Certification Examination Regulations and Course Discription

This Certification Examination Regulations of the Steinbeis+Academy applies to the following course on the basis of the valid Framework for the Implementation of Certificate Courses (RZLG) in the current version.

Course title	**Clinical Research and Regulatory Affairs**

Fields of competences

Management	Personality Development	Education Management	Healthcare	Technology
			X	

Place(s) of implementation

Berlin				

Graduation

Diploma of Advanced Studies (DAS)	Certificate of Advanced Studies (CAS)	Diploma of Basic Studies (DBS)	Certificate of Basic Studies (CBS)
	X		

Qualification aim

The course participants learn the required expert knowledge on frameworks, methods and procedures of clinical research and approval of new medical products for the European and the US-American market. Due to the strongly job-market relevant content, they will afterwards be able to take responsibility for documentation and verification of the quality, effectiveness and safety of drugs in approval applications and gain the expertise for planning, perform and evaluate clinical studies conform to regulatory requirements.

RZLG-Supplementary admission requirement

Teaching method

Classroom	Classroom/ Online	Online
	X	

Language

English			

Workload in hours

Total	Seminar time	Self-study time	Transfer time
346	27	100	219

Type of performance records (LNW)	Examination (K)	Presentation/ Oral examination (P)	Case (C)	Transfer paper (TA)	Project study paper (PSA)
				X	

Contents

Modules	Key topics	Seminar time (h)
Introduction and Fundamentals of Clinical Research and Regulatory Affairs	Challenges of Clinical Research and Regulatory Affairs; Fundamentals, Efficacy and Safety of Clinical Trials; Fundamentals of Regulatory Affairs	9
Clinical Trial Operation	Authorisation and Management of Clinical Trials; Quality Asurance of Clinical Trials; Applied Biostatistics; Drug Safety	9
Strategic Clinical Development and Best Practice	Best Practice of Clinical Trials; Product Classification and Borderlines; Regulatory Dossier Labeling; Best Practice of Regulatory Affairs	9