Module Title:	**Medical Writing**	
Module No.: MW	**Semester / Term:** --	**Duration:** 1 Semester
Module Type(s): Pflicht		**Regularly offered in:** WS, SS
Workload: 150 h		**Credit Points:** 5
Admission Requirements: None		**Language of Instruction:** Englisch
Contributing Courses to Module: • Medical Writing (MW)		**Workload:** Lectures: 30 h Self-study: 90h Self-testing: 30 h
Course Coordinator(s) / Tutor(s):		**Module Director:** Dr. Andrea Schaefer
References to Other Programs: • N/A		**References to Other Modules in the Program:** • Drug Development • Conducting Clinical Trials • Statistical Thinking for Clinical Trials

Qualification and Educational Objectives of the Module:

This course is a thorough introduction to medical writing in which students learn about the variety of documents required throughout the development, marketing authorization, and post marketing periods of pharmaceutical products. Regulatory requirements for certain relevant documents will also be presented.

Course Content of the Module:

• Introduction and overview of the world of medical writing
• Guidelines for medical writing
• Techniques and skills for professional medical writing and use of templates
• Processes: From initial information to the final document
• Documents for clinical studies: Protocol, clinical study report, and subject information with informed consent form
• Regulatory documents: Investigator's brochure, common technical documents, summary of product characteristics, and submission documents
• Medical and scientific communication
• Documentation in pharmacovigilance

Teaching Methods:	See the contributing course outline(s)

Literature:	See the contributing course outline(s)	
Percentage of the Module Grade Relative to the Final Grade for the Program: --	**Prerequisites to Qualify for Assessment:**	**Assessment:**
	See course outline(s)	Research essay, 15-20 pages (DIN A4), 100%

Course No.: MW	**Course Title:** Medical Writing	**Hours Total:** 150 h
		Credit Points: 5 ECTS
Course Type: Pflicht **Course Availability:** **Course Duration:** 1 Semester		**Admission Requirements:** None
Course Coordinator / Instructor: See current list of tutors in the Learning Management System		**References to Other Modules:** Please see module description

Course Description:

Medical writing is involved in the entire process during the development of a pharmaceutical product. The main focus of this course will be on the documents relevant for the conduct of a clinical trial, starting with the generation of the fundamental clinical study protocol to the final study report at the end of a clinical trial as well as the common technical document (CTD) and all relevant subdocuments necessary for compilation of the CTD.

Students will be introduced to the documents involved and will be given the opportunity to write certain documents on their own.

International guidelines and local laws have to be followed for the successful conduct of a study and for the successful submission of a dossier for marketing application.

Course Objectives and Outcome:

On successful completion of this module, students will be able to:

- write a subject information and informed consent form
- structure a protocol
- describe the content of the clinical study report
- describe the structure of the CTD
- write a review based on 2-3 publications

Teaching Methods:

This course is taught in blended format. It consists of 120 h directed, remote learning (via recorded presentations, self-readings, and exercises), followed by 4 days of full-time, face-to-face training in form of lectures, supplemented by class discussions. Class discussions refer to the concepts being introduced and case studies.

Course Content:

1 Introduction and Overview of the World of Medical Writing

2 Guidelines for Medical Writing

3 Techniques and Skills for Professional Medical Writing and Use of Templates

4 Processes: From Initial Information to the Final Document

5 Documents for Clinical Studies: Protocol, Clinical Study Report, and Subject Information with Informed Consent Form.

6 Regulatory Documents: Investigator’s Brochure, Common Technical Documents, Summary of Product Characteristics, and Submission Documents

7 Medical and Scientific Communication

8 Documentation in Pharmacovigilance

Literature:

• ICH E6. Note for guidance on good clinical practice (CPMP/ICH/135/95)
• ICH E3. ICH Harmonised Tripartite Guideline: Structure and content of clinical study reports.
• ICH M3. Common technical document (CTD)

Examinations:

• Research essay, 15-20 pages (DIN A4)

Student Workload (in hours): 150

Lectures: 30
Self-study: 90
Self-testing: 30