

# Edata Integrity Report

Healthcare Industry Best Practices, Case Studies, Analysis & News

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## OUTLOOK: 2008 PROMISES TO BE BUSY YEAR FOR LIFE SCIENCES COMPANIES

*By Patricia Santos-Serrão*

Now that 2007 has come to an end and some companies are still wrapping up projects from last year, forward thinking companies have already been planning for challenges

that they will face in 2008. With that in mind, there are a number of initiatives and programs that are going to keep life sciences companies of all sizes busy in 2008

### **eCTD Deadline: January 1, 2008**

The much discussed topic of mandatory eCTD has arrived, and as many already know, starting January 1, 2008 the Center for Drug Evaluation and Research (CDER) division of the Food and Drug Administration (FDA) has mandated that all investigational and/or marketing applications be submitted in electronic format be submitted in an electronic Common Technical Document (eCTD) format.

Companies looking to implement an eCTD publishing solution inhouse should look for more than a solution that will merely produce eCTD compatible output. Getting a company eCTD ready is more than just the ability to produce PDF files with the appropriate hierarchy and XML backbone for navigations. The lifecycle management of the product as a whole becomes critical in managing changes and requests for information from global agencies. The impact of document management and document changes is significant in its relation to product registrations and submission lifecycles. An ideal integrated solution must manage the document, submission, and product lifecycles globally.

### **Developing a Regulatory Strategy for Products**

The development of a Global Regulatory Strategy Document (GRSD) is a valuable resource that should also be on the "to do list" of regulatory professionals. A Global Regulatory Strategy Document is a game-plan type document that outlines a regulatory strategy for achieving a company's objectives in marketing and supporting a drug or device. There are no guidelines or regulations around how a regulatory strategy should be compiled. However, a number of industry organizations have resources and conferences that can assist in outlining what should be included for pharmaceuticals, biologics and medical devices.

### **Developing a RiskMAP Strategy**

Companies should also develop a Risk Minimization Action Plan (RiskMAP) either as part of a more diverse GRSD or as a separate initiative. A RiskMAP includes both risk assessment and risk minimization and a RiskMAP strategy should be multidimensional and address various methods of minimizing risk.

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A RiskMAP should be developed to reduce and control the potential risks of drug/device misuse, abuse, and general increased risk due to target populations demographics and/or contraindications. A RiskMAP strategy must focus on outlining the following:

- Appropriate drug labeling (i.e., black box warnings)
- Responsible product promotion (including warnings)
- Controls on distribution (highly addictive products)
- Proactive pharmacovigilance
- Appropriate education of healthcare professionals, patients and sales personnel

The year 2008 will be another challenging year for life sciences companies given the ever evolving requirements of the FDA. Perhaps it can be viewed as more challenging than ever since the FDA is finally implementing the formal process whereby applications must be submitted in electronic format. This should really come as no surprise to anyone, but still, companies need to be prepared and have the ability to move quickly so as to not compromise their businesses in both the short and long-term.

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