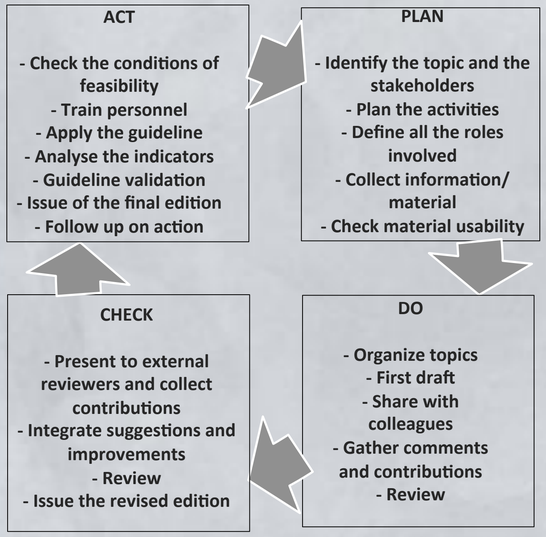
1. Application of the Decision Grid to select the guideline to draft

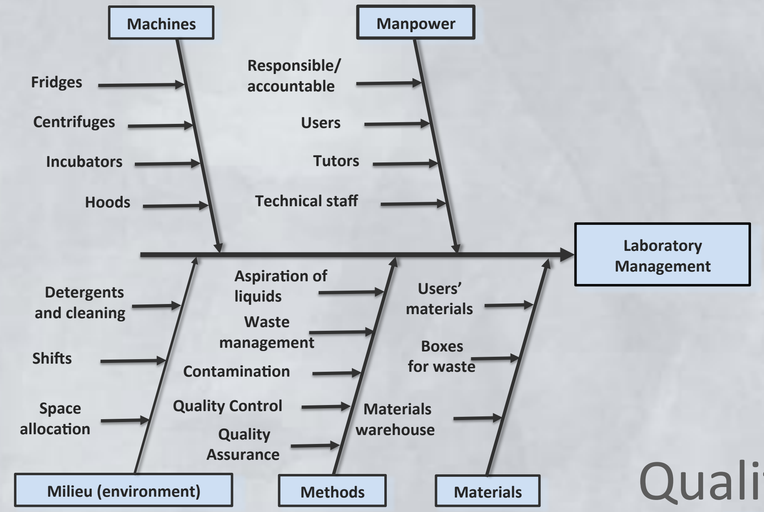
	Life Sciences Guidelines	W	Impact 5 A	Impact 5 Score	Priority 4 A	Priority 4 Score	Skills 5 A	Skills 5 Score	Total	Field	QMS	DG
0.	Quality model for guideline	5	25	5	25	5	25	75	QM		DG1
1.	Management of experimental procedures	5	25	4	16	5	25	66	B	yes	DG3
2.	Design of Experiments	5	25	4	16	5	25	66	QM		DG1&4
3.	Glass-washing and solution preparation centre facilities	5	25	4	16	5	25	66	F		DG1
4.	Cell culture facilities	4	20	5	20	5	25	65	F		DG1
5.	Equipment management	5	25	4.5	18	4	20	63	E	yes	DG2&3
6.	Failure Mode Effect Analysis of a scientific process	5	25	3	12	5	25	62	QM		DG2
7.	Writing the lab notebook	4	20	4	16	5	25	61	B	yes	DG3
8.	Personnel management	5	25	4	16	4	20	61	B	yes	DG2&3
9.	Management of reagents and materials	5	25	4	16	4	20	61	B	yes	DG1
10.	Animal house facilities	4	20	4	16	5	25	61	F		DG1
11.	Sea urchin acquarium management	3	15	4	16	5	25	56	E	yes	DG3
12.	Working with *D. melanogaster*	3	15	3	12	5	25	52	RA		DG1
13.	Working with *P. lividus*	3	15	3	12	5	25	52	RA	yes	DG3
	Working with iPS cells	4	20	4	16	2	10	46			
	Working with *C. elegans*	3	15	3	12	2	10	37			

Legend: W = weight of criterion; A = Assessment of guideline *vs.* criterion; Score = W x A; B = Basic; E = Equipment; F = Facilities; RA = Research activities; QM = Quality methodology; QMS = Quality Management System; DG = Drafting Group.

2. PDCA cycle of the activities



3. Organizations of the topics through Ishikawa categories



Quality Tools

An innovative Quality-based model for drafting scientific guidelines

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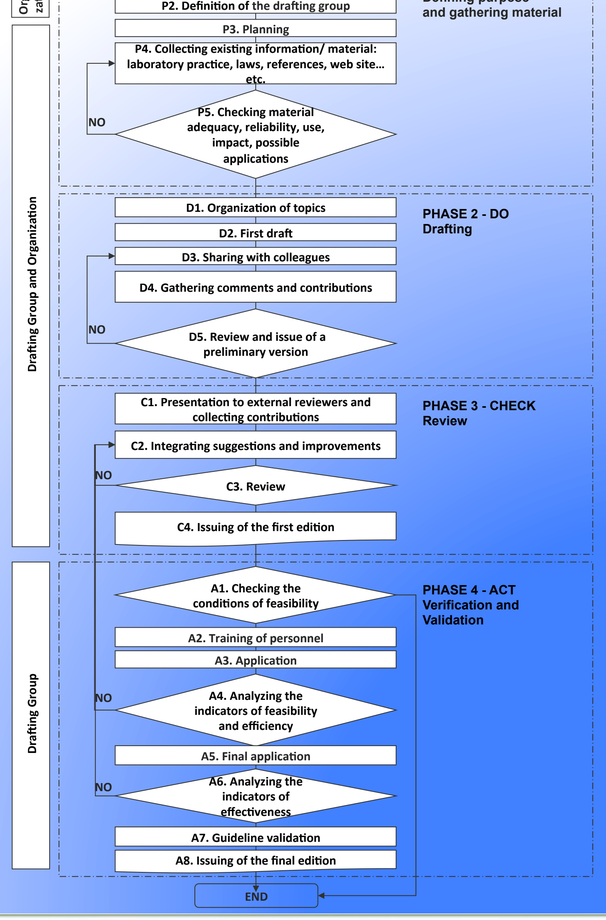
The biological research is undergoing profound changes, driven by powerful emerging technologies and global economic forces. In this context of constant change, there is an increasing necessity to define adequate standards and to identify and validate general guidelines for scientific activity Guidelines 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.

4. The operational flowchart



CONCLUSIONS

Our experience shows that the model for guidelines we have developed identifies all the steps to follow in the drafting and validation of guidelines. The flow chart makes drafting guidelines easier and more immediate as demonstrated by the high number of guidelines written by the qPMO group in 18 months of activity. Significantly, it is applicable to different scientific contexts and disciplines, including both non-regulated and technology-transfer oriented research, and also the QMS of a scientific laboratory. It can also be also used to define the operative procedures required for GLP certification. For more details please see the paper by Digilio et al., in press on Accreditation and Quality Assurance

Be updated on our website
quality4lab.igb.cnr.it/en