

**Minutes
SIDI Working Group
In-person Meeting**

June 22, 2010, 8:30 am – 3:30 pm EDT
CHPA Board Room
900 19th Street, NW, Suite 700
Washington, DC 20006

I. Presentation by Rx360 representative

Kenneth Drost, Executive Director External Quality at Amgen, presented to the SIDI WG the background of the Rx-360 initiative, its framework, achievements and challenges. Rx-360 is an initiative for the pharmaceuticals industry that parallels what the SIDI WG is attempting to do in that it addresses supply chain issues, including supplier qualification and shared audit system to reduce the burden of onsite audits. The tragic consequences of raw material contamination leading to tainted drug products and the philosophy that patient safety comes before competitive advantage provided impetus for pharmaceutical industry self-regulation to make secure the supply chain for all those at stake. First initiated by a consortium of pharmaceutical companies, Rx-360 is now an international non-profit, volunteer and membership-based organization (of about 30 companies) managed by an independent law firm. In a relatively short period of time, Rx-360 it has made many strides, gaining traction within the pharmaceuticals industry as well as with FDA, and is close to launching a pilot audit. Since March 2009, the Rx-360 website was successfully launched to distribute information to registered users, such as emerging issues that would impact the pharmaceutical industry, and two standards have been approved with two more on the way. Not without obstacles, the organizers of Rx-360 faced resistance from those proponents of the status quo (companies want to conduct their own audits). The organization's goal is still to recruit support from more companies—for a total of 50—to cover about 90% of the industry. Fortunately, Rx-360 was able to gain the support of FDA (though not publicly) and industry trade groups, many of which actively participate in Rx-360 meetings as observers.

Some of the key ideas behind Rx-360 include:

- Non-competitive; instead, leverage strengths of all parties
- Broad and inclusive membership (pharma companies pay \$2500/mo; suppliers pay \$500/mo)
- Not designed to replace regulatory systems or oversight; proactive self-regulatory initiative
- Flexibility as to level of involvement of members
- Transparency in processes; information shared with the public
- Third party management of Rx-360 and ownership of audit database
- Set standards to create a level playing field – endorse existing best practices, implement quickly, continuously refine

- Sharing audits – increase compliance, quality and efficiency; leads to safety and confidence for patients
 - Audit information from one member company is shared with many members
 - Members can sponsor and audit
 - Rx-360 may initiate audit based on consortium input
 - Members access existing audits (redacted and housed in secure database) by subscription
 - Third party auditors are used and selected by application process

SIDI WG and Mr. Drost shared questions, comments and answers:

- Are there guidelines for sharing supplier audit reports?
 - There are guidelines to ensure confidentiality protection for suppliers (suppliers may choose to share or not to share audit reports)
- In Rx-360's experience, some international standards are better accepted than regional standards
- Standards approval process – Ken Drost will send to Andrew Shao
- Confidential information is redacted by the law firm who is the third party project manager and owner of the audit database (members do not have direct access).
- The law firm, company and third party auditor work together to make sure audit findings are closed out.

Contact information for Rx-360 <http://www.rx-360.org>

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Discussion among SIDI WG members:

- Some suppliers e.g., BASF, find the 3rd party auditor concept challenging and prefer group audits as an alternative to single audits
- 3rd party audit system provides balance to the current situation where some suppliers are constantly audited while some do not get audited at all.
- The dietary supplement industry is far from being able to have a shared audit system; it first needs a shared language i.e., standards that everyone in the industry understands and accepts

II. Update on the governance of the SIDI WG

The trade associations are initiating an agreement document, with the help of CHPA's legal counsel, Alison Manhoff, to formalize the governance of the SIDI WG which consists of members of five trade associations. The CHPA Task Group Agreement document will be used

as a model. Some of the issues addressed by this agreement document include the governance structure of the Working Group (not expected to be significantly different from the process already in use), ownership and branding of documents produced by the Working Group, website approval and maintenance, etc. Once a draft is completed, the SIDI WG association representatives will be convened to vote on the agreement document.

III. Update from Subcommittee #4 (Supplier Qualification Guideline)

Mike Bradley, chair of subcommittee #4, updated the WG on the Supplier Qualification Guideline development process, current status and expected next steps. At the SIDI WG meeting held in December 2009, subcommittee #4 was tasked with developing an umbrella document necessary to address the ambiguity in the DS GMPs concerning supplier qualification and overcome the lack of FDA clarity as to its expectations for compliance—proactively defining expectations ahead of FDA guidance (We can see that FDA is gearing up enforcement through FDA issued warning letters for GMP violations and its plans to overhaul food GMPs to emphasize supplier quality management.) Also, this guideline looks at supplier qualification from a broad perspective, which is necessary prior to defining individual guidelines such as the certificate analyses verification and dietary supplement component GMP guidelines.

