



SO YOU WANT TO BE A REGULATORY MEDICAL WRITER? A TRAINING PROGRAMME FOR THE UNINITIATED

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Starting a new medical writing career starts with a test, so here is a test.

Add punctuation to the following text and capitalize as needed.
Shout out where you would add punctuation, and of what sort

Dear Jack I want a man who knows what love is all about you are very generous kind and thoughtful people who are not like you admit to being useless and inferior you have ruined me for other men I yearn for you I have no feelings whatsoever when we're apart I can be forever happy will you let me be yours Jill

MEDICAL WRITING TEST

Dear Jack,

I want a man who knows what love is all about. You are very generous, kind, thoughtful. People who are not like you admit to being useless and inferior. You have ruined me for other men. I yearn for you. I have no feelings whatsoever when we're apart. I can be forever happy — will you let me be yours?

Jill

Dear Jack,

I want a man who knows what love is. All about you are very generous, kind, thoughtful people, who are not like you. Admit to being useless and inferior. You have ruined me. For other men I yearn! For you I have no feelings whatsoever. When we're apart I can be forever happy. Will you let me be?

Yours,

Jill

What did you learn from this?

OVERVIEW



- What are the essential differences between regulatory and comms medical writing?
- What are the core skills and competencies of a regulatory MW?
- What might the training look like – PAREXEL’s experience running a training programme for beginning writers

LONDON, U.K.



REGULATORY vs. COMMUNICATIONS

REGULATORY vs. COMMUNICATIONS

Here are some initial (admittedly generalised) thoughts regulatory and communications medical writing, to give a feel for my experience of the differences between the two

REGULATORY

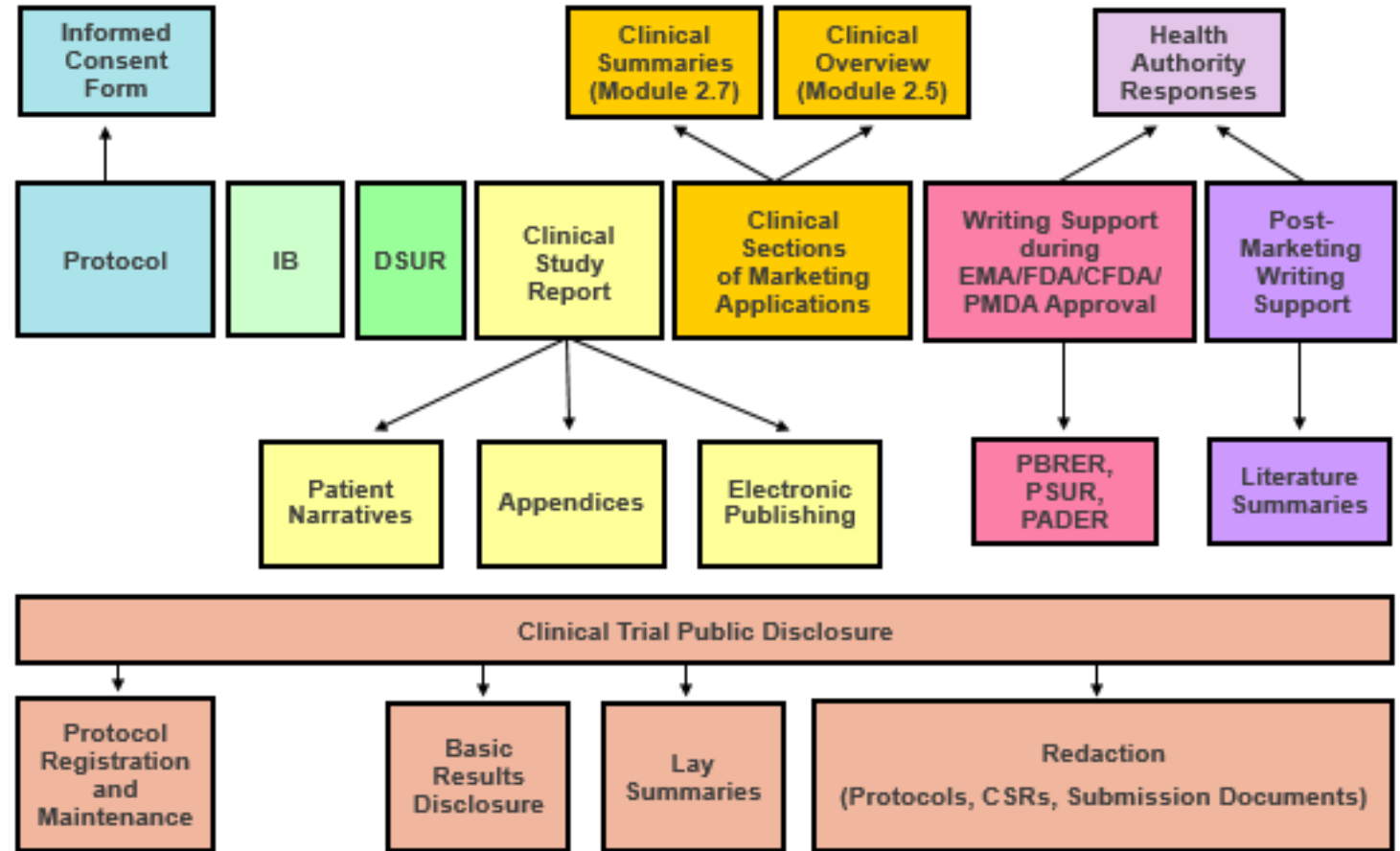
- Driven by templates and guidelines, with each project based on a standard structure
- Sources are often a single block of programmed data outputs provided by statisticians
- Writing can be formulaic, few chances for discursive prose
- Audiences include investigators, ethics committees, patients, regulatory authorities

