



# **MEDICAL WRITING**

## **NEW CHALLENGES AND OPPORTUNITIES**

Zhiyun Lynn Guan  
Medical Writer, Medtronic  
April 9, 2018

# Disclaimer

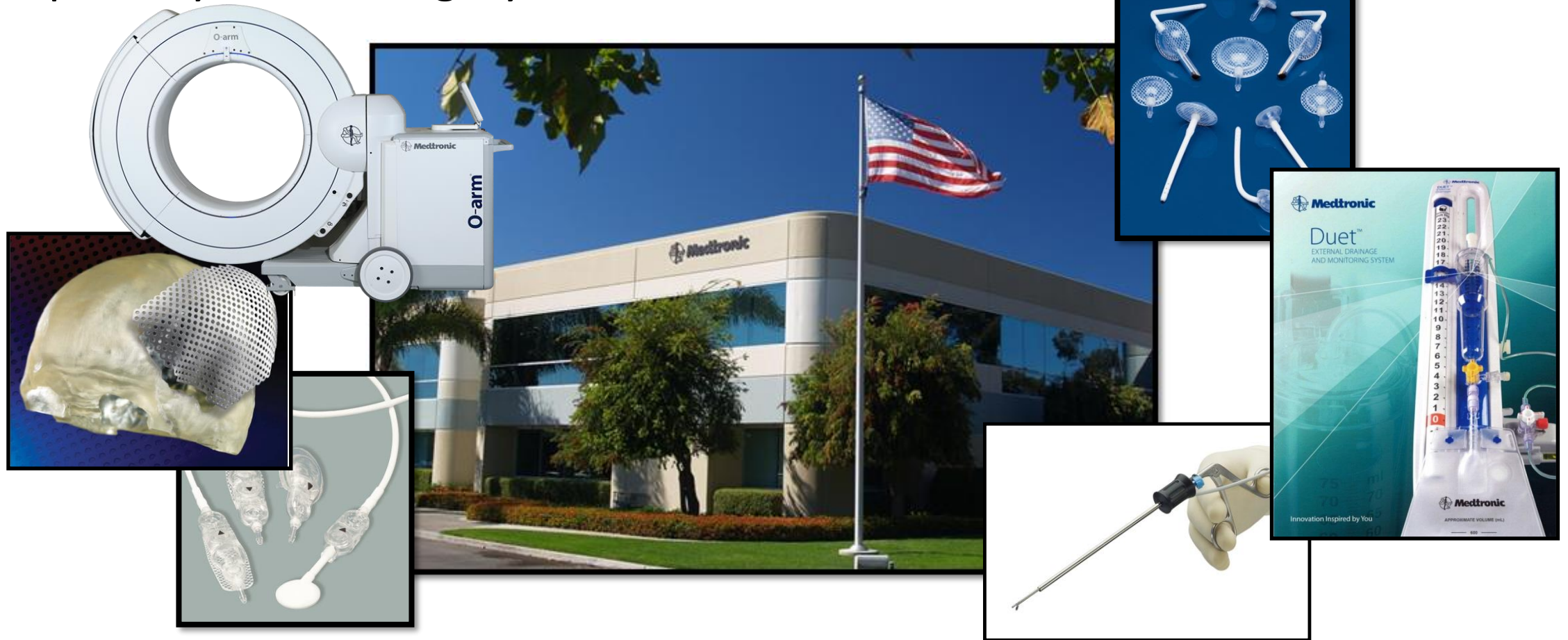
The views in this presentation are my own, and do not represent those of Medtronic or the American Medical Writers Association.

# Overview

- Introduction to medical writing
  - What do we do, and is it right for you?
- Medical writing in the device industry...and elsewhere!
- Resources for new and aspiring writers
  - American Medical Writers Association (AMWA)
  - Other online resources

