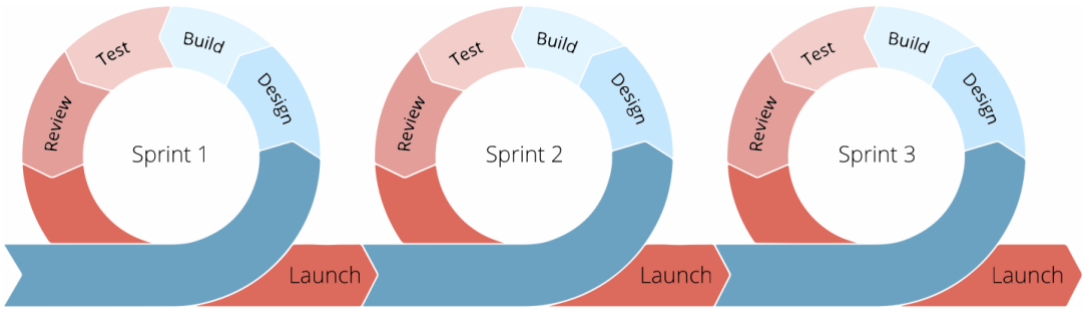

Image 1. Example of Agile feedback loops (Grinaker, 2020)

In response to the intense competition within the pharmaceutical industry, companies are increasingly embracing Agile principles in their daily work to drive innovation and stay ahead. The adoption of Agile methodologies enables companies to accelerate innovation and development. Implementing Agile principles leads to significant changes in operational matters, such as streamlining the decision-making process. (Businessmap, n.d.)

3.2 Combining DevOps methodology with Agile framework

DevOps is a software development methodology encompassing a set of practices and tools aimed to enhance an organization's capacity to deliver software solutions more swiftly compared to traditional software development methodologies. One example of a traditionally used software development methodology is the waterfall model. Using DevOps in software development offers several advantages. It facilitates speed, enabling organizations to innovate faster, adapt to dynamic markets, and optimize efficiency in achieving business outcomes. (Synopsys, n.d.)

DevOps software development principles and practices highlight a comprehensive approach to collaboration, automation, and continuous improvement throughout the entire lifecycle of delivering software. These fundamentals ensure seamless integration of continuous integration (CI) for early detection of issues, continuous delivery (CD) for reliable automated version code deployment, and infrastructure as code (IaC) for consistent and reliable infrastructure management. Due to the continuous nature of DevOps, the development cycle can be seen as an infinity loop to demonstrate interconnected phases (Image 2). DevOps emphasizes collaboration and shared responsibility between project teams. It integrates monitoring, feedback, and security into development and deployment phases. In addition, DevOps fosters continuous learning and innovation for enhanced efficiency and resilience in the software landscape. (Hakim, 2023) The adoption of these DevOps principles enhances pharmaceutical companies' ability to develop and release software solutions more quickly and efficiently. Additionally, it improves product quality and reliability. (Karheliya, 2022)

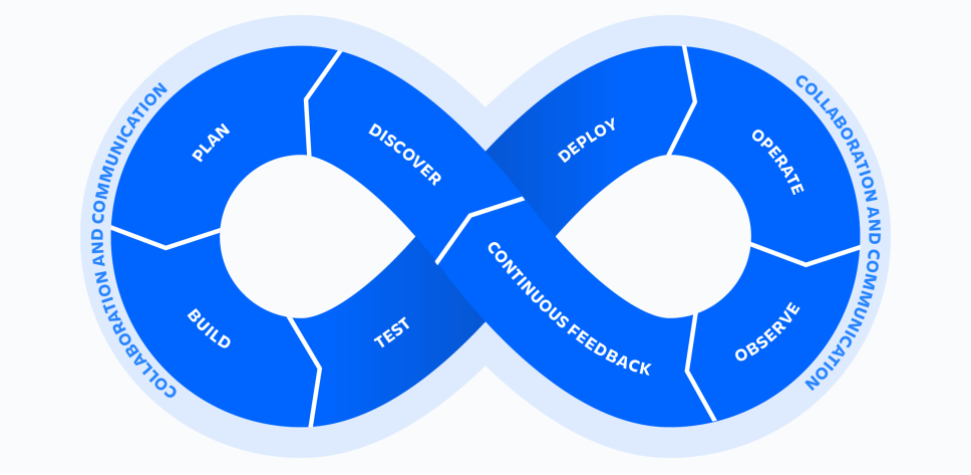

Image 2. The DevOps lifecycle infinity loop (Atlassian, n.d.)

Not only does DevOps have a significant impact on high-performance development, but when combined with Agile methodologies, a more comprehensive and efficient approach is achieved. Combining Agile methodologies with DevOps creates significant benefits in software development projects. The integration of both approaches streamlines process releases, enhancing product features and maximizing collaboration between stakeholders. By implementing CI/CD pipelines, each process release delivers more value with fewer risks and bugs, and nimble fixes. In addition, this approach expands visibility throughout the whole development cycle, which leads to higher customer satisfaction and the delivery of high-quality products. All aspects considered, the combination of Agile and DevOps promotes faster innovation, enables adaptation to changing dynamics within organizations, and optimizes efficiency to achieve project outcomes. (Srivastava, 2023)

3.3 Combining Agile methodologies and GMP principles

Combining Agile methodologies with pharmaceutical industry's GMP principles presets a hard challenge due to the opposite nature of their principles and practices. Despite differing viewpoints on the implementation of Agile in different business regions, there is a lack of clear understanding regarding how to implement Agile practices while adhering to regulations. The perspectives that

