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9 INDUSTRY, INNOVATION AND INFRASTRUCTURE

12 RESPONSIBLE CONSUMPTION AND PRODUCTION

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ABBREVIATIONS

- **AEFI:** Asociación Española de Farmacéuticos de la Industria
- **AENOR:** Asociación Española de Normalización y Certificación
- **CAPA:** Corrective Actions and Preventive actions
- **CRAI:** Centre de Recursos per l'aprenentatge i la investigació
- **ICH:** International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use.
- **ISO:** International Organization for Standardization
- **N/A:** Not applicable
- **R&D:** Research and Development
- **SDM:** Servei de Desenvolupament del Medicament (*Service of Development of Medicines)*
- **SWOT:** Strengths, Weaknesses, Opportunities and Threats Analysis
- **UQF:** Unitat de Química Farmacèutica
- **UNE:** Una Norma Española
- **UTF:** Unitat de Tecnologia Farmacèutica

INTEGRATION OF FIELDS

The implementation of a quality management system in the areas of research and investigation highlights that the main scope of work is in Pharmaceutical Technology (Tecnologia Farmacèutica). The study aims to be applied in a research organization in order to assess personnel compliance and evaluate task management.

Secondly, for the design of the questionnaire, it was necessary to select and compile all the articles from official regulations such as ISO 9001, UNE 16602, ICH Q8, ICH Q9, ICH Q10, among others, that could be specifically applied in the research and quality areas. To carry out this task, access to all international regulations was required, and they were carefully read to search for and choose all the relevant sections. For this reason, the first secondary domain has been Legislation and Deontology (Legislació i Deontologia).

Finally, the last domain has been Health and Environmental Management (Sanitat i Gestió Ambiental). This decision has been made considering that the questionnaire evaluates aspects of sustainability applied to responsible management. These aspects ensure the long-term viability of the organization and its contribution to social and environmental well-being. Additionally, the promotion of resource conservation in the activities and procedures carried out by the staff has been taken into consideration.

Sustainable Development Goals (SDM)

The quality management system in R&D that is being promoted in this study has been conducted with the aim of improving efficiency and sustainability in research, innovation, and development processes. A reference framework has been established by creating a questionnaire based on official regulations, to assess the level of compliance of research personnel in research centres.

Based on this, audits are conducted in different entities to evaluate the degree of compliance with established regulations and identify areas where improvements can be made to achieve greater sustainability in R&D processes. This specific focus on research personnel is crucial because sustainable development relies on researchers' ability to adopt responsible and efficient practices.

For this reason, this work is directly contributing to the Planet aspect of SDG 12, which calls for *"Ensuring sustainable consumption and production patterns".* Specifically, it applies to target 12a, which aims to *"support developing countries to strengthen their scientific and technological capacities to move towards more sustainable patterns of consumption and production".*

With this study, scientific and technological capacity in the investigation is being reinforced. Knowledge and technology transfer to research centres are being fostered, helping them to adopt quality management practices in line with recognized international standards. This has a positive impact on encouraging sustainable development and preserving natural resources and the environment.

Furthermore, it also aligns with the Prosperity aspect, specifically SDG 9, which calls for *"Building resilient infrastructure, promoting inclusive and sustainable industrialization, and fostering innovation".* It specifically relates to target 9.5, aimed at "*enhancing scientific research and improving the technological capabilities of industrial sectors in all countries, particularly developing countries, by 2030*".

By applying regulations and conducting audits of research personnel, scientific research is being enhanced, and innovation is being fostered. This task is essential for improving technological capacity in all countries. Moreover, the ability to extrapolate the questionnaire to any organization allows for adaptation and customization to specific contexts, whether in the Western world or in developing countries.

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ABSTRACT

The implementation of a consolidated and integrated quality management system in Research and Development and innovation (R&D) provides a conceptual framework for the evaluation and continuous improvement of the projects carried out. It is also a key element in ensuring the effectiveness and validity of the results.

Research often fails to give the priority it deserves (1). It is assumed that it is more beneficial to invest all the time and resources exclusively in scientific investigation. This represents a missed opportunity to improve team coordination and increase project success (2,3).

From the main international regulations such as ISO 9001, UNE 16602, ICH Q8, ICH Q9, ICH Q10, among others, the most reference points in the research have been selected and unified to produce an auditable questionnaire. It consists of 19 different sections with a total of 167 yes/no/ongoing/NA answer questions. It focuses exclusively on the audit of research personnel and their activities. Thus, it allows to create a global and current idea of the management system in R&D and the organization and to evaluate its degree of compliance.

Based on the questionnaire, four audits were carried out on three different study groups: the Service of Development of Medicines, the Unit of Pharmaceutical Technology and the Pharmaceutical Chemistry Laboratory. The audit has made it possible to compare and analyse in detail the different levels of compliance and to identify the strengths and weaknesses of each organization. It has also proven useful in assessing the current status of organizations and highlighting areas of optimization.

Keywords: Quality Audit, Quality Management System, ISO 9001, UNE 16602.

RESUM

L'aplicació d'un sistema de gestió de qualitat en R&D consolidat i integrat ofereix un marc de referència per a l'avaluació i millora contínua dels projectes realitzats. A més, constitueix un element clau per assegurar l'efectivitat i validesa dels resultats.

Sovint, des de l'àmbit de la investigació no es dóna la prioritat que es mereix (1). S'assumeix que és més beneficiós invertir tot el temps i recursos disponibles exclusivament en recerca. Això suposa la pèrdua d'una gran oportunitat per millorar la coordinació de l'equip i augmentar l'èxit dels projectes (2,3).

A partir de les principals normatives oficials com la ISO 9001, UNE 16602, ICH Q8, ICH Q9, ICH Q10, entre d'altres; s'ha seleccionat i unificat tots els punts referents a la recerca per elaborar un qüestionari auditable. Aquest, està conformat per 19 blocs diferents amb un total de 167 preguntes de resposta si/no/en curs/NA. Està focalitzat exclusivament en l'auditoria del personal investigador i les seves activitats. Permet, doncs, generar una idea global i actual del sistema de gestió en I+D+i de l'organització i avaluar el seu grau de compliment.

En base al qüestionari s'han realitzat 4 auditories aplicades a tres grups d'estudi diferents: el Servei de Desenvolupament del Medicament, la Unitat de Tecnologia Farmacèutica i la Unitat de Química Farmacèutica. L'auditoria ha permès comparar i analitzar de manera detallada els diferents nivells de compliment i identificar els punts forts i febles de cada organització. També ha demostrat la seva utilitat per avaluar l'estat actual de les organitzacions i destacar les àrees d'optimització.

Paraules clau: Auditoria de Qualitat, Sistema de Gestió de Qualitat, ISO 9001, UNE 16602

INTRODUCTION:

The implementation of a quality management system in research and investigation provides a frame of reference for assessment and continuous improvement to optimize the projects carried out and is a key element in ensuring the effectiveness and validity of the results. Unfortunately, in certain departments and organizations, there is a lack of interest or priority in delving into the implementation of quality systems applied to the entity (1). It is often believed that dedicating all the time to research will be more profitable. This mindset overlooks a great opportunity to improve team coordination and enhance success in projects (2,3).

Furthermore, a factor that hampers this consideration is the lack of specific guidelines for the fields of research and investigation. Existing regulations tend to have a more general and global tone to accommodate any organization, but they often lack specification and direct applicability to the research and investigation context. Scientific institutions that do comply with these regulations are more likely to promote and understand the benefits that their practical implementation brings. In this study, the Service of Development of Medicines (SDM) is the institution that incorporates compliance with ISO 9001:2015 standards unlike the other groups studied.

The SDM was founded in 1996 as a pharmaceutical technology pilot plant within the Faculty of Pharmacy at the University of Barcelona. Its purpose was to establish educational and research offerings and promote collaboration between the university and the pharmaceutical industry to become a reference centre in Barcelona.

The SDM is responsible for creating technical, scientific, research, and development projects and services in the field of human pharmaceuticals, veterinary pharmaceuticals, and healthcare products within the pharmaceutical sector. Additionally, it is used to enhance practical teaching for university courses, as well as specialized training for pharmacists in the industrial sector, and other technical and qualified personnel in the pharmaceutical and related sectors. This includes offering specific continuing education programs for personnel in the pharmaceutical and related industries.

Driven by Senior Management, the SDM is divided into three departments: the Formulation Development, the Analysis and Quality Control, and the Quality Assurance. The research and development activities promoted by the SDM align with the quality requirements of the ISO 9001:2015 guideline.

On the other hand, the Pharmaceutical Technology Unit (UTF) and the Pharmaceutical Chemistry Unit (UQF) of the Faculty of Pharmacy of the University of Barcelona are also taken into account. Both areas have PhD students and technicians conducting research and investigation in their respective fields. They are supervised by professors with periodic reviews as needed. However, unlike the SDM, researchers in the UTF and UQF do not comply with ISO 9001:2015 or any related standards.

The ISO 9001:2015 is developed by the International Organization for Standardization to determine the requirements for a Quality Management System. The objective is to demonstrate its ability to consistently provide products and services that meet customer and applicable legal and regulatory requirements. It also aims to enhance customer satisfaction through the effective application of the system, including processes for system improvement and ensuring conformity with customer and applicable legal and regulatory requirements (4).

The UNE 166002 standard has been taken as the fundamental guideline and the basis for the study structure. This standard delves into the promotion, management, and improvement of R&D systems and provides the requirements for establishing, implementing, maintaining, and continuously improving such a system. It promotes a greater ability to manage uncertainty, resource productivity, sustainability, and resilience, as well as better reputation, evaluation, and customer satisfaction, and greater ease of compliance with relevant regulations and other requirements (5).

Other standards have also been necessary to obtain more detailed and precise knowledge of the main points to consider. These guidelines are:

UNE-ISO 9000:2015 which provides a more defined and concise context for understanding ISO 9001:2015 better (6).

ISO 9004 specifies the principles and practices that organizations can adopt to improve their performance and ability to meet stakeholder expectations. It promotes a process-based approach, continuous learning, and systematic improvement as means to achieve organizational excellence (7).

UNE-ISO 10013 establishes the fundamental principles for document management. That includes identification, development, approval, distribution, and control of documents related to the quality management system. It promotes the effective use of documentation as a tool to ensure coherence, transparency, and proper management of processes and activities within the organization (8).

UNE-ISO 10014, which encourages a set of principles and guidelines for the effective application of quality management practices to achieve optimized and high-quality results (9).

UNE-ISO 10005, which provides guidance for the development of quality plans, whether in the context of an established quality management system or as an independent management activity. It facilitates a means to relate specific requirements of processes, products, services, projects, or contracts with methods and work practices (10).

UNE-ISO 10006 provides guidelines for quality management in projects, focusing on the principles and practices necessary to achieve quality objectives. It uses a process approach, including the Plan-Do-Check-Act (PDCA) cycle and risk-based thinking. It distinguishes between quality management in projects and quality management systems in projects, addressing aspects such as management responsibility, resource management, product or service realization, and continuous improvement (11).

UNE-ISO 10007 improves understanding of configuration management, promotes its use, and helps organizations applying it to enhance their performance. It offers an overview of responsibilities and authorities before describing the configuration management process, which includes planning, configuration identification, change control, configuration status accounting, and auditing (12).

UNE-ISO/PAS 17004 covers the agreed principles that underpin the Information Disclosure element and the intended requirements for assessing its conformity (13).

UNE 412001 is a tool for structuring knowledge management in any organization in an integrated and systematic manner. It aims to avoid fragmentation or loss of knowledge during personnel changes and to add value to know-how (14).

UNE-ISO 10015 provides guidelines for establishing, implementing, maintaining, and improving systems for competence management. It promotes the development of individuals to positively impact product and service results and meet the needs and expectations of relevant interested parties (15).

