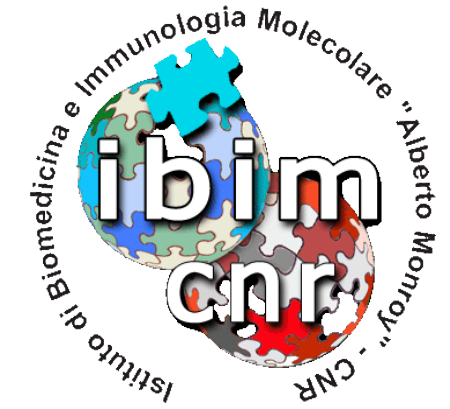


MarLab: a marine research laboratory organized according to a quality management system

Antonella Bongiovanni¹, Luca Caruana¹, Loredana Riccobono¹, Maria Di Bernardo¹, Laura La Gattuta¹, Letizia Anello¹, Daniele P. Romancino¹, Alessandro Pensato¹, Annamaria Kisslinger², Giovanna Liguori³, Gianni Colotti⁴, Antonella Lanati⁵, Anna Mascia², Anna Cirafici², Giuseppina Lacerra³, Anna Digilio⁶, and Marta Di Carlo¹

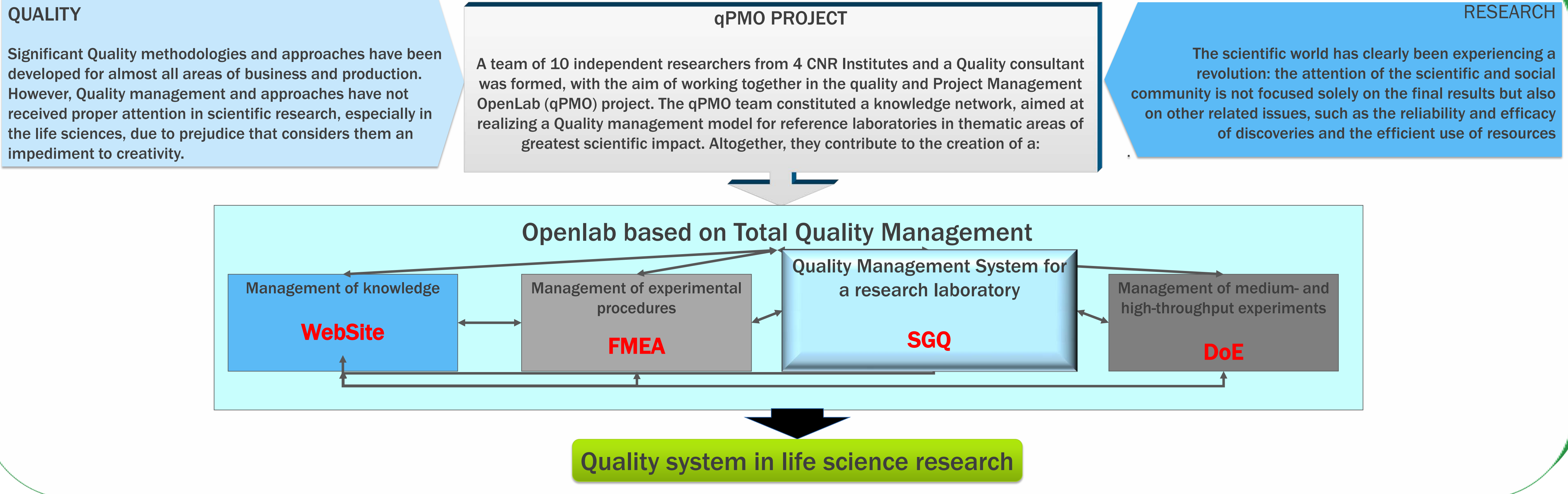


Consiglio Nazionale delle Ricerche

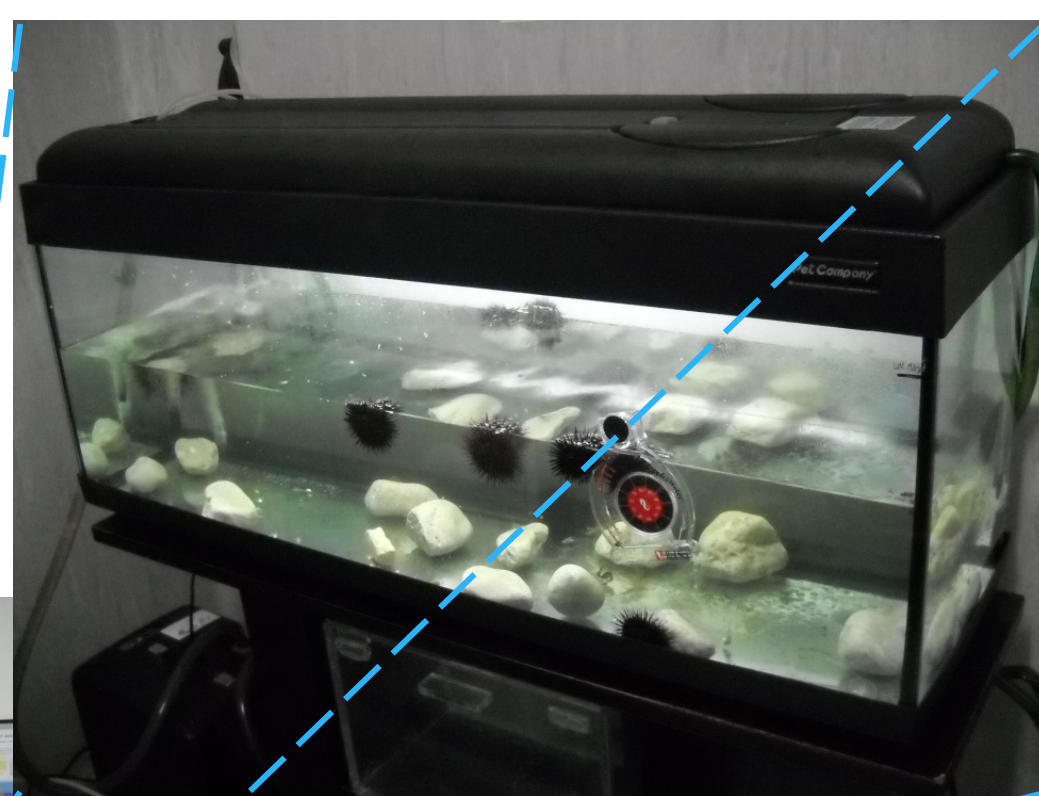
¹IBIM-CNR, Palermo; ²IEOS-CNR, Napoli; ³IGB-CNR, Napoli; ⁴IBMN-CNR, Roma; ⁵Valore Qualità, Pavia; ⁶IBBR-CNR, Napoli