Agile emphasizes can be seen as the opposite of GMP requirements. (Jain, 2022)

Agile methodologies emphasize adaptability, flexibility, and rapid iterations, targeting to deliver value to customers efficiently (Brush & Silverthorne, 2022). In turn, GMP regulations mandate strict adherence to standardized processes, precise documentation, and quality control to ensure product safety and efficacy (Macdonell, 2023). While Agile works in short sprints, regulatory requirements may not fit within that timeline. In each sprint, Agile focuses on delivering functional features creating the highest business value, and in this case, regulatory requirements may not be the paramount priority. Additionally, Agile prioritizes feature implementation over detailed and comprehensive documentation, yet complying with regulations may require detailed documentation. However, there are ways to integrate regulatory compliance with Agile ways of working without losing sight of the key benefits: fast delivery with continuous feedback from the stakeholders. (Jain, 2022)

Although these challenges may seem demanding, they are possible to overcome. In an Agile approach, it is possible to combine regulatory compliance into the Agile cycles while keeping two main goals in mind: fast delivery and continuous improvement. This approach requires a shift of mindset and practices, where regulatory requirements are seen as integral parts of the development process rather than obstacle to agility. By fostering collaboration between regulatory experts and stakeholders, establishing clear communication channels, and leveraging project management tools, project teams can streamline the incorporation of regulatory compliance into Agile workflows while still utilizing the benefits of agility and rapid delivery. (Jain, 2022)

4 Establishing cornerstones in pharmaceutical software development

Successful outcomes in software development projects rely on carefully planned project structure. The pharmaceutical industry operates under stringent regulatory framework. Therefore, it is necessary to adhere to GMP guidelines and standards. Consequently, project management in this domain requires a versatile approach, requiring a variety of management roles and processes. This ensures efficient and professional execution of projects with valuable outcomes. (Emma International, 2023) Additionally, careful consideration of the project management methods for implementation and execution are essential.

Within the context of in-house software development projects, the requirements are particularly high, as the outcomes directly impact the end users. In in-house software development projects, the company's internal personnel create, maintain, and update software tailored to the company's needs. Companies must therefore use and coordinate their own resources to manage projects. (Pham, 2023) In this aspect, effective project management becomes primarily important. When projects are conducted inside the company, the combination of Agile methodologies, regulatory compliance and the end-user needs form the cornerstone of successful project management. Additionally, it is important for personnel operating in the pharmaceutical industry to understand the different management roles and their contribution to various tasks. (Pattanaik, 2014)

4.1 Roles in Agile project management

In Agile project management, various roles have essential responsibilities in steering projects towards successful outcomes. Agile methodologies emphasize collaboration, adaptability, and an iterative approach. Therefore, using this methodology requires different management roles with diverse skills and responsibilities. Key roles include the product owner (PO), team lead, development team and stakeholders. Together, they form an Agile team. The

composition of an Agile team structure depends on the company's resources and the desired outcome. (Chervenkova, 2024) Thus, the team structure can be tailored to meet the project's objectives.

The PO acts as a liaison connecting stakeholders and the development team. The PO is responsible for managing the project requirements, managing the product backlog, and prioritizing features based on business value and end-user needs. The PO acts as the voice of the customer and ensures that the software being developed meets stakeholder expectations while being compliant with regulatory standards. (Chervenkova, 2024)

The team lead ensures coordination and supports the progress of the project among the project team members, while ensuring that tasks are executed accordingly. Key responsibilities include facilitating daily Agile principles and sprint initiatives, communicating changing requirements, and coaching project team members to deliver results. In addition, the team lead takes care of administrative tasks. These tasks include implementing changes, coordinating stakeholders, and optimizing backlog planning. (Raza, 2019)

In Agile project management, the development team consists of personnel with diverse responsibilities, covering product development and various tasks related to product ideation. The development team typically includes product designers, writers, programmers, testers, and UX specialists who collaborate with each other to effectively complete project tasks. Their primary responsibilities include performing tasks related to sprints based on requirements provided by the PO and coordinated by the team lead. Regular catch-up meetings are held within the team to facilitate transparent communication of project progress and enable modifications based on feedback. (Raza, 2019)

Stakeholders also have a key role in steering the direction of an ongoing project. They ensure that the project meets business goals, needs, and end-user expectations. Although not directly involved in the product development process, stakeholders represent various roles that influence decisions within the Agile project team. Stakeholders often include end users of the product,

company executives, personnel from production, investors, external partners, and members from associated projects. Stakeholder input is paramount to direct the project towards its objectives. Additionally, involving stakeholders in the project ensures that product development is aligned with business objectives and user needs. (Raza, 2019)

4.2 Understanding the pivotal role of a product owner

In the context of Agile project management, the role of the product owner is crucial for any Agile team, as it maximizes value creation (Scaled Agile, 2023). As stated earlier, the PO has several responsibilities, the most important of which is the duty to act as the voice of the customer. According to Motiso, the responsibilities of the PO include the following. (Motiso, 2023) First of all, PO is responsible for creating a vision for product development. Creating and having a vision is crucial in product development, as it guides the whole project team towards a common objective. The PO of an Agile team articulates an aligned vision to stakeholders, besides explaining project phases and direction. In addition, PO ensures that User Stories are defined. The PO is responsible for developing User Stories, prioritizing tasks, and ensuring coherence. The PO also refines customer expectations and features of product under development to align with project team's objectives.

As stated by Motiso, PO needs to control the product backlog. It is important for the PO to maintain and manage the product backlog, the so-called to-do list, as it is a comprehensive directory of activities that guide the team's iterative project process. Typically, the product backlog is maintained in a project management tool, which guarantees transparency between team members.

