Introduction to Medical Writing



Topic 1

What is Medical Writing?

"Medical writing is the activity of writing scientific documentation by someone who is a specialized writer (a medical writer) and is generally not one of the scientists or doctors whose research it was."

Accurately presenting and effectively communicating information for any medical document is of paramount importance



A **medical writer** is the writer engaged in communication in the medical or allied professions and sciences

Examples of Medical Writing

- Journal articles
 - Original research
 - Review articles
 - Editorials, case reports, etc.
- Abstracts
 - Publication in journals
 - Submission to medical meetings
- Posters
 - Presentation at medical meetings



Examples of Medical Writing (contd)

- Slide presentations
 - Original research
 - Symposia
 - Roundtables
 - Advisory boards
- Medical education materials
 - Monographs
 - Training materials
 - Prescribing information



Examples of Medical Writing (contd)

- Regulatory documents
 - Clinical Trial Reports (CTR)
 - New Drug Applications (NDA)
 - Investigational New Drug Application (IND)
- Marketing materials
 - Advertisements
 - Public relations materials
 - Internet documents
 - Patient education

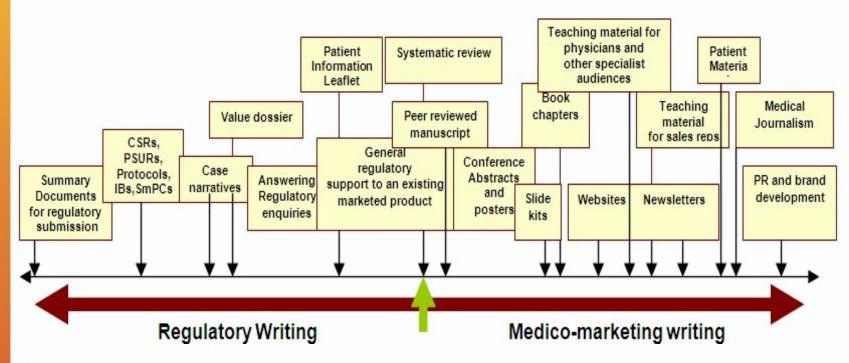


Good medical writing include:

- Thorough research
- Accuracy
- Logical organization
- Clear thinking and writing
- Readability



Types of Medical Writing





Drug development stages and MW involvement

IND

Development support

- Experimental strategy: – Go/No-Go criteria
- Regulatory strategy

Dev

Development support

- Medical monitoring
- · Study design
- Endpoints selection
- · IB, protocol

Development support

- Medical monitoring
- · Study design
- · POC
- · Biomarkers
- · Go/No-Go

NDA

Development support

- Medical monitoring
- · Study design
- Regulatory strategy

- Periodic Safety Update Report
- Risk
 Management
 Plan
- Post Marketing Surveillance planning

Preclinical

Phase I

Phase II

Phase III

Phase IV

Product Strategy

- Target product profiles (TPP)
- · Indications
- Epidemiologic assessment
- Competitive intelligence

Product Strategy

- Risk assessment
- Safety management plan
- Regulatory strategy

Product Strategy

- Population and disease characteristics
- Regulatory strategy
- Product differentiation

Product Strategy

- Regulatory strategy
- Product differentiation
- Product monogram
- Post-licensure commitment studies
- REMS
- · Drug utilization

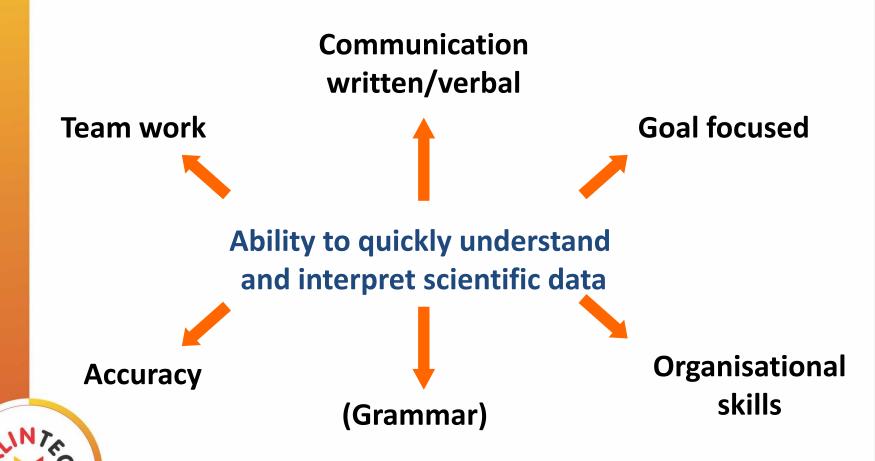


Medical Writers - Different Backgrounds

- BSc/MSc medical/life science
- PhD (and post-doc/lecturers)
- Pharmacy (BPharm/MPharm)
- Pharma / Industry (Experience)
- Medicine (BAMS/MBBS/BDS/MD/MS/DM)
- Other, Science (Mathematics/Chemistry)