COMMUNICATIONS

- Often free-form, with each new project potentially being unique
- Can have multiple sources, of widely differing types, derived from a number of places
- Writing likely to be more creatively used, with free prose and discussion more likely
- Audiences include scientific community, patients, healthcare professionals

A REGULATORY WRITER HAS A STANDARD SET OF DOCUMENTS

- One important difference between regulatory and communications medical writing is the standard set of documents.
- This might be seen as restrictive, but does allow the writer to become very experienced with each document type



CTD = Common Technical Document
PBRER = Periodic Benefit-Risk Evaluation Report

PADER = Periodic Adverse Drug Experience Report
IB = Investigator Brochure

DSUR = Development Safety Update Report
PSUR = Periodic Safety Update Report

TOKYO, JAPAN

CORE SKILLS AND COMPETENCIES



SO, WHAT DO I NEED TO KNOW TO BE A REGULATORY WRITER?

- This is perhaps the question you might ask yourself if you are thinking of becoming or training to become a regulatory medical writer
- But it is also not the most useful one because there is a huge gap between knowing and doing
- When I was a teacher planning a lesson, I had three questions that are relevant here
- Putting myself in the student's shoes I asked myself, at the end of the lesson/training:
 - What should I *know*?
 - What should I *understand*?
 - What should I *be able to do*?
- For me, with any training it is that last (*what can I do?*) that really is important

WHAT ARE THE CORE SKILLS OF THE REGULATORY MEDICAL WRITER?

- From these questions around knowing, understanding and doing come the concepts of medical writing core skills and competencies
- For the purpose of training new writers from scratch, we had to think from first principles about what someone with no experience needs to bring them to the point where they can act as a functional writer
- What do *you* think the core skills for a regulatory medical writer are?

WHAT ARE THE CORE SKILLS OF THE REGULATORY MEDICAL WRITER?