It is also crucial for PO to understand customer requirements. Using customer insights to guide product development is paramount to ensure compatibility between customer requirements and value creation. Ongoing interaction with customers, for instance through meetings and interviews, is one way to achieve this compatibility. In addition, The PO also needs to prioritize requirements. The

PO must have the ability to prioritize requirements, which requires an overall understanding of the project objectives and stakeholder needs. This includes the project fundamentals, such as resource capacity, and potential risks.

The PO is also responsible for monitoring product development. The PO must have a deep understanding of the vision, priorities, and overall strategy of the team. This includes planning, design, quality assurance and task reviews. Additionally, The PO in Agile team needs to assess the development process at various stages to ensure compatibility with customer requirements and compliance with project management standards. This also includes reviewing completed phases, approving progress to the next phase, and adding any tasks to meet changing project needs within a predefined scope.

Motiso emphasizes communication at every stage of the project. The PO is a liaison between stakeholders and team members. The PO plays an important role in facilitating communication between stakeholders and the project team. The PO engages stakeholders in the product development process. Additionally, the PO communicates with project team members to share stakeholder feedback, instructions, and expectations, enabling efficient task prioritization.

4.3 Clarifying the key working processes of the product owner

When considering the list of responsibilities of the PO regarding Agile, the PO has several tasks to carry out. However, the role of the PO becomes more important in pharmaceutical software development. In addition to managing the project backlog and prioritizing several tasks, the PO must adhere to a broad regulatory framework while ensuring that the software development project is aligned with industry standards and end-user requirements. This requires an understanding the technical aspects of software development and knowledge of GMP standards in the pharmaceutical industry.

In this context, the PO must facilitate effective communication between development teams, stakeholders, and regulatory bodies, while ensuring that

final software solution is compliant. Consequently, traditional Agile practices outlined in Agile textbooks may not accurately reflect the responsibilities of a PO working in a pharmaceutical environment.

Therefore, examining and clarifying the key working processes of the PO in the pharmaceutical in-house software development becomes essential to streamline processes and ensure successful and high-quality delivery of software solutions. In this bachelor's thesis, the topic will be further explored, shedding light on the multiple responsibilities and tasks of the PO in the field of Agile software development for the pharmaceutical industry.

4.4 Balancing end-user needs with regulatory compliance

In addition to focusing on the responsibilities of the PO, the PO also faces challenges related to regulatory compliance. PO is required to apply a compliant way of working while ensuring regulatory compliance. Requirements must be considered in the pursuit of user-centric software solutions that deliver maximum benefit.

One of the primary challenges encountered by PO is the need to prioritize end-user needs while ensuring compliance with GMP standards. Regulatory requirements can limit the flexibility and agility of the software development process, potentially impacting the challenging delivery of user-centric features. Therefore, the PO needs to develop innovative ways to manage the project progress while incorporating user feedback into the development process while respecting guidelines.

How can Agile software development in the pharmaceutical sector be achieved when there are various bureaucratic guidelines and considerations to keep an eye on? How can product owners ensure that value is delivered to end users while complying with GMP requirements? In addition to identifying the key responsibilities of the PO, this bachelor's thesis focuses on discovering best practices to maximise value creation in the regulated field of pharmaceutical software development, approached through Agile project management.

5 Implementing action research method

5.1 Selecting the methodological framework

The research methodology of this bachelor's thesis is qualitative action research, chosen for its dynamic and participatory nature. In this study, the research process is guided by principles of action research methodology, as outlined by Robert N. Rapoport in "Three Dilemmas in Action Research: With Special Reference to the Tavistock Experience" and M. D. Myers and D. E. Avison in "Qualitative Research in Information Systems".

Action research combines inquiry with intervention, allowing the PO to actively engage in project assignments with other stakeholders. Through this engagement, the PO identifies challenges, implements changes, designs actions, and reflects outcomes. The PO fosters continuous cycles of planning, action, observation, and reflection, while working in a real-life environment. This methodology matches the complex and dynamic landscape of pharmaceutical software development and project management, where traditional research approaches may inadequately capture the intricacies of real-world implementation. The use of dynamic methods is suitable when functioning in an area of Agile project management that is unfamiliar to the project team.

The decision to apply action research arises from the research questions posed in this thesis. These research questions focus on implementing Agile project management in practice while following the regulatory requirements and guidelines for pharmaceutical software development. This approach allows to see the results of the implementation process in a real environment. By adopting action research, the PO aims to directly engage with stakeholders, including developers and regulatory bodies, to deeply understand their perspectives, challenges, and needs while working with Agile principles. This qualitative action research approach fosters collaborative creation of knowledge and the development of practical solutions tailored to the specific context of the

pharmaceutical domain. Additionally, action research emphasizes the importance of understanding phenomena in Bayer's socio-cultural environment.

Through action research, this study seeks to generate valuable insights into effective Agile project management practices. The PO actively participates in the Agile project management process with the aim to observe, document, and analyze the challenges, success, and insights gained. In addition, the aim is to contribute to the broader understanding of Agile methodologies and foster valuable collaboration within the pharmaceutical software development project team.

5.2 Data collecting and processing procedures

The approach of data collecting and processing in this action research will be multifaceted and participatory, aligning closely with the principles of action research. As the research framework is interactive, data collection methods will include qualitative techniques such as observations, unstructured and semi-structured discussions, and document analysis.

The data collection process begins by engaging stakeholders in project activities, such as meetings, to actively involve them in the on-going software development project. Through unstructured and semi-structured discussions, valuable insights into participants' experiences, perspectives, challenges, and needs will be gathered. These interactions will yield qualitative data, enabling a deep exploration of the dynamics involved in the successful implementation of Agile methodologies within the context of software development.

