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

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Consiglio Nazionale delle Ricerche

QUALITY

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.

RESEARCH

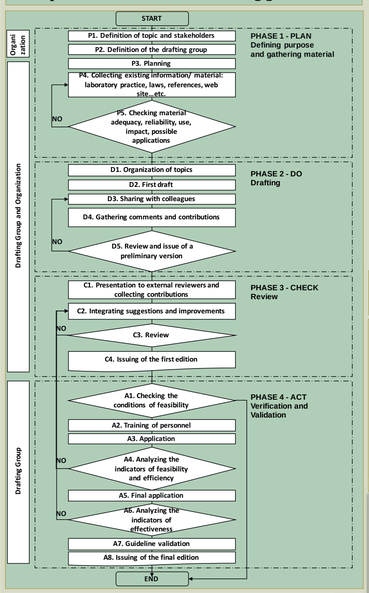
The scientific world is facing the "quality revolution": not only results have been led to research and social community attention, but also reliability, safety and efficacy of discoveries and efficiency of fund exploitation.

Quality and Project Management Openlab (qPMO)

The 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. qPMO covers four different fields to experiment with a specific Quality approach to scientific research and to generate models for the implementation of Quality methodologies in science. Our goal is to 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.

Management of knowledge

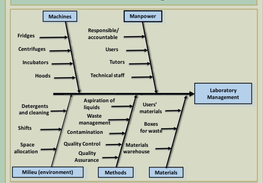
Operational flowchart for drafting guidelines



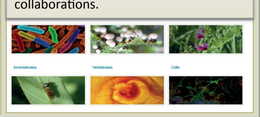
List of guidelines

0. Quality model for guideline
1. Management of experimental procedures
2. Design of Experiments
3. Glass-washing and solution preparation centre facilities
4. Cell culture facilities
5. Equipment management
6. Failure Mode Effect Analysis of a scientific process
7. Writing the lab notebook
8. Personnel management
9. Management of reagents and materials
10. Animal house facilities
11. Sea urchin aquarium management
12. Working with *D. melanogaster*
13. Working with *P. lividus*

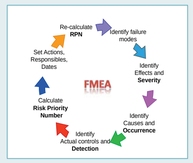
Organizations of the topics through Ishikawa categories



To respond to the increasing demand for the assessment, validation and diffusion of standard procedures for research laboratories, we provided a **Quality-based model** for drafting guidelines that has been applied and validated in a network of CNR Institutes. Moreover we developed a **web platform** for the collection of the know-how inside CNR scientific community and the promotion of homogeneity of procedures as well as scientific collaborations.



Management of experimental procedures (Failure Mode and Effect Analysis, FMEA)



FMEA is a proactive tool, technique and quality method widely used in risk control and product/process optimization.

OUTCOMES:

- documented evidence of due care
- a set of improvement actions covering most laboratory aspects: equipment management, supplies and materials management, staff training and protocols.

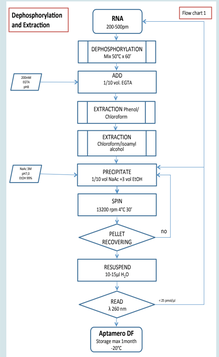
BENEFITS:

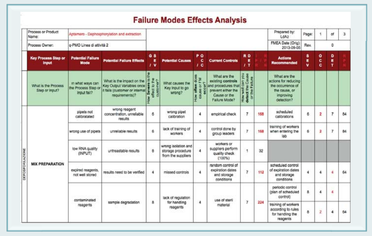
- improve the quality, reliability and safety of the analyzed processes
- validate and support research activities and results
- create a standard and controlled workplace

FMEA analysis on a «pilot» process

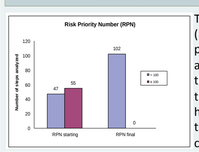
FMEA analysis begins by identifying, for each activity in the flowchart, all probable failure modes, related causes and effects. Activities are evaluated by means of the Risk Priority Number **(RPN)** and compared with an acceptance threshold. Failure modes exceeding the threshold are addressed with improvement actions

A detailed flowchart of activity identifies each process component





Corrective actions reduce **RPN**



The risk priority number (RPN), calculated for each process operation, showed an initial value greater than the fixed threshold in more than 50 % of the steps and has been reduced to 0 after the implementation of corrective actions identified.