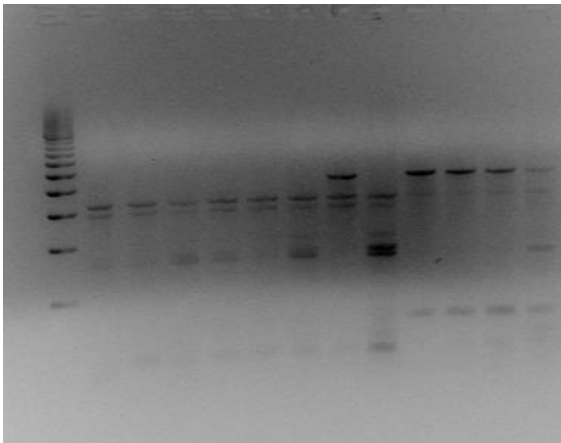
# About me

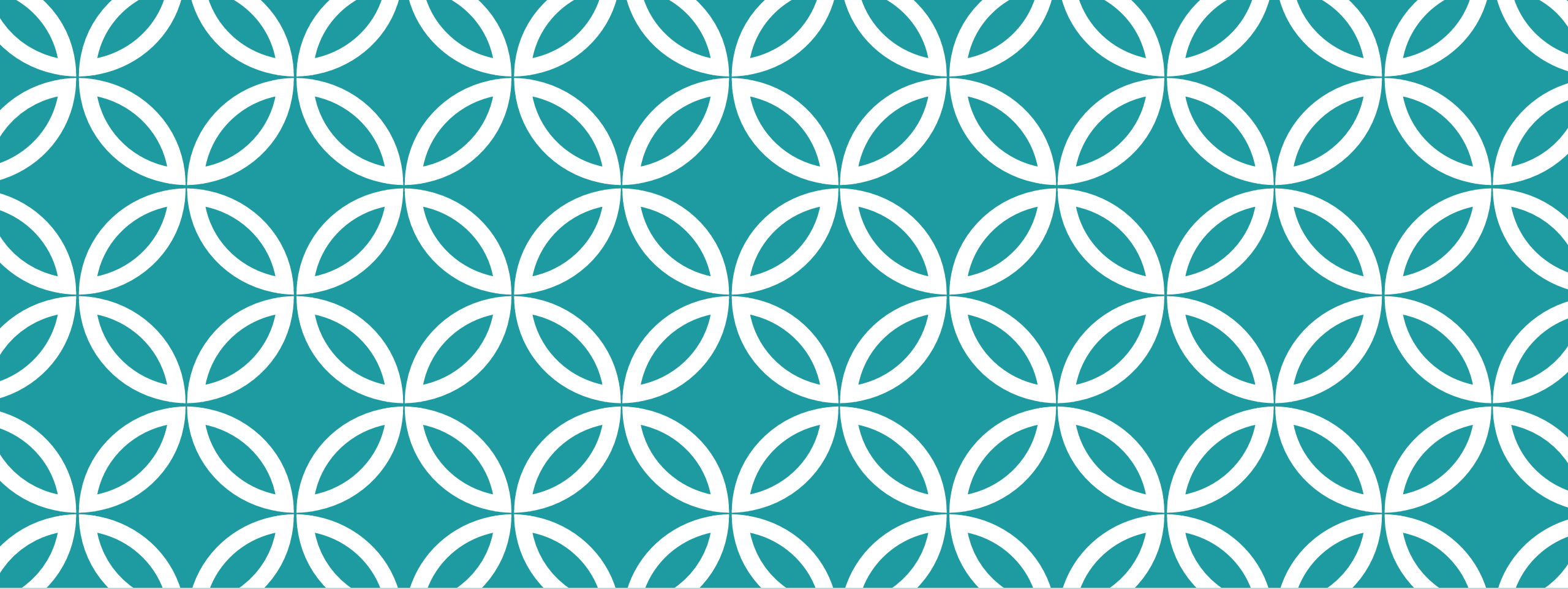
- Medical Writer at Medtronic in Goleta, CA
- Specialty: Neurosurgery medical devices



# About me

- UCI Biological Chemistry alum
- How (and why) go from this.....to this?





# **INTRODUCTION TO MEDICAL WRITING**



# What is Medical Writing?



- The Wikipedia definition:

“A **medical writer**, working with doctors, scientists, and other subject matter experts, creates documents that effectively and clearly describe research results, product use, and other medical information. The medical writers also ensures that their documents comply with regulatory, journal, or other guidelines in terms of content, format, and structure.”

- A professional writer who communicates medical information clearly, concisely, and in compliance with relevant standards.

# Topics at medical writing conferences

- From Lab to Laptop
  - Discussing the Transition from Laboratory Scientist to Clinical/Regulatory Medical Writer
- From Bench Top to Desktop
  - How to Effectively Transition From a Scientist to a Medical Writer
- Transitioning from the Academic Track to Medical Writing
- Principles of Regulatory Writing for Academic and Scientific Writers



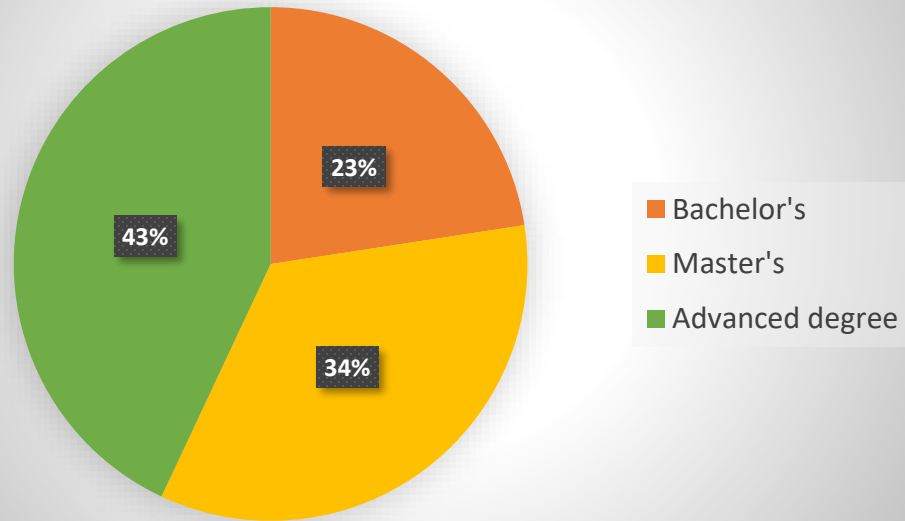
# Medical writing may be a good fit if you...