Additionally, observations of project meetings and daily operations will be conducted to capture real-time interactions, decision-making processes, and the overall dynamics of the project's progress. This approach enables the PO, acting as the researcher, to gain firsthand experience and a comprehensive understanding of the challenges and success factors encountered during the implementation of Agile methodologies.

Furthermore, conducting document analysis, which includes reviewing meeting notes, project plans, and regulatory compliance documentation, will supplement the qualitative data gathered from discussions and observations. These documents are valuable sources of information, providing perspectives into the formalized aspects of Agile project management and regulatory adherence.

Throughout the entire software development project, data will be collected and analyzed simultaneously using qualitative data analysis techniques, such as thematic analysis and constant comparative analysis. Through iterative data processing, various themes are identified and leveraged to guide Agile project management. The insights obtained from these analyses will offer a comprehensive understanding of the implementation of Agile principles inherent in Agile project management in a pharmaceutical environment.

The selected data collection and processing procedures embody a comprehensive approach following the principles of action research framework. These methodologies generate actionable insights for continuous improvement in Agile project management practices, tailored to meet the specific needs of the targeted software development project.

5.3 Adopting an action research approach

Selecting and implementing this action research approach signifies a commitment to progressive development and collaborative problem-solving. By using this methodological framework, this research seeks to combine aspects of theoretical foundation with practice. Additionally, this approach promotes meaningful discussions and knowledge creation of Agile principles among the stakeholders participating in the ongoing project.

One of the key principles of adopting action research is that it enables emphasis on reflexivity and self-reflection. The approach provides firsthand experience to stakeholders while creating a deeper understanding of the challenges and opportunities of Agile project management within the pharmaceutical environment.

Action research remains responsive to the evolving needs of the pharmaceutical sector and facilitates collaboration and innovation. By actively involving stakeholders in the research process, this approach aims to drive continuous improvement in project management and contribute to the implementation of Agile practices within the in-house software development project.

6 Implementing Agile way of working in pharmaceutical software development project

The practical implementation of Agile methodologies in the ongoing project was done from the perspective of the PO. The implementation process was carried out by the PO with the help of other stakeholders, such as the team lead, participating in the software development project. The practical section focuses on the implementation process, emphasizing the working methods and actions made by the PO. In parallel, the key management processes of the PO are being captured. Through discussions, meetings with stakeholders and facilitating team communication, the practical section provides a comprehensive view of the actions taken related to Agile. These actions were carried out in the ongoing project. In addition, project management tools to facilitate software development are being introduced. These tools were used to streamline project processes and improve efficiency throughout the MVP phase.

This section offers insights into the daily activities, responsibilities and decision-making processes related to the PO's role. According to action research principles, the methods and actions are tailored to meet the demands of the ongoing project. The content within this section offers insights into the day-to-day activities and decision-making processes encountered by the PO. According to action research principles, the methods and actions are tailored to meet the demands of the ongoing project and implemented into the MVP phase of the project. In this context, MVP phase refers to a stage of the software development project where a product is developed so that it meets the minimum usage requirements of the customer organization.

The software development project started from the initiative from the customer side, MSAT department at Bayer. The MSAT department saw a need for an advanced software development solution to help them carry out daily tasks more efficiently and with less time-consuming. Once the need was identified, the project began by creating a vision for the software solution to facilitate daily tasks and automate manual tasks.

6.1 Project planning and launching

The project began with the formation of the planning phase. The aim was to apply Agile principles to an existing project from the MVP phase. In this process, the main responsibility was given to the PO.

Before starting the actual Agile sprints, the PO had to build a solid foundation around the MVP phase of the project. The MVP phase started by formatting the Agile project team with the team lead. The PO and the team lead gathered the entire Agile project team participants starting from the customer. The customers included participants from the MSAT department, which were also the end users of the software solution. The selection required participants to actively engage in the project meetings and activities and to work towards common goals. The Agile project team also involved a participant from the validation department. It was necessary to include a representative of the validation department to ensure compliance. Additionally, a development team was formed, including the PO and a programmer. Due to limited resources resulting from in-house execution of the project, the entire Agile project team consisted of the team lead, the PO, one programmer, one representative from the validation department and the customers of the MSAT department. In addition to this, the project also involved other stakeholders. These individuals were from other departments and did not necessarily participate in the project tasks or in every meeting.

When the Agile project team was formed, the PO created a preliminary timeline for the MVP phase using Jira, a cloud-based project management software. In this timeline, all actions and activities included in the MVP phase were split into phases and sprints. (Image 3) The timeline was indicative and remained adaptable as the project progressed. Additionally, the timeline included key activities and actions that also required the responsibility of the whole project team and not just the PO.

Image 3. Preliminary MVP phase timeline

Once the Agile project team was formed and the timeline was preliminary created, the PO organized a meeting including every team member of the project. This meeting was the kick-off meeting for the MVP phase of the software development project. In this meeting, the PO aligned the vision and objectives of the project with the stakeholders. The whole project team jointly defined the project objectives for the MVP phase. The main project objective of the MVP phase was to create an MVP from the software solution. The overall objectives were set to align with the business objectives. In addition to these, the agenda of this meeting also included the alignment of the timeline and the presentation of the Agile implementation method.

After the kick-off meeting, the PO established a communication channel using Microsoft Teams as the main communication tool. All information related to the MVP phase was published on the project's internal Teams channel. The PO also informed the Agile project team that communication should take place at

an exceptionally low level. This was due to one of the principles of Agile, which is to have close interaction between project team members.

