A Quality Management System for scientific research activities and its related management software

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Introduction: Quality disciplines have been widely used for decades in industrial and business fields. It is only in recent times, however, that Quality management and approaches have received proper attention in life science (including basic research), overcoming the prejudice that they are an impediment to creativity [1-6]. Here, we present the development, optimization, and validation of an innovative way of planning and organizing research, inspired by Quality and Project Management (PM) principles. We propose a model of a Quality management system (QMS) for the study-based scientific research activities, which are the bases for the preclinical step of the drug discovery process (Fig. 1).

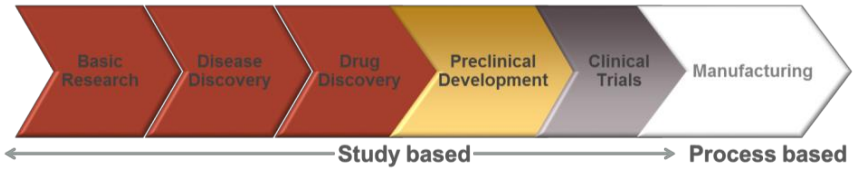

Figure 1 - Workflow of the drug discovery process

Methods: To create this Quality model it was necessary to translate the methods and skills related to Quality in industry and apply them in scientific research. Firstly, we have selected the pilot laboratory: a research laboratory of the Italian National Research Council (C.N.R.), working with marine animal models (mainly the Sea Urchin *Paracentrotus lividus*) in the scientific area of drug discovery and embryonic development.
From a range of available models (*i.e.*, GLP, ISO17025, etc.), the international standard **ISO 9001** was selected. We have then generated, applied, and validated the QMS for the pilot laboratory with the final purpose to generate a TQM (Total Quality Management) model to be easily transferred to other research laboratories and eventually institution.

Results: The operational (research activity, student training and science communication) and support processes (*e.g.*, provision, personnel and instrument management, economic resources and verification and improvement, management of records, internal and external communication) to be managed were selected and placed under Quality control (Fig. 2). Stakeholders, recipients, results, metrics, and suppliers for the research laboratory were also identified and, finally, procedures, operating instructions, guidelines, laboratory notebook formats, and layouts to cover all laboratory-related processes were generated. The laboratory has been certified and thus validated with ISO 9001:2008 and it received and passed the surveillance audits.

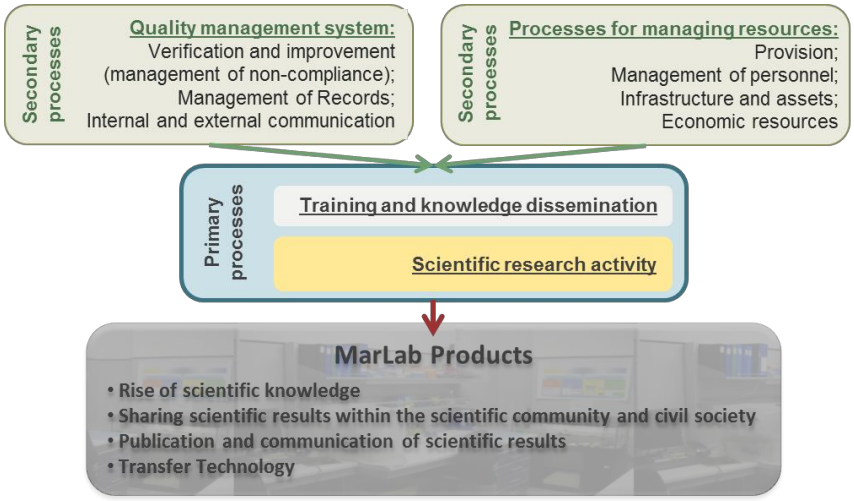

Figure 2 - The operational and support processes of a research laboratory

Based on our quality management system, we have created a modular software prototype, which we named Help4Lab. Help4Lab represents an innovative alternative to commercial available research data information systems, since it supports the management of all the different research laboratory processes (Fig. 2) and their related documentations. Thus, different users will benefit from its usage (*e.g.* researcher, students, technicians, and administrative staff). In this regard, Help4Lab has restricted access, any user with the username and password can navigate within it, limited to their role. The laboratory technical and quality managers and scientific director have full access and the chance to enter and edit data. Help4Lab contains a section "*Processes*" that helps the management of all documentation (management procedures, guidelines, operating instructions and forms) inherent to processes identified in the research laboratory (Fig. 2). A second "*Provision*" section manages the entire path of the product and includes suppliers list and ratings, warehouse, etc. Furthermore, "*Instruments*" and "M*anagement tools*" sections assist the maintenance and calibration of instruments.

A proof of concept of our QMS and its related Help4Lab software efficacy in the pioneering laboratory has been derived from the evaluation of selected quantitative indicators (*i.e.*, staff motivation rating, number of non-conformity, efficiency of aquarium management, and number of published scientific papers) three years after certification, during the internal audit. As far as the management of the sea urchin housing in the aquarium was concerned, the related indicator was found to be ‘‘excellent”, ever since the first year of QMS application. Moreover since the application of QMS, none of the programmed experiments had to be postponed or cancelled due to lack of suitable biological material, namely the sea urchin embryos, thus confirming the good management of the aquarium under this management system. Furthermore, we could demonstrate that a proper and accurate transfer of Quality culture and methodologies to intellectual and scientific production can facilitate and strengthen research, providing new tools to make it faster and more efficient without imposing any constraints on the research work itself.

Conclusions: The QMS model and the management software Help4Lab related to it could be a new tool for improving and simplifying the organization of research laboratories. This QMS model has motivated the staff towards a continuous improvement of shared operations and enhancing communication between all management levels and personnel. Such a system also ensures the reliability of the results of research laboratories. Furthermore, the QMS model would increase the prestige of the laboratory and the Public Research Institution.

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