Key Attributes To Fulfill The Role

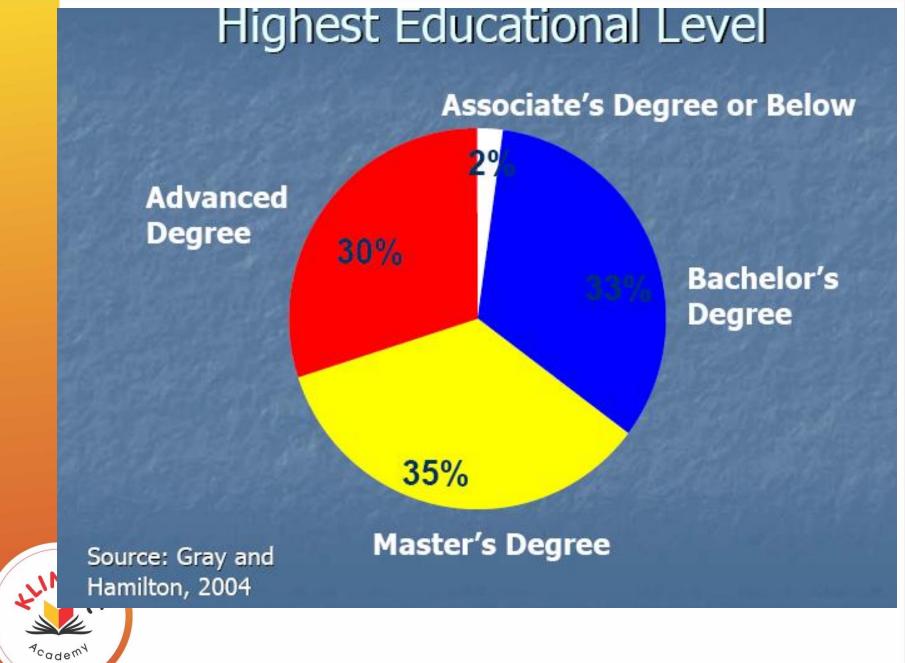


Flexibility, commitment, attention to detail, ability to work under pressure, business awareness

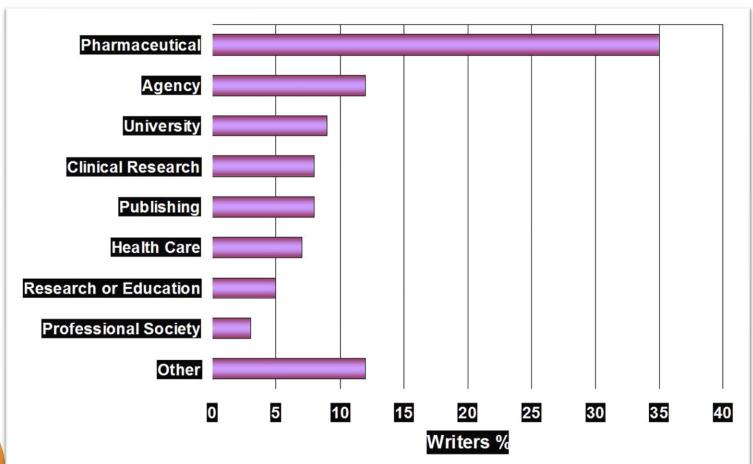
Qualifications and Skills

- Ability to write and enjoy writing!
- Life sciences degree
- Ability to assimilate information quickly
- Enjoy working with huge amounts of data
- Attention to detail
- Work under pressure and meet deadlines
- An understanding of statistics
- Proficiency in Microsoft Word





Primary Employers of Medical Writers





What Employers Look For:

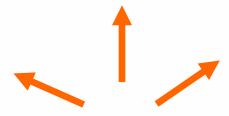
- Experience
- Ability to do the Job
- Initiative
- Self-Confidence
- Leadership

- Compatibility
- Attitude
- Social Skills
- Involvement
- Integrity
- Communication

