

EWG M2 Recommendation to the ICH Steering Committee
Electronic Standards for the Transfer of Regulatory Information (ESTRI)
File Format Recommendation – XML

10NOV2005

Title: XML

Background:

It is recognized that there is a need to exchange regulatory information in a common electronic interchange format. The information may be tabular data, graphic, or structured text.

Recommendation:

The M2 EWG recommends the adoption of Extensible Markup language (XML) as a standard interchange format.

XML fulfills the following requirements:

- It is an open standard (developed by a working group at the World Wide Web Consortium - W3C);
- Many compatible software products are available;
- XML allows the transfer of electronic files whose contents can then be extracted into functional databases;
- XML allows the use of viewers which are open source, or freely and widely available;
- XML source documents are text files which are human readable.

Conditions:

None

Remarks:

XML documents can be standalone (“well-formed”) or they can be created according to a Schema or Document Type Definition (DTD). XML documents may be rendered for display in a web browser through the use of a stylesheet. The Expert Working Group places no restriction on the use of XML in these ways. It is expected that these additional criteria will be defined by application specific specifications or by regulatory authority requirements.

Additional information can be found at the W3C web site at www.w3.org