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# Acronyms

CCC – Command and Control Centre;

DMAIC – define, measure, analyze, improve, control;

ISO – international standards organization;

IT – information technologies;

PPDR – public protection and disaster relief;

R&D – research and development;

SIPOC – suppliers, inputs, processes, outputs, customers;

SMART – specific, measurable, achievable, relevant, time-bound.



# Abstract

Quality is essential both for products and processes. In addition to lowering the probability of failure, quality guarantees the satisfaction of customers and their willingness to use the company's services again, in the future.

To achieve that level of quality, it is necessary to have the mechanisms in place to assure that the processes are effective and efficient and that the product has all the necessary features and performs well under every circumstance.

This becomes even more imperative in safety critical systems, that have lives depending on it. The platform which is the object of study in this thesis, Mobitrust, will be used in emergency situations where lives and property are at stake. Therefore, any failure can have disastrous consequences.

With that in mind, the goal of this internship is to assure that the platform, Mobitrust, has quality, by implementing quality of product and quality of processes. To do so, in addition to producing the documentation related to the project, to assure the quality of the platform, the work includes specifying and implementing a quality methodology considered to be the most adequate to improve the quality of processes related to the Mobitrust platform. This last part, improving the quality of processes, means establish the necessary steps to assure compliance with quality standards of the methodology chosen.

The methodology proposed in this thesis combines the drawing up the project documentation (requirements specification, risk analysis, architecture and design and test plan) with ISO 9000 standards (focussing on ISO 9001) to assure that Mobitrust meets the quality requirements for Public Protection and Disaster Relief (PPDR) markets.

## **Key words:**

Quality, ISO 9000, Agile, safety-critical, project documentation



# Resumo

Num projeto de software é essencial ter qualidade, tanto nos produtos como nos processos. Para além de diminuir a probabilidade de falhas, a qualidade garante a satisfação dos clientes e faz com que estejam mais abertos a voltar a contratar os serviços da empresa no futuro.

Atingir esse nível de qualidade implica por em prática os mecanismos que asseguram que os processos são efetivos e eficientes e que os produtos têm todas as funcionalidades implementadas. Para além disso, os produtos têm de ter bom desempenho, sejam quais forem as circunstâncias.

Isto torna-se ainda mais crucial quando há vidas que dependem do bom funcionamento do sistema, como é o caso dos sistemas críticos de segurança. A plataforma que vai ser objeto de estudo neste relatório, Mobitrust, vai ser usada em situações de emergência, em que há vidas em risco. Por isso, qualquer falha do sistema pode ter consequências desastrosas.

Assim sendo, o objetivo deste estágio será assegurar a qualidade da plataforma em estudo, Mobitrust, através da implementação de metodologias que aumentam a qualidade de processos e de produtos. Para isso, para além da produção de documentos relacionados com o projeto, que garantem a qualidade da plataforma, o trabalho inclui especificar e implementar a metodologia de qualidade considerada mais adequada para melhorar a qualidade dos processos relacionados com o projeto. A segunda parte, melhorar a qualidade dos processos relacionados com o projeto, significa descrever os passos necessários para assegurar conformidade com os padrões de qualidade da metodologia escolhida.

A metodologia proposta neste relatório combina a escrita da documentação do projeto (especificação de requisitos, análise de riscos, arquitetura e design e plano de testes) com os padrões ISO 9000 (focando-se no ISO 9001) para assegurar que o Mobitrust tem a qualidade requerida em sistemas críticos de segurança que serão usados em situações de emergência pelas entidades competentes.

## **Palavras-chave:**

Qualidade, ISO 9000, Agile, sistemas críticos de segurança, documentação de projetos

# 1. Introduction

Quality is essential in any software project, since it is the best way of standing out in the face of competition and get profit to the enterprises, by keeping customers satisfied. Quality leads to safety and becomes even more crucial when building safety critical systems, where failure can lead to dramatic consequences for the environment, for equipment and property or, in the worst-case scenario, for people.

To achieve that aim, it is necessary to have a quality management system in place to guarantee that both the processes and the products have the necessary quality. The goal of this system, despite of what many might think, is not just to find defects in the code, but also to assure that the product fulfils the costumers' wants and needs and to assure efficient processes in the development of software solutions (e.g. quality of code, testing procedures).

The specification of a quality management system includes two main parts: the quality methodology and the quality of product. The quality methodology aims to enhance the quality of processes, using a cycle of continuous improvement. This cycle, in the beginning of each iteration, evaluates the current state of the process quality, and makes educated guesses on what and how to improve. The quality of product includes not only the tests, but also the documenting of functional and non-functional requirements, architectural decisions and reviews of documents and code produced.

The biggest challenge, after understanding how to implement a quality management system, will be its coexistence with the Agile life cycle, that will be used in the development of the platform. Agile is divided in small steps called iterations, after each there is an advance in the project, such as the addition of a new feature. This life cycle embraces frequent changes, since the requirements are only valid for the current iteration and are constantly updated. This poses as a difficulty when using quality methodologies, because of the antithesis of constant changes embraced by Agile and rigid structure of any quality methodology.

Taking all of that into account, the internship consisted of choosing the quality methodology that best applies to Mobitrust, by comparing the most used quality methodologies and researching the required steps to implement it. After choosing ISO 9000, the documentation necessary to comply with this methodology was produced, as well as the documentation related to the project, that aims to assure quality of product.

This report will start by presenting the company, the project and the internship goals, and discussing the definition of quality. After that, the most relevant quality methodologies will

be introduced and compared, as a way of supporting the choice of ISO 9000 as the methodology to be used in this project. Then, the requirements for the chosen methodology and its coexistence with the Agile life cycle will be discussed and the work done towards ISO 9000 compliance will be explained. Documentation of the project and data protection will also be scrutinized, not only by presenting them and discussing its importance, but also by describing the work accomplished in these areas. Finally, the conclusions and future work, will be presented.

## *1.1. OneSource*

The internship took place at OneSource, Consultoria Informática Lda. This is a company that provides several services related to the IT area, such as auditing, consulting and network administration.

The consulting and auditing services provided by the company are focused on security (namely backup, recovery and data privacy and protection), Networking and information technology (IT) Infrastructures (namely forensics and on-field surveys) and information systems (namely planning and integration of information systems).