WRITING SKILLS

Use a keyboard

Attention to detail

Use of language

Consistency

Effective communication

QC and review

Editing skills

TECHNICAL SKILLS

Proficient with MS Word

Working with templates

Knowledge of regulatory documents

Competence with client-facing situations

Scientific and statistical understanding

Data interpretation

SOFT/PROJECT MGMT SKILLS

Team leadership

Team working

Time- and project management

Proactivity

Problem solving

Provide solutions

Negotiation skills

BERLIN, GERMANY

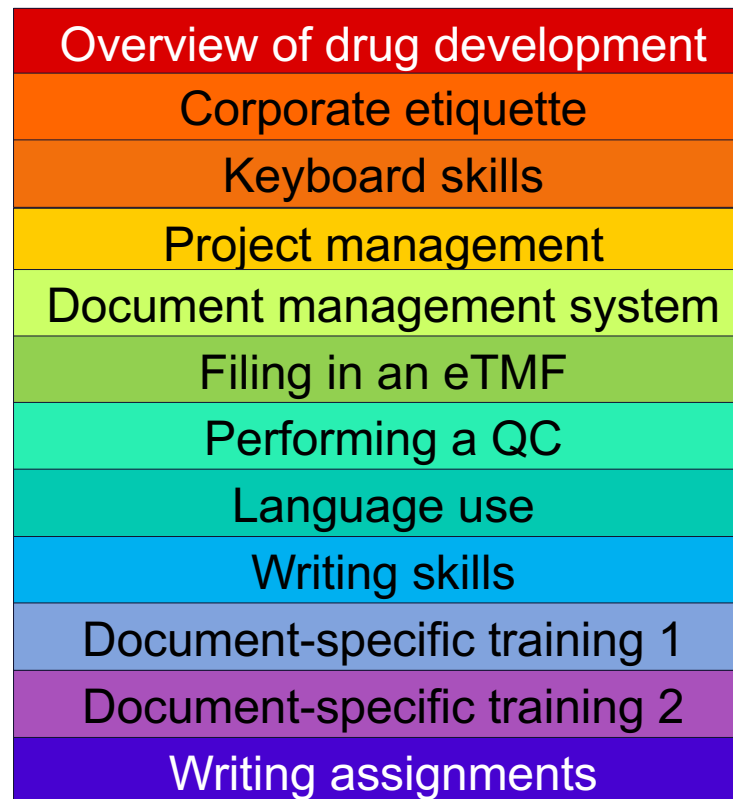
CREATING A PROGRAMME



WHAT WOULD A TRAINING PROGRAMME LOOK LIKE?

Since the new starters were going to have no experience of the industry, we had to start from first principles:

For writing skills, in the end we chose to work with our existing MW Skill Standards and worked to see if we could develop a workshop that would allow us to address each identified skill that an Associate Medical Writer is expected to possess



SAMPLE LESSON

Each lesson had its own lesson plan

Topic Area:	Language and writing		
Lesson Title:	Summarising and paraphrasing		
Trainer:	Jim Newman	Time Required:	95 min
Week /Day:		Date:	

Lesson Objectives (numbered):		How I will measure the level of understanding/knowledge/ability?
Objectives:	1. Be able to summarise information 2. Be able to paraphrase others' text	
At the start of the lesson*		
It is assumed that the student will know:	English	
By the end of the lesson*		
Students will know:	The difference between summarising and paraphrasing.	
Students will understand:	When it is appropriate to summarise text and when to paraphrase it.	
Students will be able to:	Take information from one source and re-write it for inclusion in another, using summarisation and paraphrasing as appropriate.	

* only use a standard where appropriate. Adapt these examples to your lesson's needs.

Skill Standards:		Related SOP, Resources and Materials:
Document Type	Narratives, ICFs, All	Review and Quality Control of Documents Produced by Medical Writing Services
Functional Competency	Quality	Resources: Flip chart, pens, sample text
Other		Exercises:

Segment:	Time:	Obj. No.	Activity:
1. Warm Up	10 min	1	A to Z game. Theme is adjectives. Two teams. Each team to nominate one writer to come to the forward and stand at the board and write their team's answers. Each team has to write the longest word they can. There is only one board, so longest and fastest they can go, the better. One point per letter. Team with most letters wins.
2. Introduction	10 min	1	In pairs, take some time and jot down your thoughts on the difference between summarising and paraphrasing text. Also, answer this question – what do you understand about plagiarism? What are the ethics of plagiarism?
3. Presentation	15 min	1,2	Go through presentation Powerpoint
4. Practice	20 min	1	Look at the example text. Write a summary of it. In pairs, look at your summaries. Talk about what the differences are. When done, present to the rest of the team about what you discovered. What were the differences in getting this done? Was one particularly easier? If so, why? Does everyone agree?
5. Presentation	10 min	2	
6. Practice	20 min	2	Look at the example text. Write a paraphrased version of it. In pairs, look at your summaries. Talk about what the differences are. When done, present to the rest of the team about what you discovered. What were the differences in getting this done? Was one particularly easier? If so,

WHAT WOULD A TRAINING PROGRAMME LOOK LIKE?

We looked at each document type and developed a set of trainings that would give the background and allow the trainee to develop the basic skills that would be needed.

Narrative specific				
Introduction to narratives: types of narratives				
Introducing the various sources that can be referenced to draft narratives				
Preparation of narratives for inclusion in Clinical Study Reports				
Data interpretation and presenting as a narrative				
ICH E6 Guideline for Good Clinical Practice				
Patient Narratives				
Draft sample narratives				
Discussion on the narratives drafted				
Draft sample narratives				
Discussion on the narratives drafted				

In addition, we knew that plenty of practice and feedback were going to be essential, so we worked that in.

Each trainee should, at the end of the programme, be competent to take a new assignment of each type in the programme, and know enough to be able to take it forward.

SUMMARY OF WRITING ETHOS FOR A REGULATORY MEDICAL WRITER

<i>CLEAR</i>	<i>PRECISE</i>	<i>CONCISE</i>	<i>CONSISTENT</i>	<i>OBJECTIVE</i>
Comprehensible on first reading	Correct use of terminology	Don't use filler words	Check for domino effects as you go	No opinions – only facts
Active voice	Client drug first	Don't use flowery language	Read through your document when you have finished and correct inconsistencies	Avoid superlatives!
Unambiguous words	Don't round numbers	Don't try to 'sound' scientific		CSR is no place for marketing
No double meanings	Correctly state and use variables			
No jargon	Avoid 'comparable' and words without inherent meaning			
No convoluted sentences	Avoid hedging and roundabout phraseology			
Minimal repetition				
Minimal verbosity				

REDUNDANT PHRASES



ACTIVITY

Which parts of the following phrases are redundant?