Medical Writers

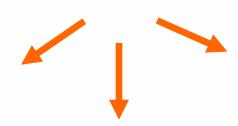


Pharma. companies



Scientific press

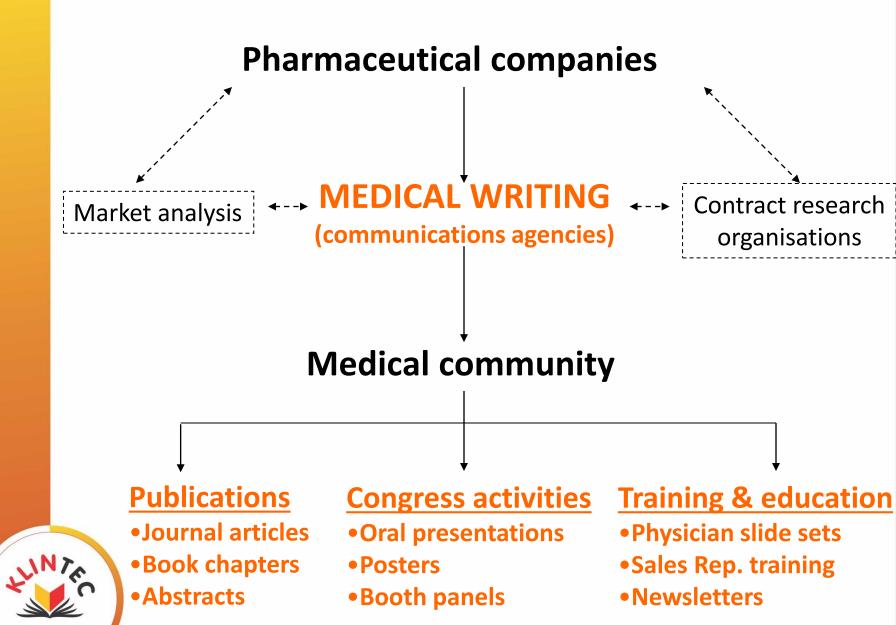
Advertising agencies



Clinical research organisations



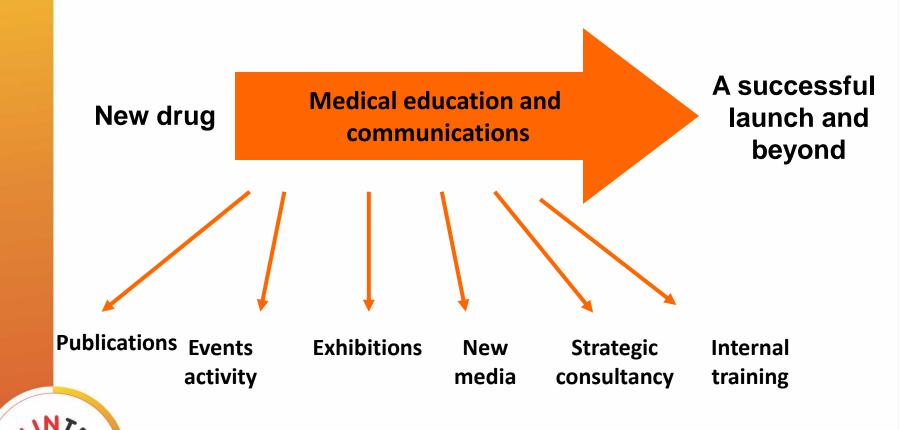




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Academ

Product/publication managers clinical scientists



Academ



Sample Jobs



- Medical writer for medical communications firm: to create pharmaceutical/health care educational programs
- Scientific medical writer for medical communications company: to prepare clinical and pre-clinical manuscripts, abstracts, and posters; clinical trial reports; and medical education materials
- Director of scientific editing for a biotech company: to edit and/or re-write scientific papers and grant applications, and educate and train staff in scientific writing and editing

Source: AMWA-DVC Web site, 2004

Career Paths to Medical Writing

There are two main career paths to becoming a medical writer:

- Writers who learn to write about medicine
- Scientists who learn to write

Newer path is to study to become a medical writer (e.g. University of the Sciences in Philadelphia Masters in Biomedical Communications)

How to Get Started?

- Contract Research Organizations/ Companies willing to take on those with aptitude
- Written a thesis
- Published papers
- Be prepared to take a test
- EMWA
 - A career guide to Medical Writing. Published on EMWA website summarises this whole topic beautifully



Informal Medical Writing Training

- Read medical and pharmaceutical journals
- Subscribe to online newsletters (e.g. National Center for Education in Maternal and Child Health)
- Develop an understanding of basic statistics

- Obtain and be familiar with style guides and medical dictionaries (e.g. AMA)
- Keep up to date with
 - FDA guidelines
 - Software skills (MS Word, PowerPoint, Acrobat)

Source: AMWA-DVC Web site, 2004



Formal Medical Writing Training

- Complete a course in statistics, pharmacology or life sciences
- Enroll in AMWA's continuing education certification program
- Undertake a medical writing program through college or university

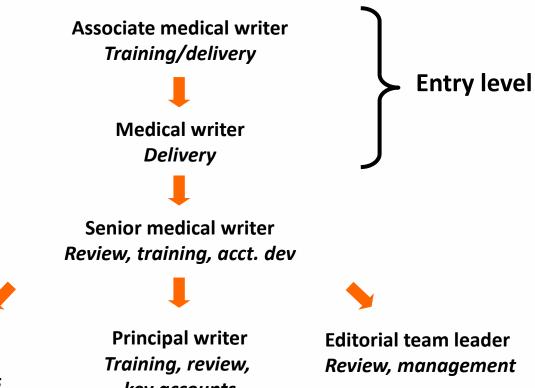
Source: AMWA-DVC Web site, 2004

Medical writers Association

- American Medical Writers Association (AMWA)
- European Medical writers Association (EMWA)
- Australian Medical Writers Association (AuMWA)



Career Structure



Scientific director Review, strategic acc. dev, new business

Academ

key accounts

Editorial unit manager /Editorial vice president