OneSource is also responsible for the planning, deployment and monitoring of networks, some of them with thousands of users, that are configured to fit the customers' needs.

Finally, the company is involved in some Research and Development (R&D) projects, in which platforms are custom-tailored with the purpose of supporting telecommunications, health or e-government systems, for instance.

## *1.2. Mobitrust*

Mobitrust is a platform designed to support the work of Public Protection and Disaster Relief (PPDR) entities, such as firefighters, police, military, amongst others.

One of the main concerns during an emergency is having a communication system that is fast, effective and secure between all the agents involved in a mission. This platform will provide means of communication to suppress those needs, that include voice, text and small

files. It will also include a panic button, for emergency situations where the person is incapable of verbally asking for help. The quality of these communications is of the utmost importance because unlike many communication systems miscommunication can have disastrous consequences.

In addition, it will facilitate the management of people and assets and their assignment to missions. For this, it is possible to consider the availability and the proximity to the place where the emergency is occurring to make allocation choices. Having all the information stored in the same place will make it easier to access the necessary data and use it to make informed decisions about the assignments to missions.

Users on the field will have their biometric parameters measured by sensors. When the values read by the sensors are not in the expected defined interval (set previously to the mission), an alert is generated to send immediate help to the user in distress. This will fasten the request for help, since the system registers the anomalies that may be life threatening before they have severe consequences. Also, it will allow the detection of problematic situations where the person is not conscious and, therefore, incapable of asking for help and act accordingly.

To avoid accesses by unauthorized users, if a device is lost or stolen, it is immediately locked and wiped, to prevent any unlawful access to classified information or system tampering (by changing information or sending misleading messages).

As it can be seen in the image bellow (Figure 1), the system is divided in three parts:

- **The sensors**, that measure biometric and environmental parameters;
- **The terminal**, that corresponds to the smartphone used by operators on the field to communicate and access the information being broadcasted;
- **The Command and Control Centre (CCC)**, that is used by operators of the control centre to perform the managing tasks, command the ongoing missions, receive alerts (so the operators can act accordingly) and to perform the wipe and lock actions (if they are needed).



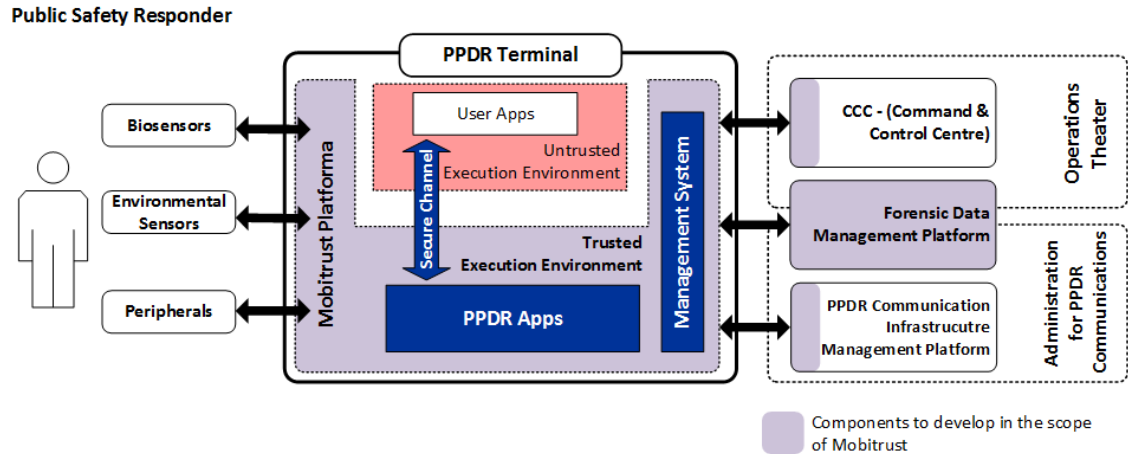


Figure 1 - General Overview of Mobitrust.

Mobitrust has to be highly adaptable, because it is going to be used in distinct scenarios, each with different requirements. For instance, the work done by firefighters is not exactly the same as the one done by the police and putting out fires does not have the same requirements as rescuing someone. That being, the platform has to be adjustable as possible to each scenario.

Given not only the features of the system (that make it safety critical), but also the storage of sensitive data (personal and medical), it becomes obvious the importance and necessity of quality assurance mechanisms.

### 1.3. Defining quality

Given that the goal of the work done during the internship was to achieve process and product quality, it is important to start by defining what is meant by quality. However, the definition of quality does not have a consensus among the researchers and quality professionals so, some of the existing definitions will be discussed in this section.

To start, quality in software is often understood as the absence of defects. This is a utopian train of thought, since it is impossible to completely test systems and find and correct all defects.

Philip Crosby sees quality as the “conformance to requirements” [1, 2]. Even though this is a necessary part of quality, this definition is far from encompassing the true meaning of quality. Furthermore, if we consider that the requirements can also have defects (for instance, be wrong, incomplete, incorrect or ambiguous), a project that conforms to requirements may not have good quality.

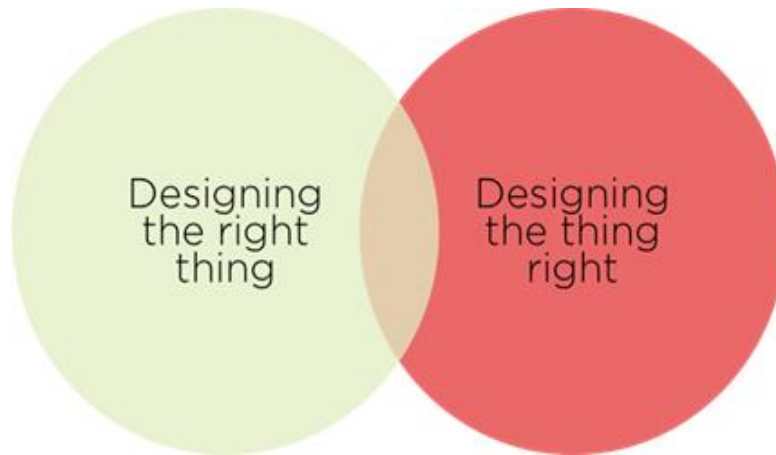
Another definition is based on the company’s main goal, which is to achieve customer satisfaction. Hence, a measure of quality can be “delighting the customer by fully meeting their needs and expectations” [3], meaning that the product should be what the customer wants and really needs.

