University Program

Master of Science in Medical Writing

Curriculum*

Medical University of Innsbruck

*This is a translation of the original, German document found here: https://www.i-med.ac.at/mitteilungsblatt/2012/58.pdf

1. Aims of the master program - Qualifications:

Medical texts are required in numerous situations in everyday life, and the content and style of such texts varies enormously, from texts targeting the general public in the lay press to articles in scientific journals from texts with a strong regulatory and legal background to proposals for scientific grant programs.
The ability to write competitively and successfully is essential for all medical researchers and constitutes a profession of its own for those who are part of a research team as professional medical writers.
This university course is aimed at all those who write medical and scientific texts and who publish or wish to publish texts in medical and scientific journals, or who wish to work as medical writers within the pharmaceutical industry and related sectors. Alternatively, they may have studied languages and wish to specialize in the preparation of medical and scientific texts.
In addition to an introduction to the basics of medical knowledge (for non-physicians) and the fundamentals of scientific and medical texts, the major focus of the course is on the preparation of the entire range of scientific and medical texts, from where to find information, study design, ethics committee approval to data evaluation, and preparation of integrated reports, regulatory writing, the preparation and review of manuscripts, and the field of medical communications.
An introduction to statistics is as much part of the program as presentation techniques and the creation of slide kits for conference presentations. During the second year of the program participants will be introduced to the field of quality control and editing of texts written by others since medical writers, more often than not, also work as editors for journals, companies or research teams. An introduction to medical ethics and good clinical practice rounds out the course program.
The academic degree “Master of Science in Medical Writing” (MSc.) will be granted to persons who successfully finish the course.

2. Eligibility

2.1 Requirements for admission:

Applicants with the following study background will be considered:

a) Graduates with an academic degree in medicine,
b) Graduates with an academic degree in natural science,
c) Graduates with an academic degree in psychology,
d) Graduates with an academic degree in linguistics, literature, English, translation studies, journalism or similar
e) Persons with extensive work experience in an appropriate field (e.g. in a biomedical company, the pharmaceutical sector or journalism) will also be considered

In addition, students need to have a certain level of proficiency in English:

a) Native speaker
   OR
b) Holding a non-expired certificate for English as a foreign language like TOEFL (iBT 100+) or the Cambridge Certificate (Level C1)

2.2 Application procedure and acceptance:

2.2.1 Applications must be submitted before the deadline set by the Medical University of Innsbruck. The date is published in good time before the start of the semester on the home page of the Medical University and in other print media. Applications must

include the **application form**, **CV**, **certified copies of degree certificates**, a **letter of motivation** and **proof of professional experience**, if required.

2.2.2 The course director will decide upon acceptance based on the formal qualifications of the applicants and their reasons for wishing to take the course. Until the course fees are paid (including the ÖH fees) accepted students will be granted a temporary place in the course program.

2.2.3 The minimum number of students is 15, the maximum number is 30.

2.2.4 Participants who fulfil all requirements, are accepted by the head of the master program, and paid the course fees, will be enrolled as exceptional students at the Medical University of Innsbruck.

3. Duration and structure of the program:

The course begins in February and last for 2 years (4 semesters) of study consisting of 94 ECTS credits.

The course consists of blocks with obligatory attendance of all participants.

The program is run using extensive distance learning which will be realized through the eLearning platform of the Medical University (ILIAS).

4. Module names and descriptions:

4.1 The classroom language is English. All materials and presentations, including distance learning materials, will be in English.

4.2 All modules of the course program are obligatory unless a formal waiver is given by the course director. Physicians are not required to take Module C (Medicine for medical writers).

4.3 Waivers are only given on course content and do not reduce the course fee.

4.4 Module descriptions:

Module A - Medical English: Writing, editing and reading skills	**ECTS: 6**

Type:	SE
ECTS on-site training:	1.5
ECTS e-Learning:	4.5
Hours on-site:	38
Hours e-Learning:	112

This module will not be waived for native speakers of English.

After completing this module, students will be able to:

- Identify correct and incorrect usage of nouns etc, punctuation, spelling, and sentence structure
- Recognize when a sentence is unclear and know how to rewrite the sentence for clarity
- Edit texts using correct grammar and punctuation
- Identify and correct inappropriate use of language in biomedical texts
- Copyedit and proofread documents
- Use references and citations properly
- Identify useful style guides and other language resources

Module B - Scientific tools for medical writers	**ECTS: 10**

Type:	SE
ECTS on-site training:	2.5
ECTS e-Learning:	7.5
Hours on-site:	63
Hours e-Learning:	187

Basics of study design

Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will be able to:

