Visiting the Garden of Medical Writing?

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AMWA Pacific Southwest Chapter
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Intercept Pharmaceuticals Inc
That’s my bicycle, I planted those flowers, and I approve this message 😊

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Types of Medical Writing

Medical Writers write and edit. Medical Communicators also include medical illustrators and designers.

- **Scientific and Regulatory**
  - Publications – journal manuscripts, abstracts
  - Pharmaceutical regulatory documents

- **Educational and promotional literature** (drug- or disease-related)
  - for healthcare providers / patients
  - for Clinical study sites / sales training materials

- **Marketing and Journalism**
  - Content for healthcare websites, magazines, news articles

Medical Communicators write, edit or develop materials related to medicine or healthcare

[http://www.amwa.org/about_med_communictions](http://www.amwa.org/about_med_communictions)

A Rose is not *just* a Rose: Types of Documents* Medical Communicators Create:

<table>
<thead>
<tr>
<th>Materials</th>
<th>Audience</th>
</tr>
</thead>
<tbody>
<tr>
<td>Peer-reviewed journal articles</td>
<td>Physicians, healthcare providers and researchers</td>
</tr>
<tr>
<td>Conference abstracts, posters, slide-decks</td>
<td>Healthcare providers, investors</td>
</tr>
<tr>
<td>Conference reporting, advisory boards</td>
<td>Study investigators, strategy</td>
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<tr>
<td>Regulatory documents</td>
<td>Regulatory agencies, eg, FDA, EMA</td>
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<tr>
<td>HEOR and healthcare policy monographs and white papers</td>
<td>Pricing and reimbursement bodies</td>
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<tr>
<td>Education materials: healthcare providers</td>
<td>CME monographs; web-based, video</td>
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<tr>
<td>Education materials: patients</td>
<td>Patient education brochures or pamphlets, websites (branded drugs)</td>
</tr>
<tr>
<td>Sales training and marketing presentations</td>
<td>Healthcare providers</td>
</tr>
</tbody>
</table>

*Documents created within and outside the biopharma environment.
### Medical Communication *Beyond* BioPharma

<table>
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<tr>
<th>Materials</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Grant proposals</td>
<td>Research scientists and institutions</td>
</tr>
<tr>
<td>Science and research reporting (print/web)</td>
<td>University’s communication dept; peer-reviewed journals, magazines; trade journals for HCPs; nonprofit organizations’ pubs</td>
</tr>
<tr>
<td>Books, including indexing</td>
<td></td>
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<tr>
<td>Medical/legal briefs</td>
<td>Law, insurance claims</td>
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*Pict source: https://www.flickr.com/photos/miss604/15136130857*
Where Do Medical Communicators Work?

- Biotech/Pharma/Medical Device companies
- Clinical or Contract research organizations (CRO)
- Medical Communication Agencies
- Universities / Medical Schools / Research centers
- Government agencies -- FDA
- Health care organizations or providers
- Medical journals/books publishers
- Professional societies for health care professionals
- Trade journals and magazines for health care professionals
- Nonprofits and patient advocacy organizations
- Online healthcare portals

Freelance / Self-employed
Qualifications Required

- Proof of good English language skills
- Higher degree in life sciences, chemistry, medicine (even physics)
- Familiarity with medical concepts and drug development process
The Tools: Knowledge, Skills and Abilities (KSA)

- English Language
- Medical Terminology
- Drug Development Process
- Literature Search
- Statistics, data interpretation and presentation
- Use of software: MS Office, EndNote, graphing, document sharing, etc
- Ethical issues
Acquiring / Improving Skills

• No single path to a full-time medical writing career

• Two options:
  • Certificate programs
  • Self-designed
About AMWA
www.amwa.org

American Medical Writers Association

- Founded in 1940 by George B Lake and 5 other physicians as Mississippi Valley Medical Writers Association (MVMWA)
- In 1948, under Harold Swanberg, MD, became a national organization, AMWA
- >5000 members from the US and 26 countries
- 19 US and Canadian chapters
- AMWA’s PURPOSE: Seeking excellence in medical writing and communications
AMWA Resources

- AMWA Certificates
  - Essential Skills
  - Composition & Publication
  - Regulatory & Research

- Online / Email Resources
  - AMWA Webinars (live and on-demand)
  - AMWA Online-learning
  - AMWA Pocket Trainings
  - AMWA Engage, Member and Freelance Directory, AMWA Salary Survey

- Journal, Guidelines
  - AMWA Journal (quarterly)
  - Guidelines for Document Design
  - CORE Reference
  - Code of Ethics

- Conferences
  - Medical Writing & Communications Meeting
    - Workshops, open sessions, networking
    - Chapter Conferences

- Certification
  - Medical Writer Certified, MWC™

AMWA Certificates

**Essential Skills**
- Requires eight credits
- Seven self-study workbooks or workshops
  - Basic editing, writing, communication, statistics and bibliographic skills, and ethics

**Composition and Publication**
- Specialized editorial and publication skills
- In-depth study of issues in writing, editing, bibliographic skills

**Regulatory and Research**
- Data analysis, regulatory document preparation, knowledge of guidelines and regulations

Package: $950 (members), $1250 (non-members)*

*Price as of Nov 07, 2016.
What it is

Scientific Medical Writing: Peer-reviewed journals, regulatory documents, medical education materials and/or research grant proposals

What it is NOT

Communicating scientific information to lay audiences, e.g., science journalism, marketing communications or patient communications

Program Cost, Duration & Expectations

• 22-unit program
• May take 18 months approx to complete
• Overall cost $4,000 approx

