

Why “Context Driven Content Management” should be considered by the pharmaceutical industry

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ABSTRACT

ECM (Enterprise Content Management) has today evolved into a technology complex that promises seamless integration across business processes and organisational barriers while enforcing highly controlled content capture, maintenance, storage and distribution. A shortcoming is, however, that typical ECM systems offer limited or no support for the business context. A business context, such as clinical development is dynamic and changes over time. This typically results in a costly race with system and data corrections in order to keep up with regulations and changing end user requirements.

Pharmaceutical companies have the need for effectively controlling the ever extending amount of content involved in e.g. producing the Electronic Trial Master File (eTMF) and preparing documents for electronic submissions, while at the same time supporting the ever changing business environment. This calls for an extension to ECM systems, an extension that can manage, preserve, retire and store records according to their relations to business contexts.

INTRODUCTION

This paper describes how Context Driven Content Management (CDCM) offers an important addition to Enterprise Content Management systems (ECM). Over the years, traditional content management systems have successfully developed into ECM systems, which can fully capture, store, manage, preserve, and deliver content throughout the enterprise. However, a major shortcoming in ECM systems is that they have difficulties supporting the business context, making it hard to reorganise the content according to changes in the business environment. CDCM initiates the next generation of ECM systems because a context driven system allows for extensive business modelling and a seamless adaptation to change.

According to CDCM, documents are not just documents, but are seen in the context in which they are created. This means that if the business environment changes, documents and metadata can be easily rearranged in order to reflect that change. The benefits of CDCM are obvious. A CDCM system is responsive to change, requires far less validation, and brings customisation down to a minimum. In a business environment undergoing continuous change, this frees up resources and reduces the total cost of ownership.

This paper covers two main topics: The development of Enterprise Content Management (ECM) – and its shortcomings, and secondly, the concept of Context Driven Content Management (CDCM) – and its benefits.

NNIT has participated in a wide range of ECM projects and has repeatedly witnessed how end users, system administrators and owners struggle to enforce the proper use of the system, handle the assignment of correct metadata, and to ensure that the system adopts the intended use. Based on this experience, NNIT has defined the concept “Context Driven Content Management” as described in this paper. Please note that the paper describes a concept and not an actual system in production today.

THE EVOLUTION OF CONTENT MANAGEMENT

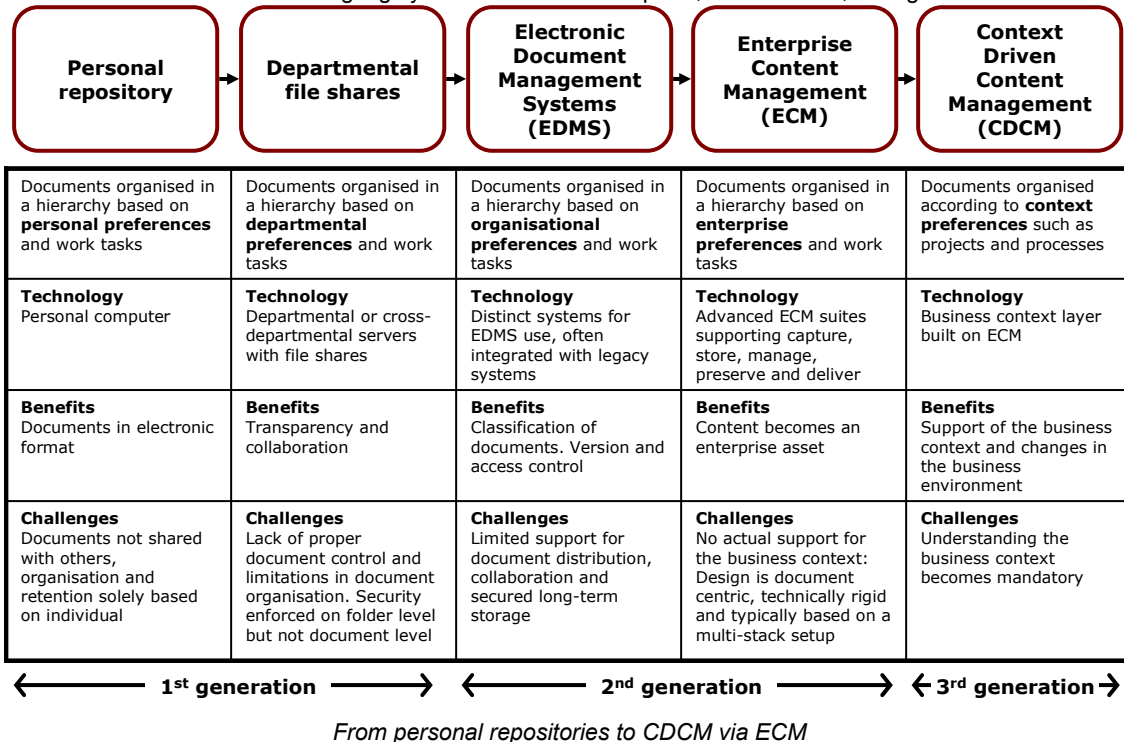
Personal computers have been around for decades and with them the ability to create, store and print electronic documents. Computer networks for office use increased their potential and were quickly adopted in order to share documents at the departmental and cross-departmental level. Among the obvious advantages were collaboration and reuse of documents throughout the organisation. The challenge, however, was to ensure proper document control and to eliminate the inherent risk of exposing sensitive documents.