- Explain the differences between Phase 1–4 studies
- Describe the differences between and the pros/cons of interventional, observational, and cross-sectional studies as well as case-control, cohort and epidemiological studies
- Explain the differences between laboratory, preclinical, and clinical studies
- Differentiate between prospective and retrospective studies and identify the pros and cons of each
- Explain the reasons why ethics approval is required for certain types of studies
- State the question or objective of a study

Software applications used by medical writers		
LV-Type: SE	**On-site (h): 6**	**e-Learning (h): 18**
After completing this module, students will be able to: • Make efficient use of the Microsoft Office Suite and Adobe Acrobat, including use of comment functions • Make efficient use of referencing software (e.g. EndNote)		
Statistics		
LV-Type: SE	**On-site (h): 21**	**e-Learning (h): 61**
After completing this module, students will be able to: • Define and use correctly basic statistical terminology • Explain when and why the most common statistical tests are used • Report statistics correctly in journal articles and abstracts • Determine when to report statistics in verbal and/or graphical or tabular form • Choose the best graphical or tabular method for reporting statistical outcomes • Identify the methods needed to correctly determine appropriate sample size and study power before a study is begun • Understand the basics of using statistical analysis software packages		
Information sources for medical writers		
LV-Type: SE	**On-site (h): 6**	**e-Learning (h): 18**
After completing this module, students will be able to: • Use online bibliographic resources to conduct literature searches, including proper selection of key words and search strings • Use a referencing software program to create personal reference library files, download references from online bibliographic databases, and insert correctly formatted references into manuscripts		
Data presentation techniques		
LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**
After completing this module, students will be able to: • Select the correct medium in which to display data from a scientific study • Evaluate the text, data and images for a scientific poster and determine the most appropriate design layout • Create clear, succinct, high impact PowerPoint presentations to report study progress and/or study results		

Module C – Medicine for Medical Writers	**ECTS: 12**

Type:	SE
ECTS on-site training:	3
ECTS e-Learning:	9
Hours on-site:	75
Hours e-Learning:	225

Physicians are not required to take this module

Introduction to anatomy

LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will:

- Have a general idea of how the body is built. Example: the heart has 4 chambers and how they are related to each other, the major vessels, and their basic function.

Introduction to physiology and common diseases, disorders and syndromes

LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will:

- Have a general idea of how the most important organ systems work, what their functions are, and the most common diseases that affect the normal functioning of these systems.

Diagnostic variables and procedures

LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will:

- Be aware of the most common diagnostic procedures used in medicine, and will be familiar with routine variables and their diagnostic value..

Therapeutic procedures

LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will:

- Be aware of the most common diagnostic a general idea of the different approaches to treatment (drug, non-drug and surgical) and situations where each approach is preferred. They will also understand the importance of pharmacology, pharmacokinetics and pharmacodynamics.

Measuring therapeutic success

LV-Type: SE	**On-site (h): 15**	**e-Learning (h): 45**

After completing this module, students will:

- Understand which variables are measured and why for the most common diseases and disease groups. They will also understand what role these play in the measurement of therapeutic success..

Module D – Medical publication writing	**ECTS: 10**

Type:	SE
ECTS on-site training:	2.5
ECTS e-Learning:	7.5
Hours on-site:	63
Hours e-Learning:	187

After completing this module, students will be able to:

- Identify the different kind of medical publications
- Explain the role of ICMJE Guidelines, CONSORT Guidelines, and Good Publishing Practice in the preparation of medical publications
- Identify the sections of a medical publication and describe specifically what should be included in each section of a manuscript and explain why it belongs there
- Realistically assess the level of work of a particular manuscript and target the most appropriate journal for that level of work.
- Identify the best target journal for a medical article and explain to co-authors why a particular journal is the most appropriate choice.
- Write and explain the purpose of an outline for a manuscript
- Write each section of a manuscript in its entirety including correct references, figures, tables, graphs
- Explain what qualifies for authorship vs. an acknowledgement
- Explain what a conflict of interest is and complete a conflicts of interest form
- Determine the most appropriate title for a manuscript
- Write a concise abstract
- Perform quality control on a manuscript to ensure that it complies with instructions for authors and related guidance documents.
- Construct an effective cover letter that improves the chances of acceptance
- Write an appropriate response to reviewer's comments

Module E - First-year Project	**ECTS: 7**

Type:	SE
ECTS on-site training:	1.75
ECTS e-Learning:	5.25
Hours on-site:	44
Hours e-Learning:	131

Students supply a completed journal article ready for submission to the target journal.

