

The CDS is Dead! Long Live the CDS!

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Introduction

The company Core Data Sheet (CDS) is one of the most important documents a pharmaceutical company creates. The CDS stores information that originates in several areas of the business. This content includes information such as:

- Dosing requirements
- Method(s) of administration
- Patient population concerns
- Packaging and storage
- Incompatibilities
- Pharmacological properties

Though never published on its own, the CDS is a master repository for this information. The content in the CDS is reused in other documents, such as:

- United States Prescribing Information (USPI)
- Summary of Pharmaceutical Characteristics (SmPC)
- Patient Information Leaflet (PIL)
- Medications Guide

A lot of critical information goes into the CDS and a lot of critical information is created from the CDS.

Over time, medical writers continue to add content to the CDS. They also copy and paste content from the CDS to other documents. In this way, the CDS is treated as a repository, storing critical information in one location.

Why, then, are pharma companies using the most arcane, inefficient, and error-prone method of creating, storing, and managing the CDS?

The CDS is almost always a Microsoft Word document. Unfortunately, a Word document is neither suited to be a repository nor does it have the necessary features that we need in a repository.



Why Word Doesn't Work

There are many reasons why Microsoft Word is the wrong tool for the CDS. First and foremost is the mechanism by which we create Word documents.

Word is a document authoring tool that has a great feature set for a single writer creating a single document. Even though recent versions of Office365 allow for multiple authors, a Word document is still just a document.

To create the CDS, medical writers copy and paste content from source documents into the CDS Word file. As soon as this happens, there are two versions of the information: one in the source document and the second in the CDS.

As time goes on, iterations happen. Information is altered, corrected, and updated. Changes are made. Keeping all of the documents that contain the information in sync is a manual, and often overlooked, task. If even one change fails to be back-propagated, the information bifurcates and the copies are no longer identical.

When a document is created from the CDS, the same thing happens. Content is copied and pasted into the new document, for example, the USPI or SmPC.

Now, we have at least three versions of the very same content:

- The source content that is used to create the CDS
- The CDS
- The destination content that is created from the CDS

If changes are made to the USPI or SmPC, those changes must also be made to the CDS in order to keep them in sync. In fact, the change might need to be back-propagated all the way back to CDS source documents. The more changes that are made, the more out of sync the information becomes.

A Better Solution

Rather than using a Word document as a repository, a much better solution is to use a dedicated repository in the form of a component-based, structured content management (SCM) system.

Here is how it works:

Rather than creating documents, content is written in small chunks called components. A component is a piece of information that describes a single topic or idea. Therapeutic indications and methods of administration are



examples of components. Each component is written, stored, and managed one time. If there is a change, it occurs once, in the only instance of the component.

To produce documents, components are assembled into the required order and hierarchy. You can choose to automate document assembly, assemble components manually, or combine automation and manual efforts.

Let's take global labeling documents as an example. Regional labels provide much of the same information as the USPI and the SmPC. These labeling documents can be pre-populated from the CDS with reused content, boilerplate text, pre-formatted tables, and data retrieved from other sources. Authors can then add the unique content as required for the region or type of document.

Using structured content, content is created and data is integrated without a lot of formatting. Instead of authors assigning heading styles and manually creating every table, the system provides document formatting and layout based on your stylesheets and output templates. You can output the document to just about any file format you need, from PDF or Word to XML or Adobe InDesign.

Authors and SMEs can use their time to create valuable content rather than copying and pasting, formatting a Word document, or manually moving components into place.

Why a Repository of Components is Better

There are many reasons why a component-based SCM is much better than using a Word document as a repository.

Single source of truth. Using a component-based repository ensures that there is one, and only one, instance of the component. That means any changes made to the component are automatically reflected when the output is published. No more guessing. No more back-propagating changes.

Efficiency. A single source of truth -- one component -- is easier and more efficient to create, maintain, and manage. If a component already exists, nothing needs to be done to it in order to publish it to a label or any other output you need.

Version Control. Because there is a single source of truth, the latest version is always available. If you need to look at a previous version, your SCM keeps previous versions. Each version includes tracking information such as when a change was made and who made the change.



Management. The SCM also keeps track of where each component is used, so you know, without guessing, which documents need to be republished when you make a change.

Free of Format. Components are created and stored in the SCM free of format. You are not stuck always having a .DOC or .DOCX file. Instead, the format is applied to the document when you publish it. This means you can create content for print, desktop, web, smartphone, and even an app from the same components. Write once, publish everywhere.

Do We Still Need the CDS?

A case could be made that when you use an SCM and component-based content, the need for the CDS is eliminated. After all, the CDS is never published. It is simply a holding tank for pieces of information.

If you use a true repository for all of these pieces of information, the need for the CDS as a document largely goes away.

That said, you can still publish a CDS if you need one. All you need to do is select all of the components you want, in the order you want them. Just like any other document that you create from the components. Then publish your CDS to Word, PDF, HTML, XML, and format it for print, screen, tablet, or smartphone.

Using an SCM and component-based content provides the most flexibility and security for the least amount of time and effort.

About Content Rules

Content Rules, Inc. is one of the oldest and most established content strategy firms in the industry. Our content transformation methodology has been proven in life sciences over the past 20 years. Our content strategists are experienced with the unique challenges of pharma content, as well as the common content challenges that all enterprises face. Contact us to learn more about how we can help you solve your content challenges.