UNE-ISO 10018 provides guidelines for engaging people in an organization's quality management system, promoting their active participation and competence. It focuses on achieving emotional commitment of individuals to the organization and its goals (16).

The European Foundation for Quality Management (EFQM Model) provides a widely used framework for assessing and managing quality and excellence in organizations. It is based on the principles of excellence and provides a comprehensive structure for the assessment and continuous improvement of the organization (17).

ICH Q8: Pharmaceutical Development promotes the quality, effectiveness, and safety of drugs through the application of scientific principles and the optimization of pharmaceutical development processes. This guidance encourages flexibility and adaptability in drug design to meet patient needs and promote innovation in the pharmaceutical industry (18).

ICH Q9: Quality Risk Management provides a framework for identifying, assessing, and controlling risks related to the quality of drugs, with the aim of ensuring public health protection and promoting continuous improvement in the pharmaceutical field. It encourages the application of risk management methodologies to make evidence-based decisions and promotes a culture of quality and safety throughout the drug development process (19).

ICH Q10: Pharmaceutical Quality System provides guidance for implementing a quality system throughout the various stages of the pharmaceutical product lifecycle, with the goal of strengthening the link between pharmaceutical development and manufacture and improving the quality and availability of drugs for the benefit of public health (20).

OBJECTIVES:

1) Design an auditable unified questionnaire by selecting relevant points from representative official regulations within the research and quality field.

2) Evaluate the specificity and adaptability of the questionnaire to each organization where personnel from three different organizations have been audited: SDM, UTF and UQF. Each of them has different contexts and levels of compliance with official regulations.

3) Compare organizations in a detailed and precise manner to identify the areas where each organization excels or falls behind when analysed together. The intention is to assess the current state of the organizations more accurately and concisely and observe their differences.

MATERIALS AND METHODS

In order to develop the questionnaire, the relevant regulations that could contribute value were consulted. This was possible thanks to the availability of the CRAI access to AENOR standards. The research objective of these regulations focused on selecting points that could be applicable to the research field. (1)

The main standard that served as the foundation for structuring the blocks and sections of the questionnaire was the UNE 166002 standard (5). This decision was made because, compared to other standards, it is the one that is closest to the research field and can provide clearer and more robust foundations for constructing the questionnaire.

Along with UNE 166002, ISO 9001:2015 (4) was essential for covering quality aspects not addressed in the UNE standard and consolidating the majority of the questionnaire. From there, each of the used standards was allowed for the inclusion of necessary nuances to understand the entirety of the quality management system. Together, the proposed questionnaire will provide a summary of the requirements from each standard per section. The other guidelines used are shown in Figure 1.

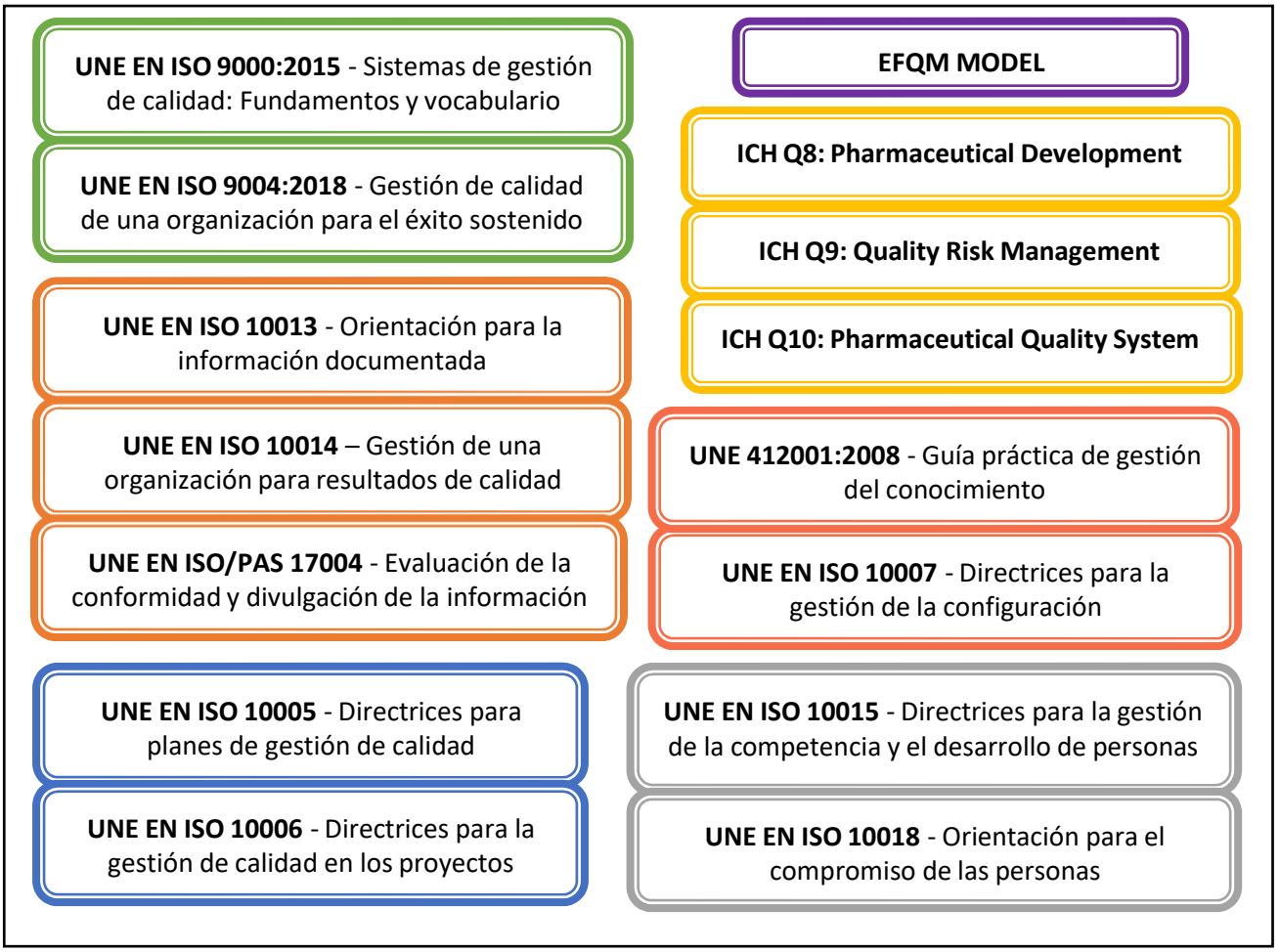

Figure 1: Graphic diagram representing and encompassing each of the standards used in their respective areas: In green, the supporting documents of ISO 9001:2015; in orange, those related to data integrity; in blue, those applied to quality management of plans and projects; in purple, the business excellence model; in gold, the ICH standards, with ICH Q9 being highlighted as part of the GMP annexes; in red, those related to knowledge and configuration management; in gray, those applied to people development in research enterprises. Own-production.

To evaluate the questionnaire, contact has been made with 4 volunteers from the 3 study groups. Two PhD students from the UTF took part. One member from each organization of the SDM and the UQF also took part, selected for their experience and knowledge of the centre where they are located. Each audit lasted approximately two hours to verify compliance with the points proposed in the questionnaire (1).

Once the audits were conducted, the obtained results were compared with the expected results, and the differences and similarities between them were analysed. In this way, strengths, weaknesses, and improvement opportunities were identified, and the effectiveness of the questionnaire in providing meaningful information about the research centre's status was evaluated.

RESULTS AND DISCUSSION

QUESTIONNAIRE

The first achievement obtained was the questionnaire itself, which was used to conduct audits in the various study groups. The questionnaire was developed with 167 questions distributed in 19 blocks, using questions with only three possible responses: Yes, No, In progress, or N/A. It is applicable to any research centre, but it is specific and detailed for each section. The binary questions provide the means to obtain clearer and more precise answers.

This questionnaire, due to its length, can be found in Appendix 1. Furthermore, it includes the respondents' answers for each section. They have been differentiated by colours: the representative of UQF in green, the representative of SDM in red, investigator 1 of UTF in black, and investigator 2 of UTF in blue. However, the details of each section are specified below: See figure 2.

BLOCK 1	Context of the organization
BLOCK 2	Quality Management System and Plan *2.1) Determination of the Scope of the Quality Management System* *2.2) R&D Quality Management System* *2.3) Quality Plans*
BLOCK 3	Leadership, Vision and Strategy
BLOCK 4	Policy and Values
BLOCK 5	Risk Management
BLOCK 6	Individual Objectives
BLOCK 7	Roles and Responsibilities
BLOCK 8	Resources
BLOCK 9	Competences

BLOCK 10	Communication
BLOCK 11	Documented Information
BLOCK 12	Knowledge Management
BLOCK 13	Knowledge Transfer
BLOCK 14	Collaboration
BLOCK 15	Project Management *15.1) R&D Projects* *15.2) Identification of opportunities* *15.3) Validation* *15.4) Solution Development* *15.5) Change control*
BLOCK 16	Exploitation of Results and Intellectual and Industrial Property
BLOCK 17	Supervision, Measurement, Analysis
BLOCK 18	Internal Audits
BLOCK 19	Quality System Improvements

Figure 2: Summary of each of the 19 blocks that make up the questionnaire. Own production.

Block 1: Context of the organization

The staff is asked about their knowledge of the organization and the context in which they operate within it. The aim is to determine if the staff is able to position themselves within the organizational context, defining their role in relation to the organizational hierarchy, and if they have documented information in this regard.

It is important to understand if the personnel is clear about the objectives they are expected to fulfil and if they understand the requirements for carrying out their work effectively, as well as the consequences of non-compliance.

The intention is to assess whether the staff is aware of the quality policy and their contribution to the effectiveness and improvement of the system, as well as the implications of failing to meet the requirements. It is also important to determine if there is an internal analysis of the system's sustainability and if there are studies on funding opportunities.

Block 2: Quality Management System and Plan

In the chapter concerning the determination of the Scope of the Quality Management System (section 2.1), the aim is to find out if the staff has defined the limits that affect their capacity and responsibility and the scope of their work. It is also important to consider the potential impact of processes, products, or services and the effectiveness of the applied controls.

In the section on Research and Development (R&D) Quality Management System (section 2.2), the goal is to determine if management or internal reviews are conducted to ensure the continuity and adequacy of the quality management system and to identify improvement opportunities. It is significant to evaluate whether there is supervision and analysis of results to identify opportunities for enhancing the R&D management system. Additionally, it is crucial to determine if the necessary criteria and methods are established to support activities before they are initiated.

Moreover, the aim is to assess the analysis of internal and external factors impacting the R&D management system. In addition, it involves determining the availability of a process map and flowchart to facilitate the identification of improvement opportunities and establish a more streamlined and productive framework. It is relevant to assess if controls, analyses, and assessments are conducted on external activities contracted by the organization and if the requirements for externally contracted entities are defined and their effectiveness evaluated. It is important to ensure that the management system can achieve the intended results and to seek improvements in desired effects while preventing or reducing undesired consequences.

In the section on Quality Plans (section 2.3), the objective is to determine if there is a quality plan that defines activities, procedures, and policies to ensure that a product, service, or a process meets specified quality requirements, and if there is documented information regarding this.

It is relevant to know if the requirements, objectives, regulations, specifications, methods, and resources are determined for a specific case, as well as if the scope of a process is established based on resources, validity, organizational context, or process extent. The purpose is to find out if monitoring, analysis, and traceability of quality

plan implementation are conducted, and if there is documented information about the controls to be performed.

It is important to assess if internal and external communications in a quality plan are carried out properly, and if the implementation and success of a quality plan are evaluated. The intention is to determine if there are quality plans for products, processes, and services external to the organization, and if these plans are periodically reviewed and accepted.

