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Continuously Improving IT Service Management in the Pharmaceutical Industry

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Abstract

This paper presents a case study of IT Service Management (ITSM) adoption in the highly regulated pharmaceutical sector. The outcomes in the case company included (1) the integration of regulatory requirements into ITSM workflows, (2) refining IT Infrastructure Library (ITIL) modules, and (3) establishing a comprehensive Configuration Management Database (CMDB). The project was conducted for nearly a year and started with a maturity assessment to identify areas requiring improvement. ITSM case studies in the pharmaceutical industry are scarce, and new guidelines are necessary to assist IT departments in their mission. For practitioners, this paper describes critical steps on how to assess and improve service management using the Plan-Do-Check-Act (PDCA) approach. For academics, our work identifies sector-specific compliance requirements for ITSM and a solution to address them with ITSM tools. Our approach can be crucial to IT departments operating in economic sectors with an impact on human safety. This paper provides a compelling argument for consistently refining ITSM practices, which can lead to relevant improvements in IT service quality.

Keywords: ITSM;compliance requirements;ITIL;CMDB;Easyvista;pharmaceutical.

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1. Introduction

Information technology (IT) management is increasingly challenging in today's rapidly evolving business landscape. Thus, IT departments must have a robust and efficient IT Service Management (ITSM) system. According to [31], the advances in IT practices, ITSM tools, and automation provide an opportunity to establish and maintain the qualified state of IT infrastructures. In doing so, the risk of failures in IT infrastructures can be minimized, safeguarding regulated applications and data. In the pharmaceutical industry, where compliance is paramount, ITSM significantly reduces company risk and ensures the alignment between IT and the regulatory space [20].

The IT Infrastructure Library (ITIL) provides a comprehensive framework of best practices for ITSM [29]. However, as industries and regulatory requirements evolve, IT departments must adapt their ITSM practices to remain relevant in supporting digitized organizational strategies. According to [17], data integrity in computerized systems is indispensable. The non-compliance of systems may arise from various factors, such as duplicate or incomplete data or a lack of documentation during the reintroduction of systems involved in product quality.

Our work started after some contacts with a leading pharmaceutical company in Portugal. Their IT department put ITSM at the top of their priorities, and their recent investments in the Easyvista ITSM tool required a strategy to increase the maturity of their IT service practices. Compliance with multiple regulations and the shortcoming of detailed examples of continuous ITSM improvement were additional motivations for a new research project. Our study explores how the IT department achieved its objectives by incorporating regulatory requirements into service management workflows and refining various ITIL modules (e.g., Change Management or Incident Management).

The remainder of this paper is structured as follows. Section 2 overviews relevant concepts like ITSM and ITIL, Configuration Management Database (CMDB), and process maturity assessment models. The continuous improvement methodology follows, and Section 4 details de assessment made in the case company. Subsequently, section 5 presents the improvement plan, discussing the main results achieved. The paper concludes in section 6, presenting the main limitations and opportunities for future work.

2. Background

2.1. Information Technology Service Management

ITSM is a subfield of IT management that encompasses all activities related to an organization's IT, from incident resolution to implementation and management of operations involving software and hardware [5]. Several frameworks have been designed to articulate best practices in supporting IT services [10]. These frameworks aim to provide a structured approach to managing IT services by guiding how to combine technology, processes, and human resources in the most effective way possible. Thus, using an ITSM framework provides numerous benefits, such as employing recommended practices and pre-defined standardized processes, providing a structure and guidance for IT, reducing risks, and improving operational efficiency.

There is a shortcoming of studies about the prevalence of different IT management frameworks. However, some frameworks are more popular than others, such as ITIL, which, according to [3], is the most adopted framework worldwide, along with COBIT (Control Objectives for Information and Related Technology) and the enhanced Telecom Operations Map (eTOM). Each framework has a distinct emphasis on different aspects of IT management [25]. For instance, ITIL focuses on practices and processes, guiding good IT service management. Conversely, the COBIT framework is designed to assist organizations in organizing, developing, and implementing strategies related to the governance and alignment of their objectives with IT. At the same time, the eTOM emerged to address the unique needs of the telecommunications industry and is based on a three-level process model.

ITIL has gained its place in service management, particularly in highly regulated sectors like banking or pharmaceutical. This framework outlines the best practices to facilitate delivering high-quality IT services at a justifiable cost [13]. Adopting ITIL-based implementation yields several benefits, including service quality and operational efficiency improvement, alignment between the business and IT, reduced system downtime, increased automation and customer satisfaction, and enhanced decision-making about IT resources [6., 9., 19]. Nevertheless, the practices described in ITIL need to be adapted according to individual realities [29], and creating a configuration management database is a critical step in the process.

