

Adding Value to Biomedical and Life Sciences Research: The qPMO Way

ANTONELLA LANATI AND THE qPMO NETWORK

Quality disciplines have been widely used for decades in industrial and business fields. It is only in recent times, however, that Quality Management (QM) approaches have received proper attention in life sciences (including basic research), overcoming the prejudice that they are an impediment to creativity. It is noteworthy that in many European work programmes, professional project management is required to ensure the successful accomplishment of the project's goals.



The perception and dissemination of an innovative way of planning and organising research activity, inspired by Quality and Project Management (QPM) principles, was the aim of this project implemented by a network of the Italian National Research Council (CNR) Institutes.

As a follow-up to the course on 'Quality principles, methodologies and tools applied to Life Sciences', a group of participants working in different CNR research institutes (Naples, Palermo, and Rome) spontaneously formed around the course leader, driven by the will to improve the efficiency and effectiveness of their scientific research. Under the guidance of a quality consultant, a specific research project was identified to apply the principles of QPM to verify the outcome in terms of improved management of the different activities and increased quality of the results.

The use of QPM tools allowed the definition of general objectives, specific tasks, deliverables and a well-traced roadmap for reaching those objectives. Overall, it was possible to set up the entire project, designed with well-identified targets, in a few weeks. More specifically, the group applied quality techniques such as Plan-Do-Check-Act, brainstorming, decision grid, formal debriefing, project charter, Gantt and meeting minutes. The problem with the different locations of the participants was overcome by conventional online communication tools such as video conference, e-mail and cloud document sharing. The project was called 'Quality and Project Management Openlab' (qPMO), to underline the aim to create a laboratory model according to the principles of Total Quality Management (TQM) and Project Management. The whole project was organised into four work-packages (WPs) to address four specific tasks of research management (Fig. 1).

A working group was assigned to each WP.

- Management of knowledge: Standards for the drafting of guidelines in Life Sciences, Guidelines for specific activities in a Life Sciences laboratory, Web platform for the collection, cataloguing and dissemination of scientific information.
- Management of experimental procedures: Application of the risk management method Failure Mode and Effect Analysis (FMEA) on a 'pilot process'.
- Quality Management System for a research laboratory: Quality Management of a research laboratory, in the area of Life Sciences, based on ISO 9001:2008 Quality Management Standards.
- Management of multivariable assays: Design of Experiment (DoE) models suitable for different kinds of scientific experiments.

Overall coordination was achieved through regular meetings of the four working groups, while frequent sessions were scheduled by the quality consultant with each working group to deliver in-depth training and supervise the correct application of quality methods. By using this way of working, the group succeeded in creating a real team that was more than the sum of the individuals, where each one feels deeply involved in the project. The team soon became able to maintain and, in some cases, even work ahead of the activities timeline.

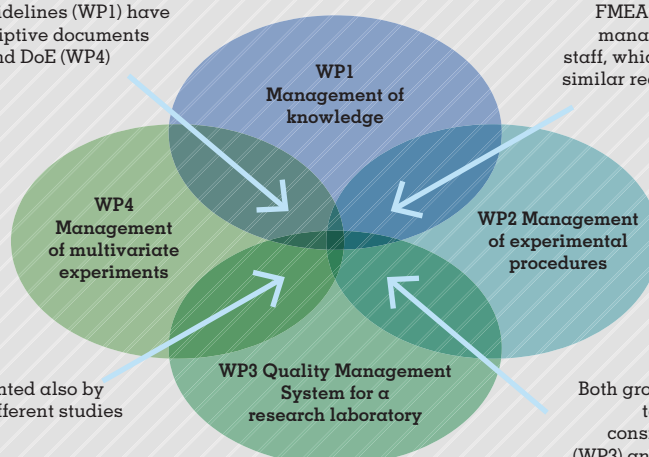
Basic principles of QPM were carefully analysed and discussed with all the participants, before being interpreted and translated into a language familiar to scientific researchers. This activity enabled participants to exploit the approaches of quality management in the organisation of their research laboratories. Overall, the 4 WPs contributed to the creation of a 'concept laboratory', which is referred to as the qPMO Model, that entails the successful implementation of procedures able to save money, time and intellectual resources to be invested in research creativity. The results of the three-year project are summarised in Figure 1.

