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XML Initiatives in Pharma

Dale **Waldt**

Abstract

The pharmaceutical industry has been slow to adopt XML until recently. Initiatives in the US and EU, as well as other jurisdictions, have begun that use XML to define important documentation formats as part of the drug product life cycle. In the US the FDA is mandating that drug product descriptions called "labels" be submitted in an XML format called the Standard Product Label (SPL) language by the end of 2005 and similar mandates are being made in the EU and other regions. Since most pharmaceutical companies are international, companies are scrambling to figure out the best method for managing their data in order to meet all of meeting these specific requirements. Also, drug label information will become an important component in the broader set of medical records and prescription standards that are being developed concurrently. This session will describe the roles and status of these standards, initiatives for adoption in the US and the EU, and provide some ideas on strategies for managing data within this complex set of requirements.

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Biography

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Mr. Waldt provides XML and electronic system/product development support through aXtive Minds, Inc. aXtive Minds focuses on XML solutions for publishing, compliance, legislative & regulatory, and related applications. Dale previously served as an Industry Consultant to OASIS. Mr. Waldt was VP Product Technology at RIA, the tax publishing business unit of the Thomson Corporation where, for 11 years, he led teams in SGML and XML system and product development and was an integral member of the senior management team. In the 1980's, Dale participated system development at the IRS in Washington, DC. Dale co-authored The SGML Implementation Guide (Springer 1995) and was founder and publisher of <TAG> The SGML Newsletter for 11 years. Dale has taught, spoken, and written on SGML/XML and related standards and technology worldwide for many years.

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