The qPMO project: applying Quality principles and methodologies in Life Sciences research

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QUALITY

Significant Quality methodologies and approaches have been developed for almost all areas of business and production, from management systems to production control, from project and innovation management to statistical tools. However, Quality management and approaches have not received proper attention in scientific research, especially in the life sciences, due to prejudice that considers them an impediment to creativity.

qPMO PROJECT

A team of 10 independent researchers from 4 CNR Institutes and a Quality consultant was formed, with the aim of working together in the quality and Project Management OpenLab (qPMO) project. The qPMO team constituted a knowledge network, aimed at realizing a Quality management model for reference laboratories in thematic areas of greatest scientific impact. The resulting "qPMO project" received the approval of CNR management and adequate financial support. The strength of the project is that it is intended as a research project, run by scientists working in public research Institutes who experience, test and optimize both Quality (such as PDCA, Ishikawa diagram, FMEA and DoE) and Teamworking methodologies (such as Debriefing, Brainstorming and Decision grid) for designing and carrying out scientific projects. Each of the 4 WPs identified has the goal of experimenting with a different Quality approach to scientific research and generating models for the implementation of Quality methodologies in science. Altogether, they contribute to the creation of a:

RESEARCH

In recent years, the scientific world has clearly been experiencing a revolution: the attention of the scientific and social community is not focused solely on the final results but also on other related issues, such as the reliability, safety, and efficacy of discoveries and the efficient and effective use of resources

Quality and Project Management Openlab

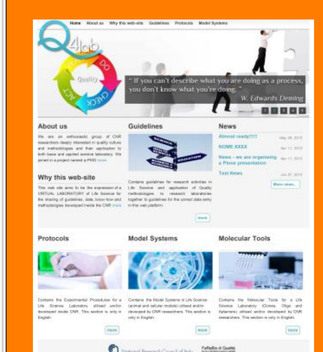
Management of knowledge (Guidelines and Website)

ACT
- Revise the platform
- Promote the platform

PLAN
- ✓Design the web platform
- ✓Define the flow chart for the drafting and editing of a guideline
- ✓Identify the guidelines to be written
- ✓Identify the criteria for including the data on the web platform

CHECK
- Check applicability and externally revise guidelines
- Monitor the platform

DO
- ✓Set up the web platform
- ✓Draft the guidelines
- ✓Collect, validate and enter data



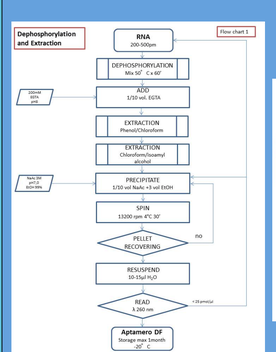
Management of experimental procedures (Failure Mode and Effect Analysis, FMEA)

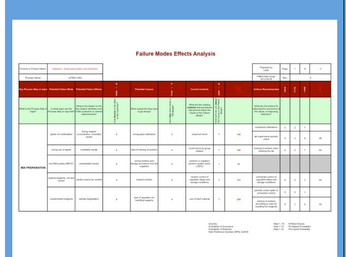
ACT
- Extend the Model t to the FaReBio Reference Laboratories and other labs

PLAN
- ✓Identify "pilot processes" (PP)
- ✓Define fields of application
- ✓Activate / consolidate business partners

DO
- ✓Analyse three PP (flow chart)
- ✓Perform FMEA of three PP
- ✓Draw up action plans related to:
  - Training and personnel management;
  - Management instrumentation and control of incoming and store material;
  - Miscellaneous

CHECK
- Review activities





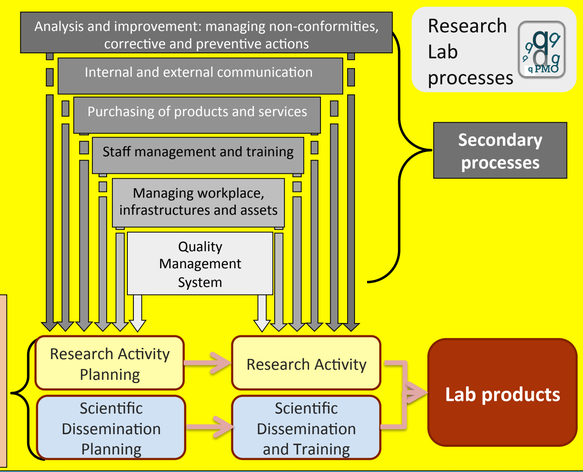
Management of a research laboratory (Quality Management System, QMS)

ACT
- Validate and improve QMS model
- Disseminate QMS model
- Export QMS model to different labs

PLAN
- ✓ Set up the organizational chart
- ✓ Assess equipment and instruments
- ✓ Evaluate lab goals, input, processes, and output
- ✓ Identify critical control points

CHECK
- Reviews and internal audits
- ISO 9001:2008 certification

DO
- ✓ Document the complete QMS
- ✓ Apply the QMS



Management of simple to high-throughput assays by means of Design of Experiment (DoE)

ACT
- Repeat the experiment in optimized conditions
- Validate and optimize DoE model
- Publish the model and the optimized experiment
- Disseminate DoE to other experiments

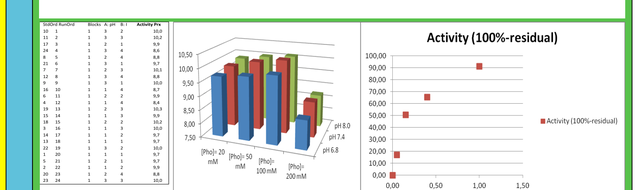
PLAN
- ✓Study the state of the art
- ✓Evaluate instrumentation
- ✓For each experiment, individuate objectives, input, process, output
- ✓Identify critical points

CHECK
- Analyse results and statistics
- Analyse factors influencing the output
- Analyse optimized conditions

DO
- ✓Design the experiment
- ✓Prepare samples, instrumentation
- ✓Write the protocol and programs
- ✓Perform the experiment

One-step optimization of physico-chemical experimental conditions

1. Matrix design
2. Analysis of results and statistics
3. Experiment (in optimized conditions)



Our goal is to demonstrate that a proper and accurate transfer of Quality culture and methodologies from areas in which they are highly developed 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.

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