School of Governance
Risk & Compliance
Steinbeis-Hochschule
Berlin

Certificate Programme Clinical Research & Regulatory Affairs

CERTIFICATE PROFILE

State approved part-time vocational distance learning program in English language with self-study Exercises (E-Book based) and In-class-units in Berlin, focusing on strongly job-market relevant pharmaceutical content

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. This is necessary 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 essentially influenced by regulatory affairs. The consideration of these regulatory affairs 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, a university, or a public health agency. Our program graduates take responsibility for documenting and verifying the quality, effectiveness and safety of drugs in approval applications. The program enables to assess and document the conformance of clinical studies to regulatory requirements. Program graduates issue pertinent specifications for the planning, performance and evaluation of clinical studies to the departments concerned. They use the results of such studies in the clinical study report, the approval dossier, the medical documentation and the patient information leaflet. Moreover, they 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 interdependencies between clinical research and drug licensing**

ZFU Nr. 285817

www.school-grc.de

School of Governance
Risk & Compliance
Steinbeis-Hochschule
Berlin

Certificate Programme Clinical Research & Regulatory Affairs

DEGREE

Certificate „Clinical Research & Regulatory Affairs“ CRRA

START OF THE CERTICATE

2 x a year, next start: 1st November, 2018

STUDY PERIOD

6 months part-time vocational training

Mode of STUDY

part-time / vocational distance learning program (blended learning) with E-Books and two In-class-units (3 1/2 days at Berlin-Training Center of 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

At least good English language skills

TUITION FEES

3.800,- Euro

TARGET GROUP

The certificate program is specifically addressed to graduates from the field of life sciences. Their focus is on pharmacy, biology, biochemistry, biotechnology, chemistry or human and veterinary medicine. Participants come from a pharmaceutical company/industry, from a clinical practice, from university or from health authorities with (proficient or first) working experience. Or they aim for gaining experience in these areas.

School of Governance, Risk & Compliance • Chausseestraße 13 • 10115 Berlin-Mitte
030 - 275 817 48 0 • studienbetreuung@school-grc.de • www.school-grc.de