Background: Quality principles and methodologies have been widely used in industrial and business applications, giving positive advantages in terms of good management, results improvement and cost reduction. This approach has long been ignored in scientific research which by their nature are often far from the industrial and business fields. Our aim was to generate and apply a Quality management system (QMS) for a research lab, working in the area of Life Sciences. From among various others (i.e., GLP, ISO17025, etc.), we chose to implement the ISO 9001:2008 Quality system.

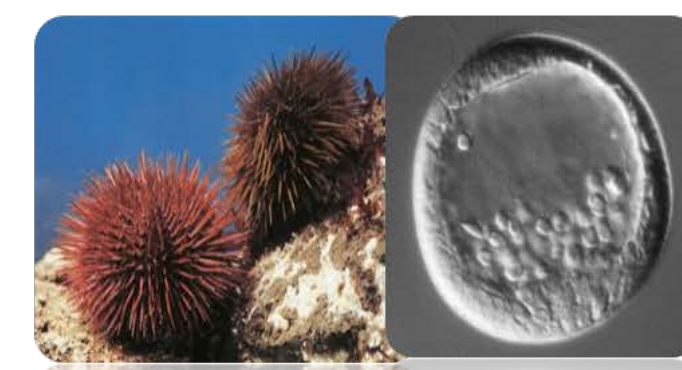
Question 1. Quality methodologies and principles in Scientific Research?



