Introduction to quality management systems (QMS)

Topic area:	(Self-) management
Format:	Online or in-house workshop
Workload:	3 webinars of 1.5 h each = 1 workshop day
Trainer:	Lisa Steinhauser
Target group:	MSc and PhD students, postdocs

In many companies, quality management knowledge is expected of graduates from the life sciences, but is rarely taught at universities. For this reason, this course offers an initial overview of the various quality management systems (QMS) and industry-associated processes. The aim is to understand job advertisements' requirements and keywords and assess possible future professional fields better.

Good Laboratory Practice (GLP) is a quality management system that is used in certified laboratories. It is necessary, among other things, for the analysis of drugs in the development stage (animal (in vivo) and cell (in vitro) studies), but also for environmental safety tests. In this part of the course, the 10 basic principles such as the requirements for personnel, apparatus and measurement results are explained.

Good Clinical Practice (GCP) encompasses the ethical and scientific quality requirements for conducting clinical trials on humans. GCP is relevant for pharmaceutical companies and the contract research laboratories and clinics involved. After an overview of the different drug testing and approval phases, the guideline's most essential terms and content are explained.

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Good Manufacturing Practice (GMP) includes guidelines for quality assurance in the production of pharmaceuticals, cosmetics, food and feed. Among other things, it regulates standard operation procedures, documentation requirements, the management of deviations and changes in the process, the qualification of systems and the validation of methods.