Following the kick-off meeting, the PO organized a new meeting to gather the needs and requirements of the MSAT department. In this meeting, the PO identified the customer's requirements for a new software solution initiative. The meeting used an open discussion format and leading questions to keep the discussion and the need manageable. All aspects, insights and needs which came up during this meeting were precisely written down by the PO. After the collaborative discussion with the stakeholders, the PO identified and prioritized the minimum set of user needs to align with the MVP phase objectives. When the prioritization was done, the PO started to create User Stories based on the prioritized needs. The needs that were not included in the MVP phase after prioritization were added to the project's backlog. Customers' needs were identified and separated into features for the new software solution. The PO created the User Stories using a three-step sentence structure (Image 4). These User Stories were formatted as brief descriptions of a product's features, written from the perspective of the end user, MSAT department.

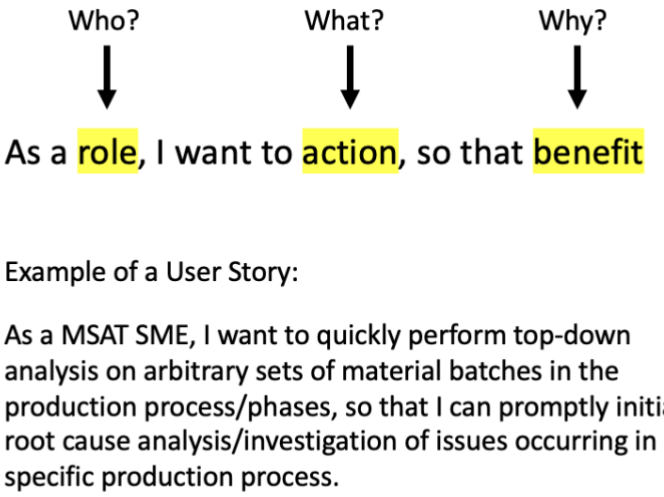

Image 4. Example of how User Stories were created

Once the User Stories had been created for the MVP phase, the PO organized a new meeting to present these User Stories to the MSAT department. In this meeting, the stakeholders had the opportunity to express their thoughts on whether the User Stories corresponded to their needs regarding prioritization and content. At this stage, the PO made the proposed final modifications to the content and prioritization of the User Stories.

At this point, the PO introduced a new project tracking tool for the Agile project team members. The project tracking tool which enables seamless collaboration in a cloud-based environment is called Azure DevOps (ADO). This tool leverages DevOps principles. In addition to the User Stories, the backlog was implemented into the tool which enables a visual view of the features and created User Stories (Image 5). All members of the Agile project team were given access to the tool. This ensured transparency throughout the whole MVP project phase.

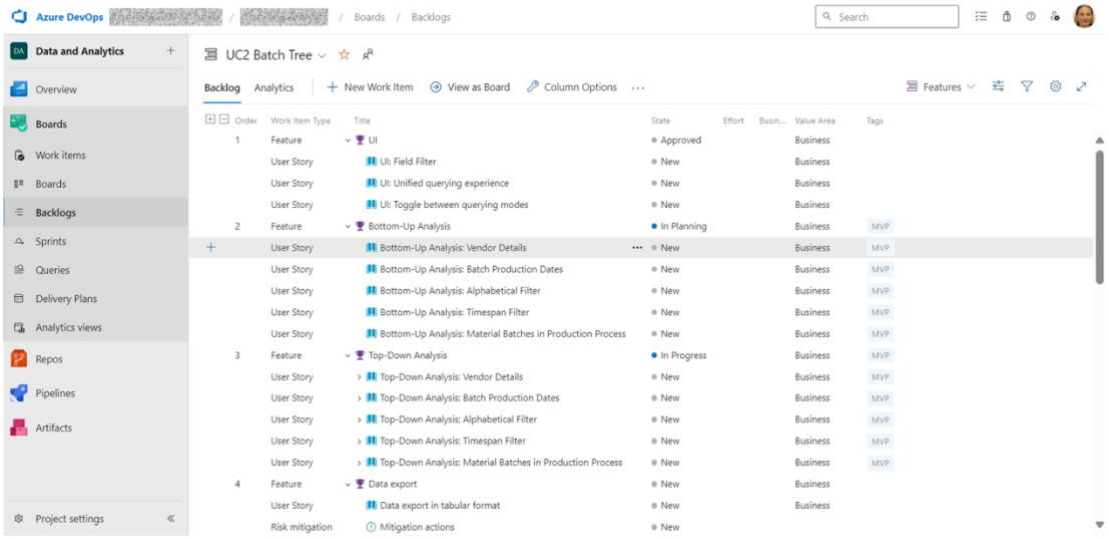

Image 5. Overview of the Azure DevOps feature and the User Story backlog

After identifying the MVP features and User Stories, the PO organized a new meeting with the development team. In this meeting, the features to be developed were defined and the scope of the first development sprint was

decided. The PO ensured that the scope and workload of the first sprint was reasonable and commensurate with the resources available.

Once all the planning work was done, the PO organized the first sprint planning meeting. The whole Agile project team was invited to this meeting. The PO presented the scope of the first sprint, including the User Stories under development. Also, the timeline and duration of the upcoming sprint were presented for the whole Agile project team. The duration of one sprint was set at 21 working days. The 21 working days is the duration in calendar days and does not reflect the resources available to the project team per calendar day. The PO ensured that the open discussion continued despite the start of the sprint, and the issues raised were recorded in the ADO backlog.