Block 3: Leadership, Vision and Strategy

In the ISO 9001:2015 and UNE 16602 standards this section is usually applied to managerial positions or personnel in higher positions within the research organization. Therefore, in this questionnaire, the focus is not on their decision-making ability but rather on their knowledge of the organization's strategy, vision, and policies, and to what extent they are aware of them. Having a clearer perspective on the centre's objectives allows for a sense of belonging to a larger collective with more defined ideals, which helps strengthen the team.

In the section on Management Commitment (section 3.1), the aim is to determine if the personnel is aware of the strategy, vision, and policies followed by the centre's management team and the achievement of the overall objectives set. It is also important to assess their awareness of the centre's current state, future role, and the desired impact they seek to convey (section 3.2). If this information is not known, it is crucial to understand to what extent this knowledge is being transmitted within the organization.

Block 4: Policy and Values

Regarding the environment fostered by the organization, it is important to assess whether a culture of innovation is promoted and if personal ambition to challenge current procedures in the presence of improvement opportunities is valued. Additionally, understanding whether a framework is provided for the fulfilment of any task is crucial. This means determining if a set of parameters is established to serve as a reference point for understanding, analysing, or interpreting the activities to be carried out.

Block 5: Risk Management

It is acknowledged that any new project, due to its innovative nature, entails a certain degree of risk and uncertainty. In this section, the focus is on determining whether the organization takes into account the uncertainties associated with new opportunities and whether there is an acceptable level or type of risk. Furthermore, comparing the effects of accepting risks with the effects of prevention is essential to get to a clearer and more thoughtful solution.

One key aspect in this regard is the use of a risk management program. It is important to ascertain whether such a program is established and whether identified risks are prioritized. Even if there is no formalized program in place, it is important to verify if certain management points, as defined in ICH Q9, are being addressed.

Thus, it is relevant to determine if strategies have been developed to minimize and control risks, as well as to evaluate the effectiveness of control measures using indicators. It is important to know if there is internal and external communication regarding identified risks and the actions taken, as well as if periodic reviews are conducted to assess the proper control of risks and the effectiveness of implemented measures.

Block 6: Individual Objectives

This section aims to assess the overall management of individual objectives by personnel. It evaluates whether the objectives align with the established policy and if they are quantifiable and subject to tracking. Additionally, it seeks to determine if these objectives are regularly updated or revalidated, and if an evaluation of appropriate indicators is conducted to measure objective attainment.

These questions are crucial for achieving effective risk planning and management, as well as ensuring that established objectives are coherent, measurable, and adequately monitored. Their responses will help identify areas for improvement and enable necessary measures to be taken to ensure effective risk management and successful achievement of objectives.

Block 7: Roles and Responsibilities

In this segment, the intention is to examine whether roles and responsibilities of the personnel are defined at the outset and if mechanisms are in place to assign them appropriately. Additionally, it seeks to identify if an updated organizational chart exists that illustrates the relationships and responsibilities among the personnel. The final aspect under consideration is whether there is an integrated management of role and responsibility changes over time. This provides more flexibility and individualized adaptation for the personnel and their capabilities.

Block 8: Resources

The objective is to comprehend how the necessary resources for carrying out personnel activities are determined. Moreover, it aims to ascertain if the organization promotes a responsible attitude towards the efficient utilization of resources and if periodic evaluations are conducted to ensure their adequacy and efficiency. Furthermore, it strives to evaluate if the available resources enable the fulfilment and maintenance of a quality management system, as well as if the potential of new technologies is leveraged to maximize benefits and overall effectiveness.

Block 9: Competences

This section aims to obtain information on how personnel competencies are determined. It seeks to determine if these competencies are established in writing and if actions are implemented to acquire them in case of deficiencies. Additionally, it considers whether the competencies considered critical for each role and responsibility are identified, as well as the future competence and development needs of the personnel. It also aims to assess the current levels of competence against the required needs.

Block 10: Communication

It explores how responsibilities, objectives, and compliance requirements are communicated to each member of the personnel. It aims to determine if all individuals who need to receive relevant information are identified and if a communication plan is in place to standardize how the information should be transmitted.

It also seeks to find out if multiple communication channels are used to ensure the proper receipt of information and if there is structured management of misunderstandings. Additionally, it seeks to determine if a system exists to manage complaints or improvement suggestions and if the feedback received is evaluated to assess the conducted activities.

Block 11: Documented Information

The objective is to evaluate how it is ensured that all the necessary information for the effectiveness of the system is documented. It aims to determine if relevant documentation is created, identified, shared, updated, stored, controlled, and protected adequately. Furthermore, it seeks to determine if measures are taken to ensure the confidentiality, integrity, and availability of documented information. Moreover, it seeks to understand the policy for retention of documented information and if externally sourced information necessary for the planning and operation of the system is identified and controlled appropriately.

Block 12: Knowledge Management

It aims to determine if continuous training plans have been established to maintain a good level of knowledge among the personnel. It seeks to ascertain if the organization promotes a culture of continuous training and learning, and if it recognizes and rewards this culture. It also intends to determine if individual learning is encouraged and if evaluations of newly acquired knowledge are conducted.

Additionally, it seeks to understand if personnel have access to new training opportunities and if measures are taken to protect and maintain appropriate confidentiality. Furthermore, it aims to assess the effectiveness of relevant training based on its consistency and alignment with personnel activities.

Block 13: Knowledge Transference

It focuses on determining if access to existing knowledge is facilitated to prevent loss or duplication. It also aims to determine if systems are implemented to encourage knowledge transfer, both through documentation and personnel availability. It seeks to identify if learning and knowledge transfer occur through errors, if responsible individuals are designated for transfers, and if periodic monitoring and evaluation of the effectiveness of these transfers are carried out.

Block 14: Collaboration

The purpose is to identify the potential advantages and risks related to existing or future collaborations. It also seeks to determine if periodic assessments are conducted to evaluate the strategic relevance of collaborations and if the organization promotes internal and external collaboration among its personnel. It aims to understand the organization's attitude towards collaboration and whether it is considered an integral part of the overall strategy.

Block 15: Project Management

It focuses on all the factors to be considered for the effective development of a project and maximizing the performance of all parties involved. Firstly (section 15.1), it inquires about the existence of a detailed prior planning of the process to be carried out, including the objectives to be achieved within suitable timeframes. It also evaluates whether there is ongoing planning during project execution or progress evaluations. Managing interactions is emphasized, encompassing all the unplanned factors that can affect the viability of a project and become obstacles.

Additionally, it takes into account whether the organization values the efficiency and goal attainment by its personnel and rewards such achievements. Finally, in the case of multiple project development, integrated management of a project portfolio and its review once they have been completed are assessed.

In the section of Opportunity Identification (section 15.2), it is asked whether there is a shared interest among the personnel and the organization to identify opportunities for R&D, such as new technologies, solutions, research sources, collaborations, areas of expansion and research, process improvements, sustainability, and image. Prioritisation of opportunities based on their relevance, urgency, or other criteria, considering the potential impact or value they can attain, it is also taken into account.

In the Validation section (section 15.3), the focus is on whether the generated concepts are validated to assess their viability and suitability before implementation. It investigates whether validations of initial versions of the concepts are conducted and if criteria is established for such validation, such as analysis, tests, experiments, taking into account uncertainties and critical risks. It also evaluates whether further adjustments and considerations are made through feedback processes.

In the Solution Development section (section 15.4), it demands whether there is a development plan for solutions within the R&D management system. This plan defines a clear and systematic path to achieve development objectives and ensure project success. The effectiveness of the applied methodology is checked, and it is ensured that the developed solution is truly effective. The results obtained in solution development are recorded and evaluated. The risks associated with the consequences that arise during development, such as technical capabilities, budget, goal attainment, and image, are identified and addressed.

During project or activity execution, it is crucial to have structured management of unplanned changes in direction that may arise. In this section (section 15.5), it seeks to determine if there is structured management of changes in project or activity direction once initiated. This is important to ensure an adequate response and efficient adaptability to eventualities that may arise during execution.

It aims to understand if the organization allows flexibility and ease of adaptation to any project changes. This helps to find out if the organization is open to changes and has the capacity to respond and adapt quickly to new circumstances. In some cases, it may be necessary for the organization to approve a justification to allow a project change. Therefore, an established process is needed to assess and approve changes, ensuring informed decisions based on specific criteria. It is also interested in which documentation is available to record any changes during project execution. It is assessed and analyzed whether there is a prior assessment of the cost-benefit balance of implementing any changes during the project.

The potential consequences should be considered, and the benefits and risks associated with each change should be evaluated. It is important to understand if the necessary resources are assessed and if proper management is carried out to accommodate the changes and ensure efficient project execution. Additionally, the effectiveness of the implemented changes is evaluated.

Block 16: Exploitation of Results and Intellectual and Industrial Property

The section on exploitation of results, products, and services (section 16.1) is based on the organization's ability to promote and disseminate the achieved results effectively. It asks whether the results and their traceability in exploitation and generated impact are identified. It also inquires about the existence of a systematic plan for result exploitation that evaluates their use and viability. In the case of scientific publications, it assesses whether the organization considers the most important aspects to comply with and evaluates the validity of indicators such as periodicity, quantity of articles, and impact factor.

In the field of Intellectual and Industrial Property (section 16.2), it seeks to determine if procedures have been established to protect intellectual and/or industrial property by the organization. Additionally, it aims to ascertain whether the rights of authors associated with innovation results are protected and if measures are implemented to ensure compliance with these rights.

Block 17: Monitoring, Measurement, Analysis, and Evaluation

This block focuses on the effectiveness of monitoring, measurement, analysis, and evaluation of activities, as well as the use of appropriate tools and indicators to obtain useful information. It seeks to determine whether evaluations are conducted frequently and consistently to ensure proper monitoring and whether the obtained results are useful for continuous improvement. Furthermore, it aims to assess the effectiveness of the R&D management system and whether relevant information is communicated to interested personnel.

Block 18: Internal Audits

This block explores aspects related to the audit process. It asks whether procedures, responsibilities, and requirements for audit planning and execution, as well as the maintenance of corresponding records, are defined. It also demands information about the planned frequency of audits and whether periodic reviews are conducted. Additionally, it inquiries about the evaluation of audit effectiveness and the implementation of corrective actions based on previous results.

Moreover, it questions whether the organization has a SWOT analysis system that provides a methodology to assess the strengths and weaknesses of the organization, maintain sustained success, and identify improvement opportunities.

Block 19: Improvement of the R&D Management System

This block addresses the commitment to promoting continuous improvement, the identification and recording of non-conformities or deviations and their causes. It explores whether the organization has a system for implementing preventive and corrective actions (CAPA) to address detected deviations or non-conformities and their causes. It also investigates whether the effectiveness of this action system is ensured, ensuring proper implementation. Finally, it seeks to determine if there is an analysis and prioritisation of proposals for improving the R&D management system, enabling the organization to continue evolving and innovating in its R&D management processes.

ANALYSIS OF QUESTIONNAIRE RESPONSES

Through the questionnaire, it was possible to compare the requirements that a research centre should achieve to have an excellent quality management system with the requirements actually obtained. This capability allows not only identifying similarities with the ideal but also proposing specific opportunities for improvement.

Additionally, obtaining these results demonstrates the questionnaire's ability to adapt to any entity and within the context of each one, analyse its level of compliance. The results obtained for each study group are explained in detail below.

Study group: Unitat de Química Farmacèutica (UQF)

For the study group representing the UQF, one of the most experienced and a knowledgeable member in the unit was audited. The individual in question was a doctoral student from 2016 to 2021 and subsequently became an associate professor at UB. Over the past 7 years, tasks as a researcher at UQF have been carried out.

The personnel have a clear understanding of the objectives and requirements they need to meet individually to carry out their work. However, despite having knowledge of the organizational hierarchy, there is no written organizational chart, and the limits of capabilities and responsibilities are not fully defined.

Regarding Quality Management Systems, it demonstrates good organization but lacks systematic aspects. There is no process map or quality plans in place. This can lead to inefficiency and increased risk of errors. It is important to establish and follow well-defined practices to ensure success and excellence in research.

