



Professional Development Programme

Expert course

Introduction to Quality Management Systems (QMS)

Dr. Lisa Steinhauser www.naturalscience.careers

25 May 2023

09.00 - 13.00 hrs. in person

1 June 2023

09.00 - 10.30 hrs. online

Objectives

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 over-view 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.

Topics

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.

<u>Good Clinical Practice (GCP)</u> 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.

<u>Good Manufacturing Practice (GMP)</u> 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.

Venue on day 1

MARUM, University of Bremen, Leobener Str. 8, 28359 Bremen, Germany MARUM I (main) building, room 2070





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The Trainer

Dr. Lisa Steinhauser brings along experiences from four different companies. She worked in the areas of pharma research, food analytics and analytical instruments for multinationals as well as SMEs. She took a variety of roles, from product manager and sales manager to a position as team leader for nine co-workers in a pharma company. All of these experiences enrich her seminars and coaching work about leadership and self-organisation.

Lisa studied <u>chemistry</u> at the University of Tübingen. During her PhD, she worked on the analytics of natural products and spent three months as guest researcher at the National Institute of Standards and Technology (NIST).

Registration

To register for this course, please visit the course web page: https://www.marum.de/en/education-career/professional-development/2023/2023-05-25.html

Please note that your registration will be binding.

The registration deadline for this course is 16 May 2023.

Any enquiries regarding this event can be addressed to early-career@marum.de.