Regulatory Freelancing

Normandy Farm

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Conflict of Interest Disclaimers

- Not affiliated with any search firm, university, or publisher
- Work as a consultant for pharma companies
- Currently employed by BMS via Delta Pharma
- Currently working in Medical Affairs, not Regulatory

Objectives

- At the end of this presentation you can:
  - Describe the degree of difference between regulatory and other clinically oriented writing
  - Describe the level of present and future need for the function
  - List the basic tools and tasks of regulatory writing

Agenda

- Introduction
- The regulatory writing world
- Requirements for regulatory writers
  - Skills
  - Knowledge
- Advice
- Resources

Is regulatory writing very different?

- Your current knowledge of medicine is useful
  - Adverse event reporting
  - Laboratory reports
- Your writing expertise may not be used as much
  - Not really a writing job
- Understanding of clinical studies WILL be used:
  - Statistics
  - FDA guidance docs (available on the web)

What is the regulatory world like?

- You live in a world of huge documents
- There are elaborate SOPs and guidance docs—too many
- Enormous amount of data per study
- You use templates (if you're lucky)
  - (take up lots of computer memory)
  - (take a while to learn to use)
  - SNAFUs are common
- As usual, your work is deadline-driven and goes through many revisions and iterations (and you start to hate the docs)
- Your audience is the FDA
- There's no issue about ghost authoring of a CSR: all the authors must sign and date the final draft
- In comparison, there are few references (except in Introduction and certain summary sections)

Present and future regulatory writing

- Regulatory writing is in demand
  - Outsourced to India (China is future!)
    - This is proof that it can be outsourced
    - Forces pay for US writers down
  - Difficult to crack into the reg writing world
- Efforts to make it easier are underway
  - USIP, AMWA, other groups?
    - AMWA ad hoc task force (Kate Casano, et al)

Changing regulations

- Increased trial/results registries (FDAAA)
- New laws making post-marketing safety reporting more stringent
  - Should theoretically result in more work for reg writers
- More emphasis on degreed writers (as in Phd, PharmD, MD)

Technical skills

- Working in elaborate tables and multiple attachments and sub attachments
- Creating a Table of Contents for a very long document and updating it can cause issues
- Using two monitors
- Expert use of MSWord and Adobe
  - Creating PDFs and linked documents
  - XML backbone
  - Hyperlinks

Barriers to experience

- Regulatory documents are often confidential
- Few opportunities to learn on-the-job
- The Big Divide (BD) in medical writing
  - Commercial (as if it isn't regulated)
  - Regulatory writing (as if it ain't commercial)
- The BD is largely perceptual
  - We all write about clinical study results
  - General medical/clinical study knowledge is key to success

Skills

- Interpersonal skills (it's a team effort)
- Attention to detail is an absolute must
  - It's the rare writer who has both of the above
- Requires Job-like patience every day
- Strong ethics and intellectual curiosity
- MS Word/general computer experience
- Diplomacy
- Persistence

Knowledge

- Drug development process
- Common Technical Document (ich.org)
  - Learn the structure of an ICH submission
- Statistics (basic understanding)
- Current regulations and issues at FDA
  - Web savvy
    - Clinical studies (clinicaltrials.gov; clinicalstudyresults.gov)
- MS Word
  - Shortcut keystrokes
- SAS (very rudimentary familiarity)

Attitudes

- Requires a careful, cautious approach to making a statement
- But then so does pure advertising copywriting
  - It's all based on the labeling in both cases

Overcoming barriers

- Get CRO experience
- Find a position in regulatory affairs or clinical trial administration
- QC some regulatory documents as a volunteer
- Subcontract for someone doing regulatory writing
- Take classes and read—treat it like a job
- Stalk the FDA website and try to navigate it
  - (Good luck)
  - http://clinicaltrials.gov/ct2/info/understand
- Volunteer (Oneworldhealth.com; San Francisco)