This leads us to the “build the right thing; build the thing right” [4] philosophy. The first part, “build the right thing”, is what was defined above as quality, meaning it is provided to the client what he has required and really needs. The last part, “build the thing right”, is what was missing in this definition: have the appropriate processes, documentation and efficient resources management.

In addition to having a quality product, it is important to have quality in the processes that lead to that product. In fact, since this results in smaller costs, less resources and faster deliveries (especially because there is less rework), we must consider both product and process to define quality. That being, we can think of quality as “building the right thing and building the thing right” [4]. This last definition of quality, that embraces both quality of processes and quality of product, is the one that was used in this internship.

Anchored by this definition of quality and the idea of continuous improvement (followed by most of the quality methodologies), we are driven to the discussion of the possibility of achieving quality. The truth is that quality can be considered a spectrum rather than an aimed final target and all that can be done is getting closer and closer to higher standards quality, by evaluating and improving processes and products.

Framed by this theoretical stream, the actions taken towards quality will involve applying quality methodologies (that are mostly concerned with process quality) and project documentation (that assures monitorization and subsequent improvement actions leading towards optimization of product quality).



*Figure 2 - Definition of quality [5].*

In this report, the most used and well-known quality methodologies will be described and compared. Afterwards, the choice of ISO 9000 series as the quality methodology to be used in Mobitrust will be explained. Later on, the project documentation will be discussed, as well as its role in the overall quality.

## **1.4. Goals**

In this internship, the main goal was to create the necessary mechanisms to assure that Mobitrust had the expected quality. That way, the risk of failure is lower, which is of the utmost importance, since there are lives depending on this platform.

With that in mind, a quality methodology was used as a way of guaranteeing the quality in the processes. That is, the platform was built in a controlled way, by capable people that use the resources in an efficient way.

Documents describing the platform, the risks and the test plan lead to product quality. This assured that the product had the necessary features and had a low probability of failing unexpectedly. The performance requirements were also be verified.

In the end of the internship a quality management system had to be designed, which implied:

- **The definition of a quality methodology**, capable of guaranteeing quality of processes for a safety critical system, without compromising the use of an Agile methodology;
- **Implementing that methodology**, by following the necessary steps and producing the necessary documentation;
- **Implementing quality of product**, for a safety critical system to be used in emergency situation, by creating the documentation related to the platform.

## *1.5. Work process*

The beginning of the internship consisted in getting to know the project and the technologies involved. This involved meetings to demonstrate and discuss the prototype that had already been built and researching the state of art for communication in emergency situations and the technologies used in the prototype.

After that, the actual work towards quality started, with the writing of the requirements specification document and, later on, the research of quality methodologies to improve the quality of processes. Finally, the other documents related to the project were written, alongside the documents related to the ISO 9000 methodology.

The intermediate report and the present report were written in the end of each semester, as a way of presenting the work that was done.

Most of these tasks were independent from the work of other team members, but there were several meetings that not only had an important role in the understanding of the project, but also were also the basis of the knowledge to write the project documentation.



## 2. Quality methodologies

In this section some of the most popular quality methodologies will be presented and compared. To do this comparison, some criteria that are relevant in the context of the project will be used:

- **Widely used:** It is important that the methodology is widely used to assure that it is recognised by others, namely by clients that require a quality certification. This also mean that it has not been overshadowed by a better methodology;
- **Has improvement measures:** It is necessary to identify the areas that need to be improved, but that is pointless if there are not measures to accomplish that improvement;
- **Time frame:** Not only because of the tight schedule of the process, but also because of a life cycle that depends on small iteration (Agile), it is important to have fast results;
- **Output:** The output should result in an improvement of quality;
- **Focus on client satisfaction:** Since what makes a company sustainable is having clients, it is important to keep them satisfied, so they will use the services of the company again and recommend it to other people;
- **Scope:** The scope of the quality management system should comprehend at least most of the areas of the company.

By the implementation one of the quality methodologies, the aim is to achieve quality of processes through continuous improvement. This means that is followed a cycle that evaluates the current processes and introduces changes where they are most needed.

Although this is essential to achieve quality, as it was shown in the previous section, this is only one part of the quality system, since it only focus in the processes and has little influence in product quality.

The information delivered here grounds the choice of the methodology to be used in this project, as a way of guaranteeing process quality.

## *2.1. Total Quality Management*

Total Quality Management is a management approach whose main target is customer satisfaction. It consists of a set of techniques that aim to continuously improve the processes based on the measurement and analysis of the current performance data and the identification of the main areas that need to be improved. To do that identification, a set of techniques (not included in Total Quality Management) have to be used, so this methodology can then be applied to the identified areas. The goal is to make sure that customer requirements are consistently met or exceeded [6].

In addition to that, this methodology tries to assure effective communications between all the parts, both inside and outside the company, by involving everyone in the quality management process. This means not only making sure everyone is aware of their role in the quality management system, but also getting feedback to identify the aspects that need improvement.

The output of Total Quality Management is not documentation (which may not even be produced), but the improvement of quality in the process itself and reaching the best possible outcome. This methodology focuses on the long haul, instead of the immediate results, which means that it may take some time before the effects of this methodology are visible [7].

Although Total Quality Management is very comprehensive, embracing all aspects of an organization, it has been overshadowed by Six Sigma and Lean Manufacturing (that evolved to Lean Six Sigma) in the last few years [8].

## 2.2. *Lean Six Sigma*

Lean Six Sigma is a combination of two methods, Lean Manufacturing and Six Sigma which complement each other create to improve the effectiveness and efficiency of processes.

The main idea of Lean Manufacturing is to throw out the waste, which means erasing everything that does not add value, and enhance process control. This also means that the processes become faster, more efficient and more economical [35].

Six Sigma uses specific metrics, statistical analysis and hypothesis testing to improve the way the processes occur. This improvement is achieved by reducing variation, which represents consistence and predictability in the way processes work. It has the goal of reducing the number of defects to an average of 3.4 per million opportunities [11, 35].

By combining these two methodologies into Lean Six Sigma, it is possible to achieve all of this by implementing just one methodology, that is, all the resources are allocated in the most efficient way, waste is eliminated and the processes have more predictable outcomes.

