A validated Quality Management System for a research lab
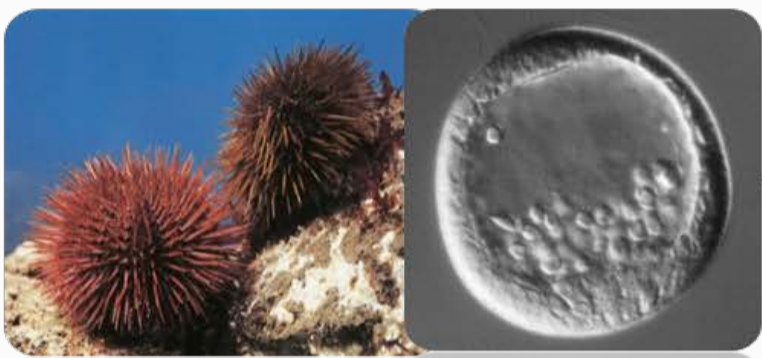
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ABSTRACT: The perception and dissemination of an innovative and simplified way of planning and organizing research activity, inspired by Quality and Project Management (PM) principles, was the aim of the present work. Hence, we have generated a Quality Management System (QMS) for a pilot laboratory that deals with the housing and handling of marine organisms. The MarLab laboratory has been certified with ISO 9001:2008 in June 2014 and April 28, 2015 it received and passed the surveillance audit.
Based on our quality management system, we have also created a modular software, Help4Lab, to manage Quality, safety, environment and documents in a research laboratory.

MarLab: What

Screening of libraries of active compounds

Identification of new biomolecules

Toxicological studies

Knowledge dissemination

The choice of a pivotal laboratory: MarLab

We have selected a research laboratory working with marine animal models (mainly the Sea Urchin *Paracentrotus lividus*) in the scientific area of drug discovery and embryonic development as pivotal laboratory. From among various others (i.e., GLP, ISO17025, etc.), we chose to implement the **ISO 9001:2008 Quality system**.

Generation of the Quality Management System (QMS).
The main goal is to ensure the Quality management of a research lab, working in the area of Life Sciences. Therefore, we have designed a Quality system in MarLab in order to generate a TQM (Total Quality Management) model to be easily transferred to other research laboratories.

Secondary processes
Processes for managing resources
Provision, management of personnel, Infrastructure and assets, economic resources

Primary processes

Training and knowledge dissemination

Scientific Research Activity

MarLab Products

Secondary processes
Quality management system
Verification and improvement (management of non-compliance), Management of Records, Internal and external communication

We have identified operational and support processes to be managed, stakeholders, recipients, and suppliers.

We also generated the procedures, operating instructions, guidelines and forms to cover all laboratory aspects.

The MarLab laboratory has been certified with ISO 9001:2008 in June 2014 and April 28, 2015 it received and passed the surveillance audit.

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

Accesso riservato
Salve Luca Caruana,
Esci

Menu principale
- Home
- Intro
- Tutorial del sito

Processi MarLab
- Pianificazione e attività di ricerca
  - Progetti Di Bernardo
  - Progetti Di Carlo
  - Progetto qPMO
- Programmazione e divulgazione
- Sistema Gestione Qualità
- Direzione
- Ambienti di lavoro, beni e risorse
- Gestione personale
- Approvvigionamento beni e servizi
- Modulistica

Politica per la Qualità
- Politica per la Qualità

Gestione Materiale
- Elenco Fornitori
- Valutazioni Fornitori
- Inserimento Scorta Minima
- Elenco Prodotti Acquistati
- Magazzino
- Prelievo ricci

Gestione Strumenti
- Elenco registrazioni acquario
- Elenco dati frigo
- Elenco dati frigotermostato
- Elenco attrezzature – Anagrafica
- Diario eventi manutenzione
- Calendario MarLab
- Datalogger

Prossime manutenzioni
Acquario – Controllo nitriti, nitrati e durezza dell'acqua in scadenza il 16/03/2016

Help4Lab has restricted access, any user with the username and password can navigate within it, limited to their role. Technical and quality manager, and scientific director has full access and the chance to enter and edit data.

"Processes" section 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; and secondary processes: management processes, quality management system, etc.).

"Material handling" section manages the entire path that a product does. Starting from a list of suppliers which includes the companies treated, the contacts, the type of product and, if present, certifications. Each supplier is subject to an evaluation, dictated by specific variables that determine the reliability of the sales service and the quality of the product.
Once purchased, products are recorded and cataloged, as well as the consumption of each product, the quantities are thus continuously updated. To avoid being suddenly devoid of a product due to a higher consumption not expected we have fixed a 'threshold' (minimum stock) * quantity, below which the system sends an alarm reminding you to obtain the product in question .

Each instruments must be recorded, and cataloged as well as their maintenance. In the summary data windows there are highlighted the good operating range, so as to provide the operator with an immediate graphical feedback of the trend. A diary and a calendar complete this section of our management.
All the maintenance operations are scheduled in a specific and timely manner, with alarms connected to email addresses and phone numbers.
In this section all maintenance alarms are identified and processed by the events diary maintenance and alert the technical manager.

Conclusion: This QMS model is a new laboratory organization, motivating the staff towards a continuous improvement of shared operations and enhancing communication between all management levels and personnel.
The QMS model and the management software Help4Lab related to it, could be a new tool for improving and simplifying the organization of research laboratories. Such a system could also ensure the reliability of the research laboratories results, increasing the prestige of the laboratory.

TUTORIAL Help4Lab

MarLab

GATHERING SEA URCHIN