6.2 Working in a sprint

During a sprint, the PO had several responsibilities. The PO continued to prioritize items in the product backlog in ADO. The prioritization was done based on changing business needs and stakeholder feedback. The PO ensured the development team was developing the most valuable features to stakeholders. If there were uncertainties or questions regarding the written User Stories scheduled for the ongoing sprint, the PO clarified these User Stories for the development team. The PO provided explanations and examples to ensure a collective understanding.

At the same time, the PO gathered stakeholders' feedback and insights during the sprint and added these to the backlog. Feedback was collected on the functionality of features already released. The PO made sure that the development team was aware of any sudden changes that needed to be made to the features they were working on. Otherwise, the development team was left to focus on feature development. As new requirements and needs emerged or priorities shifted, the PO remained flexible and adapted to the change in the sprint backlog accordingly.

Within the sprint period, the PO was the primary point of contact for the MSAT department and the stakeholders. The PO provided updates on the progress of the sprint and gathered feedback. The PO addressed any questions or requirements that were raised regarding the project. During each sprint, the PO was the communication bridge between the development team, the MSAT department and other stakeholders.

As features were developed and completed during each sprint, the PO reviewed the work done by the development team and provided feedback. When necessary, the PO offered feedback, guidance, and direction to the development team to ensure that the delivered features met customer expectations and project's objectives.

Due to limited resources, the PO did not organize daily stand-up meetings typical to the Agile approach. Instead, the PO highlighted their availability to the project team's members if they had any concerns or questions about the project or the ongoing sprint. The PO was available throughout the sprint if any questions arose.

During a sprint, the PO ensured that each member of the Agile team adhered to requirements and that all software development activities performed adhered to GMP and other relevant guidelines. As the project was carried out in an in-house pharmaceutical environment, all members were already aware of the compliance requirements throughout the project.

Before reaching the end of the sprint on schedule, the PO arranged a meeting with the development team. This meeting outlined the content of the upcoming sprint before presenting it to the MSAT department and stakeholders.

In the end of the sprint, the PO arranged a sprint review meeting with the whole Agile project team. In this sprint review meeting, the completed User Stories were presented to the MSAT department and other stakeholders. This was done in collaboration with the development team, who had the best knowledge of how the features work in the software solution. Each feature developed was demonstrated and reviewed at the meeting. The PO gathered and collected

feedback on the features presented. Based on this feedback, the PO made changes to the product backlog.

A planning meeting for the next sprint was held with the sprint review meeting. The sprint review and planning meetings for the next sprint were held together, as it was challenging to find two separate slots in the project team members' calendars for two different meetings due to other important work. The sprint cycle remained the same for each sprint, which required the same actions taken by the PO.

6.3 After sprints

Once the required number of sprints has been completed to cover all features included in the MVP phase, the closing phase of the project begins. Due to limited time resources of the PO, the PO was not able to carry out all their responsibilities within the period of this action research. Therefore, the PO made an action plan and instruction guidelines on how to proceed with the responsibilities and tasks in the role. These tasks and responsibilities belong to the PO and will be done as the project progresses.

The PO will organize an MVP retrospective meeting after the required number of sprints are carried out. The whole Agile project team will be invited to this meeting. In this retrospective meeting, the sprint process and outcomes are being reflected. Additionally, the project process will be reviewed, and an assessment will be made of whether the objectives of the MVP phase were achieved. The PO will also lead the discussion and collect feedback from the whole Agile project team on what went well and what could have been improved during the sprints. In this retrospective meeting, the success of each sprint will be identified and analyzed. Challenges and areas for improvement in collaboration, communication and productivity will also be identified. The PO will discuss the problems and obstacles encountered during the sprints and will consider solutions to solve them in the future. These discussions will provide a

basis for what needs to be improved during the sprints of the next project phase.

After the retrospective meeting is held, the PO will organize a meeting with the development team. In this meeting, the work of the development team will be assessed. The discussion will include insights on what went well and what could have been improved in the development work, for instance programming and the pace.

At the end of the MVP project phase, the PO will address issues and objectives for future improvements. The issues and objectives are being made based on the insights gained from the retrospective meeting with the whole Agile project team and the meeting with the development team. The aim is to improve the team performance and project results in the following sprints. The PO will promote continuous improvement, stakeholder collaboration, and alignment with the project's objectives, so that subsequent projects can be guided towards the objectives and greater success. This will be done by highlighting the recognized areas of improvement discussed in the retrospective meeting.

6.4 Other product owner's duties during the project

During the MVP phase, the PO was also responsible for tasks not specifically relevant to a sprint cycle. The PO was accountable for creating User Acceptance Testing (UAT) and conducting Risk Assessments. As mentioned about the PO's time constraints, the PO created a guideline on how to conduct UAT and Risk Assessments which will be implemented later in the project. The PO created guidelines based on the project plan and discussions with Bayer's stakeholders. UAT, Risk Assessments and mitigations will be done before the software solution is deployed. Risk Assessments will be carried out before UAT, as UAT will be conducted based on Risk Assessments. Risk Assessments and UAT can be either done after all features of the MVP phase are developed or during a specific sprint. By integrating Risk Assessments and UAT as part of a

sprint, a deeper Agile way of working will be achieved, and potential development targets will be identified at early stages of the developed feature.

6.4.1 Guideline for Risk Assessments

By conducting Risk Assessments, the PO will ensure that all the risks related to the usage of the software solution are recognized and mitigated if necessary. In GMP, Risk Assessments will be done based on patient safety. In addition, business and quality risks must also be considered.