Module F - Writing for drug development and regulatory affairs	**ECTS: 16**

Type:	SE
ECTS on-site training:	4
ECTS e-Learning:	12
Hours on-site:	100
Hours e-Learning:	300

After completing this module, students will be able to describe in detail:

- The templates available for international drug and device approval
- The content and purpose of all documents required for drug and device approval
- The documents required for interactions with health authorities
- The safety documentation required by the health authorities
- The need to register clinical trials and their results in public databases and how to do this efficiently and correctly
- The basic requirements and elements of electronic submissions
- How to prepare a bibliographic submission and suitable products for such submissions

Module G - Writing for medical communications	**ECTS: 10**

Type:	SE
ECTS on-site training:	2.5
ECTS e-Learning:	7.5
Hours on-site:	63
Hours e-Learning:	187

After completing this module, students will be able to:

- Prepare a conference abstract
- Prepare a conference poster
- Write an overview article on any special medical topic for the interested lay audience
- Plan the publication strategy of a company while developing a new medicinal product. Define what types of documents are required in each phase and how to prepare them
- Prepare educational materials for different target groups (e.g. customers, patients, sales representatives) in different media
- Understand the needs, expectations and constraints of the R&D, Marketing and Regulatory departments in a pharmaceutical or medical device company and be able to meet the medical communication expectations of these departments when writing medical texts
- Be aware of the need for regulatory approval of all communications materials

Module H - Advanced language skills – Quality control of written material	**ECTS: 3**

Type:	SE
ECTS on-site training:	0.75
ECTS e-Learning:	2.25
Hours on-site:	19
Hours e-Learning:	56

After completing this module, students will be able to:

- Edit manuscripts prepared by others
- Prepare objective comments on a text

Module I - Quality assurance **Good clinical practice and medical ethics**	**ECTS: 3**

Type:	SE
ECTS on-site training:	0.75
ECTS e-Learning:	2.5
Hours on-site:	19
Hours e-Learning:	56

Quality assurance, quality control and standard operating procedures		
LV-Type: SE	**On-site (h): 10**	**e-Learning (h): 28**
After completing this course, students will be aware of: • The principles of quality assurance and quality control in clinical testing and how these are established and conducted. • The principles of SOPs and their preparation.		
Good Clinical Practice and medical ethics		
LV-Type: SE	**On-site(h): 9**	**e-Learning (h): 28**
After completing this course, students will be aware of: • The principles of Good Clinical Practice and how they are implemented. • Aspects of medical ethics that can affect the writing process and how these can be recognised and accounted for.		

Module J – Master's Thesis	**ECTS: 17**
Type: SE **ECTS on-site training**: 4.25 **ECTS e-Learning**: 12.75 **Hours on-site**: 107 **Hours e-Learning**: 318	
The student will prepare a mentored Master's thesis on a topic approved by the course director, supported by a PowerPoint presentation for the thesis defence.	

5. First-year Project and Masters Thesis:

5.1 All participants must submit a written First-year Project and a Masters Thesis. A project/thesis supervisor will be assigned to each student to support them during the process.

5.2 The subjects of the First-year Project and the Masters Thesis have to be approved by the course director.

5.3 The First-year Project is a journal manuscript, ready for submission to a medical journal.

5.4 The Masters Thesis is a paper that has to be graded by the thesis supervisor.

5.5 Subjects of the Masters Thesis have to be chosen from the following areas:

a) A manuscript ready for submission to a peer reviewed scientific journal in the medical field. The paper has to be written in English. The material the paper is based upon can either be the results of individual research by the participant or the result of research of third parties, handed over to the participant for explicit use in the Masters Thesis.

b) A regulatory document ready to be handed in at a proper authority

5.6 Supervisors have to be chosen from the pool of teachers in the course

6. Exam Regulations:

6.1 The examinations for the MSc are governed by the terms of §§ 72ff UG 2002 and the relevant terms of the section "Studienrechtliche Bestimmungen der Medizinischen Universität Innsbruck" of the statutes of the Medical University of Innsbruck.

6.2 The following conditions must be fulfilled for candidates to be awarded the title "Master of Science in Medical Writing":

6.2.1 Successful completion of all obligatory and optional modules, subject to any waivers agreed (see above).

6.2.2 Successful presentation of a Masters Theses and defense of the thesis before the Defence Panel

6.3 After the successful completion of all courses within a module the head of the module calculates the overall module grade by adding together all marks and dividing them by the number of courses. If the final grade is 1.5 or lower the student receives a "passed with distinction". If the overall grade higher than 1.5 the student receives a "passed" for the module.

7. Defence Panel

The members of the Defence Panel are proposed to the vice rector for studies by the course director. The Defence Panel has at least three members.

8. Description of qualification

On achievement of a positive result for all courses, the First-Year Project, and for the Masters Thesis and defense, students are awarded the qualification "Master of Science in Medical Writing" which can be abbreviated to "MSc".