

Document templates for medical writers

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Abstract

A document template is defined as 'a file that serves as a starting point for a new document'. This article looks at the specialised templates used by medical writers in their trade with a focus on the commercially available products. Templates allow a medical writer to prepare standardised documents that comply with the regulatory format requirements, and they increase productivity and allow rapid troubleshooting and document repair. The advantages and the disadvantages of using templates and some criteria of what makes an effective template are discussed. Templates available commercially are briefly presented.

Keywords: Templates, Regulatory, Documents, Commercial

Introduction

The etymology (1670s) of the word 'template' is rooted in craftsmanship, with definitions ranging from a 'weaver's stretcher' to a 'plank or rafter' that provides support or serves as guide for a piece of work.¹ Centuries later, templates in many different forms still play an important role in professional life. For medical writers, templates are a part and parcel of the job and the advent of eCTD reinforced their importance. This article looks at the templates used by medical writers in their trade, with a focus on the commercial templates used in regulatory medical writing.

Different types of document templates

In Microsoft Word[®], a document template is 'a file that serves as a starting point for a new document'.² This file contains pre-specified formats and styles and has the file extension '.dot'. When you create a new Word document, by default, it is formatted based on the normal.dot template. However, templates can actually mean many things and come in

many different forms. The most common examples are listed below.

Built-in word templates

Ready-made templates for Word are available from office.com. These range from templates for blog posts to project proposals to party invitations (Figure 1). These are especially handy for the average Word user. Unfortunately, they are not necessarily suited to medical writing needs.

Self-made templates

For the more technically inclined who aims for individuality, one can create a template in Word by defining different styles. The template can be saved as a '.dot' file. These files can even be shared with the Word user community on office.com.

Old documents as templates

In the medical writing world, we are frequently asked to use old documents as 'templates' by deleting the existing text but retaining the headings and the subheadings that are usually standard for that specific document. Unfortunately, these old documents may come with a lot of baggage, including unruly headings and rogue styles and are therefore not the ideal foundation for a new document.

Guidance templates

Publishers and journals usually provide templates as part of their Instructions to authors. For example, MEW has one available for feature articles. Regulatory bodies provide templates for certain regulatory documents that can be downloaded for free. These templates contain standardised headings and subheadings as well as instructional texts but the styles may or may not be defined.

Commercial templates

These are ready-made templates designed by technical professionals and must be purchased. Although most of these are Word-based templates, they come