The PO will conduct Risk Assessments by following four steps (Image 6). First, the risks need to be identified. The PO will organize a session for brainstorming to identify potential risks associated with the software solution features. The Risk Assessment session will include the development team, individuals from the MSAT department and the personnel from the validation department. In this session, the risk identification techniques will be specified. The identified risks will be documented to ADO on feature level.

Image 6. Steps for Risk Assessment

When the risks are identified, the probability of each identified risk will be evaluated. A predefined scale will be used to classify the probability of each risk. The predefined scale is implemented in ADO using the scale from 1 to 3. The PO will document the risk evaluation classifications under each feature in ADO. Risks will be assessed from a multi-dimensional perspective, including patient safety, quality, and business risks.

After risk evaluation, the risks need to be prioritized. The PO will prioritize the identified risks based on their likelihood, impact, and classification. The focus must be on the highest severity and potential impact on the success of the project. The risk prioritization will be done regarding the classification scale.

As a last step, the risks need to be mitigated. If the classification of the risk is high, risk mitigation will be carried out. The PO, in collaboration with personnel involved in Risk Assessments, will tailor risk mitigation strategies for each identified risk. The Risk Assessment team will consider feasibility, compliance and cost-effectiveness when creating risk management measures. After the mitigation strategies are developed, the PO will assign responsibilities and set a timeline for implementation of mitigation measures. The identified risk mitigations will be documented to ADO by the PO.

In addition, the PO is responsible for managing and updating the risk register in ADO to reflect any changes in MVP phase scope, requirements, or external factors. The PO will continuously monitor and update the ADO's backlog to ensure transparent progress in the MVP phase. This way, each member of the Agile team involved in the project stays on track with changes and progress.

6.4.2 Guideline for User Acceptance Testing

The PO will conduct User Acceptance Testing (UAT) when all the MVP features are developed, and the Risk Assessments are done. This ensures that tests are not carried out unnecessarily for features that may not survive beyond the MVP phase. UAT will be carried out on User Story level. UAT can also be conducted during sprints if there are enough resources available. UAT checks whether the software solution corresponds with the needs of the MSAT department. During UAT, the compliance of regulatory requirements and business objectives are ensured. In GMP, UAT plans are based on the risks identified during Risk Assessments. If the risk identified in Risk Assessment is low or tolerable, testing may not be necessary. However, in the business sense it may be necessary and vice versa.

The PO will conduct UAT based on the following steps (Image 7). First, the acceptance criteria must be defined. The PO will establish clear and measurable acceptance criteria for each User Story with the stakeholders, with the MSAT department and the development team. These criteria will outline the expected functionalities and behavior of the software solution. The PO documents the acceptance criteria in the ADO under the User Story for each feature.

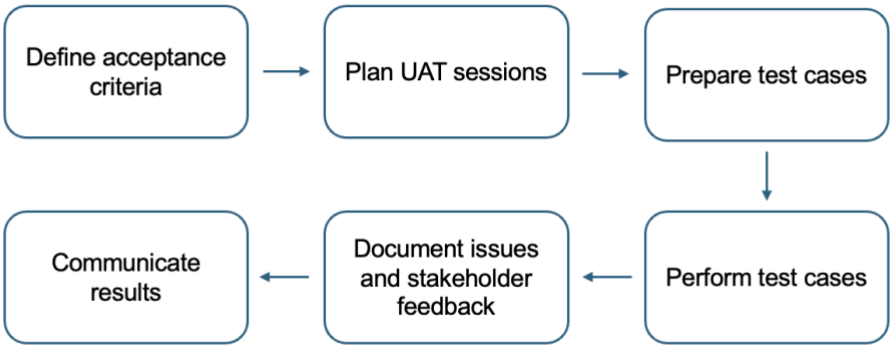

Image 7. Steps to conduct User Acceptance Testing

After the acceptance criteria are defined, the PO will plan UAT sessions. The PO will schedule UAT sessions with the MSAT department in a controlled environment. The environment should be free of any disturbing stimuli.

Before the UAT sessions will be held, The PO will prepare test cases. The PO will create test cases based on the acceptance criteria defined earlier with the stakeholders. The test cases must be comprehensive to cover various scenarios and workflows to ensure the functionality from the MSAT's usage perspective. The content of the single test case is created in such a way that it progresses step by step. When the test cases are planned, they will be performed. The PO guides the stakeholders through the performance of the prepared test cases. The stakeholders will be told to interact with the software solution as they would while completing daily tasks and duties.

During these tests, the documentation and gathering feedback are important. The PO must capture all issues detected during the execution of the UAT sessions. The PO must also gather feedback from the stakeholders who carried out the tasks. The feedback and issues will be documented in the ADO under the tested User Story.

When the UAT is completed, the PO gathers the results of the UAT, combines them and communicates them to the whole Agile project team. Also, identified issues and feedback will be presented. The results will be presented in the sprint review meeting if UAT is carried out during a specific sprint.

If UAT is carried out after all the features of the MVP phase are developed, the PO will encourage iterative testing in the future to take advantage of Agile principles and ensure continuous improvement. If UAT is carried out during a sprint, the changes and enhancements derived from the UAT sessions will be incorporated in subsequent sprint's UAT. The development team, led by the PO, will resolve problems and challenges encountered during the UAT to ensure they are not repeated.

7 Results and analysis

In summary of the action research, the analysis and discussions presented provide insights into the effectiveness of the role of the PO in an in-house software development project. By reviewing achievement, challenges, lessons learned and areas of improvement, valuable insights for future projects can be gained. In addition, reviewing these from the PO's point of view provides insights on how to deliver more value and work more effectively following Agile principles.

