

The qPMO network: quality management tools to improve research efficiency, reproducibility, data management and dissemination

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Introduction

The scientific world is facing the “quality revolution”: not only results have been led to research and social community attention, but also reliability, safety and efficacy of discoveries and efficiency of fund exploitation. In this context, quality management in scientific R&D has become an essential tool in ensuring that modern scientific development is implemented within a rigorous and robust quality framework. The need for Quality standards in non-regulated research is a matter of considerable current debate inside international research community. Researchers should strive for the highest achievable standards and quality tools in the planning, conduct and dissemination of their research and demonstrate integrity in their dealings with others. The Quality and Project Management OpenLab (qPMO) is a research network involving 5 different Institutes and two Departments of the Italian National Research Council (CNR), aimed at realizing a Total Quality Management (TQM) model for Life Sciences laboratories. This TQM OpenLab model will act as a uniform environment in which strong, innovation-oriented research projects can be designed and developed according to international Quality standards and with the planning of Horizon 2020.

Methods

The qPMO network identified four workpackages (WPs), each one focusing on a specific aspect of the integration of Quality and Life Sciences research: **Management of knowledge**: Definition of guidelines for research laboratories and development of a web platform for the cataloging and dissemination of guidelines, experimental procedures, model systems and molecular tools; **Management of experimental procedures**: Quality methodologies for technology-transfer support via Failure Mode and Effect Analysis (FMEA); **Management of a research laboratory**: management of a research lab via an ISO9001 Quality Management System (QMS); **Management of multivariable assays**: Application of Design of Experiments (DoE) to protocol set-up and optimization. The WPs cover most Quality aspects of a Life Sciences research laboratory, and the products achieved can be transferred to other research laboratories. High interconnection and interoperability among WPs are key elements of the project and contribute to the creation of a “concept laboratory”, based on Total Quality Management.

Results

We defined a model for the drafting of guidelines, based on the principles of Quality and documentation management, among them PDCA. The outcome is an operational flow describing all the phases of the process which has been validated by four different drafting groups through the production of 13 guidelines ranging from research activity to equipment and facility management, as well as addressing the design, risk identification and validation of experimental procedures. All the guidelines are currently being applied in Institutes of the CNR, and some of them have also been included in a certified Quality Management System (QMS) for a research laboratory. Furthermore, we have generated and applied a model of a management system for a laboratory for scientific research implementing the ISO 9001:2008 Quality System. To create this Quality

model it was necessary to use methods and skills related to Quality employed in industry, and apply them in research. As pilot laboratory we chose the MarLab laboratory, that deals with the housing and handling of marine organisms. It has been certified with ISO 9001:2008 in June 2014 and until now passed all the surveillance audits. In addition, based on our quality management system, we have created a modular software, Help4Lab, to manage Quality, safety, environment and documents in a research laboratory. Help4Lab contains the section "Processes" that helps the management of all documentation (management procedures, guidelines, operating instructions and forms) inherent to processes identified in the research laboratory (primary processes: Research, Student training and Science Communication; secondary processes: management processes, quality management system, etc.). A second section (Suppliers List and Ratings, Warehouse, etc.) supports the "material handling". Furthermore, the section "management tools" helps planning maintenance and calibration of instruments. We also applied further Quality tools, among them the FMEA, in order to validate and support research activities and results, to create a standard and controlled workplace, and to support the interaction between research and industrial application also. This quality approach led to several major advantages. At first, a set of improvement actions was generated covering most lab aspects, such as management of instrumentation or training of personnel involved. Then, FMEA methodology contributed to the definition of good laboratory practice, provided a strong support for the streamlining of protocols and was useful for generating information suitable for knowledge management. Finally, we took advantage of the DoE to identify the key factors influencing outcomes of the experiments, the interactions between them, and the best combination that permits to maximize the output. We used this quality statistical analysis to set up and optimize both simple and high-throughput biological assay. We generated some DoE models suitable for different kind of experiments to be transferred to scientific community, in order to improve performance, efficiency and efficacy, according to a Quality management-oriented approach. Finally, we developed a Web platform <http://quality4lab.igb.cnr.it/en> for the collection, cataloging, and dissemination of the scientific information provided by researchers working in biological fields inside the CNR, starting from our own experience of merging Quality and Research. These approaches address the need, both nationally and internationally, to enhance the wealth of knowledge present within the CNR and structure adequately processes for its diffusion and preservation, encouraging the generation of new knowledge according to international Quality principles.

Conclusions

The qPMO network provided powerful tools to promote identification and diffusion of standard procedures for research laboratories and increase the efficiency of laboratory activities, giving new opportunities to researchers for disseminating their scientific activity, and to create networking, and increasing cohesion and collaboration among CNR institutes and with others institutions. Our experience demonstrated that Quality tools can strongly support the management of scientific research through disseminating knowledge, best practice and interoperability and enhance of the economic value of project and research outcomes.

References

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