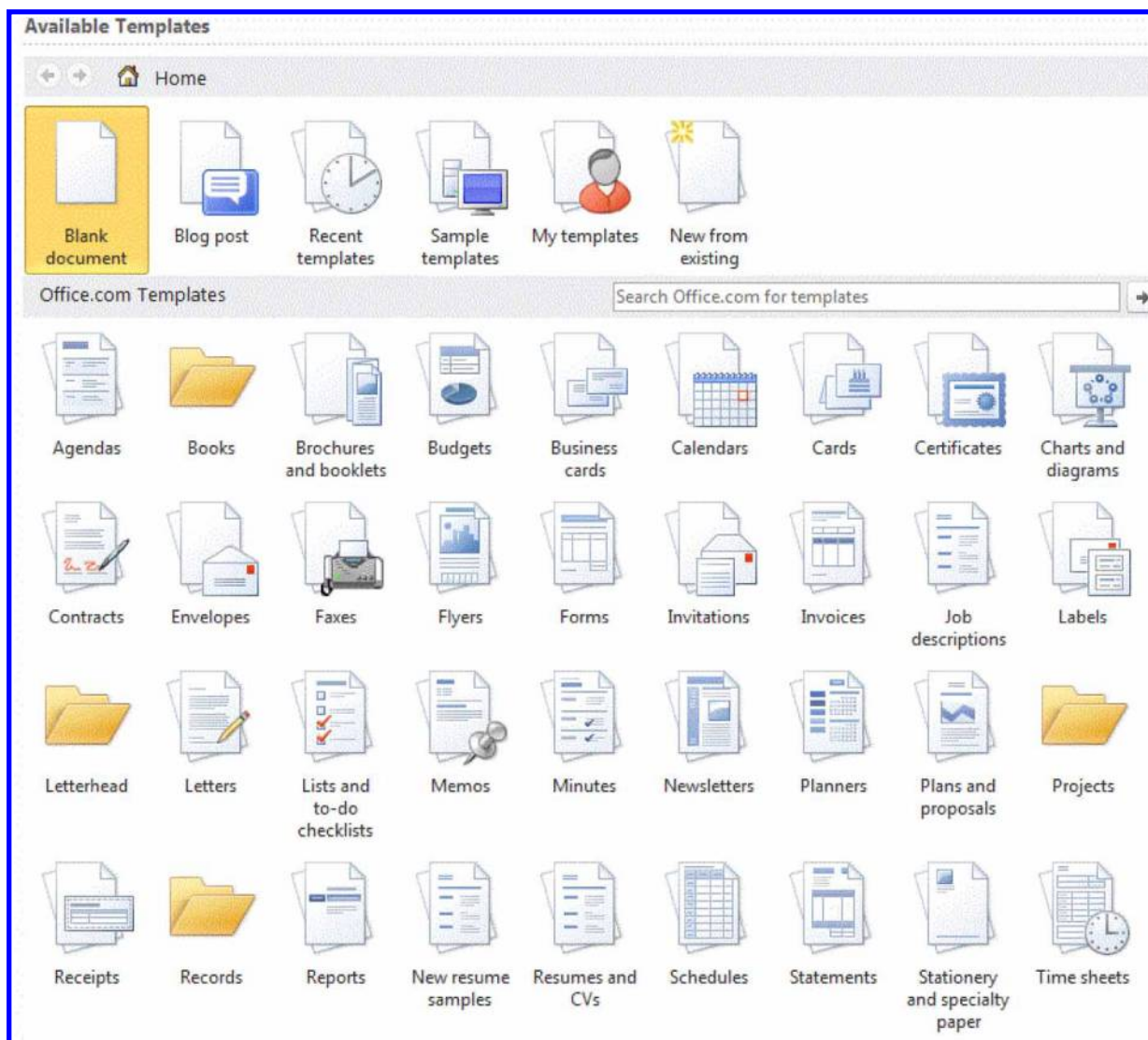


Figure 1: Office.com templates available in MS Word.

with extra plugins and macros that facilitate the writing and development of long and complex documents. These usually come as part of a set of content templates included in a document management package tool. Word classifies these as ‘installed’ templates.

Why use templates? Why not?

There are pros and cons associated with using templates, and they are discussed here with a focus on the commercial templates in regulatory writing.

Pro: Standardised documents

Companies, regardless of industry, require the use of templates in their documentation mainly to maintain a degree of consistency in the many documents that their employees write every day, from internal office email memos to full project proposals. Templates help maintain corporate identity by using standard headers and prespecified texts.

In medical regulatory writing, templates give different documents a uniform look. Whether they are used by multiple writers working on a single document or by a whole global team working on a set of documents for a dossier, templates (and the standard headings, and boiler plate and instructional texts therein) ensure that the documents are standardised in terms of formats and styles as required by the guidelines and company standard operating procedures.

Pro: Regulatory compliance

In the pharmaceutical industry, templates have a more specific and crucial function – guidance compliance. Regulatory templates are supposed to be designed to comply with the eCTD format requirements and to facilitate electronic submissions by providing correct section numbering and headings. For those who are not familiar with regulatory medical writing, the investigational medicinal

| | |
|---|--|
| {product name} | {sponsor} |
| Investigational Medicinal Product Dossier | |
| TABLE OF CONTENTS | |
| 2.2.1 | INTRODUCTION.....5 |
| 2.2.1.S | DRUG SUBSTANCE5 |
| 2.2.1.S.1 | General Information5 |
| 2.2.1.S.1.1 | Nomenclature5 |
| 2.2.1.S.1.2 | Structure6 |
| 2.2.1.S.1.3 | General Properties6 |
| 2.2.1.S.2 | Manufacture.....6 |
| 2.2.1.S.2.1 | Manufacturer(s)6 |
| 2.2.1.S.2.2 | Description of Manufacturing Process and Process Controls6 |
| 2.2.1.S.2.3 | Control of Materials6 |
| 2.2.1.S.2.4 | Controls of Critical Steps and Intermediates.....6 |
| 2.2.1.S.2.5 | Process Validation and/or Evaluation6 |
| 2.2.1.S.2.6 | Manufacturing Process Development6 |

