

XML4Pharma Newsletter

**Bimonthly newsletter of XML4Pharma, a subsidiary of
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XML4Pharma is a “CDISC Registered Solutions Provider”

As the first company in Europe, CDISC has recently appointed XML4Pharma as a “CDISC Registered Solutions Provider”.

This quality label is only given to companies and persons with a proven record in CDISC matters. By this assignment, CDISC endorses that XML4Pharma is experienced in the implementation of the CDISC standards.

For us, this rewards the knowledge investment we have made into CDISC standards for more than a year now.

So far, XML4Pharma is the only independent consultancy company in Europe that has been assigned this label.



If also your company wants to benefit from our thorough knowledge of the CDISC standards, just give us a call.

Now available: the CDISC-ODM-Checker (test version)

We are currently developing the CDISC-ODM-Checker. This software package checks a given CDISC ODM file (v.1.1) on 3 levels, which correspond to the levels developed by the CDISC Conformity Taskforce:

- Level 1: the ODM file is well-formed and valid XML (checked against the DTD).
- Level 2: the ODM is conform the standard as published on the CDISC website.
- Level 3: The ODM file uses the by CDISC recommended codelists (such as LOINC) in a correct way.

Whereas level 1 is a technical minimal requirement (otherwise computer systems will not be able to correctly read the ODM file), level 2 requires that all forms, items, are in correspondence with the study definition in the “Study” section of the ODM (which can be in another file), that coded values are found in the codelists, that values are within the range given by the study definition, and that e.g. date and timestamps are in the correct format.

We recently finished the implementation of

level 2 checking, and expect to have the full software ready and tested by the end of August.

The CDISC-ODM-Checker will be made available at no cost to CDISC members. Companies that would like to test the applicability of this tool can now receive a free test version. Just send us a short e-mail and we will send you the software.

Extensions and customizations of this software (e.g. for use as a plug-in into your own software) will become available on commercial basis.

21 CFR Part 11 and XML

How can you ensure that your electronic data are still readable within 20 years from now ? In what format will you deliver data to an FDA inspector ? In which format do you archive your legacy data so that the FDA still can read it when they inspect you ? Can the FDA read an electronic signature in the propriety format of your software provider ?

Many pharma companies are only now starting to implement 21 CFR Part 11 and are starting to think about these questions. Very many software companies are now claiming to be "21 CFR 11 compliant" without providing an answer to the above questions. So are they really compliant ? We doubt so !

Only a few software providers now provide the ability to export data in the vendor-neutral, human and machine-readable XML format. Most of them still provide propriety solution which can't be guaranteed to be supported in future.

However, even if you have a system of such a provider, there is a very good chance that all your data can be exported in XML.

Also, it is becoming very clear now, that the FDA is moving into XML as their preferred data format.

XML4Pharma has a lot of experience in developing solutions where the data are exported from a database into XML format. Just not XML format, but with such a structure that the data are easily readable, both by humans as by computer systems, and by the FDA of course.

So, if you think about archiving or exporting data into XML format, just give us a call. We are the specialists !

An interesting short article about 21 CFR Part 11 and XML can be found at:

www.pti-international.com/g/docs/issue8pharmtecharticle.pdf

Brookhaven Database goes XML

The very well known Brookhaven Database with experimental protein structures (also known as the PDB database) has recently made all its protein structures available in XML format. This rises the question whether new software packages working with protein structure will now embrace XML technology.

Personally, we don't think so. Of course the PDB format is already a well-established standard, so why have another format ? Our opinion is that the use of XML for protein structures will surely be beneficial in applications where the PDB information is embedded in or mixed with other information, where XML is already used. Also, the availability of protein structures in XML will enable object oriented developers software to develop software to work with proteins, at a much lower cost than ever before.

PDB files in XML format can be downloaded from:

<ftp://beta.rcsb.org/pub/pdb/uniformity/data/XML/>