
From: Michael Perfetto
Sent: Tuesday, April 26, 2011 3:44 PM
To: Doug Boothe
Cc: Bill Ostrowski
Subject: SOM
Attachments: Suspicious Order Monitoring (2).doc

Umesh put together this summary...for us.

We can review ...next week and move on this...

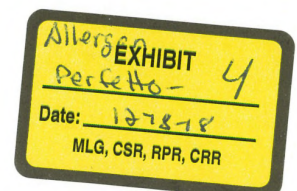
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Suspicious Order Monitoring/Reporting - Summary

Background/Objective:

DEA requires registrants who distribute controlled substances to have a mechanism to identify and subsequently report all suspicious orders – per DEA 21CFR1301.74(b).

Beginning in 2007 and continuing throughout 2008, the DEA made high profile examples of the “Big Three” in a renewed effort to bring Controlled Substance registrants into compliance with SOM (Suspicious Order Monitoring). The DEA imposed strict sanctions and significant fines on Cardinal, McKesson, Amerisource Bergen and CVS in amounts as high as \$34 million for non-compliance. A more recent example is back in June of 2010 where Harvard had their license temporarily revoked.

SOM has become one of the largest “hot topics” in the eyes of the DEA within the industry right now. It has been said that the focus of the DEA has shifted to manufacturers.

Current SOM processes at Actavis are threshold based and present a risk to Actavis for non-compliance to current standards. As a result, this requires us to upgrade to a more statistical-based model.

Approach:

Our initial approach was to expand our current model to fit DEA requirements. However, it was recognized that due to the complexity of developing the statistical-based model, we concluded that a third-party expert would help us minimize risk.

Cegedim Compliance Solutions (division of Dendrite) is an industry leader with extensive experience, and expertise in developing SOM models for the pharmaceutical industry with over 18 SOM clients to date. Cegedim offers compliant solutions that are unique in their ability to combine former high level DEA associates along with their PhD statisticians to offer the most comprehensive and defensible, customized SOM model on the market.

Cost/Benefit:

- The upfront fixed cost of \$50K plus T&E to develop SOM statistical model and associated SOP's/processes
- Ongoing Maintenance Support – less than \$25K annually (optional to support changing laws and/or other variables such as customer profile changes or changes to business model.
 - DEA compliance – avoid fines/penalties and potential lost sales
 - Streamline activities
 - Reducing costs and management burden
 - Increased customer confidence (selling point)
 - Leverage the design to manage reserve order process