As a member of the group, there is no knowledge of any vision, strategy, or future aspirations that the organization aims to achieve. There is a lack of communication regarding the organization's overall objectives, and the individual can only provide insights on factors within the centre that affect the work environment. In this case, there is a promotion of a culture of innovation, attraction of talent, motivation of personnel, ability to generate new ideas, and full transparency in actions and communications. However, there are no systems in place for rewarding or incentivizing good performance, and the organization does not exhibit tolerance for failure. Considering these aspects could substantially improve the level of work and enhance talent retention.

Despite being part of a department with significant innovative capacity, there is no formalized risk management program. It is true that risks are identified and prioritized at a more localized level, and strategies are developed to minimize them. However, establishing a systematic risk management plan would harmonize and unify actions to achieve much more efficient control.

In all projects, the necessary documentation is ensured to be identified, stored, and adequately protected. There is proper management of both internal and external information, with reliability analysis. At the same time, procedures are established to protect intellectual property and copyrights. The department stands out for its well-established collaboration capacity, both internally and externally, with more experience than other study groups.

The organization promotes a culture of continuous training and learning with mentoring and tutorship. However, there are no mechanisms in place to protect and maintain confidentiality, nor is the acquired knowledge evaluated. Another weak point is knowledge transfer. Although responsible individuals are designated to teach new members, there is no defined and unified system to preserve knowledge and prevent its loss or fragmentation. In terms of external level, there is a complaint and suggestion system with indicators and frequent feedback. However, there is no similar structure at the internal level.

Project management is fully developed: there is prior planning and ongoing execution, evaluations are conducted during progress, the effectiveness of objective achievement is assessed, and projects are reviewed upon completion. Method and process validations are only performed in some cases and not systematically. Additionally, there is no integrated project portfolio management in cases where multiple projects are carried out simultaneously. One area in which they are highly consolidated is the exploitation of results. Plans for dissemination and promotion of obtained results are in place, indicators are established to evaluate their success, and results are analysed based on customer satisfaction.

Adequate monitoring, measurement, analysis, and evaluation of activities are ensured with good frequency, promoting overall continuous improvement. However, there is no CAPA system in place to record potential corrective or preventive actions for improvement or problem-solving, nor the use of SWOT analysis to identify strengths and weaknesses to be considered. Perhaps the most significant deficiency is the absence of internal audits to assess and understand the group's current state and discover more defined opportunities for improvement.

Table 1: Strengths, Weaknesses and Opportunities for improvement of the UQF. Own production.

Strengths	• Well-established results exploitation plan. • Strong ability to foster collaborations and partnerships. • Fully developed protections for intellectual and industrial property. • Attitude and sense of responsibility to avoid resource wastage. • Informal but present learning and knowledge transfer from mistakes.
Weaknesses	• Limited knowledge of the department's strategy, vision, and objectives. • No internal audits are conducted. • There is no organizational chart, CAPA system, or any internal complaint or suggestion system in place. • No incentives or reward systems are implemented for successful outcomes. • There is no established knowledge transfer program.
Opportunities for improvement	• Conducting internal audits would provide a more defined understanding of the department's limits and capabilities. • Developing a robust knowledge transfer system would prevent fragmentation or loss of knowledge and enhance overall efficiency. • Implementing a CAPA system would enable better documentation of preventive and corrective actions. • If the department lacks clear objectives or strategy, holding global meetings to discuss ongoing projects and evaluate results or make project direction changes could be highly beneficial. • Implement systems for rewarding and incentivizing good performance. Foster a culture that tolerates failure as a learning opportunity and encourages innovation and talent retention.

Study group: Servei de Desenvolupament del Medicament (SDM)

An audit was conducted on an individual who has been pursuing a PhD in the Analysis and Quality Control Department for a period of 4 years. Initially, their involvement initiated as a collaborator, after which they progressed to the roles of researcher and technician. Additionally, they actively collaborate with the Formulation Development Department within the SDM. The responses provided by this individual have yielded the following data belonging to the Analysis and Quality Control Department.

The personnel have a well-defined organization with an organizational chart in place. They have a clear understanding of the objectives and requirements they need to meet individually to perform their job effectively, as well as the limits of their capacity. The department has a consolidated and robust quality management system with no significant gaps. The members are knowledgeable about the vision, strategy, and goals set by the management, as well as the organization's future aspirations. There is a clear promotion of innovation, talent attraction, and a tolerance for failure directly encouraged by the organization. However, there are no reward systems for successful ideas, and there is a lack of awareness in this regard.

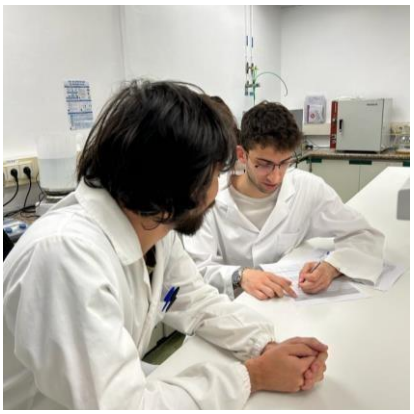

Figure 3: Photograph during the audit at SDM. Own production.

Risk management is not one of the most prominent elements as the organization is currently in the process of developing a risk management program for the future following the ICH Q9. At present, there is no prioritisation of identified risks, no review of these risks, and no control measures in place based on selected indicators. It is expected that once the program is developed, these points will be fully addressed.

The organization of roles and responsibilities is properly established, but there is no change management system in place for individual updates. Resource management is generally good, except for the lack of a widespread attitude of avoiding resource waste. The management of documented information is excellent, along with the determination of personnel competencies. However, the most critical competencies for each position and future competency needs have not been established. There is only an external system for complaints or suggestions for improvement. It would be beneficial to apply such a system internally to give more voice and decision-making power to the staff.

There are plans for continuous formation, and this training is conveyed to the interested personnel during meetings. However, there is no individual tutoring figure, and there are no ways to evaluate the knowledge acquired during the training.

Knowledge transfer is currently one of the major weaknesses as there is no consolidated system in place, making it difficult to transmit information to newly hired personnel. There is no widespread culture of learning from mistakes, no designated individuals responsible for knowledge transfer, and no periodic follow-up in place.

Collaborations are not one of the main relevant factors as they are not directly promoted by the organization, and there is no periodic review or identification of associated risks.

Regarding project management and process validations, both are fully implemented. Thorough planning is conducted before and during the execution, periodic evaluations of progress are performed, effectiveness in achieving objectives is assessed, project

reviews are conducted upon completion, and appropriate change control is exercised throughout the process. The only lacking aspect is the validation of initial versions of a concept, as they do not consider it worthwhile and instead rely on the final version.

The exploitation of results is not as comprehensive as it could be since there is no systematic plan for dissemination and promotion of results. However, the use, viability, and traceability of results are evaluated, and they are also measured in terms of end-user satisfaction. Adequate monitoring, measurement, analysis, and regular evaluation of activities are ensured, as well as a global promotion of continuous improvement.

The organization identifies and records deviations and non-conformities, and it has an effective CAPA system as well as SWOT analysis to detect strengths and weaknesses of the entity. Lastly, it stands out for conducting internal audits where procedures, requirements, and responsibilities for planning and execution are fully defined. Their effectiveness is evaluated, and revisions are performed to ensure the correction of past actions.

Table 2: Strengths, Weaknesses, and Opportunities for improvement of the SDM

Strengths	• Consolidated and robust quality management system for compliance with ISO 9001 standards. • High level of systematization and documented information in all processes. • Highly integrated project management. • Conducting internal audits. • Full knowledge of the vision, global objectives, strategy, and values of the SDM by all personnel. • Knowledge of the organization's vision, strategy, and goals. • Promotion of innovation, talent attraction, and tolerance for failure. • Identification and recording of deviations and non-conformities.
Weaknesses	• Low knowledge transference. • Limited collaboration, especially at the external level. • Lack of rewards or incentives for good performance and satisfactory results. • No developed risk management program. • Lack of a widespread attitude of resource conservation. • Inadequate competencies determined for critical positions and future competency needs. • Lack of an internal system for complaints or suggestions for improvement.

Opportunities for improvement	• Implementation of a risk management program with prioritisation, review, and control measures. • Promotion of a culture of resource conservation. • Establishment of critical competencies for each position and identification of future competency needs. • Implementation of an internal system for complaints or suggestions to empower the staff. • Introduction of individual tutoring and evaluation mechanisms for training sessions. • Establishment of a consolidated system for knowledge transfer and periodic follow-up. • Incorporation of a generalized learning from mistakes and assigning responsibility for knowledge transfer. • Implementation of a systematic dissemination and promotion plan for research results. • Regular audits to ensure adherence to procedures, requirements, and responsibilities.

Study group 3: Unitat de Tecnologia Farmacèutica (UTF)

For this unit, two audits were conducted on two doctoral students with different backgrounds. Both of them work in the same unit and in a similar environment, carrying out research and investigation tasks in their respective fields for their PhD thesis. They are supervised by professors who provide periodic supervision and reviews upon request.

Both researchers have achieved similar results, and the differences between them are often minor and can be attributed to variations in their respective advisors and the nature of their relationships with them. Researcher 1 is currently a PhD student conducting their thesis within the unit. Prior to starting the thesis, they were already part of the research group within the unit. On the other hand, Researcher 2 has been working in the unit as a PhD student for several years. They have a different background, having previously worked in the pharmaceutical industry as a researcher, where they were used to work according to official regulations. However, it is worth noting that currently, the Unit does not comply with any specific official regulations.

Figure 4: Photograph during the audit at the UTF. Own production.

Regarding the Unit's context, neither of the two PhD students has an organizational chart that identifies the organizational hierarchy. However, they have a clear understanding of their positions and the objectives and requirements to be fulfilled. Both agree that there is no well-established quality management system in place, as there are no quality plans, and the management in this regard relies more on personal willingness.

As for the Management commitment, there is no information provided about the vision, strategy, or future aspirations of the organization. There is a lack of clear communication regarding the unit’s overall objectives, and the response is limited to internal factors within the centre that affect the work environment. Nevertheless, there is a culture of talent attraction and motivation among the staff, although there are no systems in place for rewards or incentives for good performance. Both agree that the organization promotes tolerance towards failure, and in cases of negative results, support is provided to the researchers.

There is no established and systematized risk management program. The risks that are identified are minimized as much as possible, but there are no clear strategies, indicators, risk levels, or periodic reviews in place. Roles and responsibilities are defined, but there are no documented procedures for assigning or updating them. The necessary resources for carrying out activities are determined, but there are no evaluations of the available resources or assessments of their suitability and availability.

The required time for document retention is not specified in the documented information, and there are no measures in place to ensure its confidentiality, integrity, and availability. Although the organization promotes a culture of continuous training, there is no established plan for ongoing training, and the effectiveness of acquired knowledge is not evaluated. Additionally, there are no adequate means of protection and confidentiality. However, it is noteworthy that the assessment varies depending on the assigned tutor. In one case, the tutor's role is well-established, and regular meetings (once a week) are conducted. In the other case, the tutor's role is less defined, and periodic meetings are held only once a year.

On the other hand, probably due to the PhD students' profile, there is no strict determination of the required competencies for the personnel, nor the necessary competencies in case of a lack thereof. Neither the organization nor the individuals work with the intention of promoting knowledge transfer from their activities, nor do they promote learning from mistakes.

Project management differs significantly in each situation. In the case of investigator 2, there is a defined planning with detailed monitoring guidelines. There is also planning during the execution and control of interactions, all managed at an individual level. The validation of concepts is not systematized, nor are the criteria considered. The lack

of systematization also affects the exploitation of results, where there is no plan for the dissemination and promotion of the obtained results.