Adjectives	Adverbs	Prepositional phrases
advance planning	already reported	2am in the morning
both alike	completely surrounded	at this point in time
close proximity	definitely proved	estimated at about
end result	equally as well as	extreme in degree
final outcome	join together	few in number
general rule	lifted up	large in size
past history	may possibly	light in weight
personal opinion	refer back	oval in shape
single unit	repeat again	qualitative in nature
time period	summarise briefly	short in duration

Style guides and manuals may list more examples – e.g. ‘each and every’

REDUNDANT PHRASES

ANSWERS

Redundant items are marked in *italics*

Adjectives	Adverbs	Prepositional phrases
<i>advance</i> planning	<i>already</i> reported	2am <i>in the morning</i>
<i>both</i> alike	<i>completely</i> surrounded	at this point <i>in time</i>
<i>close</i> proximity	<i>definitely</i> proved	estimated <i>at about</i>
<i>end</i> result	<i>equally</i> as well as	extreme <i>in degree</i>
<i>final</i> outcome	join <i>together</i>	few <i>in number</i>
<i>general</i> rule	lifted <i>up</i>	large <i>in size</i>
<i>past</i> history	may <i>possibly</i>	light <i>in weight</i>
<i>personal</i> opinion	refer <i>back</i>	oval <i>in shape</i>
<i>single</i> unit	repeat <i>again</i>	qualitative <i>in nature</i>
<i>time</i> period	summarise <i>briefly</i>	short <i>in duration</i>

Style guides and manuals may list more examples – e.g. ‘each and every’

ROUNABOUT EXPRESSIONS

- Roundabout language avoids getting to the point and obscures meaning in medical writing.
- Look at the roundabout expressions below. I've added answers for **two** for you – can you identify any of the others?



a majority of (most)	for the purpose of	in the case of
a number of (many, several)	for the reason that	in the course of
a small number of	has the opportunity	in the event that
are known to be	is able to	in the near future
at the same time	in a routine manner	it is often the case that
at present, at this point in time	in order to	it is possible that
could potentially	in regard to	it is worth pointing out that
due to the fact that	with respect to	it would appear that
during the course of	in spite of the fact that	prior to
fewer in number	in terms of	subsequent to

CONSISTENCY OF STRUCTURE

A scientific or technical document written in a consistent manner requires less brain power to understand. Data interpretation is one area where consistency is essential. After a number of years being frustrated during QCs, I developed a template to help writers keep their data reporting clear and consistent. What do you think?

<difference statement> <variable> <time point> <treatment groups> (data: X vs. Y, p=X.XXX, <analysis set>)

Example:

- There was **no notable difference** in **change from baseline of TSS at Week 28** between the **A and B arms** (72.0% vs. 69.7%, p=0.549, ITT)
- A **greater percentage of subjects** achieved **overall response at Week 28** in the **A arm than in the B arm** (75.0% vs. 50.0%, p<0.001, ITT)

A more complex example might be:

- Using blinded assessment, **a greater percentage of subjects** achieved **overall response at Week 28** in the **A arm than in the B arm** (75.0% vs. 50.0%, p<0.001, ITT); however, using investigator assessment, **no notable difference** was observed (75.0% vs. 72.0%, p=0.741, ITT).

IN SUMMARY

- **Regulatory writing generally requires a highly-structured, template-driven approach**
- **Can appear formulaic**
- **Key to success for regulatory writing is an approach centred around being clear, concise, precise, consistent and objective**
- **Our recent experience with developing a training programme was very successful – individuals new to the industry were fully trained in a 4-month window**
- **The intensive training programme was developed from a first-principles standpoint**
- **Workshops were designed to be as interactive as possible, so that each individual was actively learning**
- **Games at the start of each day and ‘what did we learn’ summary sessions at the end of each day were used to reinforce learning**
- **And finally...**

THE PROBLEM WITH MEDICAL WRITING

“In many ways, medical writing is its own worst enemy. The reason is that the better the writing, the more invisible it becomes. In contrast to literary writing, where the writing itself is in the foreground and to be enjoyed for its own sake, the aim of medical writing is to transmit complex information to the reader as unobtrusively as possible.” *Stephen DeLooze*

This is important, because in my experience, when the writing itself ‘becomes visible’ it is often because it is causing trouble for the reader in some way



THANK YOU

TIME- AND PROJECT MANAGEMENT

- If you have done any project management, you will recognise this feeling
- News Flash: it never gets any better
- But, we can put into place systems to make it more manageable

