XML4Pharma Newsletter

Bimonthly newsletter of XML4Pharma, a subsidiary of
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XML4Pharma lectures at international eCTD course

Jozef Aerts of XML4Pharma will lecture about XML in electronic submissions at the international eCTD course on September, 19th, in London. This 2-day course is organized by IBC Life Sciences (http://www.ibc-lifesci.com/). The lecture is named: "What do I need to know about XML to work with the eCTD". The topics treated are:

- Do I need to understand XML ?
- Working with XML-elements in the eCTD
- Help, I don't understand the DTD !
- Do I need software ?
- Integration with other new Pharma IT-standards
- The (technical) future of the eCTD. Can I prepare for it ?

The FDA requires the "Common Technical Document" (CTD) as per mid 2003. The electronic version of the CTD, the eCTD, can save submitting companies a considerable amount of time and money compared to when using a paper submission. Therefore, moving directly to the eCTD is strongly advised. The course tackles all aspects of the eCTD, including the IT aspects. The course is given by a number of internationally recognized experts.

Website in XHTML

It wouldn't be appropriate to promote the use of XML, and have our website in good old-fashion HTML. Therefore we are now transforming all our web pages from HTML to XHTML. The tool we use for this is called Amaya, and can be downloaded for free from http://www.w3.org/Amaya/. Moving to XHTML opens a new range of possibilities, such as tranformation to Java Server Pages (JSP), to embed applications using databases and production of rich, dynamic content.

XML4Pharma invited to give post-conference course at InfoTechPharma 2003

XML4Pharma has been invited to give the post-conference course on XML at InfoTechPharma 2003. The InfoTechPharma Conference and Exhibition is the yearly most important meeting place for leading informatics and IT specialists in the Life Sciences industry. It is now in its seventh year.
By organizing an XML course, the organizers recognize the importance of XML in Pharma IT, and the necessity of education in it (the other post-conference course is on 21 CFR Part 11).
More information will soon be available at **www.InfoTechPharma.com**

XML4Pharma tips: filtering in XML

Many developers of applications that read text (e.g. from web forms) and store it into XML files, forget that the text itself can lead to invalid XML files. This is e.g. the case for applications developed for electronic submissions or clinical data management. For example, if a user of the application enters the sentence, "using doses <5 or >20 mg", the application will introduce an XML element <5 or>, which is regarded as an (invalid) XML element. In the worst case, this will lead to refusal of the application to work with the generated XML files, even refusal to show the contents of the XML file.
Therefore, applications that read text and store it into XML files should contain a filter that transforms every occurrence of '**<**' and '**>**' (there are a few others) into their entities, i.e. **<** and **>** . The Java classes (which can easily be converted to VB or C# or any other classes) to do this can be found at our website under **http://www.CompChemCons.com/goodies**.
Even commercial software does not always take this issue into account. So, in order to prevent invalid XML files, users can best be careful, and use the entities **<** , **>** for the characters '<' and '>' (or test the software on this issue before use).

Volunteering at CDISC

XML4Pharma is an active supporter of the CDISC (Clinical Data Interchange Standards Consortium) initiative, which is developing a new set of standards (in XML) for the retrieval, storage and exchange of clinical data. We believe this new set of standards is an important step in accelerating clinical data exchange between CRO's, sponsors and authorities.
Therefore, at the last meeting in Frankfurt, we volunteered to become a member of the E3C working group (the European CDISC group). CDISC acknowledged this and asked us to act as the XML expert within E3C.
XML4Pharma has already developed some tools for working with the new CDISC standards. Some of these are freely available from our website:
www.CompChemCons.com/CDISC/