v. 3, n. 36, 2023

Journal of Engineering Research

A HYBRID REQUIREMENTS MANAGEMENT MODEL FOR SOFTWARE DEVELOPMENT AND ACQUISITION IN THE PHARMACEUTICAL INDUSTRY

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Abstract: Pharmaceutical industries are subject to regulations that value good manufacturing practices (G.M.P). In this context, the area of information technology must provide software capable of complying with industrial needs, following the technical guidelines recommended by software engineering and ANVISA (National Health Surveillance Agency). The objective of this work is, thus, to propose a hybrid requirements management model, applying the Scrum framework for agile project management, in the process of developing and acquiring software for the pharmaceutical industry, merging requirements engineering steps – such as elicitation, analysis and negotiation, documentation, verification and validation of requirements – with the regulatory compliance proposed in the concept phase of the life cycle of ANVISA (National Health Surveillance Agency) computerized systems, with the goal to comply with good manufacturing practices. With this scenario, the pharmaceutical quality assurance area performs qualifications that validate the software's compliance with good manufacturing practices, based on the specification of user requirements (E.R.U.). Finally, a case study compares the results before and after applying the model that was proposed in this work.
Keywords: Requirements Engineering, E.R.U. (specification of user requirements), Good Manufacturing Practices (G.M.P), Scrum.

INTRODUCTION

Companies have sought to invest in the use of computerized systems that support their business processes [1]. The use of these systems by the pharmaceutical industry, such as ERP, CRM, LIMS, WMS, is essential to manage their production processes and guarantee traceability and data security [2]. ANVISA (National Health Surveillance Agency) defines the life cycle of computerized systems in four phases: concept, design, operation and retirement [4].

This work has the focus to explore the concept phase, bringing improvements to meet regulatory requirements, in conjunction with the requirements engineering phases, including elicitation, analysis and negotiation, documentation, verification and validation of requirements. These steps are applied in an iterative and incremental way, it means that in the verification event of each sprint, according to the structure defined by the Scrum framework for agile project development [5], the requirements must be reassessed and, if necessary, they need to be adjusted, to ensure its traceability against usable increments and progress towards the final system to be delivered, minimizing the risks.

Pharmaceutical validation, with the goal to achieve good manufacturing practices, has four qualification steps (QP: about the project, QI: about the installation, QO: about the operation, QD: about the performance) [4].

The other sections of this document are organized as follows: section 2 describes the theoretical framework for a better understanding of the context; section 3 details requirements management, considering the life cycle of ANVISA (National Health Surveillance Agency) computerized systems; section 4 highlights the user requirements specification document (E.R.U.); section 5 reports the pharmaceutical validation process; section 6 brings our main contribution, with the proposed hybrid model; section 7 brings a case study that highlights the before and after application of the new hybrid model, including the results obtained; Finally, section 8 describes the conclusions of this work.

THEORETICAL REFERENCE

The main goal of pharmaceutical industries is to produce medicines, which requires investment in research to develop, market and

distribute products. [10].

In Brazil, such industries emerged linked to the State, which enabled the production of serums, vaccines and medicines to supply public health [10]. In this context, pharmaceutical industries need to ensure that the product delivered to the end consumer meets good manufacturing practices (G.M.P), ensuring uniformity and reducing the risk of returns or contamination [11]. ANVISA (National Health Surveillance Agency) established by the RDC (Collegiate Board Resolution) number: 658, dated March 30, 2022, which refers to good manufacturing practice guidelines [3].

Software engineering, through a systematic, disciplined and quantifiable approach, contributes to all phases of the software development process. Requirements engineering supports software engineering, maintaining the scope of the software product within the expected quality and with the necessary requirements [12].

Scrum supports the generation of value, with adaptive solutions to complex problems. It is structured into a Scrum team (Scrum Master, Product Owner, Developers), Scrum artifacts (Product Backlog, Sprint Backlog, Usable Increment) and Scrum events (Product Backlog Refinement, Sprint Planning, Daily Scrum, Product Review Sprint, Sprint Retrospective) [5]. When developing software with this methodology, there are several increments, instead of one [6].

ANVISA (National Health Surveillance Agency) describes the life cycle of computerized systems in four phases, highlighted in the next section of this article: concept, design, operation, retirement [4]. Scrum is applied, together with requirements engineering, in the concept phase.