Failing that…

- Improve your knowledge base
- Eg, What does each lab value in a standard panel mean? What are the normal ranges? What are the clinical implications if they're not normal?
- Learn what makes a good clinical study protocol (read the FDA regulations)
- Here's a challenge: try to stay awake while reading an entire protocol

My own career path

- Teaching writing
  - Just out of college as an English major, I couldn't spell
  - Re-learned grammar and spelling (100 most misspelled words in the English Language) so I could teach
- Wrote briefly for a newspaper reporter (learned speed)
- Medical communications/CME agencies
  - Dental journal
    - Learned good publishing practices, version control, author communication, etc.
  - Medical journals (learned terminology)
- Text book publishing company (learned process)
- Pharmaceutical company (learned specific drugs)
  - Clinical development, regulatory, training
- Freelancer

How I learned med writing

- Constant reading and self-training
  - Non-stop always
- Read medical dictionaries and glossaries
- Just about memorized the Merck Manual pharmacology section
- Just about memorized a biochem textbook
- Read Bert Spilker
  - (a guru of the drug development world)
- Kids' books on physiology, genetics, cell biology etc
  - Bought expensive college text books from PU bookstore
- Read JAMA and NewEnglJMed

Why and how I learned regulatory

- Read a career book in public library that said it was steady work
- Self-taught the drug development process (got free brochure from FDA)
- Attended a conference: right place at right time in 1988 when regulations had just changed and no one was an expert
  - Decided to become an expert
- Really wanted to learn regulatory and willing to work for it

How I might do it differently today

- Don’t try to do as I did—it doesn’t work that way any longer; I’m grandfathered
- Get a graduate degree in a science
- Ask many more questions before taking on an assignment
  - Insist on a contact person or don’t take the contract

Freelance career

- Regulatory
  - (knowledge gained OTJ in CRO, big pharma)
  - Registries
  - SAEs
  - Phase 1 CSR
  - Parts of an NDA
    - Summary documents

Examples of Tasks

- Prepare public trial registry forms
- Write serious adverse event (SAE) narratives
- Assemble safety information for queries from the FDA; briefings for FDA approvals
- Write a protocol or protocol summary of changes, or protocol amendment
- Assemble a CSR
- Put hyperlinks in a CSR
- IBs, PSURs, ISS/ISE/IJPD/AR annual reports, packages to present to FDA for IND, foreign studies (experience)

Advice from an old pro (Sally Rich)

- Shouldn’t try to fake it
- There’s no book to tell you how to do it
- Don’t walk away from a low offer with on-the-job training
- Medical writing may pay less at first than a lab job, but it pays off long-term
- Don’t need 4 or 5 yrs—depends on what you’ve been doing for those 5 years

Advice from an old pro

- Manuscripts or abstracts—difficult transition from ms to regulatory documents
  - Go to the FDA site and download guidance docs
- Get Tom Lang's book as well as Statistics for Dummies
- Read drug approval process tutorial on FDA web site
- Read NEW DRUG APPROVAL PROCESS-Guarino Informa Healthcare
- Choose some USIP classes

More advice from another old pro

- Agency pays less? Too bad, at least you're working
- Study package inserts—it's all there
  - The entire clinical program is there
- Learn about PK
- Don't argue with the client if they don't know what they're doing
  - Pick your battles

Books

- Harris and Taylor. *Medical Statistics Made Easy*, ed 2. Scion, Oxfordshire, UK, 2008
- Guarino R. *New Drug Approval Process*, *ed 5*. Oxford Pharmaceutical Resources, 2009
- Spilker B: *Guide to Drug Development: a Comprehensive Review and Assessment*. Lippincott, Williams, and Wilkins, Philadelphia, 2009
- Spilker B: *Presentation of Clinical Data*. Raven Press. 1990
- Spriet A. *Good Practice of Clinical Drug Trials*. Karger, Basil, Switzerland, 1992
- CDERlearn online tutorials
- http://www.fda.gov/cder/regulatory/applications/NDA/htm