- Have skill + experience writing manuscripts and grant applications
- Enjoy communicating and synthesizing a story from data (maybe more than benchwork?)
- Are often asked by labmates to check their writing
- Think critically and read analytically
- Have good time management skills (it's never too late to start!)

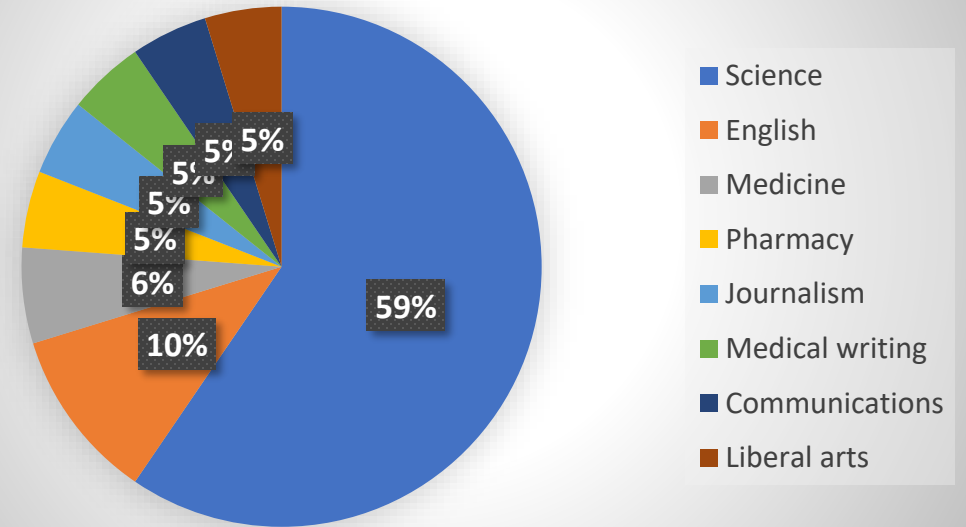


# Demographics of medical writers

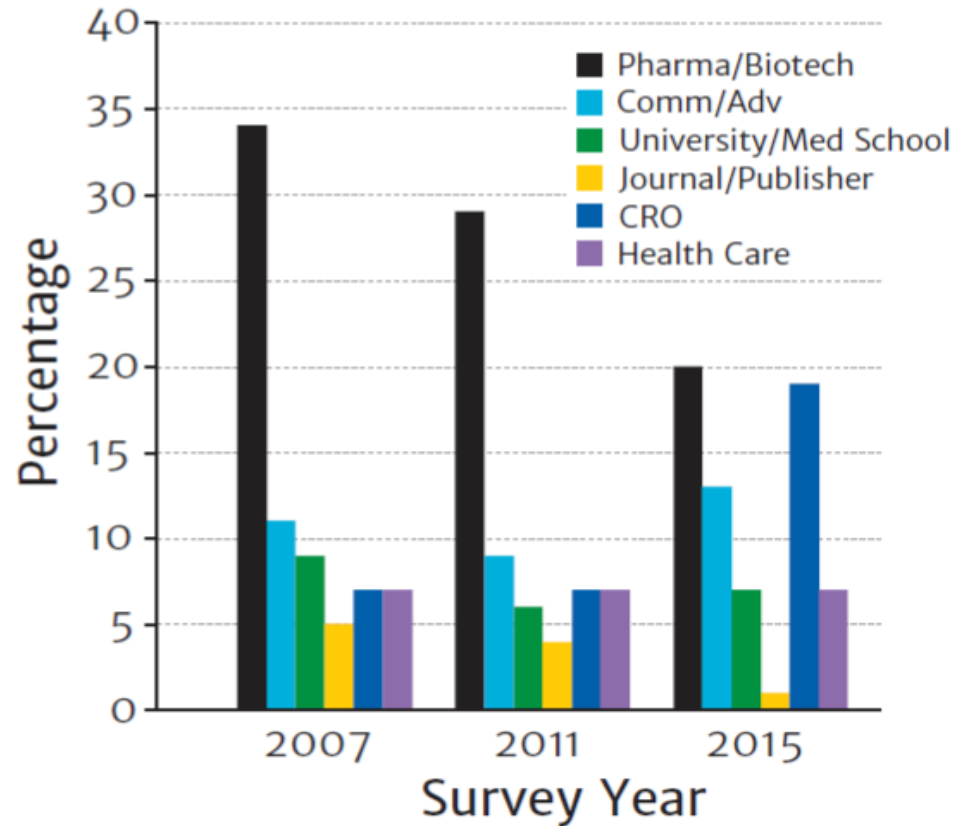
## Highest Educational Degree

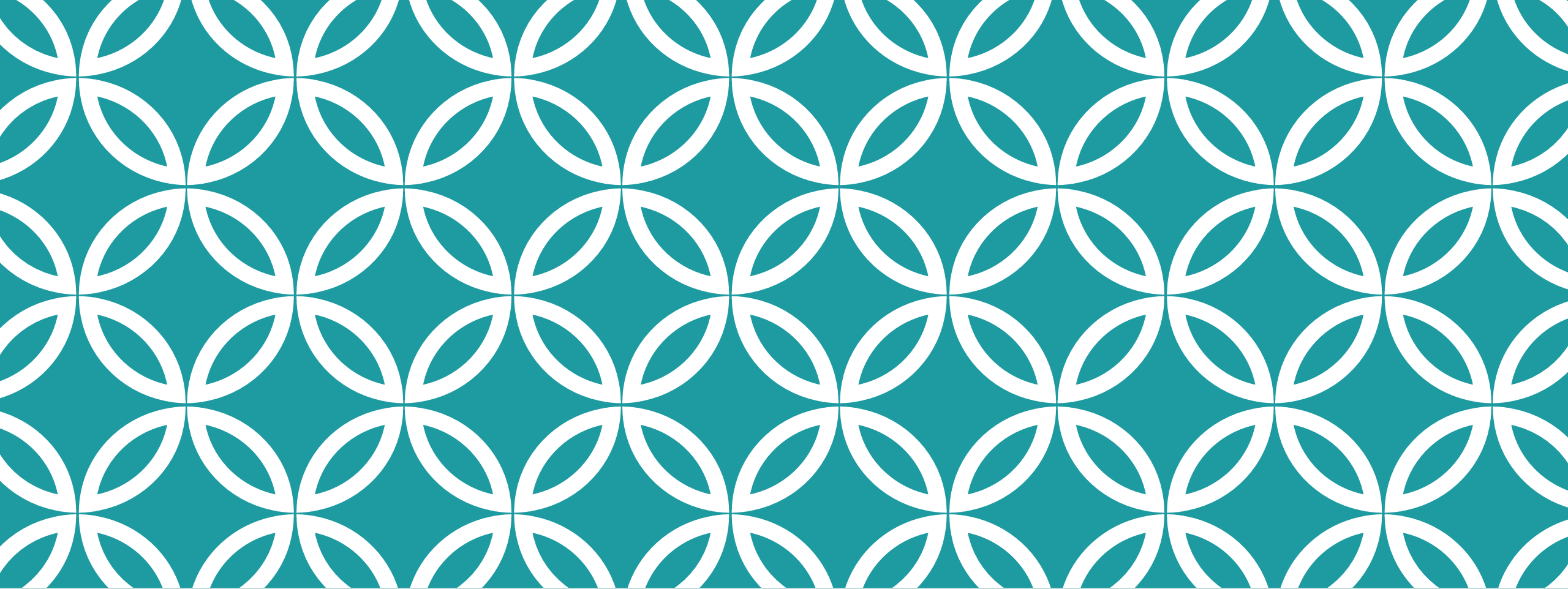


## Field of Study



# Where do medical writers work?





# **MEDICAL WRITING IN THE DEVICE INDUSTRY**



# What is a medical device?

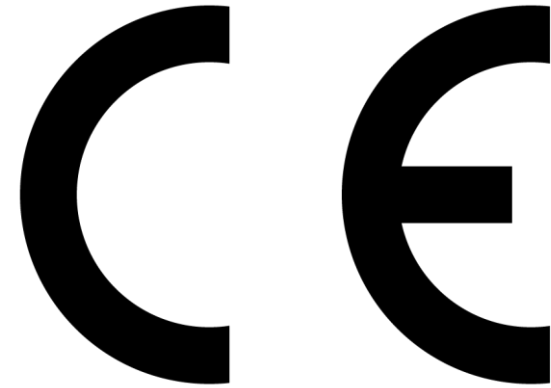
- Any instrument, apparatus, appliance, material or other article, used alone or in combination with accessories or software, intended for:
  - Diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease or injury
  - Control or support of conception
  - Cleaning, disinfection, or sterilization of medical devices
  - Does not achieve its intended action by pharmacological, immunological or metabolic means, but may be assisted in its function by such means

Medical device regulations are different—and changing—worldwide



# Medical device registration in the European Union

- CE mark shows that a product meets Essential Requirements for performance and safety in the European Economic Area (EEA)
- CE mark given in one member state recognized in other member states
- CE mark is recognized outside the EU
  - Australia, New Zealand, India...



# CE Marking Requires Clinical Evaluation

Clinical Evaluation: A methodologically sound ongoing procedure to collect, appraise, and analyze clinical data pertaining to a medical device and to evaluate whether there is sufficient clinical evidence to confirm compliance with relevant essential requirements for safety and performance when using the device according to the manufacturer's Instructions for Use.