Question 2. The choice of a pivotal laboratory: MarLab



We have selected a research laboratory working with marine animal models (mainly the Sea Urchin *P. 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**.



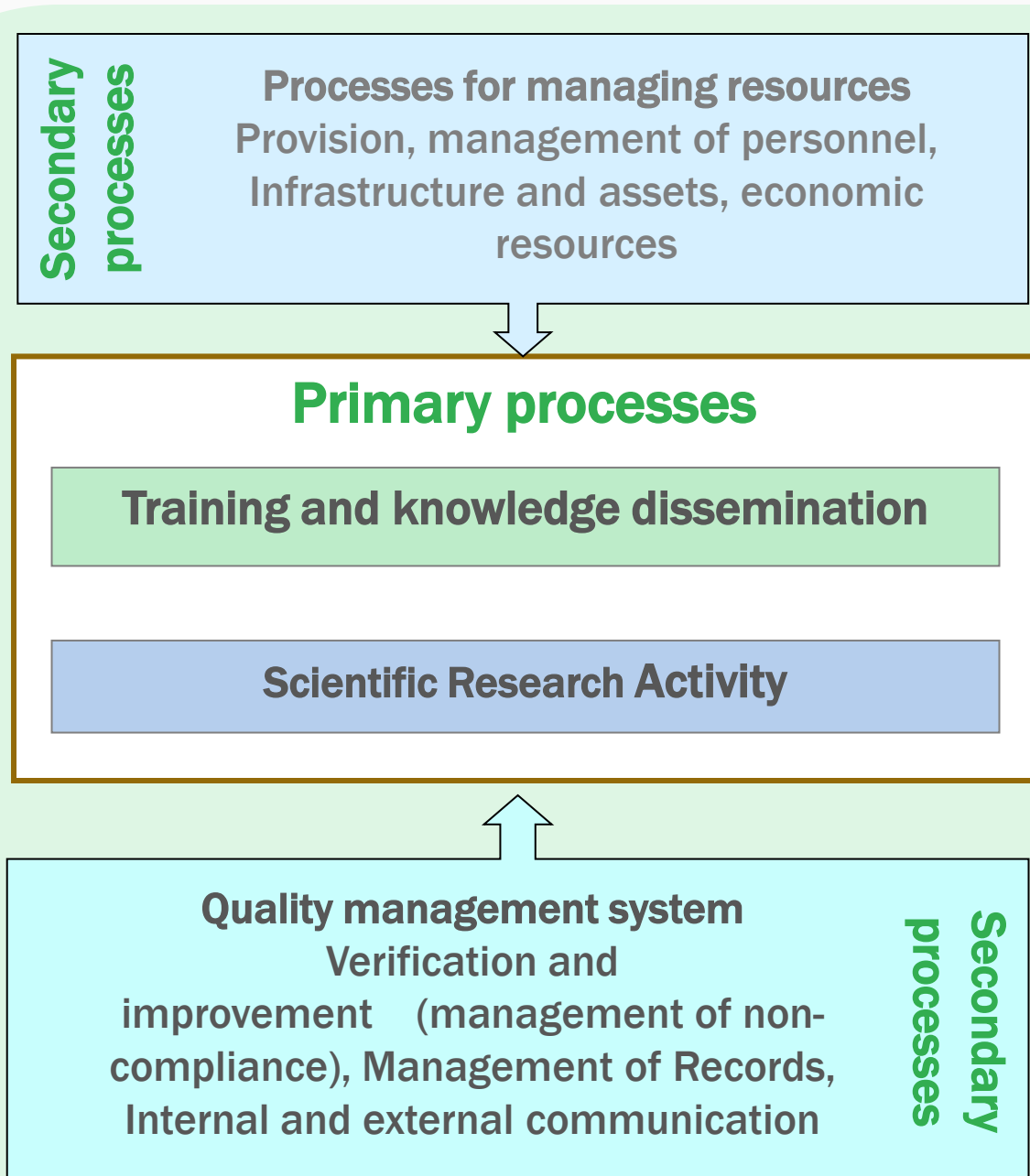