2.2 Configuration Management Database

In ITIL, the CMDB serves as a repository for critical information related to the components of an information system and their interconnections [18]. These components, referred to as configuration Items (CIs), encompass all service assets that require management within an organization, such as servers, software, licenses, and documentation [30]. Four distinct approaches can be employed when implementing a CMDB [22]: the *Top-Down*, when the analysis is initiated by identifying the most critical services for the company's functioning, and subsequently, essential elements in delivering those services are defined; *Bottom-Up*, by cataloging all the devices and applications in the organization's infrastructure; *Iterative*, characterized by a loosely defined plan that solidifies as requirements become more demanding, with an increasing level of detail and implementation strategy; and *Ad-hoc*, making implementation decisions on an as-needed basis as project requirements arise.

Some works (e.g., [4]) concluded that the Top-Down approach is usually the most suitable. This is due to its lower cost and reduced allocation of effort and resources while still considering important factors such as time allocation, management commitment, and employee knowledge [7]. Nevertheless, the work of [4] indicated that the Top-Down provided advantages to organizations in the initial stages of the project, and many companies with successful CMDB implementations adopted the Bottom-Up methodology as part of a long-term implementation strategy. Therefore, the choice between the Top-Down or Bottom-Up methodology will depend on the characteristics and needs of the organization in question. It is essential to emphasize that there are other crucial steps. [16] propose a plan consisting of five stages to optimize the CMDB implementation: defining objectives, assigning responsibilities, selecting the appropriate approach, defining content, and filling the CMDB. A brief overview of relevant service life stages for continuous improvement (transition and operation) is subsequently presented.

2.3 Service Transition

The Service Transition ensures that the service can operate under abnormal circumstances and that support for failures or errors is available [30]. It aims to maximize the business value of the organization's services, manage risks, and manage knowledge to support decision-making. In this phase, key processes to be improved are Change Management (CM), Service Asset and Configuration Management (SACM), and Knowledge Management (KM).

According to [30], a change is defined as the addition, modification, or removal of any service or component that may affect IT services. The objective of the Change Management process is to ensure that all changes are recorded and evaluated, minimizing the risk exposure and ensuring the success of implementation. Changes must be properly documented, prioritized, and tested to achieve this. Change management involves a formal Request for Change (RFC). To avoid bureaucratic approaches for insignificant changes, each may require different RFCs. Therefore, three types of changes are recommended [15, 27]: *Standard Changes*, which are pre-authorized changes with well-defined procedures and low and understood risks; *Normal Changes*, which follow specific flows according to each organization's requirements; and *Emergency Changes*, which require rapid implementations to solve critical incidents or security corrective measures, with a specific procedure for their treatment.

The Service Asset and Configuration Management processes aim to define service and infrastructure components and maintain accurate configuration records. This involves ensuring the identification, control, and reporting of all assets and configuration items and maintaining integrity with accurate information about their current, past, and future state [15, 27]. Finally, the Knowledge Management process aims to enhance management decision-making by ensuring that secure, reliable, and adequate information is accessible to employees throughout the service lifecycle. With efficient KM, information is shared, enabling informed decisions, reducing the risk of errors, unnecessary inquiries, and redundant work [15, 27].

2.4 Service Operation

The Service Operation phase represents a critical stage where organizations receive feedback on various aspects of their services. During this phase, a balance must be struck between the daily management of services and a holistic approach to their overall context. In addition to the ongoing management of activities, we highlight two important processes for this stage [28]:

- The Service Request (SR) process manages the lifecycle of all service requests from users. This process aims

to maintain user satisfaction and a positive perception of IT through efficient and professional handling of service requests. This process also plays a crucial role in assisting and receiving complaints or comments and provides information on the availability of services and the procedures to request them[28].

- The Incident Management (IM) manages the lifecycle of an incident with a focus on promptly restoring the affected service. In ITIL, an incident is characterized as an unplanned interruption, a failure that has not yet impacted the IT service, or a reduced quality of an IT service.