EU MEDDEV 2.7.1 Rev 4: Clinical Evaluation: a Guide for Manufacturers and Notified Bodies



# The Clinical Evaluation Report (CER)

- Required for CE mark for all devices sold in the EEA
- Must be maintained for the entire life cycle of the device
  - Regular periodic updates
  - If new safety concerns emerge
  - If there are changes to the device
- CER is reviewed by a Notified Body, an independent organization that reports to a Competent Authority (national agency)
- The bread and butter of a medical devices writer!

# What goes into a CER?

- Description and intended use of device
- State of the art
- **Equivalence to predicate CE-marked device**
- Non-clinical, preclinical data
- Clinical data
  - Demonstrate device safety and efficacy
  - Clinical study data, safety/complaints data, **literature review**
- Risk-benefit analysis and conclusion
- Full CER = 200-300 hours

# New regulations and guidelines

- Medical Device Vigilance system (MEDDEV) 2.7/1 Rev 4 - 2016
- Guidance document, not legislation
- Includes guidelines for CERs
- Changes:
  - CER must be updated annually for high-risk devices, 2-5 years otherwise
  - Clinical investigations required for more devices
  - Device usability must be included in CER
  - State of the art required
- Medical Device Regulation (MDR) - 2017
- Legislation applicable in all EU member states
- Replaces Medical Device Directive (MDD)
- Clearer definition of medical devices, implantable and active devices
- Much more stringent requirements on
  - Device equivalence
  - Post-market surveillance
  - Frequent re-certification
  - And many other areas!
- Manufacturers are given a 3-year period to be in compliance

# New regulations = new opportunities

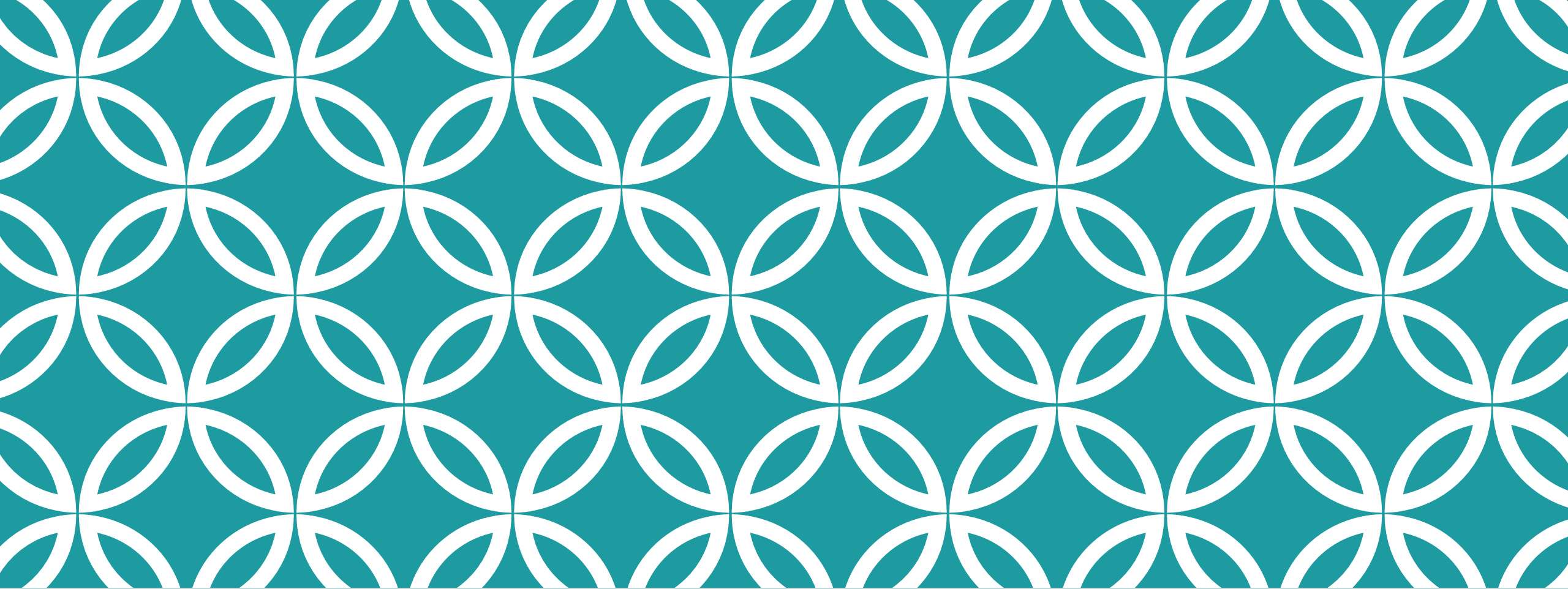
- All devices sold in the EU must conform with
  - MEDDEV 2.7/1 Rev 4 – now!
  - MDR by 2020 (2022 for IVDR)
  - No “grandfathering” of devices previously cleared for market
- All CERs must be brought up to standard and routinely updated
- Industry-wide need for medical writers who can think critically and keep up!
- Demand exceeds supply—in the 2015 AMWA survey, only 36 out of 1,292 respondents said they work full-time for a medical device company

# Meanwhile, elsewhere in the world...

- US medical device clearance
  - Premarket approval (PMA): approval for a new device
  - 510(k): clearance for market for a device equivalent to another device already on the market
- China
  - CER also required after CFDA Order 650 (2014)
  - Must analyze clinical data from China + worldwide
  - Bilingual/translation ability is a plus
  - More stringent guidelines implemented before MEDDEV 2.7/1 Rev 4 and MDR
  - CFDA will be restructured into new organization this year

# Other roles of a medical device writer

- Clinical study protocols and reports
- White papers
- Literature monitoring for device safety reports
- Ad hoc projects...you may become everyone's proofreader and editor!



