

Crossing Company Frontiers

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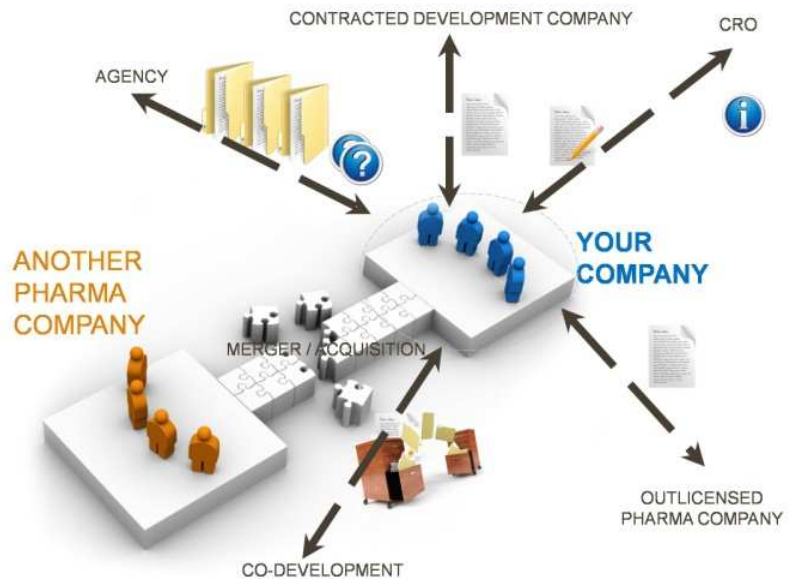
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ENTERPRISE
CONTENT
MANAGEMENT
EVENT -
BRIDGING THE
COMPANY
FRONTIERS

19th June 2009

Mechelen,

Lamot Business Centre



Business Landscape and ECM Challenges

In the fairly recent past of content and document management one company solely managed the whole process and systems used from document creation to package submission. The process was defined within the company, the electronic systems were hosted within that same company and the collaborators were even present at this very location. Exchanging documents and content was a single site business.

Content management today is not limited to one's own company, but has now crossed the company frontiers.

**Today's challenge is how to manage
the CONTENT EXCHANGE!**

Current Industry Trends

- **Mergers and acquisitions** make us want to incorporate existing systems, product documentation and portfolios in a centrally organized system environment.
- **Working with CROs** is now part of a daily business. Outsourced activities and information have to flow (in a controlled manner) between the companies.

- When companies act as **contract development** companies for others there is again a high need to exchange company documents and submission content.
- When **co-developing** a compound a very complex relationship arises where documents or dossier parts need to be exchanged and potentially maintained during the product lifecycle.

Content Management Solutions Defined

What do companies expect from their content management systems? Do the currently available systems meet the expectations?

Our Experience

Based on many years of implementing systems and using the commonly available solutions we can conclude that most systems provide a good functionality and (limited) features for collaboration. Some solutions can be considered intuitive and simplicity is in a lot of cases debatable. The main element that is missing in today's available systems is **interoperability** which will allow companies to easily exchange documents and packages of documents.

“ASSESSING
THE PRESENT –
DESIGNING
THE FUTURE”

Content Management in an Ideal World

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“ ASSESSING

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	Documentum		SharePoint		Other
	Documentum	FirstDoc	SharePoint	NextDocs	SCORE
Flexibility	●○○	●●○	●●○	●●○	●●○
Collaboration	○○○	●●●	●●○	●●○	○○○
Interoperability	○○○	○○○	○○○	○○○	○○○
Simplicity	●●○	●●○	●●○	●●○	●●○
Functionality	●●○	●●●	●○○	●○○	●●○
Compliance	●○○	●●●	●○○	●●●	●●○

Flexibility - Systems must be able to easily add new products, trials, include new CROs, other companies, etc.

Collaboration - Systems must support virtual collaborative authoring by collaborators working at any location.

Interoperability - Systems must enable exchange of documents, packages, submission modules etc. inter- and intra-company and even with agencies and regulatory authorities.

Simplicity - The application needs to have a low entry level without intensive training; preferably intuitive.

Functionality - Systems must provide all common functionalities as expected from a document management system, such as review, approval, publishing, etc.

Compliance - The system should be designed to comply with the current regulatory standards.

Tomorrow's Content Management

The challenges

- **Different platforms:** In the current situation where each company has its own technology implemented, we are confronted with Unix, SAP, Java, Microsoft, etc. platforms. Each platform uses its own programming language.
- **Different programming languages:** When trying to let these platforms 'talk' to each other, there is a need for a language that is commonly understood.
- **Content Mismatch:** Not only the document management platforms are a hurdle when working together with different companies or entities within one company, the document formats are equally a problem in different settings. Even when all companies use Microsoft based word processing, one encounters issues regularly while using different versions of the Office Suite.
- One data standard that is exchangeable is XML. This is the future solution for sharing content between different systems.
With **XML** you separate content from its formatting, and define semantic meaning of the content, which can make it discoverable by other systems.
In the recent past the authorities when allowing electronic submission already defined XML standards as the way to communicate with the industry.
- So why is the industry not communicating via XML among each other?
Currently XML is mainly used by more technically skilled people. The challenge will be to find solutions where users could have the look and feel of their word processor, while in fact processing XML.

Blueprint Services

Not only file exchange and even content exchange are hurdles when working inter-company. Planning, data synchronization, exchange of electronic signatures etc. are sometimes even harder to find a solution for.

Ideally the industry would like to be able to have access to as many tools from either company, without jeopardizing the systems security and maintaining limited access. Most importantly all this while still being compliant with all the requirements related to using electronic systems in the pharmaceutical industry.

OUR FEATURED TECHNOLOGIES



Ruby

The programming language used by XAOP is Ruby, which is a dynamic programming language that is available on the .net platform (IronRuby) and the Java platform (JRuby).

Interoperability through CMIS:

Interoperable content applications are able to consume content coming from different systems (e.g. Documentum, IBM Score, etc.). CMIS has been defined by the big players in the document management field like Oracle, Microsoft, IBM, EMC, SAP, etc. Therefore, documents maintained in any existing system can be interchanged with another system using CMIS to create an externally accessible library of documents.

XML

This is the future solution for sharing content between different systems. With XML you separate content from its formatting, and define semantic meaning of the content, which can make it readable by other systems.