The Role of the Writer in Regulatory Affairs

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How I became a regulatory writer

• Degree in Biochemistry
• DPhil in Neuropharmacology
• Medical publishing and conference organization (sales and account/project management)
• Medical writer and project coordinator in industry
• 16 years as a freelance writer (but long-term relationships with a number of companies)
• Head of Medical Writing at a CRO for 4.5 years
• Back to freelance status in 2007
Aims

Show there is an alternative to Med Comms!

Indicate where a writer can fit into Reg Affairs

Give an idea of some of the types of projects
Regulatory Affairs versus Writing

**RA Managers**
- Liaison between pharmaceutical company and regulatory bodies
- Review
- Summarize
- Manage project eg, MAA
- Guidelines and regulations
- Development plans

**Writers**
- Write Clinical Study Reports
- Write protocols
- Write manuscripts
- Write literature reviews

**Overlap**
- Write Summaries and Overviews
- Write Investigator Brochures
- Write Paediatric Investigation Plans
- Write Briefing Books
- Write responses
The Common Technical Document

Module 1
- Administrative information and prescribing information

Module 2
- Summaries and overviews

Module 3

Module 4
- Non-clinical study reports

Module 5
- Clinical study reports

Quality
Clinical Study Reports

- CSRs describe the background, rationale, methodology and full results for a clinical study
- Called integrated reports as they cover clinical and statistical aspects
- Guideline ICH E3 on structure and content of CSRs: 53 pages of ‘guidance’
- Main text often around 80-200 pages; complete reports with tables and figures plus appendices (including listing of all recorded data) are usually 1000s of pages
- Move over time from all paper to completely electronic reports – which involve ‘publishing’
- Elapsed time: 2-12 months; writing time 3-8 weeks
Contents of a CSR

- Title page
- Synopsis
- Table of contents
- List of abbreviations and definitions of terms
- Ethics
- Investigators and study administrative structure
- Introduction
- Study objectives
- Investigational Plan
- Study Subjects
- Efficacy Evaluation
- Safety Evaluation
- Discussion and Overall Conclusions
- Tables and Figures
- References
- APPENDICES Including listings
Module 2
Summaries and Overviews

- CTD Table of Contents (Module 2.1)
- CTD Introduction (Module 2.2)
- Quality Overall Summary (Module 2.3)
- Non-clinical Overview (Module 2.4)
- Clinical Overview (Module 2.5)
- Non-clinical Summary (Module 2.6)
- Clinical Summary (Module 2.7)
How Big? How Long?

Module 2.5
Overview
About 30-80 pages

4-8 weeks

Module 2.7
Summary
50 to 500 pages
(excluding appended tables)

8-20 weeks

Trend to much longer documents, especially in US
Module 2.7

2.7.1 Summary of Biopharmaceutic Studies and Associated Bioanalytical Methods
2.7.2 Summary of Clinical Pharmacology Studies
2.7.3 Summary of Clinical Efficacy
2.7.4 Summary of Clinical Safety
2.7.5 Literature References
2.7.6 Synopses of Individual Studies
# Module 2.7.3
## Summary of Clinical Efficacy

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Non-clinical and Clinical Overviews

Critical analysis of non-clinical and clinical data in CTD
Discussion and interpretation of data
Relevance to current practice
Discuss relevant literature

Strengths and limitations of development programme and results
Benefits and risks
How results support prescribing recommendations

EU versus US

Expert input
Module 2.5

2.5.1 Product Development Rationale
2.5.2 Overview of Biopharmaceutics
2.5.3 Overview of Clinical Pharmacology
2.5.4 Overview of Efficacy
2.5.5 Overview of Safety
2.5.6 Benefits and Risks Conclusions
2.5.7 Literature References
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
How to Get Started

• CROs/Companies willing to take on those with aptitude
  – Written a thesis/published papers
  – Be prepared to take a test
• EMWA
• Training Positions for Regulatory Staff
Final Few Words

Jobs in regulatory/medical writing are not for those who want to lock themselves away and work in isolation.

Working from home is common, but communication is crucial.

Freelance X