# **OTHER OPPORTUNITIES IN MEDICAL WRITING**



# Pharmaceutical medical writing

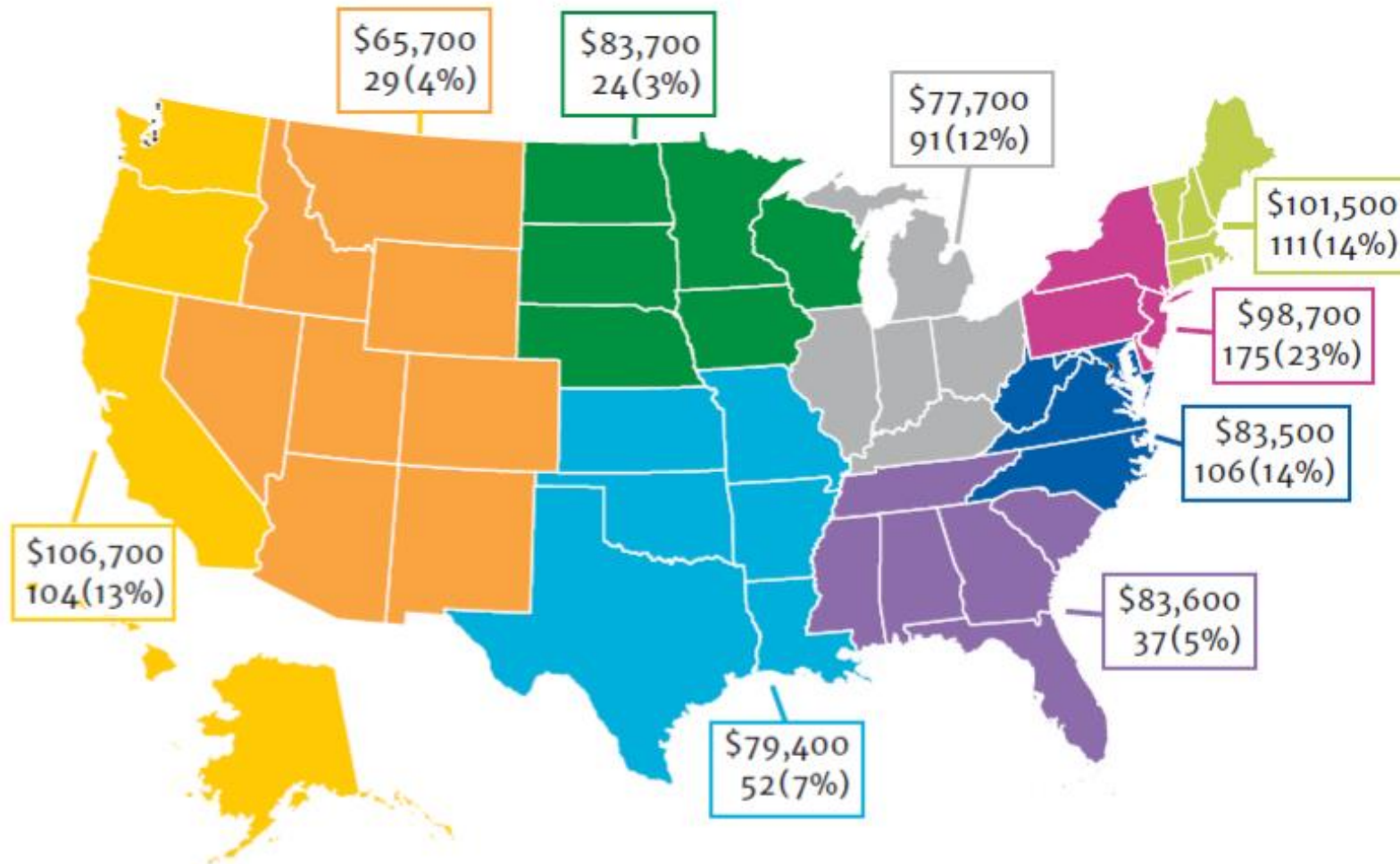
- Regulatory writing for clinical studies
  - Investigator Brochures
  - Clinical Study Reports
  - Common Technical Document (CTD) for application of new drugs
- Scientific writing
  - Peer-reviewed research and review articles
- Marketing communications



# Other specialties in medical writing

- Continuing medical education (CME)
  - Required for medical professionals to maintain license
  - Organizations & certificates exist for CME planners
- Academic and grant writing
- Writing for the lay audience
  - Patient communication
  - Books on medical science
  - Journalism
- Medical translation and editing