Figure 2: A part of the table of contents of an IMPD.

product dossier (IMPD) is a good example illustrating the complexity of regulatory documents. The headings and the subheadings in an IMPD (see Figure 2) can be challenging for a writer not familiar with Word numbering functions.

Another issue is the font type and size. The regulatory writers are aware that most regulatory agencies prefer Times New Roman, Arial, and Courier New with a minimum size of 9 point.³ The newest Word versions include Calibri as the default font for the body text in a new document. This can easily be mistaken for Arial, but it is not the same. In addition, Word offers many fonts that unfortunately have no place in a regulatory document.

Beyond the writing itself, the templates should also work seamlessly with electronic publishing, which compiles different documents into a single electronic dossier.

Pro: Increased productivity

By pre-defining headings, styles, and formats, the templates allow the writer to concentrate on generating content rather than (re)formatting. Template plugins and macros, which appear as icons in the Word ribbon, enable the writer to carry out complicated commands with a single mouse click. For example, inserting a landscape page in a document that is in standard portrait layout takes at least nine steps to accomplish in Word 2007. With the 'installed'

template I am currently using, it can be accomplished in two mouse clicks (Figure 3), without having to worry about header and footer alignments. Another useful feature is the pharmacokinetics symbols available in a pulldown menu (Figure 4).

Pro: Rapid troubleshooting and repair

Many medical writers have experienced how documents that have changed hands during the writing and review process can come back with bizarre formats and styles. Some of these changes may have been inadvertent, having been 'infected' by styles defined in other normal.dot files. Copying and pasting formatted text can also introduce rogue styles into documents. However, there are also users who just cannot resist changing or even creating new styles. A document may end up suffering from the so called 'snowflake syndrome', which is where almost no two paragraphs are formatted alike.⁴

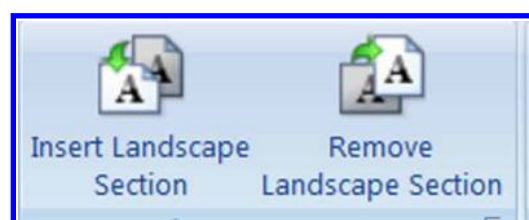


Figure 3: Icon in MS Word ribbon for inserting and removing a landscape section in a portrait document.

| | |
|----------------------|---|
| AUC _{0-t} | Area under the curve from zero up to time t |
| AUC _{0-inf} | Area under the curve from zero up to infinite time |
| A _{ave} | Average amount in the body at steady state |
| D _M | Maintenance dose |
| D _L | Loading dose |
| C _p | Plasma concentration |
| C _s | Serum concentration |
| C _u | Unbound plasma concentration |
| C _{ur} | Drug concentration in urine |
| C _{av,ss} | Average concentration at steady state |
| C _{max} | Observed maximum concentration |
| C _{max,ss} | Maximum observed concentration at steady state |
| C _{min,ss} | Minimum observed concentration at steady state |
| t _{max,ss} | Time to maximum concentration at steady state |
| t _{1/2} | Terminal half-life |
| t _{max} | Time to reach C _{max} |
| CL _{int} | Intrinsic clearance |
| CL _{CR} | Creatinine clearance |
| CL _m | Metabolic clearance |
| CL _R | Renal clearance |
| f _e | Fraction of intravenous drug excreted unchanged in urine |
| f _e /f | Fraction of orally administered drug excreted into urine |
| f _{rel} | Fraction of the dose in comparison to a standard (not IV) |
| k _e | Elimination rate constant from the central compartment |
| k _{ren} | Renal elimination |
| F _{rel} | Relative bioavailability in % |
| K _m | Michaelis-Menten constant |

Figure 4: PK symbols from a pull-down menu in MS Word ribbon.