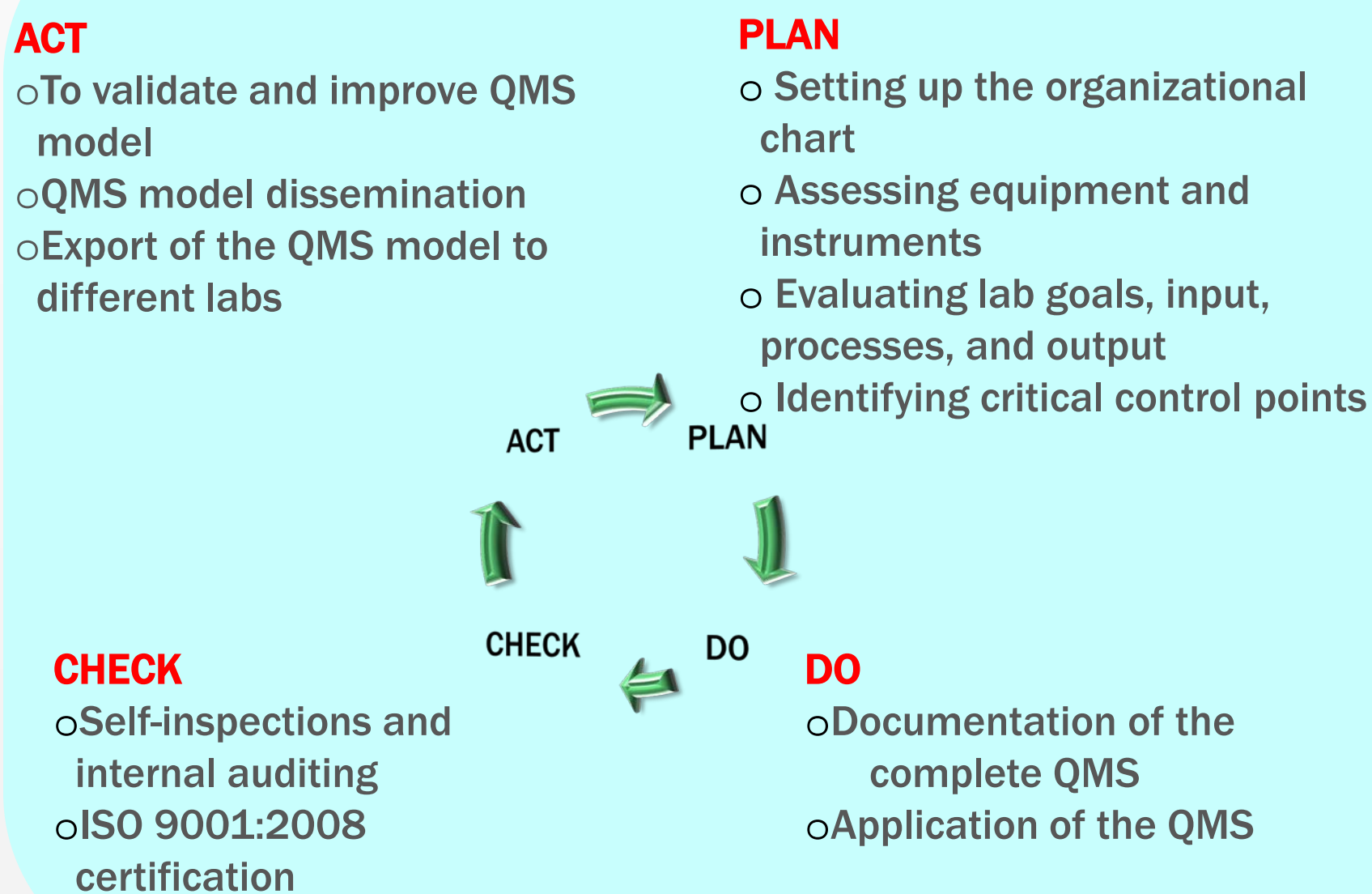
MarLab: What

- Screening of libraries of active compounds
- Drug Discovery
- Identification of new biomolecules
- Toxicologic studies



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.