This means that, at each project sprint, that is, each of the periods used to complete a part of the developed project, the software product requirements need to be reassessed and have their changes formalized, with an impact study that was performed. The use of an agile framework helps in understanding requirements, mainly due to improved communication and stakeholder involvement [13].

Pharmaceutical validation, that was detailed in section number 5, is a verification process to ensure compliance with regulatory requirements, including design (QP), installation (QI), operational (QO) and performance qualifications. (QD) [4].

LIFE CYCLE OF ANVISA (NATIONAL HEALTH SURVEILLANCE AGENCY) COMPUTERIZED SYSTEMS AND REQUIREMENTS MANAGEMENT STEPS

ANVISA (National Health Surveillance Agency) defines the life cycle of computerized systems as follows [4]: i) **concept**: requirements are developed and potential solutions are discussed; ii) **project**: steps of contracting, design, development, verifications, implementation and release of the system for operation occur; iii) **operation**: during this phase, trained people manage the system, which is already operating, and system maintenance occurs, with change management; iv) **retirement**: this phase occurs when the system in operation is discontinued, making it necessary to take measures to decide on the destination of the system and data.

According to [7], software quality must not only be in the software, but also in its creation process. Software that does not meet the customer's needs finds, at this moment, the main points of failure [9].

It is in the concept phase of ANVISA (National Health Surveillance Agency) that the new hybrid model presented in section 6 of

this work is applied, with the following phases of requirements engineering being adopted, based on the definition of [8]: elicitation, analysis and negotiation, documentation and validation. Below is a brief specification of each of these phases.

In the elicitation phase, it is up to the requesting area to identify the system's initial requirements. Meetings must take place between the parties, who need to have full knowledge of the process that will be supported by the use of the software.

In the analysis and negotiation phase, new requirements may be raised or those elicited by the requesting area may be refined or excluded. There will be a negotiation of requirements. At this step, the information technology area will study the requirements raised and support the requesting area in refining them.

In the documentation phase, requirements are written in a standard document called E.R.U. (user requirements specification), that was highlighted in section number 4.

Finally, the validation phase is the approval of the document by the drafters, reviewers and managers of the respective areas that are directly involved.

USER REQUIREMENTS SPECIFICATION DOCUMENT

According to [4], the E.R.U. (user requirements specification) must clearly and precisely define what is desired from the software. Requirements must be traceable and classified according to table 1:

Requirement Classification	Requirement Description
B – BPx	The requirements related to: a) impact on product quality; b) impact on cleaning, sanitization and sterilization conditions; c) regulatory compliance with good manufacturing practices and applicable pharmaceutical legislation; d) process requirements for critical quality attributes (ACQ) and critical process parameters (PCP).
S – Security, Health and environment	Critical requirement that may affect safety or the environment and must thus be fully met.
N – Not BPx	Necessary requirement, which helps to optimize the functionality and operation of the system, but which has no impact on good practices (BPx), health, safety and the environment. These requirements are mandatory and must be fully met.
D – Desirable	Desirable requirement, which can offer operational, control, data recording, etc. This item will be addressed when there is technical and financial availability. However, the item is recorded for future reference.
I – Informative	In some sections – for proposals and scope of work – where information needs to be provided clearly.

Table 1. Classification of system requirements in the E.R.U. (specification of user requirements).

The main characteristic is the B classification, indicating that the requirement has an impact on good manufacturing practices. Thus, the system must undergo pharmaceutical validation.

The E.R.U. (specification of user requirements) has the following structure: Objective, which defines the objective of the document; Scope, the scope of software requirements; Reference, documents used as a basis for filling out the E.R.U. (specification of user requirements); Glossary, with the main definitions of the document; General Description, in which the system requirements will be described.

The General Description is the main part of this document, as, in this topic, the Requirements that were raised, they will fall within one of the following categories: Sizing

Requirements, Process Requirements, Project Requirements, Interface Requirements, Measurement and Control Requirements, Operation Requirements, Automation and IT Requirements, Training Requirements and Validation Requirements.

PHARMACEUTICAL VALIDATION

When there are requirements classified as B in the E.R.U. (specification of user requirements), pharmaceutical validation goes through the following steps, in sequence: project qualification (QP), installation qualification (QI), operational qualification (QO), performance qualification (QD) [4].

In QP (project qualification), a documented check is elaborated whether the proposed project is adequate for the intended purpose. In QI (installation qualification), it is verified whether the system was installed according to pre-approved specifications. In QO (operational qualification), it is verified that the system works according to pre-approved specifications. In QD (performance qualification), an evaluation of the system in operation is carried out.