Lean Six Sigma uses a divide and conquer approach, by treating each process individually, using a SIPOC diagram (an abbreviation for Supplier, Inputs, Process, Output, and Customers) to represent it [9]. It also encourages the participation of all employees in the process of achieving quality of processes, which increases their effectiveness at delivering results.

This quality methodology follows a cycle of five steps, known for the initial of each step, DMAIC:

- **Define:** Define the problem and what is required to satisfy your customer.
- **Measure:** Map the current process to collect data.
- **Analyze:** Investigate and identify what causes the problem.
- **Improve:** Implement a fix that will solve the problem.
- **Control:** Sustain the improved results.



This means that the process of improvement is continuous and never finished. That being, the goal is never to achieve a level of quality, but keep improving it after each iteration [10].



Figure 3 - Lean + Six Sigma = Lean Six Sigma [5].

### 2.3. Baldrige

Baldrige is a quality program that evaluates companies in seven areas of performance, each with a different number of points and awards the ones who achieve high scores. This evaluation is very complete, including all aspects of the company (organization, finances and processes). In the end, a company can score up to 1000 points and evaluate not only how they did in general, but also in each category. The ultimate goal of this methodology is not to improve que quality management system, but only to access it and signal the areas that need improvement [12]. The companies that are awarded the Malcolm Baldrige Criteria for Performance Excellence can also use it as a prove of quality, to draw more clients to use their services.

With the scoring of each area, companies can focus on the improvement of the lower scores, usually by implementing other methodologies like Lean Six Sigma or Total Quality Management as a second reinforcing quality methodology, since applying Baldrige does no improve quality by itself.

Most companies that have used this methodology were applying for the award, but it can be done internally, just to evaluate the ongoing quality management system. Either way, it is important to say that what is evaluated by Baldrige is the general quality management system and not the product itself [13].

## 2.4. ISO 9000 series

International standards organization (ISO) created a series of five norms regarding quality. These norms focus on process quality and satisfying customer needs. Therefore, in addition to the company's financial gains, the clients are satisfied both with the process and the final product [14].

This methodology uses the divide and conquer approach, by looking to the parts of a system independently and improving each process separately. It implies the writing of documentation that describes the quality management system and taking the steps towards implementing it.

ISO 9001, titled "Quality Systems - Model for Quality Assurance in Design, Development, Production, Installation and Servicing", is particularly concerned with software development, operation and support and is used by companies worldwide.

When compared to Lean Six Sigma, the scope of ISO 9000 series is larger, "including all aspects of the business such as management responsibilities, resource management and all aspects of providing the product or service." (Mark Hammar (2015)) [9].

Since this was the chosen methodology, its requirements and the way to implement it are explained in more detail in chapter 3 of this report.

ISO 9000	Explains fundamental quality concepts and provides guidelines for the selection and application of each standard
ISO 9001	Model for quality assurance in design, development, production, installation and servicing
ISO 9002	Model for quality assurance in the production and installation of manufacturing systems
ISO 9003	Quality assurance in final inspection and testing
ISO 9004	Guidelines for the applications of standards in quality management and quality systems

Table 1 - List of ISO 9000 series standards [15].

## 2.5. Summary

Although all these methodologies can help improve quality, none of them is enough by itself to achieve quality, since they only focus on improving processes. Nevertheless, they are absolutely necessary as a step towards quality.

ISO (International Standards Organization) has created and updated a series of standards (the ISO 9000 series). These standards focus on maintaining customer satisfaction through continuous improvement of processes.

Total Quality Management was the first to comprehensive methodology, trying to include all parts of the companies and embracing practices recognized worldwide. Despite that, in the last decades, it has been widely replaced by Lean and Six Sigma standards.

Baldrige methodology is a good way of evaluating the quality of processes in a company, and trace the origin of the problems, but it does not offer solutions to improve the quality management system.

Lean Six Sigma is a combination of Lean Manufacturing and Six Sigma. This methodology is similar to Total Quality Management but focus on the short haul and uses metrics to make predictions instead of using consistency as a mean to improve.

That being said, and considering the parameters compared in Table 2, ISO 9000 series was chosen as the best methodology to use in this project. Baldrige was excluded immediately, because it is only an assessment methodology and does not improve quality by itself. Total Quality Management takes longer time to have results and it has been widely replaced in the past years. Although Lean Six Sigma was a close second, the scope of ISO 9000 standards is more comprehensive. In addition, ISO 9000 series is recognized as a sign of quality all over the world and is regularly used as a requirement to sign contracts.

The work will be mainly focused on ISO 9001, since it is the standard describing quality assurance for companies that provide services, such as OneSource.

	<b>Total Quality Management</b>	<b>Lean Six Sigma</b>	<b>Baldrige</b>	<b>ISO 9000 series</b>
<b>Widely used</b>	No	Yes	Yes	Yes
<b>Has improvement measures</b>	Yes	Yes	No	Yes

<b>Time frame</b>	Long haul	Short haul	Short haul	Short haul
<b>Output</b>	Improvement in quality	Average of 3.4 defects per million opportunities	Performance evaluation	Improvement in quality
<b>Focus on client satisfaction</b>	Yes	Yes	No	Yes
<b>Scope</b>	Comprehensive	Limited	Limited	Comprehensive

*Table 2 - Comparison between methodologies [16, 17, 18, 19].*



## 3. Chosen approaches

In this chapter the focus will be on the chosen approaches for Mobitrust. With that in mind, the concepts and relevance of ISO 9000 and the project documentation in the area of software quality will be explained, and the work done to in those areas will be explained.

After that, there is a small incursion in the area of data protection. Although this is not directly related to quality, any project must obey the national and international laws, and this becomes even more relevant when dealing with personal and medical information. Therefore, and in line with the growing concerns about privacy in technology, it is imperative to gather some knowledge about data protection.

### 3.1. *ISO 9000 and Agile*

Since the chosen quality methodology was ISO 9000 series (see chapter 2), it is necessary to understand which are the requirements to be ISO 9000 compliant.

Another relevant topic is the coexistence of our quality methodology with the development life cycle, Agile. Since ISO 9000 requires a lot of documentation and Agile reduces documentation and embraces constant changes, combining the two in the same project is not recommended by some authors, but is encouraged by others [22].