On the other hand, in the case of investigator 1, there is no comprehensive prior project planning, although there are evaluations of project progress. The effectiveness and achievement of objectives are assessed, projects are reviewed upon completion, and there is overall project portfolio management. Similarly to the previous case, the validation and exploitation of results are not governed by a systematic approach, and their development and promotion depend more on personal initiative than on established criteria by the organization.

In both cases, adequate supervision, measurement, analysis, and periodic evaluation of actions are ensured, as well as a comprehensive promotion of continuous improvement. However, investigator 2 is disadvantaged in this aspect due to the lower frequency of periodic reviews. There are no internal audits conducted, and no CAPA system is implemented to record deviations and non-conformities.

Table 3: Strengths, Weaknesses and Opportunities for improvement of the UTF. Own production.

Strengths	• Greater flexibility in handling project changes. • Consistent and similar results achieved by both doctoral students. • Effective supervision and periodic reviews provided by professors. • Researcher 2 brings valuable industry experience from the pharmaceutical sector. • A culture of talent attraction and motivation among the staff.
Weaknesses	• Lack of a well-established quality management system and quality plans. • Absence of clear communication regarding the overall objectives and strategy of the unit. • No specific regulations or compliance with official guidelines. • Insufficient systematization in project management, validation of concepts, and exploitation of results. • Limited supervision and meetings for researcher 2 compared to researcher 1. • No strict determination of required competencies and lack of knowledge transfer initiatives. • Inadequate risk management program. • No internal audits or CAPA system to address deviations and non-conformities. • Generally, there is a lack of systematized information and knowledge transfer.

	• No system for handling complaints and suggestions for improvement has been implemented. • There is no recognition or provision of incentives for good performance and satisfactory results.
Opportunities for improvement	• Develop and implement a comprehensive quality management system with clear plans and procedures. • Explore opportunities to comply with relevant regulations and official guidelines. • Systematize project management, validation of concepts, and exploitation of results. • Increase the frequency of meetings and supervision for researcher 2 to ensure adequate support. • Define and assess the required competencies for the personnel and establish knowledge transfer initiatives. • Establish a robust risk management program with clear strategies, indicators, and periodic reviews. • Conduct internal audits and implement a CAPA system to address deviations and non-conformities. • It would be beneficial to organize a meeting with all the research staff to discuss, evaluate, and reflect on the projects, exchanging ideas and results, and promoting knowledge transfer. • A system for complaints and suggestions could be established, or an agenda item could be dedicated to it during weekly meetings.

COMPARISON OF THE THREE STUDIED GROUPS

Once each group has been evaluated separately, it is possible to analyse the differences between the groups to highlight their strengths, weaknesses, and their competitive position among them. The number of responses such as Yes, No, In progress, or N/A (not applicable) provides a first idea about the current state of the study groups. These are expressed in Figure 5.

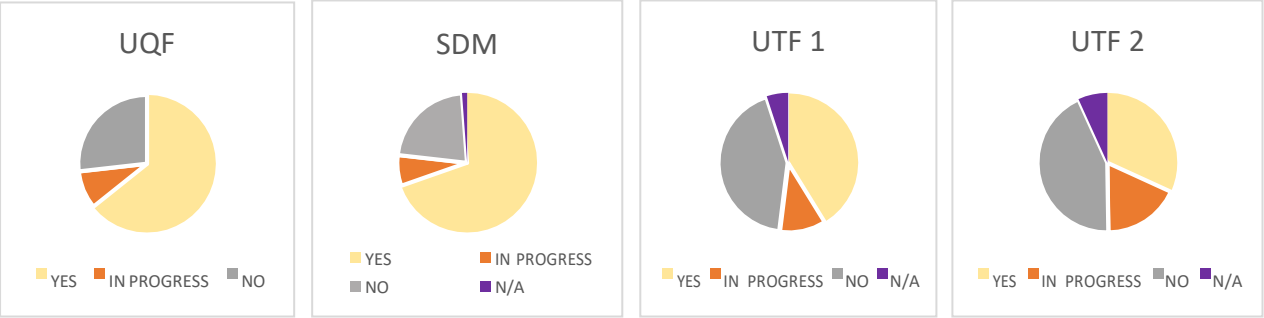

Figure 5: Circular graphical representation of the percentage of Yes, No, In progress, and N/A for each audited individual in relation with the total. Own production.

If we observe the overall Yes results, which represent the number of points complying adequately with official regulations to date, remarkable results can be obtained. It is easy to distinguish those study groups where the number of Yes responses is higher than No, as is the case with SDM and UQF. On the other hand, UTF shows a neutral or even negative balance in this aspect. UTF could achieve better results by focusing on reviewing the points that are still in progress or pending updates.

It is important to consider the effort and willingness of UQF to maintain a sufficiently robust quality system despite not complying with ISO regulations. In many cases, as will be seen later, experience and the need for improvement will be key factors that will put them on par or even above SDM.

It is interesting to note that although the SDM group stands out from the rest, it does not do so in all blocks and competes for the highest compliance with regulations with UQF. For this reason, detailed knowledge of each block provides relevant information on which aspects each study group excels in the most.

Regarding the context and knowledge of the research centre, SDM is the only one that has an organizational chart to express the organizational hierarchy, and the scope of the system and the limits affecting the capacity and responsibility of the personnel are more defined. This is probably because, as an entity that complies with ISO 9001:2015 regulations, SDM has a larger workforce compared to the other two groups, making written justification indispensable. And also, due to the high personnel rotation.

Concerning the quality management system and plans, the overall systematization of SDM provides a much more consolidated and robust system. It is the only group that has documented quality plans and a process map. This map allows for a graphical representation of workflow towards a specific objective. SDM shares with UQF an analysis of internal and external factors that can affect the system, as well as control and review of contracted external activities. On the other hand, UTF is the most penalized in terms of the lack of comprehensive management of activities and procedures, as well as the absence of any quality plan. This can be easily identified in Figure 6.

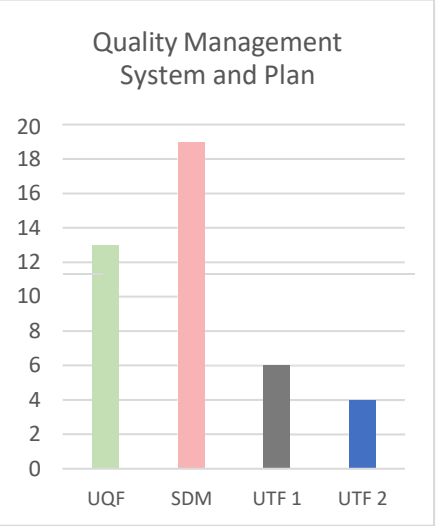

Figure 6: Graph of the total number of "Yes" in Block 2: Quality Management System and Plan. Own production.

With respect to leadership and commitment from management, only the staff of the SDM is aware of the goals, strategy, and vision that the centre wants to convey and the future state it aspires to. This difference is relevant because having shared goals fosters a sense of community and collective identity that is not present in the other cases. The staff will be more connected to the organization's mission and have a clear understanding of how their tasks contribute to the common objective. The company's vision and global goals serve as a reference point for motivation and engagement. When employees understand the broader purpose of the organization, it creates a sense of belonging. This can stimulate creativity, collaboration, and empowerment as team members feel part of a larger cause and see their impact on the research world.

The lack of implementation of these elements can lead to a lack of interest in what goes beyond individual responsibilities, resulting in the loss of this great transformative potential. This block is a clear example of what it entails to work under the ISO 9001 standards compared to those who do not. It also shows how compliance with the regulations allows for standing out above any other entity that does not operate within the same normative context. This representation can be clearly seen in Figure 7.

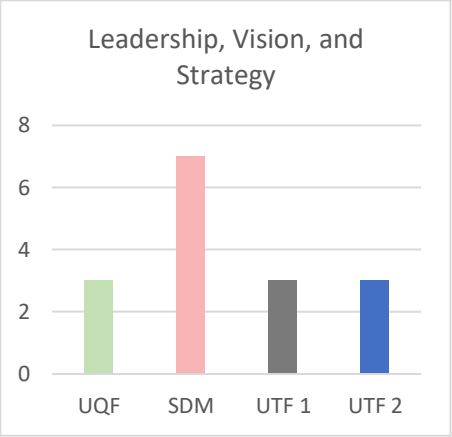

Figure 7: Graph of the total number of "Yes" in Block 3: Leadership, Vision, and Strategy. Own production.

However, in politics and values, the 4 groups often give the same responses. In all cases, the planned intervals for achieving the organization's overall objectives are not specified. They agree that there is no recognition for innovative personnel with satisfactory results, and therefore, there are no incentives to retain talent. Also, there is not an awareness of conflict where competition among staff members is used as a potential source of innovation. Nevertheless, in all cases, they feel that the value of personnel is recognized and that there is a tendency on the part of the centre to attract talent and motivate and empower staff. See Figure 8.

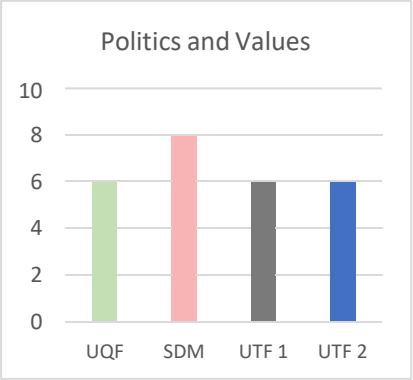

Figure 8: Graph of the total number of "Yes" responses in the block 4 of Politics and Values. Own production.

The risk management is a diverse topic in each group. None of them have a systematized risk management program, although the SDM intends to develop one. However, it is worth noting that currently the UQF has more tools to control risks. They have degrees and types of risks that may or may not be accepted and these risks are compared with the effects of prevention. The identified risks are prioritized, strategies are in place to minimize and control them, and the established control is periodically evaluated.

In this case, the significant difference between UQF can be explained by the experience based on the need. In other words, the unit where poor risk management can pose a serious danger is the one that takes more safety measures, even without having an integrated management system. Look at figure 9.

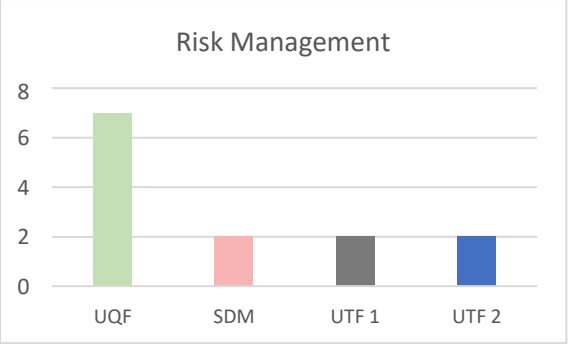

Figure 9: Graph of the total number of "Yes" responses in the Risk Management block. Own production.

In terms of individual objectives, all groups have coherent, measurable objectives that are tracked and effectively communicated to the personnel. As this is a common area, all groups exhibit a high level of compliance in this block. However, none of the groups have indicators in place to measure the achievement of these objectives.

Regarding the roles and responsibilities of the personnel, only the SDM has implemented job descriptions for all possible positions. These descriptions outline the necessary competencies, and the procedure for assigning roles and responsibilities to the personnel is documented. Take into consideration figure 10.

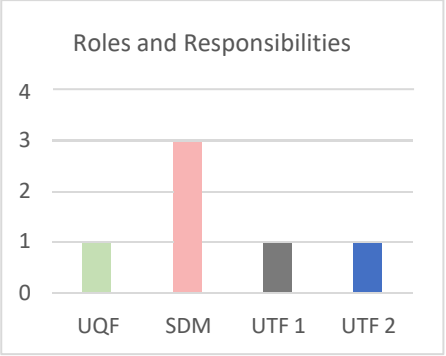

Figure 10: Graph of the total number of "Yes" in the Roles and Responsibilities block. Own production.

None of the groups have a change management or role update system in place; instead, these cases are always managed individually for each situation. This easily results in a similar pattern as shown in Figure 10. The context of ISO compliance highlights the group that incorporates them into their daily activities. It is also true that the level of responsibilities for a researcher in an institution differs from that in Units.