# Average annual medical writing salary (2015)

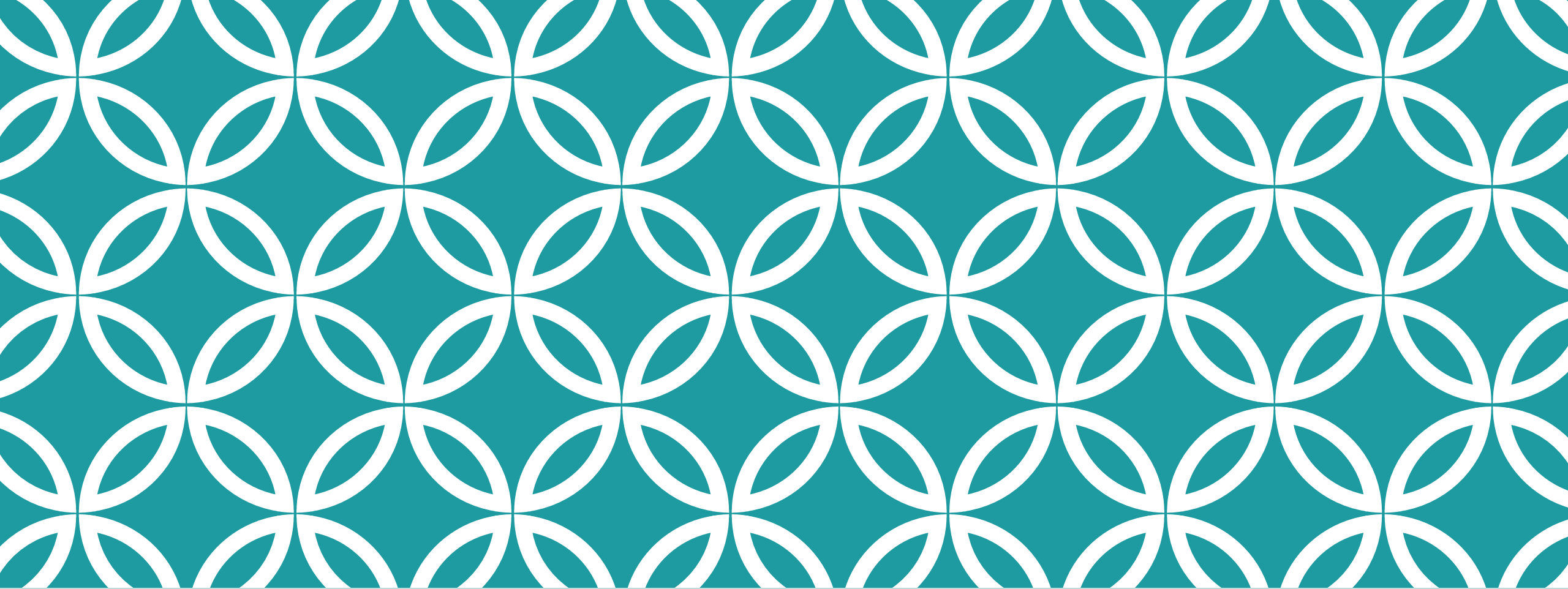


# A Note on Freelancing

- 35% of medical writers are self-described freelancers
- Another 14% freelance in addition to other job
- More resources are available through the AMWA online community

# What do I do if I don't have industry experience?

- Leverage all your writing experience in (and outside) grad school
- Be honest but confident in applications/interviews
- “If you get called back, we know you can write”: other skills will make or break the interview
- What skills set you apart?
  
- Seek out additional educational and networking experiences



# RESOURCES



# American Medical Writers Association (AMWA)

- Professional society for medical communicators (not just writers!)
- Over 4,000 members and counting
- Student membership available
- <https://www.amwa.org/>

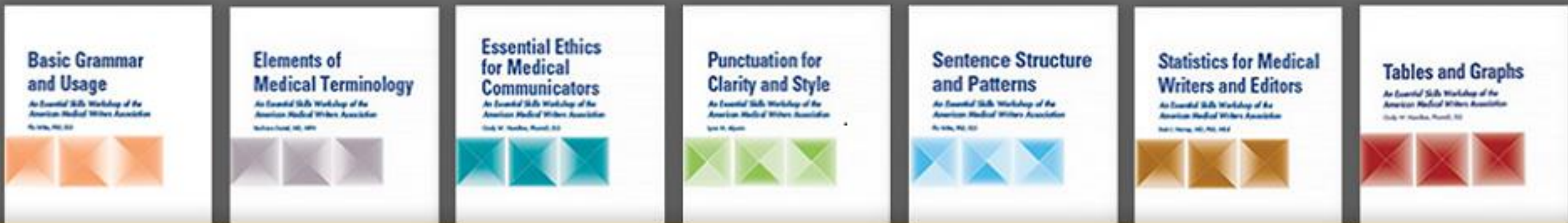


# AMWA Educational Resources

- Online learning and webinars
- AMWA quarterly journal and newsletters
- Free events
  - Annual one-day conference in Thousand Oaks
- Local/chapter conferences
- National Conference
  - November 2018: Washington, D.C.
  - November 2019: San Diego

# AMWA Certificates and Certification

- Essential Skills Certificate



- Medical Writer Certified (MWC) Certification
  - Exam-based, requires 2 years of experience and advanced degree



# AMWA Online Community



AMWA COMMUNITY  
Connect and Collaborate

Managing edits, revisions and multiple drafts

Mendeley and EndNote

Best certificate course?