In this chapter, ISO 9000 requirements and Agile will be presented and discussed. The simultaneous use of these two methodologies will also be scrutinized. In the end, the work that was done towards ISO 9000 compliance will be presented.

#### 3.1.1. *Agile life cycle*

The life cycle used in this project is Agile. Therefore, it is necessary to understand what that means and how to use Agile in a project.

A life cycle is usually composed by five phases (requirements, design, code, test and maintenance). What differentiates one life cycles from another is the timeline and duration of

each of these phases. In addition to that, some life cycles demand more detailed documentation than others.

The Agile life cycle is divided in small steps called iterations. Each iteration is an advance in the project, like the addition of a new feature. This life cycle has its focus on the clients, whom should be consulted regularly regarding the advances produced by the latest version. Before moving on the next iteration, there should be tests (to validate the result of the current iteration) and the client should approve what has been accomplished.

This means that, instead of following the typical five phases, Agile repeats those phases in a cycle, up to the point the project is completed. Even though the general idea and the basis of the documentation are set in the early stages of the project, all decisions are subject to changes almost until the project is finished. The image bellow (Illustration 2), shows the process followed by the Agile methodology.

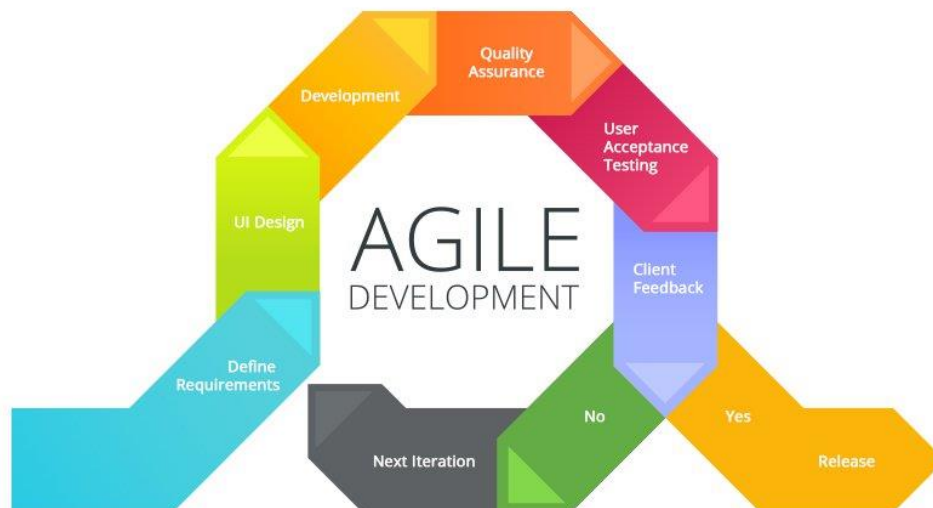


Figure 4 – Agile life cycle [20].

Another core aspect of Agile is the emphasis on the product itself, rather than the documentation. In fact, since Agile embraces constant changes, the documentation related to the project is kept to a minimum, so it does not have to be constantly changed. Nevertheless, relevant information, such as requirements and architectural decisions, should be recorded in the correspondent document, that should be kept up to date at all times [21].

Agile was chosen for this project by the management of OneSource, previously to the internship, because it is the life cycle that best adapts to the constant presentations that were

imposed by customers. It also embraces constant changes, like the addition of new features, which is necessary to adapt to the reality of the work of the entities and the company's growing understanding of that work.

The con of using Agile for this project is that a life critical system should be well documented and other life cycles are more suitable for this aspect. In this case, the documents that guide the development are not as relevant as in other projects, since there is a small team that constantly discusses the project and the roles of each person are well defined. In addition to that, the constant feedback from customers can identify gaps in the requirements and the execution of the tests can assure functionality and good performance.

That being said, Agile is the best life cycle when there is a good communication with customers and their wants and needs are not clear enough from the beginning (because the work of the entities that will use the platform is not entirely known).

### *3.1.2. Implementing ISO 9000 series*

Since many customers require an ISO certificate before they sign a contract, being ISO conformant is a very important step for any company developing software/hardware solutions.. ISO 9000 certification creates trust, because it is a proof of quality, and it is easier to verify that a company is certified, than it is to evaluate the quality standards and reliability of the organization any other way [22].

With that in mind, it is imperative to present ISO 9000 in more detail, to understand what it takes to implement this methodology.

According to Abel Pinto (2017) [13], there are twelve essential steps to implement ISO 9001:

1. **Management commitment:** Management must be committed to implementing the quality management system, and prove that they have that commitment, by creating the quality policies and objectives. They should also create the necessary conditions to involve every employee in the quality process;
2. **Identification of the company's context:** The context of work of the company should be defined, so the quality management system is aligned with that context;



3. **Selection of the team to work on the project:** Although every employee should be aware and involved in the quality management system, there should be one or more employees responsible for creating the necessary documentation and for doing the periodical evaluations to that system;
4. **Elaboration and disclosure of the quality policies:** The documentation related to the quality is absolutely necessary, specially the policies that must be followed. The employees should be aware of its existence and of its content;
5. **Definition and disclosure of the quality goals:** The management should create quality goals, that comply with the company's mission and vision and make them public for the employees;
6. **Definition of the quality plan:** Based on the quality goals, the quality plan should contain the guidelines of the processes necessary to improve quality;
7. **Training:** The company should provide the necessary training to understand and follow the quality plan;
8. **Documenting the quality management system:** the documentation of the quality system should involve feedback by the employees, so it reflects reality and can be maintained in the future;
9. **Quality audits:** Quality audits should be performed as a way of evaluating the current status of the quality management system and choose the areas to improve;
10. **Consult collaborators:** Feedback from collaborators detects situations that must be improved and reinforces the participation of everyone in the quality management system;
11. **Implementation of improvements and corrective actions:** After the detection of failures or inefficient processes, there should be taken actions to improve or correct those situations;

12. **Revision of the quality management system:** The quality management system should be reviewed and updated periodically.

The thirteenth step (which is not mandatory), is selecting the certifying entity and getting the certification, but not all companies implement ISO 9000 with the intention of being certified. So that is not required when implementing ISO 9000.