Students MUST earn a minimum passing grade of a B-/80% in every course of the Medical Writing Certificate Program.
Prerequisites
• Medical Terminology (1 unit)
• Practical Clinical Statistics for the Non-Statistician (2 units)

Required Courses (All 14 units required)
• Introduction to Medical Writing & Editing (3 units)
• Medical Writing & Editing II (3 units)
• Advanced Medical Writing & Editing (4 units)
• Designing Figures, Tables, & Graphs (2 units)
• Ethics for Medical Writers (2 units)

Electives (8 units required)
• Medical Writing: Protocols, Reports, Summaries, and Submissions (2)
• Good Documentation Practices (3 units)
• Overview of the Drug Development Process (3 units)
• Drug Development Process (3 units)
• Understanding Oncology (3 units)
• Regulation of Drugs, Biologics, Devices, and Diagnostics (3 units)
• Grant Proposal Preparation for Research Administration (2 units)
• Science of Clinical Trials Design (3 units)
The process of medical writing involves:

- Gathering,
- Evaluating,
- Organizing,
- Interpreting, and
- Presenting

information in a manner appropriate for the target audience.

The exam for MWC™ credential evaluates the following:

<table>
<thead>
<tr>
<th>Knowledge/ Skills / Abilities</th>
<th>Gathering</th>
<th>Evaluating</th>
<th>Organizing</th>
<th>Interpreting</th>
<th>Presenting</th>
</tr>
</thead>
<tbody>
<tr>
<td>Target audience? Gap analysis, Literature search (PubMed), Guidelines, etc</td>
<td>Data analysis and plotting Statistical concepts</td>
<td>Template (eg, IMRAD, ICH), Drafting, editing, Tracking and version controls Project management</td>
<td>Key messages, study design, clinical relevance</td>
<td>The act of writing! Clear, concise prose, grammar, punctuation; design and layout; standardized formats and templates;</td>
<td>Ethical standards, confidentiality, proprietary</td>
</tr>
</tbody>
</table>

Pict source: https://www.flickr.com/photos/davidreber/5850263741
• Editor in the Life Sciences (ELS) Certification
• Evaluates the proficiency of manuscript editors in the life sciences.

Application requirements
• Bachelor's degree or equivalent
• At least 2 years of experience as a manuscript editor in the life sciences.

A manuscript editor is defined here as one who is concerned not only with the form but with the intellectual content of a manuscript.

Upcoming Exam Dates:
Sat Apr 22, 2017, Austin, TX
Sat May 20, 2017, San Diego, CA
One in Two* Medical Writer is Self-Employed

ADDITIONAL CONSIDERATIONS:
- Branding, website, social media presence (y/n)
- Promoting the business, building clients
- Project management, time-logging
- Accounting, taxes, retirement plan, 401k
- Insurance (omissions and errors; business)
- “Never undersell your skills”

RESOURCES:
- AMWA Engage Forum – ask questions, get advise, get support
- AMWA workshops and open sessions
- AMWA salary survey (what to charge)

*not from survey

Freelance medical writers must consider the business-side of medical writing.
1. BELS Exam

Hello. I’d like to take the BELS exam next year and was looking for tips for those of you that have acquired your ELS. Has this certification helped your career? Would you recommend/not recommend? Any info to help me prepare would be helpful. BTW, I proofread/copyedit medical papers and submit to journals for the past 10 years. I am most familiar with AMA style and have a certificate from AMWA’s Core Curriculum in Editing/Writing.

Jennifer P
Publication Specialist

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RE: BELS Exam

Hi Jennifer,

I just took the BELS exam at the AMWA conference in Denver. I've worked in the biotech industry as a technical writer and instructional designer; I'm fairly new to medical writing and editing (currently working as a medical editor), with almost 2 yrs. in that role. I purchased the AMWA Essential Skills set (7 modules) and worked through those for about 5 months before the exam. I feel those modules really helped prepare me for the BELS exam, which I passed. Whether or not it will help my career remains to be seen. My company just got acquired by a larger firm and I may lose my position. I know that having ELS will help me stand out when I do need to send out my CV in search for my next position!

Leslie K, ELS
Medical Editor
AMWA Pacific Southwest Chapter: Your local farmers market

- Estd November 1964
- ~350 members
- Serves Southern California, Arizona, Southern Nevada Area 2x the area of UK
- Satellite group centered in Phoenix, Ariz
- Publication: POSTSCRIPTS
- www.amwa-pacsw.org
Read about the history of AMWA Pacific Southwest Chapter in the Feb/Mar 2015 issue of *Postscripts*

https://archive.org/details/v5n32
https://issuu.com/postscripts/docs/v5n32

**Chapter Leadership**

**President:**
Susan Vintilla-Friedman
president@amwa-pacsw.org

**Immediate Past President:**
Donna Simcoe
past-president@amwa-pacsw.org

**Secretary:**
Brea Midthune

**Treasurer:**
Elise Sudbeck
Postscripts
archive.org/details/@postscripts
issuu.com/postscripts/stacks

- Published about 10 times a year
- Open access, free PDF downloads
- Cover all areas of medical writing
- Tool for networking, sharing chapter activities and education

- **Portfolio builder!**

**Content (Examples)**
- AMA Style guide
- Good language skills
- Ethics
- PLUS topics related to publication, publication planning, drug development and regulation, social media, etc
- Meeting reports

December issue contains year-end TOC
Yes, it can be Done
THANK YOU FOR YOUR ATTENTION!

Contact info: ajay@amwa-pacsw.org

Aurora Alexander, MA, LPC,
Air Force Veteran, Forensic Behavioral Health Therapist, MA, LPC,