For all groups, the necessary resources for personnel activities are determined, and efforts are made to maximize the potential of existing technologies. It is noteworthy that UQF is the only one promoting a resource-saving attitude and avoiding wastefulness in all its activities, with a clear appreciation for personnel to promote compliance. In the other groups, resource-saving depends more on individual personnel and varies on a case-by-case basis.

Almost all groups appropriately record and control documented information, and they consider the reliability of external information. However, UTF lacks measures to ensure confidentiality, and there is no established documentation retention period. These factors mark the difference and clearly demonstrate the lack of systematization in this study group. See Figure 11.

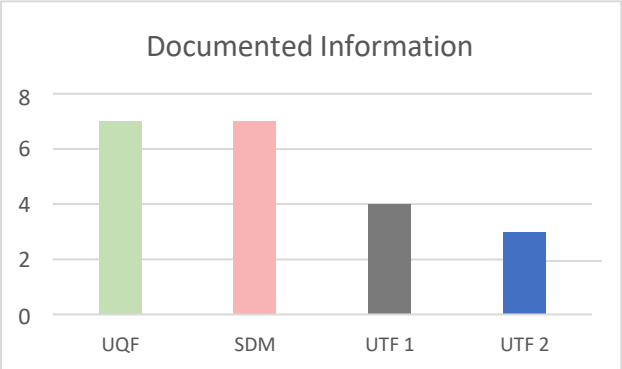

Figure 11: Graph of the total number of "Yes" responses in Block 11 of Documented Information. Own production.

Regarding knowledge management, the SDM is the only group that has continuous training plans, evaluates the effectiveness of the training conducted, and communicates the completed training to the rest of the staff through presentations and oral discussions in all-member meetings. However, the role of mentoring is not emphasized in this aspect, unlike in the UQF and for Researcher 1 in the UTF.

Knowledge transference is a challenge for everyone. Considering that the block has 5 questions, In this case, none of the groups are able to have of a majority of "Yes" responses. There is no established procedure systematically, although all groups are aware of its importance. As shown in Figure 12, only the UQF stands out because it has implemented learning and knowledge transfer from mistakes, and assigns responsibilities for knowledge transfer.

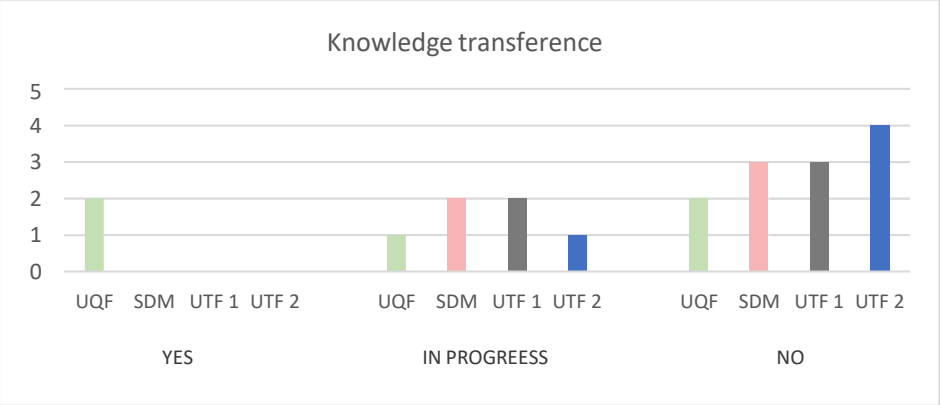

Figure 12: Graph of the total number of Yes, In progress, and No responses in the Knowledge Transference block. Own production.

The Collaboration block stands out significantly by the UQF as seen in Figure 13. It is the only group that ensures the identification of benefits and consequences of current and future collaborations, conducts periodic reviews of these collaborations, and promotes them both internally and externally. The UTF acknowledges the promotion of internal and external collaboration among personnel. However, for the SDM, collaboration is one of the major aspects that need improvement.

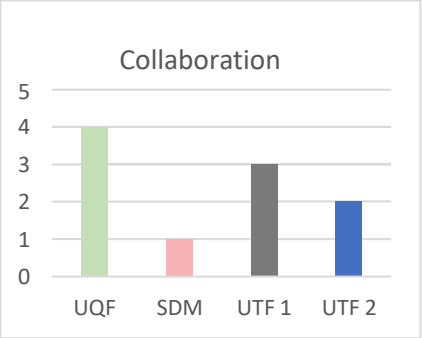

Figure 13: Graph of the total number of "Yes" in the Collaboration block. Own production.

Regarding project management, all groups have a work plan, evaluate progress and goal achievement, and manage interactions that may arise. Change control is one of the most well-established areas, not only due to its structured management but also because of the centre's flexibility in adapting conceptually and in terms of resources and consequences.

Generally, validations are considered procedures, but they are not systematically carried out. The SDM maintains a more integrated management approach, although there are not the initial versions of any process validated in any of the cases.

The UQF stands out in the area of exploitation of results, as they have a well-established plan for dissemination and promotion of results, likely due to their experience in this field. This can be seen in Figure 14. The other study groups have not implemented any plan, and the management in this aspect depends more on the opportunities that arise at the moment and individual promotion. Furthermore, the UQF gives more importance to industrial and intellectual property aspects, as they have more patent applications and therefore more experience in this field compared to the other groups.

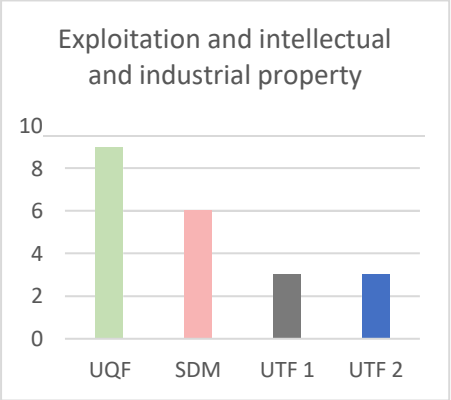

Figure 14: Graph of the total number of "Yes" in Block 16 of results exploitation and intellectual and industrial property. Own production.

SDM is the only group where internal audits are regularly conducted, analysing strengths, weaknesses, and improvement opportunities using an integrated methodology. As can be seen in Figure 15, compliance with the ISO 9001 standards has likely promoted this additional supervision. This distinguishes SDM significantly from the other entities, as none of them perform such audits. Audits serve as a source of process optimization, promote a culture of continuous improvement, and foster transparency and a sense of responsibility. Conducting regular audits communicates the importance of self-assessment and accountability. This helps establish a more robust organizational culture committed to improvement and success.

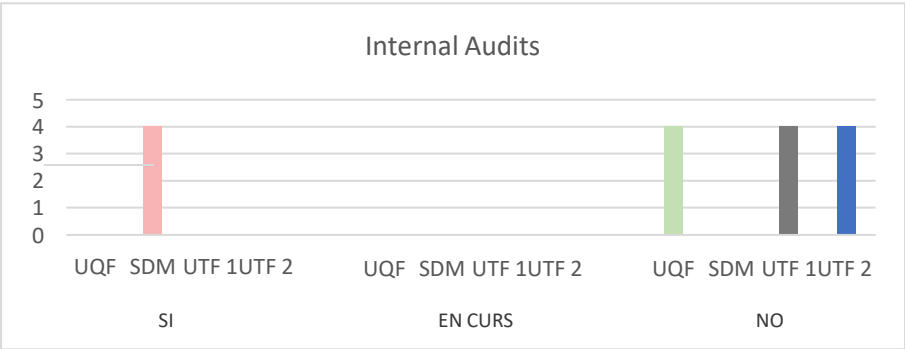

Figure 15: Graph of the total number of Yes, No, and In progress respectively in Block 18 of internal audits. Own production.

Finally, all centres express their interest in addressing opportunities for continuous improvement. However, only the SDM truly implements a CAPA system of preventive and corrective actions, which allows them to record and control any deviations in a more formal and defined manner. Additionally, the SDM, along with the UQF, analyse and prioritize improvement proposals. In contrast, the UTF relies more on personal willingness and self-organization rather than a systematic control by the group. See figure 16.

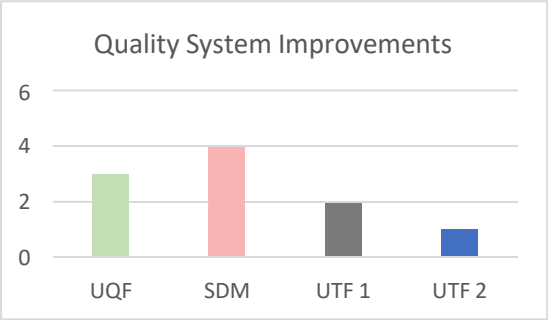

Figure 16: Graph of the total number of Yes in Block 1 of Quality System Improvements. Own production.

CONCLUSIONS

1) The elaboration of the questionnaire has allowed designing a specific audit for research personnel. Since research personnel are the majority in any research centre, a questionnaire that focuses on them will cover the entirety of the centre in a more comprehensive and collective manner.

2) The questionnaire facilitates easy comparison of the obtained results with the ideals. As the questionnaire is based on total binary response questions, "Yes" responses represent the current compliance with regulations to ensure a consolidated quality management system. For this reason, any sections deviating from the total number of "Yes" responses can be easily identified as weak points and opportunities for improvement.

3) The audit's high extrapolation capacity allows it to be applied in various centres with different contexts. The results have demonstrated that an organization that already complies with official regulations from the start obtains a better score in the results.

4) After evaluating the strengths and weaknesses of the respective entities, a comprehensive analysis has led to the identification of 5 distinct improvement opportunities for UQF, whereas SDM and UTF have yielded a total of 9 opportunities for improvement.

5) It is recommended to establish basic work procedures for all groups: develop an organizational chart for the centre, implement systematic project management, adopt quality risk management practices, enhance knowledge transfer processes, and conduct annual self-inspections.

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APPENDIX 1

This annex includes not only the entire questionnaire but also the various responses given by the researchers regarding their research centre. Each researcher is assigned to colour for identification: Green corresponds to UQF, red relates to SDM, black represents Investigator 1 from UTF, and blue corresponds to Investigator 2 from UTF. This allows for an easy way to have all the responses included for each block.

Requisit segons la normativa aplicada	Situació actual *Existeix un compliment d'això?*		
	SI	EN CURS	No
BLOC 1. CONEIXEMENT I CONTEXT DE L'ORGANITZACIÓ			
El personal és capaç de situar-se a si mateix dins del context de l'organització? *(és capaç de definir el rol que desenvolupa)*			
El personal és capaç de situar-se a si mateix respecte la jerarquia organitzativa? Es disposa d'informació documentada?			
El personal comprèn els objectius que se li demana de complir?			
El personal comprèn els requisits que ha de complir per desenvolupar una bona feina?			
El personal té consciència de la política de qualitat, contribució a l'eficàcia del sistema i a la seva millora?			
El personal comprèn les implicacions per incompliment de requisits?			
Existeix un anàlisi intern sobre la sostenibilitat del sistema? *(capacitat de l'organització que mitjançant la gestió responsable garanteix la viabilitat a llarg termini de l'organització i la seva contribució al benestar social i ambiental)*			
Es disposa d'un estudi de les oportunitats d'obtenció de fons i les necessitats dels clients?			
BLOC 2: SISTEMA I PLA DE GESTIÓ DE QUALITAT			
2.1 Determinació de l'abast del sistema de gestió de qualitat			
El personal té definit l'abast del sistema de gestió i té determinats els límits que afecten la seva capacitat i responsabilitat? *(Per assegurar que totes les seves activitats, processos i productes estiguin subjectes a la gestió de la qualitat de l'organització, i es compleixi amb les expectatives dels clients i altres parts interessades, així com amb les normes i regulacions aplicables)*			
Es té en consideració l'impacte potencial dels processos, productes o serveis i l'eficàcia dels controls aplicats?			
2.2 Sistema de gestió de qualitat de I+D+i			
Es realitzen revisions per part de la direcció o pròpia per assegurar la continuïtat i l'adequació del sistema de gestió de la qualitat i per determinar les oportunitats de millora?			
Es realitzen seguiments i anàlisi dels resultats per identificar oportunitats de millora del sistema de gestió de I+D+i?			
Es determinen els criteris i mètodes necessaris per donar suport a les activitats prèviament al seu inici?			
Es disposa d'un anàlisi dels factors interns i externs que afecten i influeixen el sistema de gestió en i+D+i?			
Existeix un mapa de processos? I diagrama de fluxos? *(Representació gràfica de les activitats, procediments i fluxos de treball sobre un determinat objectiu que permet identificar més fàcilment les oportunitats de millora i establir una estructura més eficaç i eficient)*			
Es realitzen controls, anàlisis i valoracions sobre les activitats externes contractades per l'organització?			NA NA
L'organització té definit els requisits que ha de complir qualsevol entitat contractada externament a l'organització? Se n'avalua l'eficàcia?			NA NA
S'assegura que el sistema de gestió pot aconseguir els resultats previstos?			

