School of Governance
Risk & Compliance
Steinbeis-Hochschule
Berlin

Certificate Programme Clinical Research & Regulatory Affairs

PROFILE OF THE CERTIFICATE

The marketing authorization of a new drug follows strict rules. Pharmaceutical companies are required to prove the quality, efficacy and the health safety of a medical product in the registration document, not only for the safety of patients but also for the environment in a broader sense/in general. The preparation of such an approval dossier is a central, transdisciplinary process, which in all dimensions is subject to strict rules. The compliance with these rules must be documented in the context of the approval procedure as well. In this respect, the entire research and development process of a drug is determined by regulatory affairs, whose consideration is already of great economic importance for a pharmaceutical company long before any marketable product should be taken into account.

As an expert for clinical research and regulatory affairs, you work in a pharmaceutical company, in a hospital or medical practice, or a public health agency, taking responsibility for documenting and verifying the quality, effectiveness and safety of drugs in approval applications. You assess and document the conformance of clinical studies to regulatory requirements. You issue pertinent specifications for the planning, performance and evaluation of clinical studies to the departments concerned. You use the results of such studies in the clinical study report, the approval dossier, the medical documentation and the patient information leaflet. You recognize potential risks for the approval of a drug early on and can intervene if necessary.

Course content

- **frameworks, methods and procedures of clinical research**
- **Approval of new medical products for the European and the US American market**
- **Holistic perspective on the interfaces and the intedependencies between clinical research and drug licensing**

www.school-grc.de

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DEGREE

University certificate „Clinical Research & Regulatory Affairs“

START OF THE CERTICATE

2 x a year, next start: 13th of November 2017

STUDY PERIOD

4 months (standard period of study)

SCHEDULES

November 2017

STUDY LOCATION

Berlin-Mitte , training center of the School GRC

APPLICATION DEADLINE

Applications will be accepted until one month before starting of the course. The Application documents can be downloaded as PDF-Download at www.school-grc.de

REQUIREMENTS

gute bis sehr gute Englischkenntnisse

TUITION FEES

3.800,- Euro

TARGET GROUP

The certificate program is specifically addressed to graduates from the field of life sciences. Their focus should be on pharmacy, biology, biochemistry, biotechnology, chemistry or human and veterinary medicine. Participants should be from the pharmaceutical industry or in health authorities with working experience or aiming gain experience in these areas.

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