As the technology matured, electronic document management systems (EDMS) materialised, offering more or less stand-alone platforms tailored for the organisation's critical documents. EDMS systems offered document versioning

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and security control, but were often tailored only to meet specific vertical needs within the organisation – e.g. Human Resource or Research & Development.

Later, EDMS systems evolved into true ECM which promised seamless integration across business processes and organisational barriers while enforcing highly controlled content capture, maintenance, storage and distribution.



A shortcoming of present systems is that they offer no support of the business context. A business context is dynamic and changes over time. Outside factors may often govern the business context that ECM tries to model with its metadata. This results in a costly race with system and data correction in order to keep up with regulations and end-user requirement and wishes.

ECM LEAVES OUT THE IMPORTANCE OF THE BUSINESS CONTEXT

A business context differs substantially from document lifecycles and workflows. A lifecycle is the sequence of document states that the document undergoes from creation onward. A workflow is a controlled way of administering a part of a document's lifecycle. However, a business context is a separate entity decoupled from the documents themselves. It contains separate metadata that make it possible to express the behaviour of the business context. A document belonging to an organisation and a process can be modelled by two contexts that contain the data relevant to the organisation and process. This is the same data and structure that may be subject to change as a natural effect of everyday life.

In order to show in more detail how ECM leaves out the business context, let us look at two of the most common denominators of today's ECM systems:

- **ECM is document centric**

Tradition prescribes that documents are at the centre of an ECM system. Documents are created and used in the daily business activities – supported by the ECM system which stores and organises the documents in a hierarchy of cabinets and folders within the system. It has become customary to focus ECM systems and the work tasks they support around the document lifecycle, more or less leaving out the business processes in which the documents are created and used. Before computers came around, this was also the typical approach. Paper documents were organised in suspension files, suspension files were organised in steel cabinets, and steel cabinets were lined up in rows in archive rooms. This setup ensured that documents were stored using well-defined rules so that they could easily be retrieved again.

So when computers and graphical user interfaces came around, it was easy and straightforward to adopt the filing cabinet metaphor. For basic organisation of documents, the filing cabinet metaphor is adequate. Yet, it

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does not provide a good understanding of the business processes within which the documents are created and used. The filing cabinet metaphor is a static storage metaphor that does not adequately reflect the dynamic process in which the user works. For instance, information about the process, e.g. study and research-site, is not readily available. Moreover, the mechanism of organisation is limited to a folder hierarchy with names like 'Research Project A', and sub-folders named 'Validation planning' or 'Clinical Study Site 5'. But it fails to inform the user how the processes in the 'Research Project A' are related, for instance, to the project milestones. And it fails to give the status of the specific processes and the projects in general with respect to document deliverables. It only provides some basic organisation and does not reflect any business reasoning for creating and using the document.