Es busca millorar els efectes desitjats?			
Es busca prevenir o reduir els efectes no desitjats?			
2.3 Plans de qualitat			
Es disposa d'un pla de qualitat? (*document que defineix les activitats, els procediments i les polítiques que s'han de seguir per garantir que un producte, servei o procés concret compleixi amb els requisits de qualitat especificats així com els mètodes per mesurar i avaluar el compliment dels objectius de qualitat establerts*) Es disposa d'informació documentada?			
Donat un cas concret es determinen els requisits, objectius, reglaments, especificacions mètodes i recursos?			
Es determina l'abast d'un procés definit en base a recursos, validesa, context de l'organització o extensió del procés?			
Existeix un seguiment, anàlisi i traçabilitat de la implementació d'un pla de qualitat? Hi ha informació documentada sobre els controls a realitzar?			
Es realitzen correctament les comunicacions internes i externes en un pla de qualitat?			
S'avalua la implementació i èxit d'un pla de qualitat?			
Existeixen plans de qualitat pels productes, processos i serveis externs a l'organització?			NA
Els plans de qualitat es revisen i accepten periòdicament?			
BLOC 3: LIDERATGE, VISIÓ I ESTRATÈGIA			
3.1 Compromís de la Direcció			
El personal és conscient de si l'organització estableix una visió, estratègia, política i objectius coherents amb el context de l'organització?			
El personal és conscient de si s'implementen intervals planificats d'acompliment?			
El personal és conscient de si s'assegura que es compleixin els objectius marcats per l'organització? Es comptabilitzen?			
Es reconeix el valor del personal innovador i amb resultats satisfactoris?			
Es premia el valor del personal innovador i amb resultats satisfactoris?			
El personal és conscient d'una predisposició o tendència de l'organització per atraure i potenciar el talent?			
El personal és conscient d'una predisposició o tendència de l'organització per retenir el talent?			
El personal és conscient d'una predisposició o tendència de l'organització per motivar i empoderar el personal? Hi ha incentius?			
Hi ha incentius? *(ja siguin per motivar o retenir el personal)*			
3.2 Visió d'I+D+i			
El personal és conscient de si existeix una descripció de l'estat futur al que aspira l'organització i del seu rol futur?			
Es té en compte l'impacte desitjat dels seus resultats tant internament com externament?			
Aquests objectius futurs es comuniquen al personal?			
BLOC 4: POLÍTICA I VALORS			

4.1 Política d'I+D+i			
Per valorar l'ambició personal: El personal està disposat a qüestionar els procediments actuals en el cas que detecti alguna oportunitat de millora o innovació? Està disposat a afrontar nous reptes i ampliar la seva capacitat?			
Des de l'organització es promou una cultura de la innovació i creativitat per créixer i millorar el rendiment?			
Es proporciona un marc de referència pel compliment dels objectius? *(estructura o conjunt de principis per garantir la coherència i la consistència en la gestió i establiment d'objectius, mesures i resultats definits com també per a l'avaluació comparativa entre organitzacions)*			
S'inclou un compromís de compliment de requisits o objectius personals?			
4.2 Foment de la cultura de la innovació i competència			
S'incentiva el desenvolupament de noves idees i es concedeix temps per la seva activitat?			
Existeixen sistemes de recompensa i reconeixement per les idees d'èxit?			
S'avalua l'efectivitat del foment de la cultura de la innovació?			
Es dóna suport a l'intercanvi obert d'idees i solucions entre el personal?			
El personal té mecanismes per optimitzar el sistema de gestió en I+D+i?			
Existeix transparència en tots els procediments i activitats en I+D+i?			
Existeix una consciència de conflicte com a potencial font d'innovació? Hi ha consciència d'haver de mantenir un rendiment alt d'actuació?			
L'organització proporciona tolerància front el fracàs? *(Hi ha un ambient de suport a l'investigador en cas de que es generin resultats no satisfactoris?)*			
BLOC 5: GESTIÓ DE RISCS			
Es tenen en compte les incerteses associades a les oportunitats?			
Existeix un grau o tipus de risc que pot o no acceptar-se?			
Es compara els efectes d'acceptar riscs amb els efectes de la prevenció?			
Es disposa d'un programa de gestió de riscos?			
Es prioritzen els riscos identificats?			
Existeixen estratègies per minimitzar i controlar els riscos identificats?			
S'avalua l'eficàcia de les mesures de control amb indicadors?			
Es realitzen comunicacions internes i externes respecte els riscos identificats i les mesures preses?			
Es realitzen revisions periòdiques per avaluar-ne el bon control de riscs i l'eficàcia de les mesures?			
BLOC 6: OBJECTIUS PERSONALS			
Els objectius són coherents amb la política establerta?			

Els objectius són mesurables i quantificables?			
Els objectius són objectes de seguiment?			
Els objectius es comuniquen al personal?			
Els objectius s'actualitzen o es revaliden periòdicament?			
S'avaluen els indicadors adequats per mesurar el compliment dels objectius?			
BLOC 7: ROLS I RESPONSABILITATS			
S'ha definit els rols i responsabilitats del personal?			
Es disposa d'un organigrama que mostri les relacions i responsabilitats entre el personal? S'actualitza periòdicament?			
Existeix un procediment documentat per assignar els rols i responsabilitats del personal?			
Existeix un sistema de gestió en els canvis de rols, responsabilitats i autoritats dins de l'organització?			
BLOC 8: RECURSOS			
Es determinen els recursos necessaris per les activitats del personal?			
Des de l'organització es promou una actitud i responsabilitat de no malgastar o usar en excés substàncies i matèries primes en la fabricació o manipulació de productes?			
Es valora l'eficiència pràctica, tècnica i econòmica pels casos d'excés en l'ús de matèries primes o substàncies a manipular?			
Es disposa del temps suficient pel desenvolupament de les activitats i ús de recursos pel personal?			
Es realitzen avaluacions sobre els recursos disponibles i la seva idoneïtat i ús eficient?			
Aquests recursos permeten complir i mantenir un sistema de gestió de qualitat? *(compleix els 2 punts anteriors)*			
S'avalua i s'intenta treure el màxim profit i potencial de les noves tecnologies existents per maximitzar el benefici global i eficàcia?			
BLOC 9: COMPETÈNCIES			
Es determina les competències del personal? *(en base a l'educació, formació, experiència o actitud)*			
Es determina per escrit les competències necessàries per poder treballar a l'organització en base a l'educació, formació, experiència o actitud?			
S'empren accions per adquirir les competències necessàries en cas de manca? (formacions, orientacions, reassignacions de personal, etc.)			
S'identifiquen les competències considerades més crítiques per cadascun dels rols i responsabilitats?			
Des de l'organització es determinen les necessitats futures de competència i desenvolupament del personal?			
S'avaluen els nivells de competència actual enfront les necessitats de competència requerida?			
BLOC 10: COMUNICACIÓ			

Es comunica clarament les responsabilitats, objectius i requisits de compliment per cada membre del personal?			
S'identifiquen totes les persones que han de rebre la informació pertinent? *(No es deixa ningú enrere o la comunicació es dóna lloc únicament en subgrups?)*			
Es disposa d'algun pla de comunicació per unificar el com s'ha de comunicar informacions rellevants?			
S'utilitzen múltiples canals de comunicació per assegurar la bona recepció de tota la informació rellevant?			
Hi ha una gestió estructurada dels malentesos? *(Hi ha una intencionalitat i interès en identificar les parts afectades i analitzar les causes del problema i buscar la solució més adient?)*			
Existeix algun sistema per gestionar les queixes o suggeriments de millora?			
Es promou un anàlisi de la retroalimentació rebuda per avaluar les activitats realitzades?			
BLOC 11: INFORMACIÓ DOCUMENTADA			
S'assegura que tota la informació requerida per l'eficàcia del sistema estigui documentada?			
La documentació es crea, identifica, comparteix, actualitza, s'emmagatzema, controla i protegeix de forma adequada?			
Existeixen mesures per assegurar la confidencialitat i integritat de la informació documentada?			
Existeixen mesures per assegurar la disponibilitat de la informació documentada?			
La informació documentada es conserva durant el temps necessari?			
La informació documentada d'origen extern que l'organització determina que es necessària per la planificació i operació del sistema de I+D+I s'identifica i controla adequadament?			
Quan s'accedeix a algun tipus d'informació externa, es coneix la seva fiabilitat?			
BLOC 12: GESTIÓ DEL CONEIXEMENT			
Existeixen plans de formació continuada per tal de mantenir un bon nivell de coneixement per tot el personal?			
L'organització ha promogut en el personal la cultura de formació i aprenentatge continu?			
L'organització ha premiat la cultura de formació i aprenentatge continu del personal?			
Es promou l'aprenentatge individual? Hi ha supervisió, acompanyament professional (*coaching*) o tutories?			
S'avaluen els coneixements nous adquirits?			
S'assegura que el personal tingui accés a noves formacions?			
Hi ha uns mitjans de protecció i confidencialitat adequats?			
Hi ha una valoració de les qüestions ètiques relacionades amb l'ús del coneixement?			NA NA NA
S'avalua l'eficàcia de les formacions pertinents? *(en base a la coherència i concordança amb l'activitat a realitzar del personal)*			
BLOC 13: TRANSFERÈNCIA DEL CONEIXEMENT			

Es facilita l'accés al coneixement existent per evitar-ne la pèrdua o duplicació?			
Existeixen sistemes per afavorir la transferència de coneixement? Tant documentació com disposició?			
Hi ha aprenentatge i traspàs de coneixement dels errors?			
S'estableixen responsables en les transferències de coneixements?			
Existeix un seguiment periòdic i avaluable sobre l'eficàcia de les transferències de coneixement?			
BLOC 14: COL·LABORACIÓ			
S'identifica els possibles beneficis en una col·laboració present o futura?			
S'identifiquen els possibles riscos associats a una col·laboració present o futura?			
Hi ha una revisió periòdica de la rellevància estratègica de les col·laboracions?			
Des de l'organització es promou la col·laboració interna i externa del personal?			
BLOC 15: GESTIÓ DE PROJECTES			
15.1 Projectes de I+D+i			
Hi ha una planificació prèvia dels projectes a realitzar? Se'n determinen les interaccions i interrelacions dins de l'organització o altres projectes? Hi ha un pla de gestió del projecte? *(es tenen els objectius i resultats previstos, l'estat de l'art, punts de control, les tasques a realitzar, els recursos necessaris, identificació i gestió de riscos, revisions formals, control i documentació?)*			
Es disposa d'una planificació de l'execució del procés? *(gestió del temps, especificació de propòsits, assignació de responsabilitats, punts de control, ús eficient i control de recursos)*			
Existeixen avaluacions del progrés d'un projecte? *(Idoneïtat del pla, compliment d'objectiu, resultats rellevants, facilitar la comunicació, identificació de desviacions, canvis, riscos, oportunitats de millora)*			
Hi ha una gestió de les interaccions? *(factors no planificats que afecten el projecte)*			
Es valora l'eficàcia i el compliment dels requisits i objectius d'un projecte? Es premia?			
Es premia el compliment dels requisits i objectius d'un projecte?			
En el cas d'una situació on es desenvolupin múltiples projectes en paral·lel hi ha una gestió integrada de la cartera de projectes? *(Balanç adequat entre risc i retorn, coherència de prioritats, tipus d'innovació, temps i abast, supervisió global amb revisions periòdiques, optimització dels recursos compartits, maximització del valor de la cartera de projectes)*			NA
Hi ha una revisió (de viabilitat, acompliment, etc.) sobre els projectes finalitzats?			NA
15.2 Identificació d'oportunitats			
Hi ha un interès per identificar les oportunitats per a la I+D+i? *(noves tecnologies, solucions, fonts d'investigació, col·laboracions, àrees d'expansió i recerca; millores en processos, sostenibilitat i imatge)*			
Es prioritzen les oportunitats per rellevància, urgència o qualsevol altre criteri?			
Es tenen en compte l'impacte o valor potencial que poden assolir?			