Templates solve this problem by including formatting styles that are protected and not easily altered or renamed no matter how many times the document changed hands.

Word has other quirks and instabilities, like the nightmare of disappearing cross-links and out-of-control autonumbering. Commercial templates have (theoretically) been tested for stability, and they have builtin repair systems that help fix formatting issues. The snowflake syndrome, for example, can easily be repaired with a few mouse clicks. In addition, for dire cases, there is usually technical support that can be contacted.

Cons of using templates

The main disadvantage of the commercial templates is the financial aspect, which can range from a one time licence fee (plus extra for updates) or an annual subscription fee. Another objection to the templates is their rigidity, which may 'cramp' the style of some writers. Commercial templates also make the writer dependent on the macros and plugins, causing them to forget the standard Word functions in a template-free environment.

What makes a good template?

Not all that glitters is gold. Some templates and document management tools may not actually live up to their claims. In shopping for templates, here are a few suggested criteria to consider.

Ease of use

The template and its accompanying plugins should be easy to use, otherwise it will decrease rather than increase productivity. A user with a moderate level of Word skills should be able to use the template with minimal training.

Effect on word functionality

Macros and plugins should not interfere with the standard Word functionality or drastically slow down any standard software. In addition, the document should still be readable and write enabled by other users who do not have the template installed in their computer.

Stability

The template should be acceptably stable and not lead to too many 'crashes'. Ask the vendor for their stability testing procedure.

Technical support

A minimum degree of technical support should come with the template package. User's manuals and online resources are useful, but a hotline can be crucial when a template crashes while chasing a deadline.

Adaptability

The drug regulatory process is continuously evolving and so are the documents that go with it. The template should therefore be adaptable to changes in regulations or region specific requirements. The simplest example is changing a document from US Letter to A4 size. Does your template allow this without breaking your document apart?

Price

Finally, the price of the template is, of course, of prime importance. Normally, to justify the cost of buying a set of templates, a certain critical mass of writers and regulatory documents is needed. Over the years, my experience is that big pharma companies with an extensive product pipeline can afford (and should have) these templates, whereas startups cannot necessarily afford them. In a 2010 Europharm survey, only 44% of small- and medium-sized pharmaceutical enterprises in Europe had an eCTD management tool. The rest were, at the time, still checking out vendors or opting to outsource the eCTD publishing process.⁵

Commercial templates: What's available?

Many software companies offer regulatory templates. Unfortunately, almost no data are freely available comparing the functionality, the price, and the market share of these software packages. Two of the most popular template sets are ISIWriter™ and Lipient SmartDesk™.

ISIWriter by CSC prides itself for having been created by 'expert medical writers', so it can cater in a better manner to a medical writer's needs. This template set covers the full documentation workflow from authoring to repairing and publishing, and promises a 'submission ready' end product. ISIWriter™ boasts of more than 200 content templates for regulatory submissions, including the different modules of CTD.⁶ This is the template I am most familiar with.

SmartDesk for Authoring™ by Lipient is another document template and authoring system for regulatory writing. It too covers the dossier preparation process, including writing, rendering, publishing, and preparing the eCTD. In addition, it offers a Regulatory and Clinical Services Authoring Style Manual that facilitates consistency in authoring.⁷ I have never used Smartdesk™, but I have heard positive feedback from colleagues who have.

Other template systems include the DART by Yeldell Scientific and TRS Writer by CSC.

Conclusions

We have come a long way from the weaver's stretcher or the builder's rafter as templates of craftsmanship. In the digital era, our templates reside in our computers.

Author information

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Templates are an important part of medical writing. However, take note that I never used the term 'quality documents' in this article, a buzz word that template vendors like to use. Templates enable medical writers to efficiently prepare standardised, regulatory format-compliant documents. However, at the end of the day, templates do not guarantee quality documents. Like the weaver and the builder, we, medical writers, are still fully responsible for the content.

Disclaimers

The views and the opinions written here are purely those of the author and do not necessarily reflect those of Clinipace Worldwide.

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