The twelve steps above make up the plan, execute, check and act (PDCA) cycle, that is also called continuous improvement cycle. The general idea is to periodically evaluate and adjust the quality management system, in order to improve it. Then, the changes made at the end of each cycle are evaluated on the next cycle and maintained or rolled back, depending on the results [23].

Amongst the standards in the ISO 9000 series, ISO 9001 is the one that best applies to software companies, such as OneSource. That being, this is the standard to be followed when building the quality management system.

ISO 9001 is called “Model for quality assurance in design, development, production, installation and servicing”. It is divided in eight principles, that make up every important aspect to evaluate and improve processes’ quality in a company:

1. **Customer Focus:** Satisfying the clients is the most important thing for a company, since they are the source of profit that maintains the company running. Therefore, it is imperative to consistently meet or exceed their requirements;
2. **Leadership:** Leadership is responsible for creating the vision, the mission and the quality goal, making them public to every employee. They also provide the guidance and all resources that the employees need to perform their task;
3. **Involvement of People:** Everybody should be aware of the quality management system and provide the necessary feedback to improve it;
4. **Process Approach:** Consistent and predictable results are obtained when the activities are seen as processes that interact to achieve a goal;

5. **System Approach to Management:** The processes should be interrelated to create a coherent system;
6. **Continual Improvement:** The quality should never be seen only as a target that can be achieved, but as something that can always be improved;
7. **Factual Approach to Decision Making:** The decisions should be made after analysing the present and the past data and foresee the effect of those decisions in the future;
8. **Mutually Beneficial Supplier Relationship:** To achieve long term success, all parties should have a symbiotic relationship, that is beneficial to everyone involved. [13]

The goal is to produce the documentation necessary to prove commitment to follow those principles and, as much as possible, show what practical measures will be taken towards these principles.

### *3.1.3. ISO 9000 series and Agile*

As stated in the previous sections, ISO 9000 series and Agile have ideals that may be difficult to conciliate. Although the creators of Agile did not consider this a problem, a lot of people working on the field of quality assurance did.

The biggest challenge pointed out by critics of the conjoined use of ISO 9000 and Agile is that the constant changes in an Agile environment contrast with the rigid ISO 9000 philosophy. Therefore, it is necessary to find a balance between ideologies, that consider impossible.

Agile life cycle tries to reduce written records, to easily embrace changes, whereas ISO 9000 series demands that a large number of documents is created and updated. For this, Namioka and Bran suggest working each iteration as a separate project, so the problem of the changes is suppressed [24]. Even though this solves the problem, it implies a lot of rework, so it is not the optimal solution.

McMichael and Lombardi, on the other hand, claim that there is no work to do at all, because Agile methodologies will fulfil all the ISO 9000's requirements [25]. This is not entirely true, since there are a few adjustments that need to be made, but it is closer to the solution of relaxing some ISO 9000 requirements, that was proposed by Stålhane and Hanssen [22].

The requirements that must be taken into account, according these authors, as well as the solutions to the problems that those requirements may bring, are presented in the Appendix 1 of this report.

### *3.1.4. ISO 9000 in Mobitrust*

As a part of the internship, the work done to achieve quality of processes was divided in two: choosing the most appropriate quality methodology for this project and creating the necessary documentation associated to that methodology. In the following subsections that work will be presented, by describing its relevance in the context of the quality system and pointing out the Appendixes that constitute the ISO 9000 documentation produced.

#### **Choosing quality methodology**

ISO 9000 series was chosen as the quality methodology to be used in this project. Coming to that decision involved a lot of research on the topic. After selecting the most promising methodologies, it was necessary to understand them, to analyse the pros and cons of each one. This involved studying the methodologies and summarize them (see chapter 2). After that, the main points were compared, in order to make the choice that was most appropriate in the context of the project.

The most challenging part of this process was finding detailed information about the process to apply the methodologies. Since there are consultors, training programs and documentation templates that can only be accessed by paying, thorough information available online and even in books is scarce.

The results of this research were registered in chapter 2 of this report, where the methodologies were presented and compared and the decision of choosing ISO 9000 series was explained.

## **ISO 9000 documentation**

Since it was decided to follow the ISO 9000 series, and the standard that best applies to this internship, ISO 9001, the main goal is to follow the principles of that standard. That was the basis for the creation of documents and implementation of actions within the company.

<b>Principle</b>	<b>What was done</b>
Leadership	Leadership commitment to implementing ISO 9000 is expressed in the files that were produced to document the quality management system. Those files are “company quality policy” (Appendix 8), “quality policy” (Appendix 9) and “quality manual” (Appendix 10) and they express the commitment to provide de necessary conditions, so employees can do their work in an efficient way.
Customer Focus	The intention of valuing the clients’ interests and meeting or exceeding their requirements consistently is also expressed in the “quality manual” and in the “quality policy”. The choice of an Agile life cycle is also proof that the clients’ interests are considered, since this involves constant feedback from the client, to make sure the product meets the expectations.
Involvement of People	The necessity of involving every employee in the quality process is expressed both in the “quality policy” and in the “quality manual”. This involvement includes the necessary training to understand the quality management system and the feedback that helps defining the areas that have to be improved. In addition to that, meetings where conducted to monitor progress, get feedback and discuss the decisions related to the platform.
Process Approach	The commitment to use a process approach in software development is expressed in the “quality manual”. This means that any activity can be described by processes that interact between them to create a coherent system.
System Approach to Management	The commitment to process approach, stated in the “quality manual” also implies that those processes interact with each other to create a whole quality management system. The quality processes also interact with the other processes that make up the company.
Continual Improvement	The continual improvement will be achieved through the quality audits, that are a part of the ISO 9001 standard and by the life cycle chosen, that evaluates and improves the product and the processes after each iteration. That commitment to periodically evaluate and improve is stated in the “quality policy” and in the quality manual.
Factual Approach to Decision Making	There is not much data from the past about quality, but the vow to use current and future data gathered and analysed to base the future decisions on if made on the “quality manual”. The feedback from clients and employees will be the main

	source of knowledge about the areas that need to be improved.
Mutually Beneficial Supplier Relationship	Although there are not exactly suppliers in a software company, outsourcing can be understood as a form of supplying the company where the product bought is software. That being, it is important to have a good relationship with outsourcing companies that build code in parallel with OneSource, as stated in the “quality manual”. The use of the Agile life cycle creates communication that also works towards that understanding.