How we work:



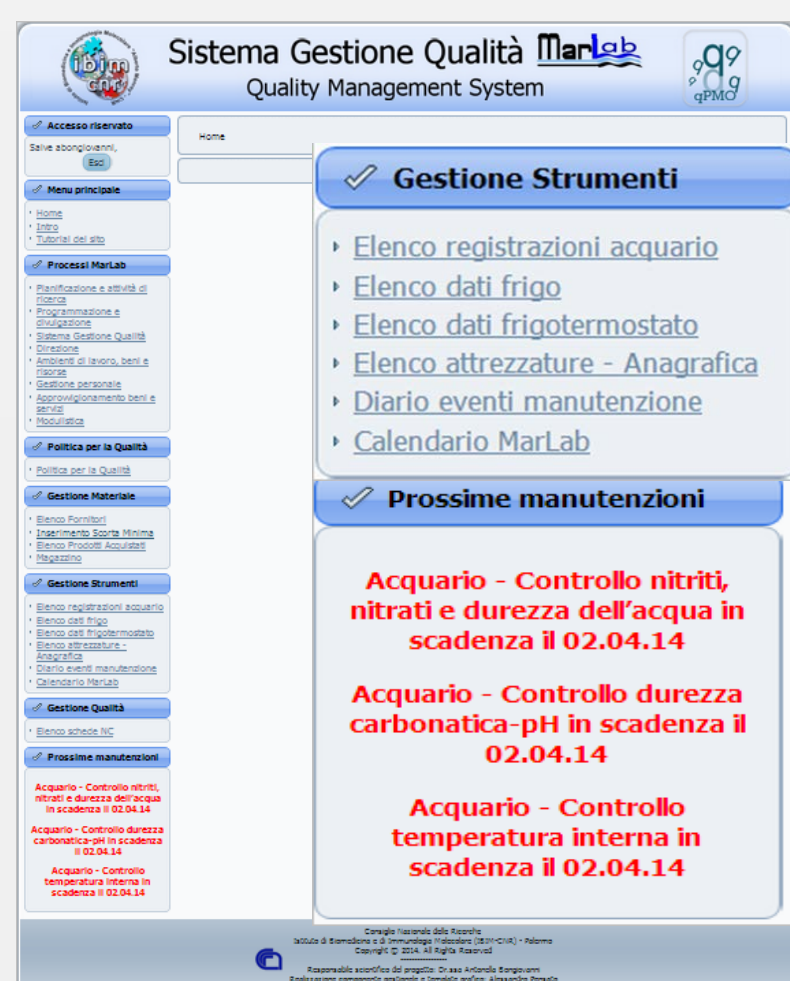
As specified by the ISO standard we first defined the Quality policy.

Next, we 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.

We have applied this QMS during 4 months of activities of the pivotal laboratory, and performed a self-inspection and internal auditing of the QMS

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



<https://help4lab.ibim.cnr.it/marlab>

Conclusions: We expected that this QMS model could be a new laboratory organization, motivating the staff towards a continuous improvement of shared operations and enhancing communication between all management levels and personnel. Such a system would also ensure the reliability of the results of research laboratories. Furthermore, the QMS model would increase the prestige of the laboratory and the Public Research Institution.



UNI EN ISO 9001:2008 certification (#585SGQ00, IAF n° 34, 38)

This work was supported by Italian Ministry of Economy and Finance ("FaReBio di Qualità" project).