Guidelines for creating a poster

Isn't "past medical history" a redundant phrase?

How to get regulatory writing experience?

Free webinar

comma or no comma before et al?

Writing for consumers

Salary negotiation

## Medical writing as a career after PhD

Medical writing test as part of interview

Medical writing for non-native English speakers

Creating online courses

OC AMWA gathering

Predatory journal red flags?

Breaking into the industry

# Regulatory Affairs Professional Society (RAPS)

- Certificate programs in medical devices and pharmaceuticals
- Regulatory Affairs Certificate: Medical Devices
  - Medical Devices: Definition & Lifecycle
  - Introductory Medical Writing
  - Role of the Regulatory Professional
  - International Medical Device Regulations
  - Good Clinical Practice (GCP)
  - Good Laboratory Practice (GLP)
  - Ethics
  - And more...

# UCSD Medical Writing Program

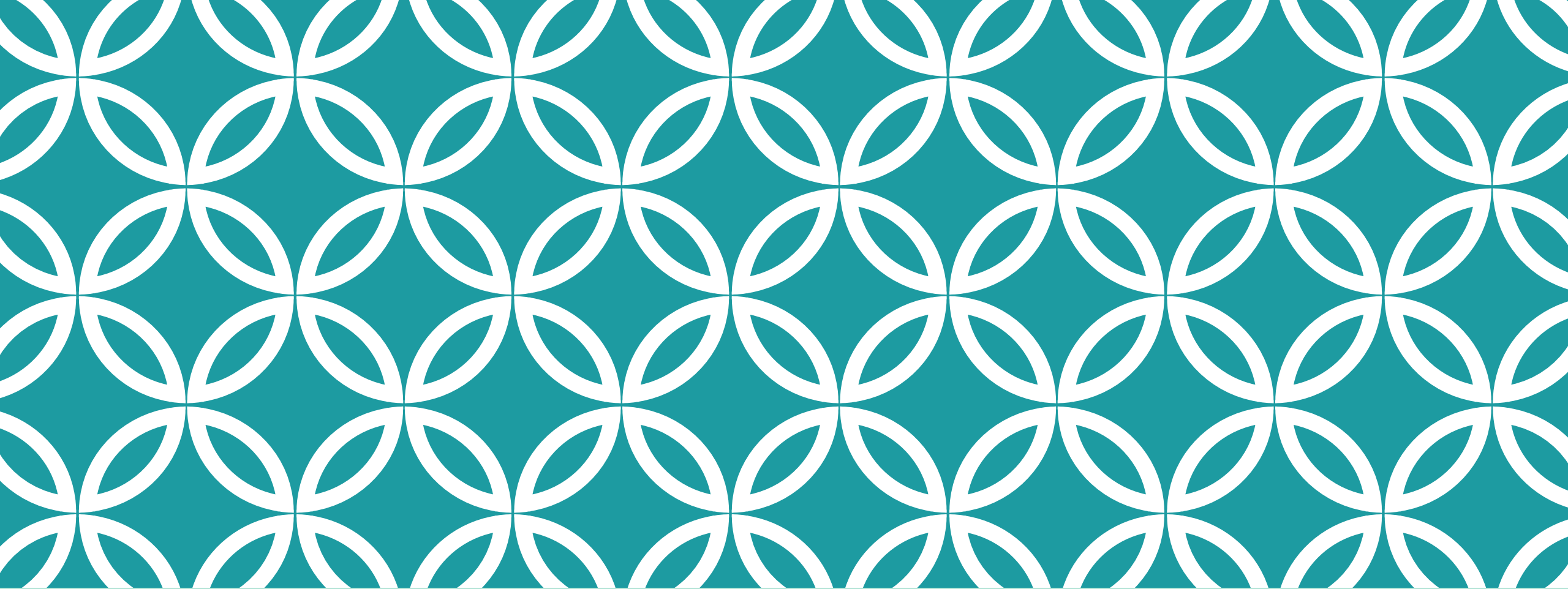
- Fully online certificate program for students with graduate background in biomedical or life sciences
- Areas of focus
  - CME
  - Scientific grants
  - Regulatory documentation
  - Journal article and publication development
- 22 units and 18 month estimated completion time
- <https://extension.ucsd.edu/courses-and-programs/medical-writing-courses>

# Medical Device News Resources

- MassDevice
  - <https://www.massdevice.com/>
  - Industry news
- Emergo (regulatory consulting group) blog
  - <https://www.emergobyul.com/blog>
  - Worldwide device regulatory news

And finally...network!





**QUESTIONS?**

