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 organisation (sales!)
• 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+ years
• Back to freelance
Aim

To provide broad information on:

- the role of writers in regulatory affairs
- some of the types of work that writers perform
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

Overlap
- Write Summaries and Overviews
- Write Investigator Brochures
- Write Paediatric Investigation Plans
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
Clinical Study Reports

Biometrics

Pharmacovigilance

Clinical

Quality Assurance
The Common Technical Document

Module 1: Administrative information and prescribing information
Module 2: Summaries and overviews
Module 3: Quality
Module 4: Non-clinical study reports
Module 5: Clinical study reports
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How Big? How Long?

Module 2.5
Overview
About 30-60 pages

4-8 weeks

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

8-20 weeks
# Module 2.7

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## Module 2.7.3
Summary of Clinical Efficacy

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Overviews

Critical analysis of non-clinical and clinical data in CTD
Discussion and interpretation of data

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

- Contract Research Organisations/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
A Final Word

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.