Before starting design qualification, system requirements need to be elicited, analyzed and negotiated, documented in the E.R.U. (specification of user requirements) and validated.

This validation of requirements can be performed in a physical or digital document through a system. In our proposal, the drafter of the E.R.U. (specification of user requirements) must indicate the owner of the process (generally the head of the area requiring the system), the reviewers (which must always contain an analyst from the information technology area and an analyst from the pharmaceutical quality assurance area) and the approvers (containing at least the head of the requesting area and the head of the pharmaceutical quality assurance area). The final document must be signed by everyone and stored by the pharmaceutical quality assurance area.

Figure 1 describes the flow of pharmaceutical validation of the E.R.U. (specification of user requirements), which is performed iteratively, that is, it is repeated at the end of each sprint, if there are changes to the requirements, seeing that, this can interfere with the project and the system as a whole.

PROPOSED HYBRID MODEL FOR REQUIREMENTS MANAGEMENT

With the information presented in the previous sections, a hybrid requirements management model applicable to pharmaceutical industries was obtained. The term ``hybrid`` refers to the fact that the method combines: i) application of the life cycle phases of computerized systems of ANVISA

(National Health Surveillance Agency); ii) knowledge of requirements engineering (including requirements elicitation, analysis and negotiation, documentation, verification and validation phases); iii) application of pharmaceutical validation and iv) application of Scrum. Initially, certain questions are asked and, from there, the flow follows as it was showed in figure 2:

Q1: Is the software viable and important to the organization?

Q2: Does the requesting area know the business process that the system will support?

Q3: Does the requesting area know the needs of the business process and are they confident in how the software can support these aspects?

Q4: Is the requesting area aware of the requirements engineering phases that will be applied in the system development or acquisition process, as well as the artifacts generated in these phases?