2.5 Process Maturity Framework

There are methods available for measuring the current maturity level of a particular area of an organization, enabling stakeholders to identify strengths and areas for improvement [24]. Adopting a maturity model allows the organization to evaluate its methods and processes according to best management practices, following a set of defined parameters [12]. There are various maturity models available to improve organizational processes. However, the ITIL framework offers a proprietary model called the Process Maturity Framework [26]. The PMF defines five levels [30]:

- Level 1 (Initial) - The process has been recognized, but there is little or no process management activity, and it is not given importance, resources, or focus within the organization.
- Level 2 (Repeatable) - The process has been recognized but is not yet correctly valued, lacking sufficient resources. Some activities may be carried out disorganizedly, without a clear strategy.
- Level 3 (Defined) - The process is recognized and documented, but there is no formal agreement or recognition of its functions within the operations of the IT department. On the other hand, the process has a process owner, formal objectives, and goals with allocated resources focused on the efficiency and effectiveness of the process. Reports and results are stored for future reference.
- Level 4 (Managed) - The IT department widely recognizes and accepts the process in question. With a clear purpose in service, its objectives and goals are aligned with the business. Fully defined and managed, the process is proactive with documented interfaces, enabling effective management and performance analysis.
- Level 5 (Optimized) - The process is widely recognized. It has strategic objectives and goals aligned with business and IT strategic objectives, establishing itself as an institutionalized daily activity for all involved in the process. A self-contained continuous improvement process exists, covering preventive practices.

The definition of each maturity level stems from an assessment relative to the five dimensions of (1) Vision and Direction - Overall direction of the position of IT within the organization, (2) Process - Procedures necessary to achieve the objectives, (3) People - Competencies and skills, (4) Technology - The existing support infrastructure, and (5) Culture - Attitudes required about IT within the organization.

3 Methodology

The Plan-Do-Check-Act (PDCA) was created in 1939 by Walter Shewhart and later modified by W. Edwards Deming, also known as the Deming cycle [21]. It is a popular approach for continuous improvements, including standards like ISO 9001, and suggests a cyclic nature. The PDCA is also a framework used for continuous improvement in the IT Service Management domain as specified in the ITIL Continual Service Improvement (CSI) stage. The case company divided its ITSM improvement into three sub-mini projects: (1) CMDB implementation, (2) Analysis and improvement of current ITIL practices, and (3) Incorporation of regulatory requirements into workflows.

The first step of our project was to analyze the maturity of the ITIL processes to be improved using the PMF framework. Areas requiring greater attention and investment were identified, enabling the planning of pertinent and targeted improvements to the implementation. A questionnaire [2] was developed to evaluate the requirements of each maturity level in each process, following a methodology similar to the one used by the authors [1] and [8]. Each questionnaire (one for each ITIL process) comprises 58 questions divided according to the maturity level and dimension to be evaluated. For each question, five response options are presented: agree - 5 points, partially agree - 4 points, neutral - 3 points, partially disagree - 2 points, and disagree - 1 point. The ITSM Easyvista coordinator and other IT team members completed the questionnaire. Next, a comprehensive ISTM improvement plan was implemented in the case company, providing an example suitable to highly regulated contexts.

4 Results

4.1 Assessing ITIL (Launching the PDCA)

The maturity levels for each of the processes are presented in Figure 1.

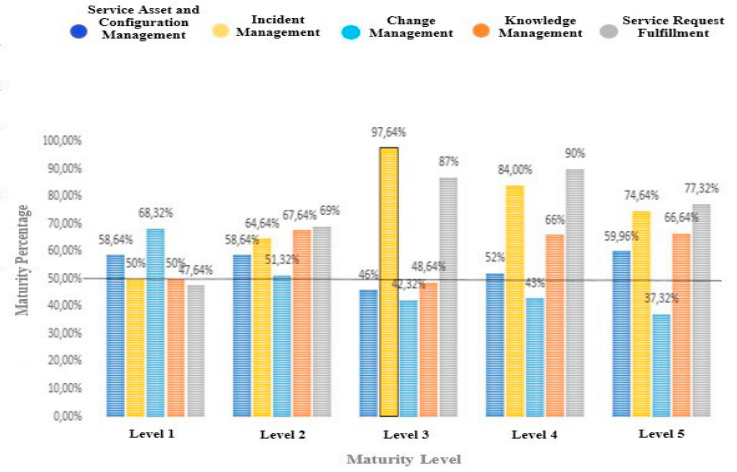

Fig. 1. Results of the Maturity Assessment

Each process being evaluated simultaneously exhibits characteristics of various maturity levels. For example, a process with a high percentage of "level 3" best practices (e.g., Incident Management) may still possess practices from level two or level one of maturity. Therefore, when we state that a process is at level 3 of maturity, we want to emphasize that most activities related to that process correspond to level 3. The analysis of Fig. 1 shows that the Incident Management process presents evidence of practices corresponding to level three of maturity, with levels four and five above average. These results suggest that the respondents consider this process to have well-structured procedures for dealing with incidents, as well as some practices for having well-defined documentation, constant proactive activities to prevent the emergence of new incidents, and an understanding of the alignment of IT practices with business practices. In this setting, the Service Request process presents the most significant evidence of level four and five maturities (bar in grey), reflecting its status as the most developed process.