Since the business context of a document cannot be effectively expressed using the filing cabinet metaphor, users need to obtain this information elsewhere. Usually this is partially achieved using document metadata and document naming rules. An experienced user of the ECM system will be able to retrieve and decipher this information, but it is often complex and cumbersome. The user is never presented with a comprehensive overview of the business processes providing an easy-to-understand summary of the business context in which the document exists and the user works.

- **ECM has a rigid technical design which makes it difficult to facilitate changes in the business environment**

It is universally recognised that the only constant is change. Businesses are constantly moving forward – projects are started, closed or divided into new projects – the name of a product is changed and business processes are redefined. Companies are merged or acquired, or new regulations introduced. These changes are often a major challenge to traditional ECM systems. The reason is that the business context of the documents – e.g. the project, process, therapeutic area, dosage or study – is stored on the documents themselves as static metadata (together with information such as author, reviewer and approver). When the context changes – changes often needs to be applied to each and every document related to the changed context. An exercise which can be costly, especially if the system is validated and the documents electronically signed.

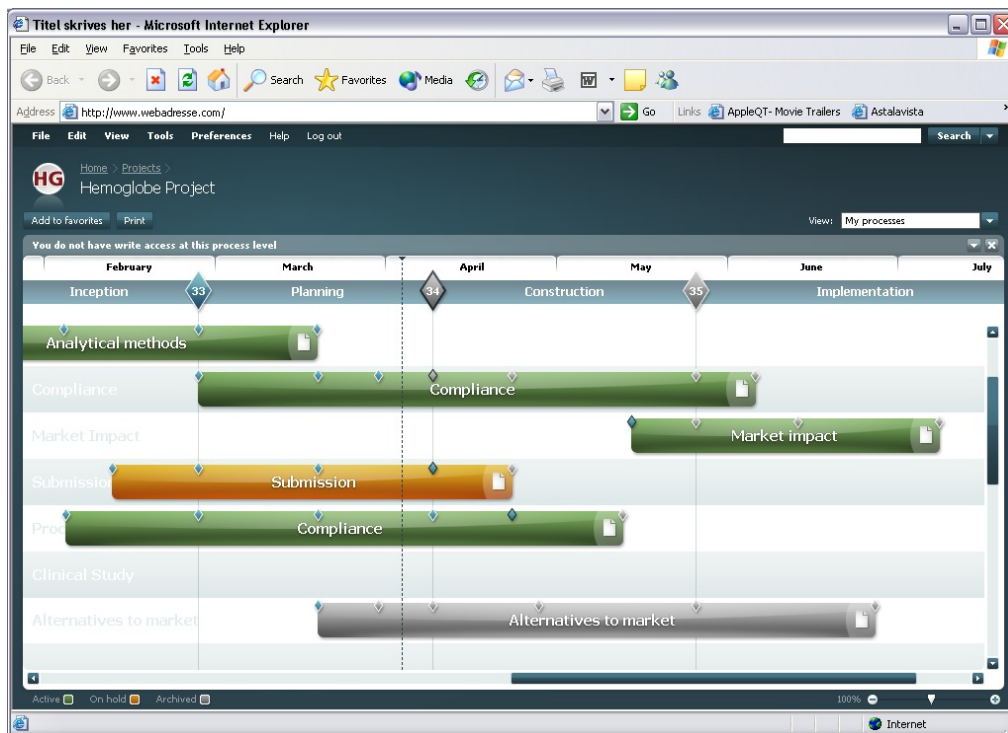
Hence, while ECM systems do provide efficient support for sharing and controlling documents, they fail to provide adequate support of the business context in which the documents are created and used. Based on the above mentioned shortcomings of ECM, this paper will now provide a framework for dealing with these shortcomings through the concept of CDCM.

