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

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Senior Manager, PAREXEL Medical Writing Services
December 2018
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
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
REGULATORY vs. COMMUNICATIONS

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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
- **PADER** = Periodic Adverse Drug Experience Report
- **DSUR** = Development Safety Update Report
- **PBRER** = Periodic Benefit-Risk Evaluation Report
- **IB** = Investigator Brochure
- **PSUR** = Periodic Safety Update Report

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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?

<table>
<thead>
<tr>
<th>WRITING SKILLS</th>
<th>TECHNICAL SKILLS</th>
<th>SOFT/PROJECT MGMT SKILLS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Use a keyboard</td>
<td>Proficient with MS Word</td>
<td>Team leadership</td>
</tr>
<tr>
<td>Attention to detail</td>
<td>Working with templates</td>
<td>Team working</td>
</tr>
<tr>
<td>Use of language</td>
<td>Knowledge of regulatory documents</td>
<td>Time- and project management</td>
</tr>
<tr>
<td>Consistency</td>
<td>Competence with client-facing situations</td>
<td>Proactivity</td>
</tr>
<tr>
<td>Effective communication</td>
<td>Scientific and statistical understanding</td>
<td>Problem solving</td>
</tr>
<tr>
<td>QC and review</td>
<td>Data interpretation</td>
<td>Provide solutions</td>
</tr>
<tr>
<td>Editing skills</td>
<td></td>
<td>Negotiation skills</td>
</tr>
</tbody>
</table>

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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:

- Overview of drug development
- Corporate etiquette
- Keyboard skills
- Project management
- Document management system
- Filing in an eTMF
- Performing a QC
- Language use
- Writing skills
- Document-specific training 1
- Document-specific training 2
- Writing assignments

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 posses.
SAMPLE LESSON

Each lesson had its own lesson plan

- **Lesson Area:** Language and writing
- **Lesson Title:** Summarising and paraphrasing
- **Trainer:** Jim Newman
- **Time Required:** 95 min

**Lesson Objectives (numbered):**

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.

**Skill Standards:**

- **Document Type:** Narratives, ICFs, All
- **Functional Competency:** Quality

**Related SOP, Resources and Materials:**

- Review and Quality Control of Documents Produced by Medical Writing Services
- Resources: Flip chart, pens, sample text

**Segment:**

1. **Warm Up**
   - **Time:** 10 min
   - **Obj. No.:** 1
   - **Activity:** 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**
   - **Time:** 10 min
   - **Obj. No.:** 1
   - **Activity:** 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**
   - **Time:** 15 min
   - **Obj. No.:** 1, 2
   - **Activity:** Go through presentation PowerPoint

4. **Practice**
   - **Time:** 20 min
   - **Obj. No.:** 1
   - **Activity:** 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**
   - **Time:** 10 min
   - **Obj. No.:** 2
   - **Activity:** 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.

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.

<table>
<thead>
<tr>
<th>Narrative specific</th>
</tr>
</thead>
<tbody>
<tr>
<td>Introduction to narratives: types of narratives</td>
</tr>
<tr>
<td>Introducing the various sources that can be referenced to draft narratives</td>
</tr>
<tr>
<td>Preparation of narratives for inclusion in Clinical Study Reports</td>
</tr>
<tr>
<td>Data interpretation and presenting as a narrative</td>
</tr>
<tr>
<td>ICH E6 Guideline for Good Clinical Practice</td>
</tr>
<tr>
<td>Patient Narratives</td>
</tr>
<tr>
<td>Draft sample narratives</td>
</tr>
<tr>
<td>Discussion on the narratives drafted</td>
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# SUMMARY OF WRITING ETHOS FOR A REGULATORY MEDICAL WRITER

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

Which parts of the following phrases are redundant?

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<th>Prepositional phrases</th>
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<td>already reported</td>
<td>2am in the morning</td>
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<tr>
<td>both alike</td>
<td>completely surrounded</td>
<td>at this point in time</td>
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<tr>
<td>close proximity</td>
<td>definitely proved</td>
<td>estimated at about</td>
</tr>
<tr>
<td>end result</td>
<td>equally as well as</td>
<td>extreme in degree</td>
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<tr>
<td>final outcome</td>
<td>join together</td>
<td>few in number</td>
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<tr>
<td>general rule</td>
<td>lifted up</td>
<td>large in size</td>
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<tr>
<td>past history</td>
<td>may possibly</td>
<td>light in weight</td>
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<tr>
<td>personal opinion</td>
<td>refer back</td>
<td>oval in shape</td>
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<tr>
<td>single unit</td>
<td>repeat again</td>
<td>qualitative in nature</td>
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<tr>
<td>time period</td>
<td>summarise briefly</td>
<td>short in duration</td>
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Style guides and manuals may list more examples – e.g. ‘each and every’
# REDUNDANT PHRASES

Redundant items are marked in *italics*

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Style guides and manuals may list more examples – e.g. ‘each and every’
ROUNDABOUT 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 and of the others?

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

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