Regarding the SACM and KM processes, the percentages of the maturity levels are scattered across various tiers, not fitting into a specific position. This inconsistency suggests that the IT team has well-defined practices at higher maturity levels, but there is a gap in more basic practices that should be anchored in the process. This is due to the recent implementation of the ITSM platform. However, due to recent changes with the implementation of this system, the small size of the IT team, and limited knowledge of ITIL best practices, some essential activities of the process have been neglected, such as updating inventories or registering all service assets. Finally, the maturity level of the Change Management Process manifests a higher percentage of level 1 (Initial) practices, thereby implying a lack of documentation and definition in this domain. Nevertheless, a few activities are perceptible in the remaining maturity levels, which arise from the already implemented automation of change requests through workflows on the platform and using specific performance indicators for the tickets associated with this process.

We found that the PMF framework facilitates the assignment of a maturity score to the evaluated processes and enables a more in-depth analysis of each one. Figure 2 illustrates these dimensions and their individual scores.

	Vision and steering	Process	People	Technology	Culture	Level Average
Level 1	2,75	4,33	4	4	2	3,416
Level 2	3,75	3,33	1	3	2	2,566
Level 3	1,75	2	2,3	2,5	2	2,116
Level 4	2,75	2,5	2,5	1	2	2,15
Level 5	2,33	1	2	2	2	1,866

Fig. 2. Change Management individual maturity assessment

The results presented in Fig. 2 show that the CM process has an initial maturity level. However, it is worth noting that the different dimensions of this process do not carry the same weight in the distribution of the results. It can be observed, for instance, that the practices related to vision and steering, which encompass the formal objectives of the process, the development of reports, and the planning of activities, have more characteristics of level 2 (Repeatable). This analysis allows for identifying areas that may be negatively impacting the process performance. To achieve a maturity level of 2, it will be necessary to investigate the causes of process irregularities, unplanned activities, or the lack of a clear definition of roles and responsibilities.

4.2 Continuous Improving ITSM (Do)

Drawing on the knowledge gained from analogous individual analysis for the rest of the processes, the interviews with the ITSM platform coordinator, and the observations of the practices implemented, a comprehensive assessment of the diverse processes in place has been conducted, revealing the following aspects, that the members of the IT department found relevant for implementation:

- Complete change management record keeping.
- Inventory updates and maintenance.
- Impact analysis.
- Rollback plan.
- Incorporation of different levels of urgency for change requests (Standard change does not involve GMP processes and does not affect the quality of the final product; Normal change affects GMP processes and may impact the product. As a result, a set of regulatory checks is required for software or infrastructure applications; and an Urgent Change that needs to replace or modify the asset in question urgently.
- Elimination of unauthorized changes.
- Restructuring of change catalogs.

Updating the IT inventories was an essential prerequisite for initiating the CMDB implementation. To follow the methodologies proposed by [16] and [27], the first step defines the objectives for CMDB implementation. Firstly, implementing the CMDB was needed to establish relationships between different databases and software to easily identify the impact of incidents and changes. Secondly, the CMDB possesses a low level of granularity, although the CIs related to production, quality, logistics, serialization, planning, and qualified systems must be detailed. Thirdly, the final solution allows for the update of the CMDB through workflows. Fourthly, the expected mid/long-term benefits of implementing the CMDB include quick risk assessment of a change, identification of the cause of an incident, and the ability to assess the architecture of systems to search for and eliminate data redundancy and scalability possibilities. Moreover, the users are able to search the CMDB dependencies, configurations, and technical documentation. The major challenges for the CMDB are the definition of responsibilities and the continuous update.

4.3 Assessing the Regulatory Space (Check)

During this project phase, the identification of regulatory requirements applicable to the regularization of computerized systems in the pharmaceutical industry was performed. To achieve this goal, a thorough analysis of the topics contained in Annex 11 of the Eudralex [11] was carried out, which gathered guidelines related to the quality and safety of medicinal products for human use in the European Union (EU). Furthermore, an analysis of the GAMP5 (Guideline for Good Automated Manufacturing Practice) [14] was performed. GAMP5 contains a set of guidelines and recommendations for the development, implementation, and maintenance of automated drug manufacturing systems. It serves as a guide for the pharmaceutical industry, assisting companies in meeting regulatory requirements and ensuring the quality and safety of the drugs produced. GAMP5 is widely used worldwide and is a vital reference for pharmaceutical companies wishing to comply with regulatory requirements in the market [31].