*Table 3 - ISO 9001 conformance.*

In addition to that, the “data quality policy” (Appendix 11) was created to define the principles that the information being gathered and transmitted must obey. This is even more relevant in a project like Mobitrust because there is sensitive data being handled.

### **Team meetings**

Throughout the internship, there were team meetings, attended by everyone involved in the project. This is one of the ways of guaranteeing ISO 9000 compliance, namely by involving people in the decision making.

In addition to such discussions, it is possible to evaluate the skills of the people involved in the project, to better assess the training needs and to assign the right person to each task, in order to achieve efficiency.

In the initial meetings, the goal was to present the project and the next steps. This included presentation of the features and technologies used, as well as demonstrations of the prototype working. This led to a research about the technologies and the state of art (Appendixes 2 and 3).

After that, there were discussions about the decisions made or to be made (namely architectural). At that time, there was a moment, usually in the beginning of the meetings, to keep track of the progress made by the participants since the last meeting and plan the next stages. That part of the meeting was vital to coordinate between team members and assign the tasks to the right person at the right time.

Those briefings were an essential part of the compliance with ISO 9000, since it is important to have regular and effective communication between people involved in the project.

In addition to that, the knowledge gathered in those moments was crucial to produce all the documents related to the project.

As the main topic of discussion was always the architecture of the platform, those meetings were the basis for the diagrams present in the architecture and design document. Such diagrams were produced and discussed as a team effort.

Considering all this, we can infer that the meetings were essential both for product and process quality.

### *3.2. Software documentation*

Software documentation is important to create a common vision between company workers and also between the company and the customers. It is also the best way of documenting decisions made and providing an overview of the system for people who are not familiar with it [26].

The first document that has to be written is the requirements specification. This document specifies what features the system should have, as well as non-functional requirements, such as performance. It can be seen as an agreement between company and customer of the wants and needs that have to be satisfied as a way of achieving quality. Therefore, this document (or at least the list of requirements) should be negotiated and accepted by both parties.

The risk analysis is a document that presents a list of possible undesirable outcomes that may occur throughout the project. Each risk is then classified according to the probability of happening and the consequences for the project if it happens. After that classification, a response plan is elaborated for the risks with the highest rank. This is very important to reduce the probability of those undesirable outcomes, as well as their consequences.

Architecture and design is a document that reports the technical decisions. This means that all the components and the connections between them are described there. This document is intended to guide the coding phase, by presenting the structure that must be followed.

Finally, the test plan describes what kind of tests will be performed to assure that the system is aligned with the requirements that were defined. The actual test cases are appendixes to this document. The goal of this document is to guide the testers through the testing phase, but it can also be used to prove compliance to requirements.

Documentation related to inspections and team meetings can be kept as a record of the defects found and as a prove of quality of the inspected document or piece of code.

The timeline to write these documents may vary, depending on the development life cycle used. The only life cycle discussed in this document is Agile, which is used in this project, but it is important to consider that other life cycles use different approaches regarding detail and timeframe for documentation. Nevertheless, despite of the life cycle chosen, documentation should always be kept up to date.

## **Software documentation for Mobitrust**

An important part of the quality, as stated in the previous sections, is the quality of the product. With that in mind, it was imperative to create the documentation associated to Mobitrust. These documents are a record of the decisions made and guide the development and testing processes.

The requirements specification (Appendix 4) was the first document to be produced. It gives an overview of the project, lists the necessary features and presents the non-functional requirements, such as performance requirements. The main concern while producing this document was creating specific, measurable, achievable, relevant and time-bound (SMART) requirements. Although the writing of the requirements started almost in the beginning of the internship, given that the life cycle is Agile, this document was subjected to changes throughout the full duration of the internship.

Another important step was to address risks and opportunities. Since the general idea of the project was already decided from the beginning, it made no sense to look for and evaluate opportunities. As a result, in this project, only the risks were addressed, by writing the risk analysis document (Appendix 5). There, the risks were listed, classified (according to probability and severity of consequences) and response plans were elaborated for the most dangerous risks. In the future, if there are changes in the probability or impact or if new risks appear, this document can and should be updated.

The architectural decisions were represented in the diagrams that compose the architecture and design document (Appendix 6). As stated in the previous section, these diagrams were envisioned, discussed and approved by the whole team, during the meetings. After their completion, each diagram was explained and commented, to build the document. Even though most architecture and design documents have more views, only the relevant for documenting decision and guiding the development process were presented.



Finally, the test plan (Appendix 7) describes the testing strategy. It provides an overview of the tests that will be performed to verify if the final product is compliant with the requirements. In addition to describing what kind of tests will be performed, it explains how to handle the defects found. The exit criteria, which is the conditions necessary to end the tests, are also explained. Lastly, and in the appendix of the test plan, the actual test cases are presented. Provided that the requirements have no defects, these tests should be enough to prove the quality of the product.

### *3.3. Data protection*

In a project where medical input is manipulated, it is essential to take into account the national and international laws regarding data protection. These laws are in constant change, due to the technological advances in the field of medicine that create new challenges in terms of privacy and data security.

The European laws (which were recently reviewed in the new version, that came into force in May) state that the use of personal data “must be fair, for specified purposes and on the basis of the consent of the person concerned” [27]. This means that having the explicit and unambiguous consent is not enough to legally manipulate sensitive data. The data gathered and stored should be minimized, so only the personal information that is strictly necessary is used. The individuals have to be informed about what data will be manipulated and the reason why it is necessary.

The most recent data protection laws also demand that any sensitive data (like the biometric parameters of a person) storage and transmission is safe. This means that confidentiality and integrity must be a concern, when dealing with classified information, such as medical reports [28]. For that, mechanisms to prevent malicious attacks have to be in place, not only for stored data, but also for what is being transmitted.

Another aspect of these regulations is that individuals should have control over their data. This means that it should be accessible to them and they should be able to ask for changes or even to delete that data. They should also be informed about how the information will be used and for how long it will be stored.

Finally, if there is any breach in security and data is illegally accessed by unauthorized parties, the national entity responsible for data control (Comissão Nacional de Proteção de

Dados) should be notified within 72 hours. If the data accessed is sensitive, the individuals must be informed of that violation [29].