Over the past 6 months, the Subcommittee has developed a mission statement that identifies risk management principles as the basis for a supplier qualification guideline that would satisfy compliance requirements of the DS GMPs, and a matrix diagram to illustrate the elements of supplier qualification according to CFR Part 111.75, elements of supplier management and recommendations for best business practices. Currently, the matrix is substantially completed and the Subcommittee is benchmarking model documents e.g., 2007 IPEC Qualification of Excipients for use in Pharmaceuticals and the 2006 ICH-Q9 Quality Risk Management document. At the Subcommittee's next meeting, it will review the ICH-Q9 criteria for defining and classifying risk, risk factors related to supplier qualification, and tools for risk evaluation.

The next step in the process is to draft the guideline document, perhaps in sections including the background/preamble, risk management principles, examples of low/high risk suppliers, major elements of qualification, etc. Mike Bradley asked that SIDI WG members volunteer to draft specific sections of the guideline.

Considerations:

- Need greater representation of supplier perspective, especially small/moderate size companies
- Participation from broader industry (beyond WG members) to garner more experts, perhaps grant observer status
- Develop an outline and target experts to draft sections
- Solicit comments on draft documents from stakeholders – post on website
- Address distributors and expectations for them in the guideline

- Risk management principles need to be defined first, or in parallel with the outline, before drafting sections.

Those who volunteered to draft sections of the guideline are:

Amy Caplette (Nutrilite)

Al Shoemaker (NBTY)

Mike Bradley (Perrigo)

Kevin Boot (Embria)

Marvin Herr (Bayer)

Paul Bolar (Pharmavite)

Ranga Velegaleti (BASF)

Andrew Shao (CRN)

Devon Powell (AHPA)

Andrew Shao and Mike Bradley will initiate the outline and send a draft to the Subcommittee for comment at the next call in mid July; then the entire WG will have a chance to comment.

IV. Update on the new SIDI WG website: <http://www.vendorqualification.com/>

Andrew Shao (CRN) presented the beta version of the website, which is available for members to view, but is not yet “live” for the public. Currently, registration is required for users (registration information allows us to solicit feedback from users). The WG expressed that the website looks professional and user friendly.

Comments from the WG:

- Include opt-in/opt out disclaimer
- Post list of companies using SIDI on the website
- Employ an analytics program to track who/what/how the site is used
- Add “How to get involved” link
- Add “Resources” link (provide SIDI Protocol, NSF Stability Testing Guideline, etc)
- Add to registration page questions about size and focus of company
- Add to SupplySide to Upcoming News section
- Add a FAQ section

Considerations

- Launch date - SupplySide West a possibility
- How to drive traffic to the site
 - Link on current SIDI websites, trade association websites
 - Need a graphical icon, a single logo or banner
 - Link on other websites -target organizations providing GMP training/consulting
 - Link on tradeshow website e.g., SupplySide West, etc
 - Post SIDI WG logo or website on booths of companies using SIDI at SupplySide
 - Use Linked-in to get connected
 - Listserves and forums

- Copyright issues; trademark SIDI WG logo
- Page for Working Group Only
 - Sharepoint/ collaborative data sharing capability or project management software
 - CHPA is transitioning to Sharepoint and will update the group
- Fundraising- post funders' logos/banners on SIDI WG website in a non-advertising way

V. Update on SIDI WG presentations at trade shows

Harry Rice (UNPA) shared with the WG that a proposal was submitted and accepted for a session at SupplySide West 2010 (<http://www.supplysideshow.com/2010/west/nutrition-2.html>)

Title: *Ingredient Supplier Qualification and GMP compliance: progress on a Supplier Qualification Voluntary Guideline*

Date: Wednesday, October 20; Nutrition Track II

Time: 3 – 3:50 pm

Participants from the WG include Harry Rice, who will present critical aspects of risk based supplier qualification and GMP compliance, and Anthony Palmieri (DSM) and Mike Bradley (Perrigo), who will present the supplier and manufacturer perspective, respectfully, on supplier qualification. The group hopes to also launch the Supplier Qualification Guideline at this show. Other trade show/events to consider include ASQ, DCAT, IFT, etc. Andrew Shao proposed formation of a meeting planning subcommittee to determine which meetings/events are appropriate to have the SIDI WG present and to develop proposals for sessions. The IFT 2010 proposal deadline is in November.

VI. Group discussion: Initiating/reconvening work in other subcommittees

Besides in Subcommittee #4, activity of other subcommittees have slowed or stopped because of the need for the umbrella guideline being developed by Subcommittee #4. The group discussed whether there is work that should be done in parallel to the Supplier Vendor Qualification Guideline (SVQG) e.g., update of the SIDI Protocol, which has issues that need to be addressed. Some expressed that the WG should focus on the SVQG to complete it quickly. Another suggestion was that other WG members not involved in current work could start other initiatives to maximize resources; both the COA Guideline and SIDI Protocol need to be periodically reviewed and expanded for global application. The trade associations will convene a meeting of their representatives to discuss recommendations for other work.

Adjourn