Through a detailed analysis of hundreds of lines and topics in the various qualifications previously carried out in the company and regulatory recommendations from Eudralex and GAMP5 documents, it was possible to group different regulatory requirements under the same general theme for ITSM. For example, the requirements "The system must have detailed, and up-to-date user manuals for all functionalities available to end-users" and "Technical documentation must include, at a minimum, database schemas, API specifications, and source code documentation"

can be included under the documentation theme, which allows workflows to involve multiple departments in the organization (e.g., IT and quality departments). Similarly, other requirements and guidelines were grouped into nine general themes to facilitate the regulatory compliance assurance of changes or implementations through the ITSM:

- Validation: The system (in this case, the Easyvista platform) must be validated to ensure it meets the specified requirements and functions consistently and reliably. Involves tests in a controlled environment.
- Data Integrity: The system must ensure the quality of the data used or generated by it. This may involve creating procedures to manage and protect the data in the company, ensuring that the entered information is accurate and complete, implementing measures to verify data reading, or access control to authorized users.
- Documentation: The IT system must contain documentation to facilitate the audit of detailed information related to the systems, such as configuration guides, user manuals, service level agreements), or tests.
- Maintenance: The system must ensure that there are regular updates as well as updating the change log to ensure that the system and corresponding inventories are up to date and functioning normally.
- Audit trail: There must be a change control that allows submitting changes to a review process and recording the changes made in the system, as well as who made the changes, and for changes involving GMP processes that are not urgent, analyzing possible risks and recovery plans.
- Data Backup: The system must ensure that data backup will exist to prevent the system from failing. A backup verification must be performed in case of a change to an existing system.
- Performance Monitoring: The system must allow analyzing and visualizing data to check the system's performance and identify potential issues.
- User Functions and Permissions: The system must allow assigning permissions to users to determine which actions can be carried out in the system.
- User Authentication: There must be user authentication through the use of credentials.

PDCA involves a cyclic approach to improvement. Based on the regulatory analysis, ten additional requirements were identified to be incorporated into the ITSM tool (restarting the P-Plan cycle after acting to ensure compliance): Verification of data integrity after a change; Continuous updating of technical documentation; Registration of the responsible party for the change; Verification of the security level of the modified equipment; Verification of backups after a change; Storage of documentation on the platform; Updating and maintenance of inventories; Complete registration of changes; Rollback plan; and Elimination of unauthorized changes. Notably, most of these requirements are aligned with the pharmaceutical industry regulations, revealing the importance of adopting ITIL in the sector.

According to the experts contacted during our research, the tailored PDCA approach with maturity assessment and regulatory analysis to support future audits was considered suitable for the pharmaceutical industry. The approach requires close contact between the IT department and quality assessors to ensure continuous improvement. Notwithstanding the analysis of relevant segments of the service lifecycle, prioritization, definition of actions, and compliance requirements, the approach evolves iteratively, and it is interesting to repeat maturity assessment regularly.

5 Conclusion

This paper presented a case study of ITSM improvement in the pharmaceutical industry. The results include the adoption of a maturity model to assess the company and deploy PDCA cycles to (1) plan the ITSM strategy of the department, (2) execute the refinement of ITIL modules and the CMDB, (3) check the regulatory requirements and incorporate them into ITSM workflows. Moreover, our work points to relevant regulations and validation procedures and explains priorities to IT departments operating in highly demanding and regulated sectors of the economy.

There are important limitations that must be recognized. First, this is a single case study of a company already adopting ITIL but requiring to move to the next stage: continuously improving ITSM. Therefore, the steps used in our research (maturity assessment, PDCA iterations) may be transferable to other contexts, but ITIL priorities may vary according to the company or economy sector. Second, our analysis did not consider the end users of the organization. On the one hand, focusing the case in the IT department allowed us to collect information from experts and decision-makers. On the other hand, it was not possible to gather feedback from the service users. Finally, we adopted a specific set of regulations suitable for our case company to check the ITSM adoption and restart the cycle of improvements. Each sector of the economy has particular regulations that must be addressed. Engaging and obtaining buy-in from stakeholders is also a challenge. Stakeholder resistance and conflicting interests can hinder progress. The project team

is addressing these challenges through effective communication, stakeholder involvement, and conflict resolution to enhance the credibility and relevance of the proposed solution.

Besides the opportunities to explore ITSM improvements in other economic sectors, addressing the limitations stated, future work is necessary to propose key performance indicators that may be used to evaluate improvements over time. Moreover, our work aims to ensure compliance, which is a distinct focus compared to authors like [23] addressing lean ITSM. It was interesting to integrate different ITSM improvement approaches in the future.

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