

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

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. In particular, the need for Quality standards in non-regulated research is a matter of considerable current debate inside international research community. The Quality and Project Management OpenLab (qPMO) is a research network involving 5 different Institutes and two Departmentes 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. Our experience demonstrates that Quality management 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.

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

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17 **Introduction**

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

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33 **Methods**

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

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48 **Results**

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50 We defined a model for the drafting of guidelines, based on the principles of Quality and
51 documentation management, among them PDCA. The outcome is an operational flow describing all
52 the phases of the process which has been validated by four different drafting groups through the
53 production of 13 guidelines ranging from research activity to equipment and facility management,
54 as well as addressing the design, risk identification and validation of experimental procedures. All
55 the guidelines are currently being applied in Institutes of the CNR, and some of them have also
56 been included in a certified Quality Management System (QMS) for a research laboratory.
57 Furthermore, we have generated and applied a model of a management system for a laboratory for
58 scientific research implementing the ISO 9001:2008 Quality System. To create this Quality model it
59 was necessary to use methods and skills related to Quality employed in industry, and apply them in
60 research. As pilot laboratory we chose the MarLab laboratory, that deals with the housing and
61 handling of marine organisms. It has been certified with ISO 9001:2008 in June 2014 and until now
62 passed all the surveillance audits. In addition, based on our quality management system, we have
63 created a modular software, Help4Lab, to manage Quality, safety, environment and documents in a
64 research laboratory. Help4Lab contains the section "Processes" that helps the management of all
65 documentation (management procedures, guidelines, operating instructions and forms) inherent to
66 processes identified in the research laboratory (primary processes: Research, Student training and
67 Science Communication; secondary processes: management processes, quality management system,
68 etc.). A second section (Suppliers List and Ratings, Warehouse, etc.) supports the "material
69 handling". Furthermore, the section "management tools" helps planning maintenance and
70 calibration of instruments. We also applied further Quality tools, among them the FMEA, in order
71 to validate and support research activities and results, to create a standard and controlled workplace,
72 and to support the interaction between research and industrial application also. This quality
73 approach led to several major advantages. At first, a set of improvement actions was generated
74 covering most lab aspects, such as management of instrumentation or training of personnel
75 involved. Then, FMEA methodology contributed to the definition of good laboratory practice,
76 provided a strong support for the streamlining of protocols and was useful for generating
77 information suitable for knowledge management. Finally, we took advantage of the DoE to identify
78 the key factors influencing outcomes of the experiments, the interactions between them, and the
79 best combination that permits to maximize the output. We used this quality statistical analysis to set
80 up and optimize both simple and high-throughput biological assay. We generated some DoE models
81 suitable for different kind of experiments to be transferred to scientific community, in order to
82 improve performance, efficiency and efficacy, according to a Quality management-oriented
83 approach. Finally, we developed a Web platform <http://quality4lab.igb.cnr.it/en> for the collection,
84 cataloging, and dissemination of the scientific information provided by researchers working in
85 biological fields inside the CNR, starting from our own experience of merging Quality and
86 Research. These approaches address the need, both nationally and internationally, to enhance the
87 wealth of knowledge present within the CNR and structure adequately processes for its diffusion
88 and preservation, encouraging the generation of new knowledge according to international Quality
89 principles.

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91 **Conclusions**

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93 The qPMO network provided powerful tools to promote identification and diffusion of standard
94 procedures for research laboratories and increase the efficiency of laboratory activities, giving new
95 opportunities to researchers for disseminating their scientific activity, and to create networking, and
96 increasing cohesion and collaboration among CNR institutes and with others institutions. Our
97 experience demonstrated that Quality tools can strongly support the management of scientific

98 research through disseminating knowledge, best practice and interoperability and enhance of the
99 economic value of project and research outcomes.

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