



Today's Quality is Tomorrow's Safety

Enhance Quality for added value with Haabio

Choose a combination of consultancy services that best meets your needs

Enriching Quality and Organization Management

- Creating, maintaining and/or improving Quality Management Systems
 - Comprehensive reviews of existing Quality Systems, with recommendations for further action e.g. before inspection by the authorities
 - Expert assistance in the creation, implementation or improvement of Quality Management review practices
 - Support for the establishment of corrective and preventative actions or Risk Management practices
- Assisting Process Management in efforts to establish, implement, review, streamline or illustrate processes (i.e. process maps or process flows)
- Formalizing Project Management practices in a more structured manner via
 - Creation of project management procedures
 - Design of project plans and project reports
 - Execution of project risk analyses
 - Establishment of project-steering practices
- Supporting organizational development and teamwork-building



Improving and conducting QA management and QA managerial duties

- Carrying out audits based on various standards, including planning, executing and reporting
 - ISO9001, ISO13485 or QSR-based internal, external and supplier audits
 - International Guideline-based preclinical or clinical study audits (GLP, GCP) and GMP audits
- Planning of the annual audit programs and audit reporting practices
- Assisting with Quality System documentation (including quality manuals, procedures, SOPs), including writing of said documents, if needed
- Consulting in different practices connecting to quality (e.g. archiving, validation, corrective actions, equipment management and maintenance)

Acting as a full-service outsourced QA unit, along with all the tasks required

Training

- Providing tailored training on a variety of QA and QM subjects, e.g. required components of Quality Systems or on Process, Project or Team Management





Company

Haabio Consulting is a service provider for companies and organizations in Health Care and the Life Sciences. Haabio offers a full-range of services, from company-level Quality, Process and Project Management consulting to specific QA managerial tasks such as preclinical, clinical or other kinds of audits. Haabio Consulting provides services as a company inside a company, enabling you to concentrate on your core business. We are also happy to offer tailored service packages to meet your company's explicit needs. Haabio's expertise provides your company with added value by assisting you to find the appropriate level of Quality that best serves your business and customer needs.

Resources and skills

Our services are based on thorough, practical expertise gathered in both managerial and operational tasks in global Health Care corporations and international and domestic Pharmaceutical and Medical Device companies and corporations. We are experienced specialists in the following standards, guidelines and models: ISO9001, ISO13485, GLP, GCP, GMP, FDA QSR (Quality System Regulations) and EFQM Model (EFQM = European Foundation for Quality Management).

Jaana Koskinen

A biochemist with a degree from Turku University, I have worked in both large and specialized units of the pharmaceutical industry for more than 15 years. My specialty is QA duties, and I have experience as a GLP, GCP and GMP auditor and QA manager. I know first-hand what it is like to work in a large pharmaceutical corporation, where processes are conducted in-house, but I am also familiar with the world of outsourcing, where almost any service can be purchased from an outside provider, creating many challenges.

Sirkku Holttinen

A biochemist with a degree from Turku University, I have many years of executive experience in global and domestic Medical Device and Pharmaceutical businesses. My responsibilities included all manner of practical expert tasks, along with managerial stewardship of a large organization with different facilities. After ten years of expert and managerial duties in Research and Development, Customer Support and Quality Assurance functions, I acquired another ten years of valuable experience as Vice-President and Director of Operations, Production and Quality Management.

Contacts

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