**An innovative Quality-based model for drafting scientific guidelines**

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The biological research is undergoing profound changes, driven by powerful emerging technologies and global economic forces. In this context of constant change, there is an increasing necessity to define adequate standards and to identify and validate general guidelines for scientific activity Guidelines are useful tools for identifying proper conduct in a laboratory environment, the correct use of instrumentation and procedures, the education and training of laboratory personnel and for aligning and standardizing the procedures used within an institute or organization. Whereas great attention has been dedicated to the identification and application of guidelines in clinical or pre-clinical studies, only recently non-regulated scientific research has been developing a common awareness of the importance of this topic. Hardly, poor literature is available giving indications on how to define guidelines applying Quality and documentation management tools, especially in the non-regulated research field.
To address this point, the Quality and Project Management OpenLab (qPMO) research network formed by five Italian National Research Council (CNR) Institute (website: quality4lab.cnr.it/en), has defined a model for the drafting of guidelines, based on the principles of Quality and documentation management, among them PDCA. The outcome is an operational flow describing all the phases of the process which has been validated by four different drafting groups through the production of 13 guidelines ranging from research activity to equipment and facility management, as well as addressing the design, risk identification and validation of experimental procedures,. All the guidelines are currently being applied in Institutes of the CNR some of them have also been included in a certified Quality Management System (QMS) for a research laboratory. In summary, the Quality-model for drafting guidelines we have developed is very effective and is applicable to different scientific contexts and disciplines, including technology-transfer oriented research and the QMS of a research laboratory.

297 words