Fig 1. The qPMO Model in biomedical research and the results of each



Fig 2. The synergies among the four work-packages

The indications for writing guidelines (WP1) have been also used to write prescriptive documents for FMEA (WP2), QMS (WP3) and DoE (WP4)



FMEA (WP2) led to several references regarding management of materials, instrumentation and staff, which can be seen as an analytical scheme of similar requirements of the ISO 9001 standard, so to be directly used in the QMS design (WP3)

DoE (WP4) has been experimented also by the WP1 and WP2 teams on different studies

Both groups working on WP1 and WP3 synergised to identify requirements for protocols to be considered validated respectively for the QMS (WP3) and for the publication on the website (WP1)

A key element for the success of this experience was the tight interaction among the WP (see Figure. 2), which shared common subjects, tools and results. The establishment of these synergistic interactions is the result of the holistic approach adopted from the beginning of the project: i.e. comprising the entire (research) system and looking out for a mutual relationship among different aspects. In this view, the project demonstrates that it took into account all the most important categories of laboratory management: resources and materials; instrumentation and tools; documentation and methods and human resources. Of note, these four categories can be seen as the 4-Ms of Ishikawa¹, namely the main cause categories of a known effect: Manpower, Machinery, Methods, and Materials.

The qPMO experience was reported in scientific papers (Bongiovanni et al², Mancinelli et al³) and has led to the qPMO Network promoting the application of the TQM Openlab model in basic biomedical and life sciences research. More scientific papers on the specific WP results are in preparation. The qPMO Network also promotes seminars inside CNR Institutes, as well as lectures in university courses in order to introduce future scientists to quality principles and tools, to face the challenges of cooperation, reliability and integrity of scientific research (Davies⁴). The dissemination of this experience via oral presentations and poster presentations to national and international events, as well as the participation in a Tech-Transfer project, has already attracted interest from different laboratories of the CNR and other organisations.

In conclusion, this experience clearly shows that a proper distribution of a Quality culture from areas of high management development (such as automotive and manufacturing industries, service industries, etc.) to intellectual and scientific production can facilitate and speed up research. Importantly, the participants felt no constraints on their research autonomy and creativity; conversely, they experienced a lower management burden, freeing resources to better embrace and accomplish research vision and strategy. This overall goal was possible thanks to the fruitful cooperation between a quality consultant and a group of researchers working together in a research project.

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Biographies



After an MSc in Electronic Engineering and 20 years' experience in industry, Antonella became professional consultant in Organisation and Management Systems. She is Adjunct Professor (MD in Medical Biotechnology, San Raffaele University), gives seminars in postgraduate schools and organises/contributes to management courses. She has published a book on 'Quality in Biotech and Pharma' and several papers in this area; Antonella is also a RQA member. In the qPMO project, she acted as quality consultant and catalyst.

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The qPMO Network was funded in 2012 by the Life Sciences Department and 'FaReBio di Qualità' of the National Research Council (CNR) and included the participation of nine researchers and technologists from five different Institutes and two Departments, with the coordination of Annamaria Kisslinger (Institute of Experimental Endocrinology and Oncology, IEOS). Four teams took charge of the four WPs reported in the article: Knowledge Management – Giovanna L. Liguori (Institute of Genetics and Biophysics, IGB, Coordinator), Giuseppina Lacerra (IGB) and F. Anna Digilio (Institute of Biosciences and Bioresources, IBBR); Management of experimental procedures - Annamaria Kisslinger (IEOS, Coordinator), Anna Mascia (IEOS) and Anna Maria Cirafici (IEOS); QMS for a research laboratory – Antonella Bongiovanni (Institute of Biomedicine and Molecular Immunology, IBIM, Coordinator) and Marta Di Carlo (IBIM); Management of multivariable assays – Gianni Colotti (Institute of Molecular Biology and Pathology, IBPM, Coordinator) and Giovanna L. Liguori (IGB).

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