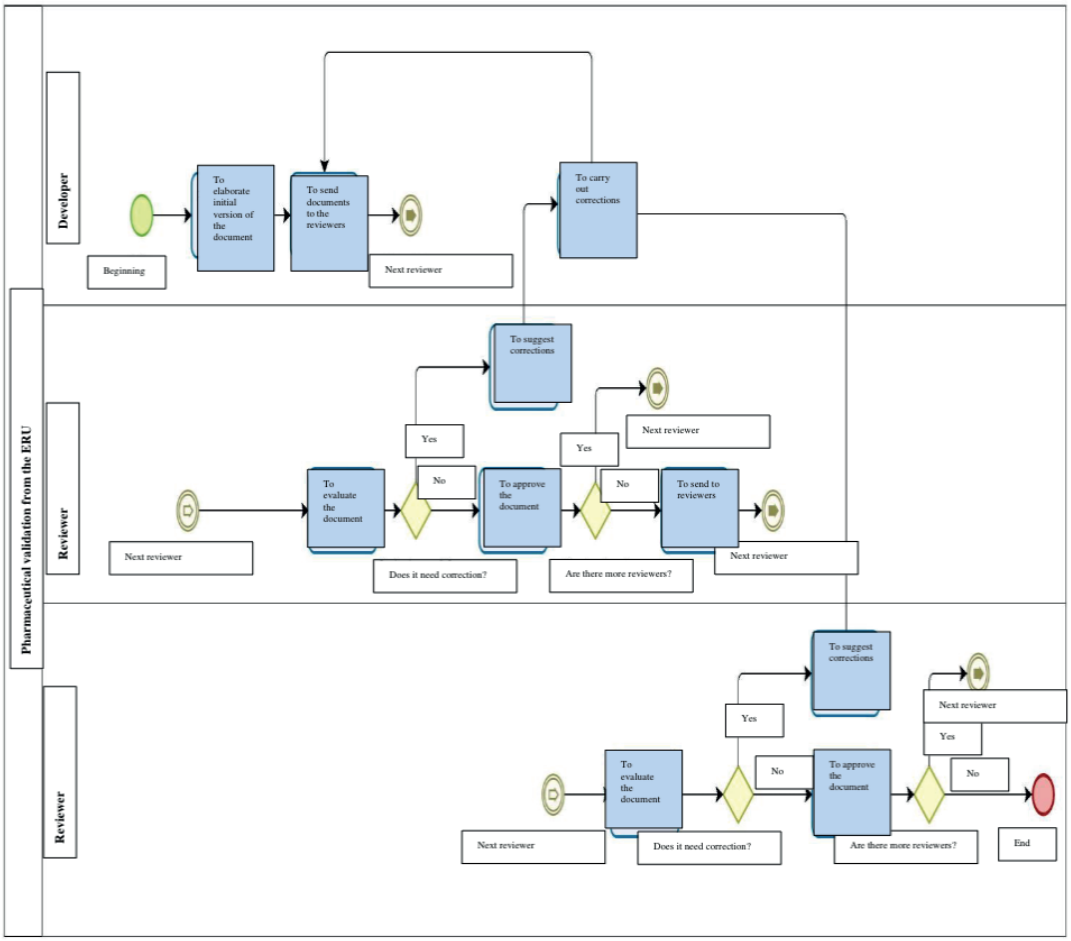

Figure 1: Pharmaceutical validation flow from the E.R.U. (specification of user requirements).

Q5: Is the requesting area aware of the life cycle phases of ANVISA (National Health Surveillance Agency) computerized systems, with special attention to the concept phase?

Q6: Are there possible impacts, direct or indirect, of the software on good manufacturing practices?

CASE STUDY AND OBTAINED RESULTS

In this case study, a system was analyzed to publish, in a transparent manner, bids and contracts processed by the purchasing, contracting and bidding sectors of a public company. A double development for this bidding system stands out. The first version was made without adopting any effective methodology for requirements management. The second one, under development, it adopted this new model. The old system presented a series of problems: i) it did not perfectly meet the needs of the demanding area; ii) the identification of members participating in the system project was compromised due to the lack of a method; iii) the system, despite not being complex, it took a long time to be developed, seeing that requirements were discovered during the development process, resulting in rework, such as database restructuring, source code refactoring and redesign of the system interface; iv) the system did not go through the impact assessment phase, nor the consequent pharmaceutical validation, seeing that, there was not E.R.U. (specification of user requirements).

The cited problems resulted in the discontinuation of the old system. The two versions of the bidding system were compared. The table number 2 shows the obtained results.

Observing table number 2, the main advances that were obtained with the new hybrid model can be analyzed: i) reduction of the chance of software failure, with interactions promoted by Scrum; ii) compliance with ANVISA (National Health Surveillance Agency) standards, with appropriate treatment of systems with an impact on good manufacturing practices; iii) guarantee of traceable artifacts for software auditing.

CONCLUSION

The hybrid model that was proposed in this document brought a unified vision for the management of requirements in the software development and acquisition process in the pharmaceutical industries, adding to the concept phase of ANVISA (National Health Surveillance Agency), the knowledge and benefits of the requirements engineering phases, in a context of applying the Scrum framework, including pharmaceutical validation from the E.R.U. (specification of user requirements).

The results that were found, they showed how much this new model has contributed to the traceability of requirements, the identification and interaction between the involved parties, the knowledge about the needs of the demanding area, the real identification of the impact on good manufacturing practices and inputs for auditing the software.

It is expected, in the near future, that other attributes will be assessed to compare the old and new bidding systems that were mentioned in the case study of this work, namely: system performance, development speed, impact on the activities of the demanding area, need for subsequent adjustments to the system and client satisfaction.