The MVP phase of the project showed positive development in the adoption of Agile working methods and the progress of the project. The PO tailored the Agile working principles to the ongoing project requirements. The formed Agile team was very optimist towards the MVP phase objectives and the outcome as the project proceeded. Also, implementing Agile principles to project management was seen as a good opportunity to adapt effective ways of working. As the initiative for the project came directly from the customer organization, the MSAT department, the project was approached with ambition. Valuable feedback was received in the project and sprint meetings on the features developed and the organization of the meetings. The customer's needs and requirements were met with the right solution. Also, the PO and the development team were praised for their joint efforts during the MVP phase.

Working in the MVP phase also included challenges. When the whole Agile project was carried out in-house, not all resources were sufficient to cover all Agile principles. As there was no Agile project team available to focus exclusively on the project activities, many of the Agile project team members did not have time to focus their time specifically on this project. Therefore, sprint planning and review meetings were not always attended. As a result, not every Agile project team member was actively involved in the project, which would have allowed the project to operate more effectively. To achieve a more efficient way of working, the PO could form an Agile project team so that participants only work on a specific Agile project without any other responsibilities. The

second option would be to hire a facilitator who facilitates the Agile project's progress and ensures that the project delivers value in a timely manner.

Also, due to limited resources, the daily standup meetings were not conducted by the PO which are related to Agile principles. Due to this, communication between the Agile project team, especially between the PO and the development team, was not active. This could have been avoided by organizing short meetings a few times a week to briefly review project progress and issues related to the project tasks.

As Agile working methods and principles were new to many Agile project team members, the project progressed by doing and learning. Agile practices were adapted to the resources available and implemented to achieve the project's optimal functionality. The PO noted that the best way to implement Agile principles is to implement and adapt them incrementally in a regulated environment. Implementing all the principles of the new project management methodology at once will not work in an environment that is used to a systematic way of managing projects.

This Agile project used a project management tool called Azure DevOps (ADO) which allowed the project to progress transparently. The tool was most specifically used by the PO to manage the project's backlog. In addition, the other Agile project team members, such as MSAT department, were granted access. Nevertheless, the tool was not actively used by the MSAT department. In the future, ADO could be used by every Agile team member to improve engagement to the project. In addition, ADO includes functionalities such as the approval of drafted features belonging to the customer, in this project to the MSAT department. In the future, the customer organization could approve the activities in ADO which would increase project commitment, transparency, and more Agile project progress. ADO also allows commenting and giving feedback on the actions documented in the system. As a result, getting feedback from the customer would be easier and clearer when the feedback is directly documented on the system in use and associated, for instance, to a specific feature or a User Story.

When the Agile project team was small, the MVP phase did not progress quickly. However, the project had no time limit or external pressure, as it was carried out as an internal project. In terms of timing, a deadline was set for the MVP phase, which facilitated progress.

To speed up the progress of the project in the future, the project team could be enlarged, and specific tasks and responsibilities should be clearly assigned to each member. If enlarging the team is not possible for instance due to limited resources, then the focus should be on the project scope and quality. By reformatting the project scope, the project would proceed more efficiently when taking the resources available into account. This would also include the overall quality of the project.

In addition, the PO could define specific working hours for each team member to ensure smooth progress of the project. Also, the PO could provide guidance on how to work in an Agile project. By instructing the Agile team members, the PO will ensure that every member is aware of Agile principles, engages the project objectives and policies, and participates actively in the project activities.

8 Conclusion

The purpose of this bachelor's thesis was to be involved in implementing Agile principles in an ongoing software development project as a product owner (PO) in a pharmaceutical environment. The objective was to understand the key responsibilities and tasks of the PO while working as part of the Agile project team. In addition, the objective was to adapt and align Agile principles to the regulated pharmaceutical environment and at the same time ensure that value is being delivered.

By implementing action research, this thesis provides a hands-on approach to understand the adoption of Agile methodology in an in-house software development project from the PO's perspective. During the action research, the PO captured best practices and areas for future improvement which should be considered when utilizing Agile principles in a regulated environment. The PO gained first-hand experience working as part of the Agile team.

This bachelor's thesis found out that Agile principles can be used in a regulated environment, but it requires a specific approach. Agile principles need to be tailored to the ongoing project, and regulatory and GMP requirements must be considered as part of the project flow and iterative development. The thesis also found out that adopting Agile principles incrementally is the most convenient way to ensure that adapting the approach does not create additional work and is done smoothly.

The results of the thesis show that the PO has a key role in Agile projects. The captured responsibilities of the PO, such as considering the needs of the customer and managing the project flow and backlog, add significant value to the project's outcome. Especially, when the thesis focused on operating at the MVP (Minimum Viable Product) phase, the correct formulation and outlining of the customer's need was pivotal to ensure that the result of the project matched the desired outcome. In an Agile project, the PO is responsible for keeping the project on track and ensuring the overall development of the project.

The bachelor's thesis provided Bayer, as the client, valuable information on how Agile principles can be utilized as part of an organization's in-house software development projects. In addition, the important role of the PO in the pharmaceutical environment was highlighted, so that the client can benefit from this aspect in future Agile projects. Besides, the client gained insights on how to implement Agile principles in their own organization and how they can be used to ensure continuous improvement and an efficient way of working.

For further research and development on this topic, it is still necessary to continue adapting Agile principles for the next phases of this or other similar projects. Agile can be seen as an opportunity to speed up the progress of projects and thus deliver results in a brief period. Additionally, future studies could implement for instance artificial intelligence (AI) into Agile principles, exploring how AI can enhance software development project outcomes. Ongoing research is also needed to evaluate the long-term impact of the usage of Agile principles.

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