MDRA-internship: Requirement profile

The compulsory six-month internship (full-time; part-time accordingly longer) must be completed in the field of “Drug Regulatory Affairs” in one of the following institutions:
a) Pharmaceutical industry
b) Contract Research Organisation (CRO)
c) Regulatory authority
d) Ministry
e) Supervisory authority
f) Consulting firm
g) Institution of the Federal Armed Forces

Please note that this list is not fully inclusive and is indicative only.
Not all these activities must be/could be done within a 6-month internship. However, it would be good if several different activities – even with a different degree of intensity- could be done.

- Assistance in the preparation, execution and finalisation of marketing authorization procedures within the EU, i.e. national procedures, MRP, DCP or CP. (e.g. first approval, Repeat Use, line extension) and outside of Europe, especially in the other ICH Regions or IND, NDA, PDUFA, 505 ANDA, 505 NDA, GDUFA in the USA (related to the contents of MDRA degree programme module: 2, 3, 12)
- Support of maintenance and care of marketing authorisations by changes (USA) and variations (EU) (preferably CMC und Labelling) (Mod. 4, 8)
- Assistance in marketing authorisation renewal procedures within the EU or USA etc. (Mod 3.)
- Assistance in the preparation, execution and finalisation of marketing authorization procedures for particular medicinal products (i.e. traditional herbal and homeopathic medicinal products, radiopharmaceuticals, vaccines, blood products), advanced therapy medicinal products and Veterinary drugs (Mod. 2, 4)
- Assistance in the preparation, execution and finalisation of marketing authorisation approval projects outside of Europe, especially in the other ICH Regions (Mod. 3, 8)
- Assistance in the preparation, submission and other regulatory support of Clinical Trial Authorisation (CTA) applications within the EU and analogous submissions in the USA and other countries (Mod. 2, 3, 7)
- Assistance in the preparation, submission and further regulatory support of Paediatric Investigation Plans (PIP) (Mod. 2, 3)
- Support to regulatory project managers in interdisciplinary projects and consultations between e.g. pre-clinical, CMC, marketing and other departments (Mod. 2, 5, 6, 7, 8, 9, 10, 11)
- Assistance in the preparation and conduct of Scientific Advice or Presubmission meetings at Regulatory Authorities (Mod. 3)

- Assistance in the compilation, testing and approval of labeling texts (e.g. SmPC and package leaflet) as well as support for the implementation in the commercial product (Mod. 2, 4, 10)
- Assistance in the compilation of dossiers (CTD module 1-5, eSubmission and / or paper submission) especially within the chemical-pharmaceutical part for regulatory approval processes, variations/changes or renewals (Mod. 3, 4, 5, 8, 9, 10)
- Participation in the preparation of pharmaco-toxicological and clinical documentation (Mod. 5, 9, 10)
- Application of knowledge gained from Module 10 to quality management systems in pharmaceutical companies (Mod. 7)
- Participation in regulatory handling of pharmacovigilance procedures in regulatory or PV-departments (Mod. 5)
- Assistance in the conformity procedure and regulatory affairs of medical devices (Mod. 7)
- Assistance in the preparation, submission and finalisation of procedures to achieve designation for orphan drugs within EU and USA (Mod. 3)

Regulatory authorities:

- Collaboration in the validation of new authorisation applications in national, decentralised or centralised or mutual recognition procedures (Mod. 2, 6, 7)
- Collaboration in the processing of applications for parallel import (Mod. 2, 7)
- Collaboration in the administration and evaluation of applications for extension of the marketing authorisation in national and European procedures (Mod. 2, 5, 6, 7)
- Collaboration in the administrative or content-related processing of amendments and variations in national and European procedures (Mod. 2, 3, 4, 5, 6, 7, 8, 10)
- Collaboration in the implementation of requirements for the risk management system and risk management plan in authorisation procedures (Mod. 2, 5, 6, 7, 8)
- Collaboration in the assessment of the content of marketing authorisation applications in the areas of quality, preclinical or clinical topics. (Mod. 2, 3, 4, 5, 6, 7, 8, 10)
- Collaboration in the administration or assessment of applications for conducting a clinical trial, e.g. in the area Quality, Safety or Clinical (Mod. 2, 3, 6, 7, 10)
- Collaboration in the development of pharmacopoeia monographs or monographs for standard marketing authorisations (Mod. 2, 4)
- Collaboration in the maintenance of the quality management system of the authority, e.g. preparation, review and revision of procedural instructions (Mod. 5, 6, 7)
- Collaboration in the preparation and administration of inspections (authorisation-related inspections according to § 25 para. 5 or 8 AMG, 64 AMG and GCP inspections as part of clinical trials) (Mod. 2, 4, 5, 7, 8, 10)
- Collaboration in the recording and evaluation of risk reports in the area of medical devices (Mod. 7)