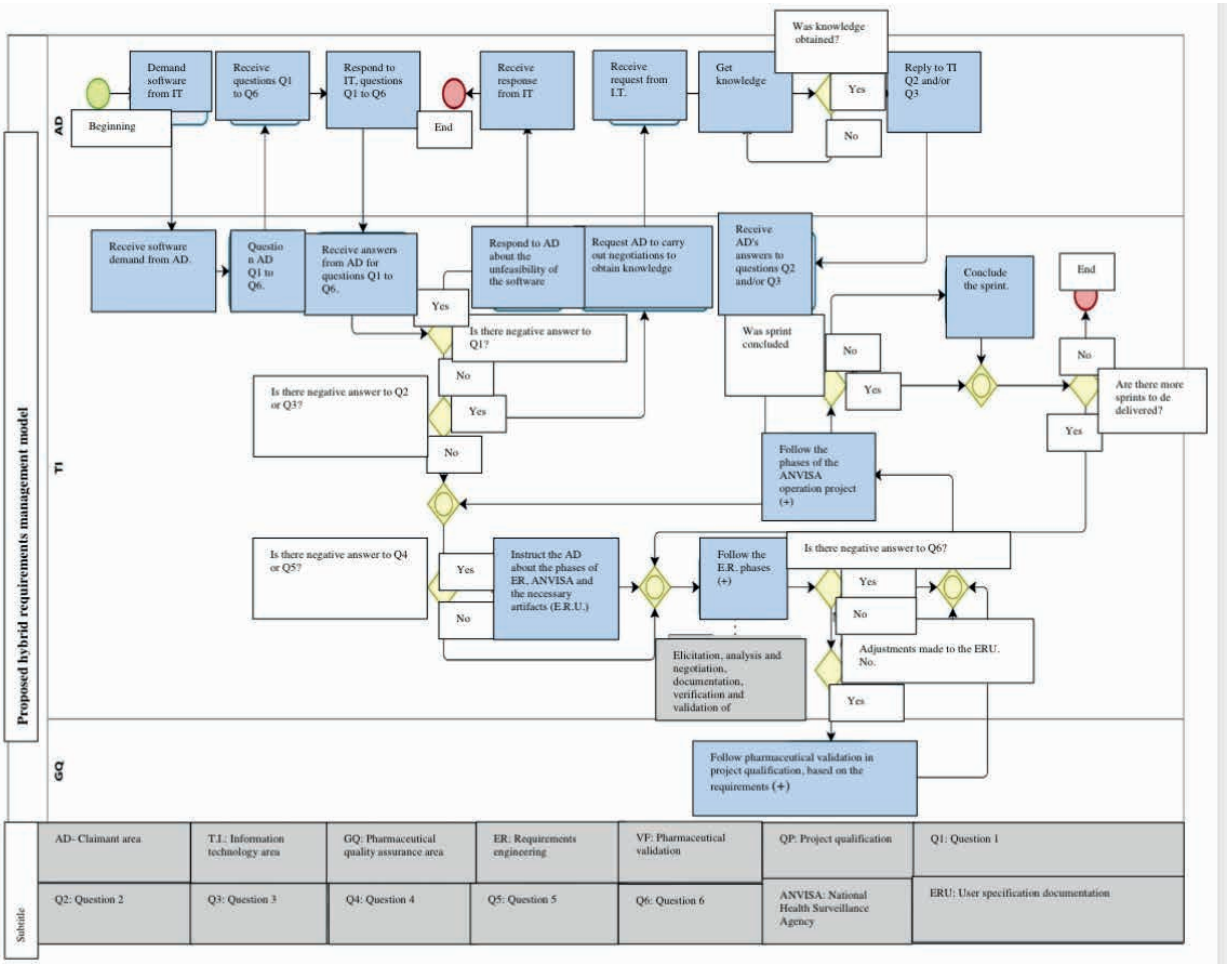

Figure 2: Proposed hybrid requirements management model.

OBTAINED RESULTS	Old Bidding System		New Bidding System	
	Answer	Comments	Answer	Comments
Application of questions (Q1 to Q6), according to section 6 of this article				
Q1	Yes	The importance was already known in the area, but without record.	Yes	The importance was already known in the area and there was a record.
Q2	Yes	The knowledge was already inherent to the area.	Yes	The knowledge was already inherent to the area.
Q3	No	Not all needs were highlighted.	Yes	The needs were visualized, through meetings, and registered in the E.R.U. (specification of user requirements).
Q4	No	There was not discussion between areas regarding the topic.	Yes	Specific meetings were held regarding the topic.
Q5	No	There was not discussion between areas regarding the topic.	Yes	Specific meetings were held regarding the topic.
Q6	No	Without registration of requirements that impact good manufacturing practices.	Yes	They were identified and registered with the E.R.U. (user requirements specification) requirements that impact on good manufacturing practices.
Evaluated attributes				
Requirements traceability	Low	There was not E.R.U. (specification of user requirements).	High	The E.R.U. (specification of user requirements) ensures traceability.
Interaction of the involved parties	Low	Not enough discussions were held between areas.	High	Scrum's iterative model enables multiple interactions.
Knowledge of the needs of the demanding area	Low	Conflicts of understanding between areas.	High	It was explored and understood between areas.
Identification of impact on good manufacturing practices	Low	Without method for identification.	High	The impacts were captured and made explicit in the E.R.U. (specification of user requirements).
Input for software audit	Low	Lack of documentation.	High	Availability of the E.R.U. (specification of user requirements.
Identification of stakeholders	Low	Lack of method for identification.	High	All were identified during the meetings.

Table 2. Results obtained in the case study.

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