COMPARISON OF REGULATORY WRITING AND PUBLICATION WRITING

	Regulatory Writing	**Publications**
Types of documents	Clinical study reports Protocols Investigator brochures Other IND/NDA sections FDA briefing packages Informed consent forms *[See a sample protocol and a protocol template at http://www.med.upenn.edu/ohr/protocol/]*	Journal manuscripts • Review articles • Clinical trial reports • Other biomedical research studies • Pharmacoeconomic studies Conference abstracts, posters, and oral presentations Publication plans Slide kits
Types of companies	Pharmaceutical Biotechnology and device companies Freelancers Contract Research Organizations	Pharmaceutical Biotechnology and device companies Freelancers Medical communications agencies
Main writing goals	Clarity, accuracy, completeness, consistency	Clarity, accuracy, conciseness, clinical relevance
Primary audiences	FDA reviewers, study investigators, and staff	Clinicians, scientists
Nature of the writing	Very long, highly structured documents Exhaustive presentation of data and procedures Keep interpretation "close to the data" Documents are small sections of larger documents Big emphasis on formatting, use of styles, document management Close connection to "publishing" steps Less literature work Confidentiality	Short documents Narrow, selective presentation of data and methods Emphasize clinical relevance rather than report everything More summarization, synthesis, interpretation Connection to current literature is critical Delivery of simple MSWord documents Style dictated by journal or conference Format less important

	Regulatory Writing	**Publications**
Skills and knowledge emphasized	Regulatory requirements and ICH guidelines Heavy use of templates and style guides, which vary across clients Sophisticated use of MSWord skills/tricks/shortcuts Organize and understand large amounts of information quickly Use boilerplate text and skillfully cut and paste Pharma industry knowledge and lingo Clinical trials and statistics/data familiarity Heavy editing (taking bad writing and making it clear)	Journal and congress requirements and conventions AMA style and client style guide Literature searching and synthesis Knowledge of general science and specific therapeutic area Knowledge of clinical trial methods and statistics Learn complicated info quickly and sound like an expert Conform to conventions of writing in a therapeutic area without direct instruction Often heavy substantive editing rather than original writing Use other client documents as sources for key points, but avoid plagiarism
Daily routines	More team involvement and meetings More self-management (reviews, tracking down documents, reviewing budget, timeline) Pore through SAS tables and listings Close work with statisticians and clinical team Formatting of tables Consistency, consistency, consistency BIG deadlines (cyclic nature of work) Being adaptable when changes come your way!	Independent work, smaller teams, fewer meetings Small, quick edit jobs with immediate turnaround Management support for writing (reviews, tracking down resources, asking questions of authors/client, timelines and budget) Search for similar types of documents before starting project Integrate conflicting comments from reviewers Reducing word counts without losing the meaning PubMed searches Medical-legal review Disclosure of conflicts

DESCRIPTIONS OF A TYPICAL PROJECTS FOR REGULATORY AND PUBLICATIONS WRITERS

Regulatory Writing: Clinical Study Report	Publications: Clinical Trial Manuscript
1. Meet with team for months before start writing 2. Write "shell" methods and tables based on protocol and statistical analysis plan • Use client template as guide to content of each section • Copy and paste large sections from other documents; adapt for clarity, continuity, consistency, tense, and format • Anticipate tables for the results section and build them • Gather missing information from clinical, medical, biostats teams • QC and other internal review 3. Possibly have review meeting with entire team 4. Incorporate comments from many different people on the team (shell review may be smaller team) 5. Receive topline tables and review with client 6. Receive final tables 7. Complete first draft (takes about 3 weeks for the writing) • Fill in shell tables with data • Spend long hours with SAS tables • Write very short discussion section and very long results • Describe all efficacy measures, usually in great detail • Write in standard ways about safety data (esp. adverse events) • Describe other safety results specific to the drug/indication/population/study • Details on individual patients with bad safety outcomes • QC and other internal review 8. Team review meeting or receive e-comments (medical monitor, biostatistics, senior review, regulatory, clinical operations) • Comments usually integrated 9. Incorporate 1-3 review cycles of comments from large teams • Formal drafts • Review cycles with hard and fast timelines	1. Meet with authors/team to discuss key points and data to be included 2. Receive key tables or extract them from a CSR 3. Draft an outline with tables and figures 4. Receive and incorporate comments and draft extended outline (or proceed to first draft) 5. Write first draft • Only relevant aspects of methods and results • Focus on group data • Summarize, be concise, keep under word limits • Connect research question and data to literature • Work with authors, editorial manager, statistician to get missing information • Copyedit and format for journal's guidelines 6. Receive and incorporate comments from authors and other team members • Authors have final say • Comments never integrated 7. Do 2-8 more rounds of revisions • May be heavy or light revision • May be different reviewers at each step • Reviews stop when the authors/team decide they are done (or budget runs out) • Soft deadlines that are hard to enforce