CONTEXT DRIVEN CONTENT MANAGEMENT (CDCM)

As noted, ECM systems support users in creating documents, checking them into a repository, forwarding them for review and approval. But they do not assist the users in understanding the business context in which they are created and used. CDCM is enterprise content management that can manage, preserve, retire and store records according to their relations to business contexts.

CDCM is a concept that allows ECM systems to centre around any type of business context, including processes. The user's tasks determine the relevant context, some of which may not naturally be modelled by processes. Gartner Group differentiates between content management vendors that address basic content services and those that address process centric applications. By being context centric, CDCM not only positions itself in the process centric approach, but expands it to include non process centric areas – thereby building further flexibility into the process centric approach. CDCM recognises that business processes provide the context: planning a clinical study, preparing for an audit, or submitting an electronic submission. These processes are the components that make up the lifecycle of the business. The users act within the processes and understand the world through the context they provide. In other words, they perform their work as defined by those contexts. Creating and using documents should not be two separate activities. In a context driven system, documents are always created as part of a business process - they are never decoupled from business processes. Hence, documents become a result of business processes.

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Business processes provide the context (illustrative)

Because business processes are so important to the organisation, it is critical that users have easy access to accurate and up-to-date information of those processes. Users should understand how the processes work and what is expected from the individuals working within the process. It might even be mandatory for users to read and understand specific documents related to work within the process and confirm their understanding by issuing an electronic signature upon completion.

CDCM expresses the need for a class of products that combine the strong content lifecycle support provided by ECM systems with vertical solutions that offer seamless integration and support of business processes as well as controlled document distribution and training. Especially within regulated industries there is a growing need for more efficient ways of creating and managing critical documents within the context of research projects – often facilitated by a stage-gate methodology. This need also exists within the confines of more generic line-of-business contexts, e.g. preparation for audits, planning and assembly of fiscal reports, or the handling of human resource documentation. Such work is always carried out within processes and requires efficient process support from IT systems.

THE COMPONENTS OF CDCM

The three major components of CDCM are:

- The **ECM system** providing the needed support of the content itself, its lifecycle (capture, store, manage, preserve and deliver) and the inherent ECM management disciplines (document management, web content management, records management, digital asset management, collaboration and content routing).
- The **context engine** providing efficient support of handling the general business context layer (projects, processes, products, units etc.) and the very dynamic context lifecycle (create, read, update and delete).
- The **business management solutions** providing efficient support of working with content in specific context management disciplines e.g. project management, process management, training management, submission management and unit management.

THE CHARACTERISTICS OF A CDCM SOLUTION

CDCM is a radically new approach to content management that solves the ECM shortcomings identified above. The very starting point of CDCM is the context. The documents' metadata are represented in contexts rather than managed by individual employees. It is no longer up to the employees to handle the documents correctly: contexts do the work. All relevant documents will appear in their updated version as soon as the employee clicks on the context. Everything is ready at hand and new documents are automatically added to the right context. To the employee, this is intuitive and time-saving and it eliminates errors.

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CDCM is therefore much more than an important addition to current ECM systems: it marks a genuine paradigm shift in content management. CDCM is a dynamic system in which documents are no longer simply seen as mere documents; they are always seen as part of a context. This context-driven approach – as opposed to the traditional ‘document-driven’ approach of ECM – makes content management a far more integral part of the business life cycle.

BENEFITS: BETTER USE AND LOWER COSTS

By its intuitive nature, CDCM offers tremendous benefits not only for the employees, but for the life science company as a whole:

- By reflecting how the employee actually ought to work, CDCM may improve work processes as well as improve the employees' understanding of these processes.
- CDCM facilitates change without any additional system maintenance and validation.
- CDCM allows user empowerment without running the risk of weakening the data quality.

At the end of the day, these three benefits all lead to better regulatory compliance as well as lower costs. Below each of these benefits are spelled out in more detail:

- **Improved process understanding:** A consequence of the context-driven approach to content management is that the employee's product and process understanding is naturally increased. In a business world with increasing employee mobility and frequently shifting work areas, employees typically no longer have the same experience and expertise within a specific field. This fact is further exacerbated by the sheer volume of new information.

