

Management Skills						
Module Code	Workload	Credits	Semester	Frequency of Module	Duration	
	180 hrs.	6	1	Each semester	1 Semester	
1	Module Components		Teaching Language	Contact Hours	Self Study	Class Size
	a) QM and GxP		a) English	a) 22,5 hrs.	a) 37,5 hrs.	a) 15
	b) Patent and Trademark Law		b) English	b) 22,5 hrs.	b) 37,5 hrs.	b) 15
	c) Laboratory and Project Management		c) English	c) 22,5 hrs.	c) 37,5 hrs.	c) 15
2	Learning Outcomes					
	After successful participation in the module the students					
	Comprehension (2)					
	... understand how to apply for a grant.					
	... understand how laboratory and project management works in practice.					
	... understand how patent and trademark law works in practice					
	Application (3)					
	... explain the basic principles of quality management (QM), good working practices (GxP)					
	... justify why a good laboratory and project management is of high importance					
3	Individual Component Content					
	<ul style="list-style-type: none"> a) - Quality management standards, ISO 9000 series of standards, quality management principles (QMP) of ISO 9001 in the current version; quality management handbook (structure and chapters), key term "process", standard operation procedures (SOP) and manuals/working instructions (WI), documentation, total-quality-management (TQM), examples. - GCP: Ethical principles for medical research involving human subjects "Declaration of Helsinki", unproven intervention: compassionate use, off-label use, ICH E6 good clinical practice, medical devices (ISO 14155:2011), efficacy guidelines in the context of GCP, principles of ICH GCP, clinical trials - GLP: ISO 17025:2017 and its relation to GLP, GLP implementation in the EU, GLP in the legal framework, Principles of GLP - Interaction of GxP: GMP, GLP, GCP, GPP, GDP b) Intellectual property rights in Europe and Germany: <ul style="list-style-type: none"> - Major parts/steps of a patent application: request for grant, description of the invention, claims, drawings, abstract. - Decision making between patent and trade secret. - Registered design, different approvals like IVDR. - European Patent Office, European Patent Convention (EPC), Patent Cooperation Treaty (PCT). - Patent searching strategies: International Patent Classification (IPC), Cooperative Patent Classification (CPC). c) - Principles of Project Management - The tasks of the laboratory manager 					

	<ul style="list-style-type: none"> - Principles of Quality Management (QM) and good working practices (GxP) - Principles of Good Clinical Practice (GCP) and Standard Operating Procedures (SOP's) in clinical medicine - Management functions - Teams, Team Process and Team Building - Principles of leadership - Motivating other people - Successful communication - Conflict management - Quality management - New Management Concepts - Human resources (HR) management - Regulatory Requirements in Laboratories (FDA, EMEA, ...) - Laboratory Safety and Emergency Management - Clinical Trials and Evidence-Based Laboratory Medicine - Development of a project plan - Content, form and application of a grant
4	<p>Teaching Methods</p> <ul style="list-style-type: none"> a) Seminar b) Lecture c) Seminar
5	<p>Prerequisites</p> <p>none</p>
6	<p>Methods of Assessment</p> <ul style="list-style-type: none"> a) Graded Assessment 1sbL (Laboratory) (2 LP) b) Graded Assessment 1sbH (Written Elaboration) (2 LP) c) Graded Assessment 1sbL (Laboratory) (2 LP)
7	<p>Applicability of Module</p> <p>Precision Medicine Diagnostics M.Sc. (PMD)</p>

8	Person Responsible for Module Prof. Dr. Hans-Peter Deigner (Module Responsible) Hartwig Becker-Feldmann (Lecturer) Markus Bläss (Lecturer) Prof. Dr. Hans-Peter Deigner (Lecturer)
9	Reading List (Core Texts and Recommended Texts) a) A Handbook on Good Laboratory Practice (GLP) - By World Health Organization. Good Laboratory Practice Regulations. Third Edition, Revised and Expanded. By - Sandy Weinberg. Good Clinical Practice (GCP) - ICH Guidelines for European Community and ICH Regions. Guidance for Industry. E6 Good Clinical Practice: Consolidated Guidance. By - ICH - for European Community and ICH Regions. b) https://www.dpma.de/english/ https://www.epo.org/ c) J. Kuster et al. (2015). Project Management Handbook. Springer. A. Gouws (2020). The Guide to Management For Laboratory Leaders: Principles of management in the field of diagnostics. Power of Process (Pty) Ltd.