HAABIO

*Today's Quality is Tomorrow's Safety*

# Haabio Ltd.

- Over 20 years' experience of Finnish and European Medical Device, Diagnostic and Pharmaceutical Industry and the corresponding authority requirements
- Co-operation network with other Life Science professionals

## Haabio's areas of competences

**Pharmaceutical products**

- EU, Finnish and OECD GLP guidelines and principles (for non-clinical health and environmental safety studies)
- EU and Finnish GMP guidelines and authority requirements (which cover all aspects of production from the starting materials, premises and equipment to the training and personal hygiene of staff)
- Haabio has two year experience of Russian EU-GMP factory set up -project in Finland

**Medical Devices, Diagnostic products**

- Principles of ISO 13485, MD / IVD Directive, CE-labeling (Research and Development, Production, Purchasing, Supplier management, Human Research management, ERP system management)

**Other type of products**

- Principles of ISO 9001, Quality System creation

## Which services can Haabio offer for your organization

- Support for EU GLP, GMP, MD / IVD Quality System creation and implementation
- Reviews and audits of the existing status of your organization, reporting of the findings and recommendations for corrective actions
- Documentation of Users' requirements for new equipment investments and premises as required by GMP and ISO 13485
- Support when searching, recruiting, selecting and interviewing competent professionals
- Tailored GLP, GMP, Medical Device and IVD guideline trainings on EU guidelines, EU directives and ISO standards. Trainings for small or large groups or organizations
- Quality system documentation support when writing instructions and procedures
- Support when creating, updating and implementing Validation and Qualification procedures
- Creation of e.g. risk management, management review or change management practices
- Project management tasks

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