Contexts can therefore ensure that the employee has the correct level of understanding to carry out his or her tasks according to the latest knowledge. Through the context, all the right documents are instantly available. The context thus becomes the employee's natural starting point, and the employee will comprehend his or her tasks directly through that context. This increases the employee's process understanding considerably

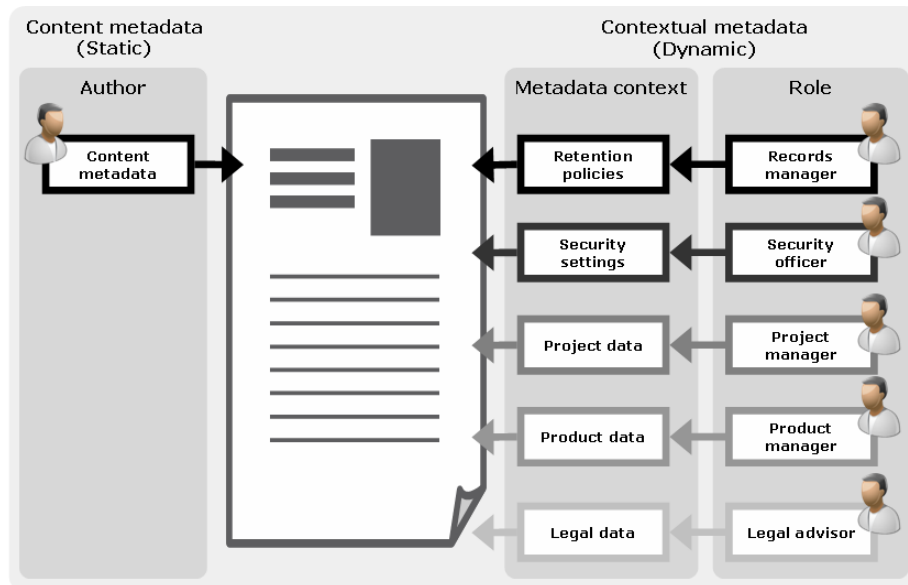
- **Facilitating change:** Since current ECM systems are essentially massive filing cabinets, they become especially cumbersome when the business changes. The metadata of the documents should be changed whenever there are changes in organisation, availability, security, data format, product line, etc. Documents should then be moved to new locations. All this should be carried out while ensuring that the system still lives up to both regulations and user requirements. At present, changes are therefore very time-consuming and costly – not least in terms of system maintenance and validation.

Organizing documents according to contexts accommodates changes far better. When the business undergoes change, it is necessary only to update the contexts – not all the documents themselves. This would then automatically change the relevant metadata and shift the documents around according to the updated contexts. CDCM thus saves time and money, but also facilitates compliance because changes are adopted seamlessly.

Since business contexts are dynamic, content management systems should not treat them as static. In ECM, all metadata are kept static and are consequently difficult to modify whereas in CDCM the relevant metadata are dynamic and easily manageable through contexts.

- **User empowerment without poor data quality:** CDCM addresses another serious challenge to current content management systems. The trend has gone clearly towards increased user empowerment; that is, the user is allowed to work with documents without constantly consulting with specialists. Unfortunately, increased user empowerment has so far almost unavoidably resulted in a deterioration of the data quality. The employee simply does not know how to handle the metadata. This poses serious risks to both knowledge preservation and regulatory compliance. In CDCM, user empowerment need not lead to poor data quality. Since contexts drive the metadata, the user can freely access and edit documents without affecting data quality.

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Metadata are derived from the context, only static metadata must be applied by the author

CONCLUSION: BUSINESS IS DYNAMIC – WHY SHOULD CONTENT MANAGEMENT BE STATIC?

The electronic filing cabinet of traditional content management systems has simply grown too big and bulky to keep up with the dynamic nature of business today. With increasing employee mobility, knowledge growth, and shifting procedures and regulations, content needs to be organised through contexts. By acknowledging contexts, CDCM makes content management an integral part of the business lifecycle – and this leads to better use and lower costs.

REFERENCES

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