15.3 Validació de conceptes			
Es validen els conceptes generats? *(s'avalua la viabilitat i la idoneïtat d'una idea, concepte o procés abans de ser implementat?)*			
Es validen les versions inicials d'un concepte?			
Hi ha criteris establerts en una validació? *(es considera un o més enfocaments com anàlisis, assajos, experiments; es tenen en compte incerteses i riscs crítics; s'ajusten i adapten per retroalimentació?)*			
Es realitzen ajustaments o millores en els conceptes a validar a partir de feedbacks i nous aprenentatges?			
15.4 Desenvolupament de solucions			
Existeix un pla de desenvolupament de solucions dins el sistema de gestió de I+D+i?			
Es comprova la viabilitat i eficàcia de la metodologia aplicada pel desenvolupament solucions?			
S'assegura que la solució desenvolupada és realment efectiva?			
Existeix un registre i avaluació dels resultats obtinguts en el desenvolupament de solucions?			
S'identifiquen i s'aborden els riscs associats a les conseqüències que es generen en el desenvolupament? *(capacitats tècniques, pressupost, compliment d'objectius, imatge)*			
15.5 Control de canvis			
Hi ha una gestió estructurada dels canvis de rumb d'un projecte o activitat un cop ja iniciada?			
L'organització permet flexibilitat i facilitat d'adaptació en qualsevol canvi de projectes?			
Cal que l'organització en certs casos aprovi una justificació per permetre un canvi de projecte?			
Es disposa de documentació per tenir constància de qualsevol canvi durant l'execució d'un projecte?			
Es valora i analitza el balanç benefici-risc a priori de tirar endavant qualsevol canvi durant el projecte? S'avaluen les conseqüències?			
Hi ha un anàlisi de la disponibilitat de recursos i de la possible reassignació de responsabilitats i autoritats?			
S'avalua l'eficàcia del canvi? *(en base a resultats obtinguts respecte els previstos, aparició de noves oportunitats de millora)*			
BLOC 16: EXPLOTACIÓ DE RESULTATS I PROPIETAT INTEL·LECTUAL I INDUSTRIAL			
16.1 Explotació de resultats, productes o serveis			
Hi ha una identificació i traçabilitat dels resultats, productes o serveis obtinguts per assegurar-ne la conformitat? Se'n conserva documentació?			
Es disposa d'un pla per l'explotació de resultats obtinguts en projectes i serveis de I+D+i?			
Es fan anàlisis sobre l'ús i viabilitat de l'explotació dels resultats?			
Es mesuren els resultats obtinguts en termes de satisfacció de l'usuari final?			
Existeixen certs aspectes que es tenen en compte en cas d'una publicació científica? *(Aspectes com la indexació, la línia editorial, periodicitat i quantitat d'articles, el factor d'impacte, el fet d'usar mitjans d'accés obert)*			

Existeix algun pla de difusió i promoció dels resultats obtinguts?			
S'estableixen indicadors per avaluar l'èxit de l'explotació de resultats?			
16.2 Propietat intel·lectual i industrial			
Existeixen procediments per protegir la propietat intel·lectual i/o industrial?			NA NA NA
Es protegeixen els drets dels autors associats als resultats de les innovacions?			
BLOC 17. SEGUIMENT, MESURA, ANÀLISI I AVALUACIÓ			
Es realitza el seguiment, mesura, anàlisi i avaluació de les activitats d'un sistema de gestió I+D+i?			
S'usen eines apropiades pel seguiment, mesura, anàlisi i avaluació de les activitats d'un sistema de gestió I+D+i? Es disposa d'indicadors?			
Les avaluacions són prou freqüents i constants per fer un bon seguiment?			
Els resultats de les avaluacions permeten obtenir informació útil?			
S'avalua l'eficàcia del sistema de gestió en I+D+i?			
Es comunica la informació rellevant al personal interessat?			
Es prenen accions per optimitzar el sistema de gestió en I+D+i?			
BLOC 18: AUDITORIES INTERNES			
Queden definits els procediments, responsabilitats, requisits per la planificació i execució d'auditories i manteniment dels registres corresponents?			
La freqüència de les auditories està planificada? Es fa revisions?			
Se'n avalua l'eficàcia? Es corregeixen les accions passades?			
Es disposa d'alguna metodologia per avaluar les fortaleses i debilitats de l'organització, el manteniment de l'èxit sostingut i de les oportunitats de millora?			
BLOC 19: MILLORA DEL SISTEMA DE GESTIÓ DE I+D+i			
Des de l'organització s'aborden les oportunitats per fomentar la millora contínua?			
L'organització identifica i registra les desviacions o no conformitats? S'identifica també les seves causes?			
Es disposa d'un sistema d'implantació d'accions preventives i correctives?			
Es garanteix que el sistema d'accions correctives i preventives sigui eficaç i s'implementi correctament?			
S'analitzen i prioritzen les propostes de millora del sistema de gestió de la I+D+i?			

APPENDIX 2

On June 6, 2023, I had the opportunity to present a poster on the first part of my degree thesis at the 41st Symposium of AEFI (Spanish Association of Pharmaceutical Industry Pharmacists). The title can be translated to English as “Quality and Research: Proposal for Questionnaire Application.” Without having analysed the data collected from the various audits yet, the objective of the poster was limited to the design of the questionnaire and its ability to determine the status of QualityManagement Systems in each study group.

CALIDAD E INVESTIGACIÓN: PROPUESTA DE CUESTIONARIO PARA EVALUAR SU APLICACIÓN

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INTRODUCCIÓN

Dentro del ámbito de la investigación no se dispone de un sistema de gestión de calidad consolidado.

La implementación de este sistema permite constituir un marco de referencia de evaluación y mejora continua.

Este marco garantiza la validez de los resultados y es un elemento clave para garantizar la eficacia de los proyectos desarrollados.

Imagen 1: Producción propia

OBJETIVOS

* Unificar los puntos más relevantes de normativas ISO, UNE e ICH, entre otras, relativas a la investigación.
* Diseñar un cuestionario para auditoria focalizado directamente en el personal de investigación para poder determinar el grado de cumplimiento del centro y las posibles oportunidades de mejora.

Imagen 2: Producción propia

METODOLOGÍA

El cuestionario usa como base estructural la normativa UNE 16602 y añade e incluye apartados de varias normativas UNE EN ISO, ISO 9001, ICH Q8, ICH Q9, ICH Q10 y el Modelo EFQM.

Se valora el contexto y objetivos del personal; el conocimiento de la visión y estrategia de la organización; la gestión de riesgos; la organización de roles y responsabilidades; el control de la información documentada y recursos; la gestión de formaciones activas, competencias y colaboraciones; la transferencia de conocimiento; el desarrollo de proyectos; la explotación de resultados; la capacidad de seguimiento y análisis; el fomento de oportunidades de mejora.

AENOR
GESTIÓN I+D+i
UNE 166002

Imagen 3: Logotipo de UNE 16602

ISO 9001:2015

Imagen 3: Logotipo de ISO 9001:2015

RESULTADOS

Se ha elaborado un cuestionario de 167 preguntas distribuidas en 19 bloques usando preguntas con solo tres posibles respuestas: Sí, No o En curso.

Es aplicable a cualquier centro de investigación, pero específico y detallado para cada bloque. Las preguntas binarias permiten obtener respuestas más claras y precisas. Debido a la longitud del cuestionario, se adjuntan solamente una pequeña representación:

Requisits segons la normativa	Situació actual		
	SÍ	EN CURS	NO
1. CONTEXT DE L'ORGANITZACIÓ			
1.1 Coneixement de l'organització i del seu context i comprensió de les necessitats i expectatives de les parts interessades			
El personal és capaç de situar-se a si mateix dins del context de l'organització? *(és capaç de definir el rol que desenvolupa)*			
El personal és capaç de situar-se a si mateix respecte la jerarquia organitzativa? Es disposa d'informació documentada?			

Tabla 1: Inicio del cuestionario valorando el conocimiento del personal en la organización.

5.1 Projectes de I+D+i			
Hi ha una planificació prèvia dels projectes a realitzar? Se'n determinen les interaccions i interrelacions dins de l'organització o altres projectes? Hi ha un pla de gestió del projecte?			
Existeixen avaluacions del progrés d'un projecte?			
Hi ha una gestió de les interaccions? *(factors no planificats que afecten el projecte)*			
Es valora l'eficàcia i el compliment dels requisits i objectius d'un projecte? Es premia?			

Tabla 3: Ejemplo de preguntas relativas a la gestión de proyectos.

4.7 Gestió del coneixement			
Existeixen plans de formació continuada per tal de mantenir un bon nivell de coneixement per tot el personal?			
L'organització ha promogut en el personal la cultura de formació i aprenentatge continu?			
L'organització ha premiat la cultura de formació i aprenentatge continu del personal?			
Es promou l'aprenentatge individual? Hi ha supervisió, acompanyament professional o tutories?			
S'avaluen els coneixements nous adquirits?			

Tabla 2: Muestra del cuestionario aplicado a la gestión del conocimiento.

5.5 Control de canvis			
Hi ha una gestió estructurada dels canvis de rumb d'un projecte o activitat un cop ja iniciada?			
L'organització permet flexibilitat i facilitat d'adaptació en qualsevol canvi de projectes?			
Cal que l'organització en certs casos aprovi una justificació per permetre un canvi de projecte?			
Es disposa de documentació per tenir constància de qualsevol canvi durant l'execució d'un projecte?			

Tabla 4: Representación del cuestionario en el capítulo de cambios en proyectos ya iniciados

CONCLUSIONES

* Herramienta útil para poder ser incorporada en cualquier centro de investigación
* Permite reconocer puntos fuertes, débiles y oportunidades de mejora
* Facilita la comparativa detallada con otras organizaciones. Por este motivo, se estan realizando auditorías a partir de este cuestionario para evaluar tres entidades distintas: el Departament de Química Farmacèutica de la UB, la Unidad de Tecnología Farmacèutica de la UB y el SDM de la UB

BIBLIOGRAFIA

Normativas usadas: UNE 16602:2018, ISO 9001:2015, UNE EN ISO 9000:2015, UNE EN ISO 9004:2018, UNE EN ISO 10013, UNE EN ISO 10014, UNE EN ISO 10005, UNE EN ISO 10006, UNE EN ISO 10007, UNE EN ISO/PAS 17004 IN, UNE 412001:2008, UNE EN ISO 10015, UNE EN ISO 10018, MODEL EFQM, ICH Q8, ICH Q9 e ICH Q10.

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