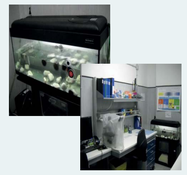
FMEA: Preventing a Failure Before Any Harm Is Done

Management of a research laboratory

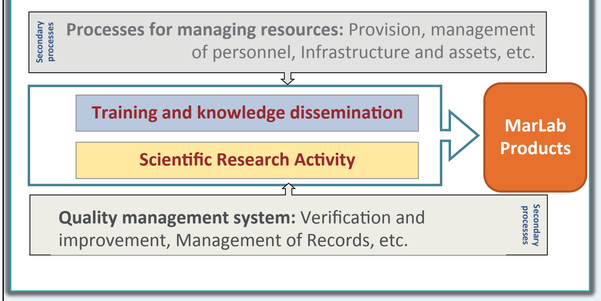
(Quality Management System, QMS, via an **ISO9001**)

The choice of a pivotal laboratory:

A research laboratory working with marine animal models in the scientific area of drug discovery and embryonic development



Generation of the Quality Management System (QMS)



Help4Lab, an ad hoc modular software to manage instruments, quality, and safety documents (currently under the process of copyrighting)

TUTORIAL Help4Lab

MarLab

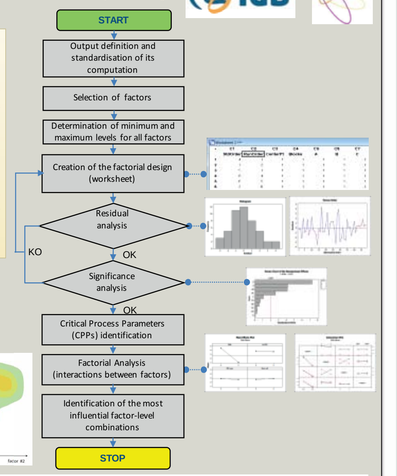
ITALCERT UNI EN ISO 9001

Conclusion:

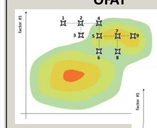
The **QMS model** and the management **software Help4Lab**, are new tools for improving and simplifying the organization of research laboratories, ensuring the reliability of the results, increasing the prestige of the laboratory

Management of simple to high-throughput assays (Design of Experiments, DoE)

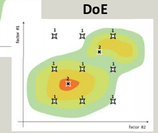
DoE approach permits the simultaneous evaluation of the effects of different factors on experimental performance and the analysis of their interactions in order to identify their optimal combinations. Compared to the classical methods based on changing only one factor at a time (OFAT), DoE facilitates the exploration of a broader range of parameters combinations, reducing the number of experimental tests.



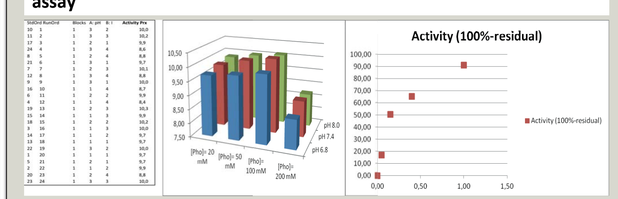
OFAT



DoE



a. One-step optimization of experimental conditions of enzymatic assay



b. One-step optimization of conditions of nucleic acid stability

c. One-step optimization of the landscape of protein thermal stability

d. Cell Toxicity Assay

e. Cell Transfection optimization

PRODUCTS: 1. Publications Bongiovanni A., et al., (2015). Applying Quality principles and Project Management methodologies in biomedical research: a public research network's case study. *Accreditation and Quality Assurance* 20:203–213; Mancinelli S., et al., (2015). Applying Design of Experiments methodology to PEI toxicity assay on neural progenitor cells. Mathematical Models in Biology - Bringing Mathematics to Life (Springer); Digilio F.A., et al., (2016). Quality-based model for life sciences research guidelines. *Accreditation and Quality Assurance* 21: 221-230 .

2. ICT tools (quality4lab website, Help4Lab software).

3. Laboratory notebook (LN) layout.

4. Quality tools (Quality management system for a research laboratory, certified ITALCERT; Research-related guidelines).

5. Dissemination (Training Courses; Seminars; Meeting organization; Undergraduate/PhD theses)