The following table (Table 3) shows the most important principles of data protection and the explanation of each one.

<b>Principle</b>	<b>What does it mean?</b>
Lawfulness, fairness and transparency	Data has to be processed in accordance with the European Union and Member State laws, data controllers have to be transparent with patients regarding what happens to their personal data.
Purpose limitation	The data must be collected for a specific explicit and legitimate purpose and cannot be used for other purposes beyond that. It is, however, considered that further processing for scientific research, archiving or statistical purposes is not incompatible with this principle. So, data can be re-used for research.
Data minimisation	It means that data controller should only ask patients information that is needed and relevant for the purpose for which they are collecting data.
Accuracy	Controllers must ensure that their data is accurate. If it is not, the controller should take every reasonable step to rectify it.
Limited storage	Data can only be stored for a limited period, except for archiving and scientific research purposes.
Integrity and confidentiality	Data has to be processed in a manner that minimises risks to confidentiality and integrity of the data (which means ensuring its consistency and accuracy, as opposed to data corruption).
Accountability	This is a new principle compared to the 1995 Directive. It means the data controllers should not only apply the principles in the law, but they also must be able to prove that they are accountable and respect the above principles, it means the burden of the proof is with them.

*Table 4 - Data protection principles [27].*

## **Data protection in Mobitrust**

In a platform that manipulates personal and medical records, it is imperative to mind the laws that regulate the transmission, storage and manipulation of sensitive data. Although this is not directly a part of the quality process, there are laws and ethical principles that have to be obeyed, in order to “build the thing right and the right thing” [4].

With that in mind, there was the need to research the national and international laws in place that apply to this project. The result of that investigation was summarized and discussed in chapter 3.3 of this report.

For this project, information about an individual cannot be deleted as easily as in other cases, because it is highly likely that some of that information can be used to solve and judge crimes. That being, any deletion of data related to the platform users has to be carefully handled.

## 4. Conclusions and future work

In this section the summary of what was done and the conclusions are presented. After that, future measures to be taken will be presented.

### 4.1. *Conclusions*

Quality is essential to stand out in a competitive world and keep the costumers satisfied. Although the process of improving quality is often seen as a waste of time and other resources, it can have the opposite effect, if there is a commitment from all parties involved in the project. For instance, by thoroughly planning and testing, the number of defects in the software can be largely reduced, which decreases the amount of rework, the probability of failure and, consequently, the overall costs of the project.

It is a common mistake to confuse quality and testing. Even though testing takes a crucial role in the quality management system, it is only a small part of what can be done to create quality products, that are built efficiently. Quality can be divided in two core aspects: quality of products, which is concerned with the software developed, and quality of processes, which assures effectiveness and efficiency of work methods.

To achieve quality of processes and become able to demonstrate that quality, it is necessary to choose and follow a quality methodology that guides the continuous improvement of the quality management system. After the implementation of the aforementioned methodology, it is possible to have an external audit to get an official certification, that is a prove of quality for outside parties, namely clients.

Quality of product is accomplished by documenting the project, including the requirements, the architectural decisions made and the ways of proving quality, such as testing. This is common practice for most software companies, but the detail of those documents varies according to the life cycle chosen and the company's commitment to quality.

Despite of our best endeavours, it is utopic to reach a perfection in the field of quality, but it is possible to constantly improve the quality management system to reach better results after each iteration.

In addition to this concern with quality, there has to be a concern with the national and international laws. In projects that deal with sensitive (personal and medical) data, data

protection laws must be taken into consideration. This is a concern that has been growing with the raising of awareness of the questions regarding privacy in the virtual world, and that has led to constant changes in the laws that intend to regulate the transmission and storage of sensitive data.

Considering all of this, the work done during the internship had the goal of assuring the quality of a platform, Mobitrust. To do so, quality of product, in association with quality of processes had to be implemented.

To do so, quality methodologies were researched and compared in order to choose the most appropriate for the project at hands. The choice fell upon ISO 9000, which is a series of quality standards that establish requirements and guidelines for improving the quality management system. This methodology follows a cycle of continuous improvement, which means that the quality management system is constantly being evaluated and upgraded.

In addition to that, documentation related to the project was produced, as a way of recording the decisions made, namely regarding the requirements and the architecture of the platform. The test plan was also written, as a way of proving functionality, performance and compliance to the requirements.

Since it is impossible to have quality and not obey the national and international laws, there was a small incursion in the field of data protections laws. This specific field was chosen due to the recent discussions on the topic and its relevance to a project that deals with sensitive data. The research was mainly focused in the new changes to the European laws, that started being enforced in May.

For the internship there were three goals, that were achieved (however, as explained throughout this report, this does not mean that quality cannot continue to improve). This means that at the end of the internship the quality methodology to improve the quality of processes (ISO 9000) was described and the requirements to achieve compliance to that methodology were presented (see chapter 3.1.2). To achieve the other two goals, implementing that methodology and assuring quality of product, the required documents were produced (see chapters 3.1.4 and 3.2).

Although what was achieved in the end of the internship was not an entirely functioning quality management system, the documentation produced together with the summaries of the investigations should be enough to guide the company in the process of making the necessary changes to reach the ultimate goal of implementing a solid quality management system.

## *4.2. Future work*

To continue the work that has been done and continuously improve the quality in the company and in the platform, Mobitrust, it is necessary that OneSource puts into practice what was described in this report and keeps the documents that were produced updated.

Ultimately, if that is a goal for the company, it is possible to ask for an external audit that may award an ISO 9001 certification (ISO 9001 is the only ISO 9000 standard that can lead to a certification). As stated before, this is not necessary to have a good quality management system in place, but it is necessary to prove it to outside sources.

The main tasks that should be performed include inspections, both to the requirements and the code and internal audits. These inspections are necessary, because they are the only way of guaranteeing good code and requirements (not wrong, incomplete, incorrect or ambiguous) and catching errors early prevents them from propagating to the next phases, which decreases the cost of fixing them. The internal audits are an essential step for the quality assurance cycle, since they are the best way of evaluating the parts of the system that need to be improved. They should follow rigorous procedures described in documentation elaborated by the International Organization for Standardization.

If all of this is achieved, the quality management system in place will assure that both the processes and the products built have good quality.



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