Rx-360 & BSI

PharmaLink, 2017

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Rx-360 Mission

Protect patient safety by sharing information and developing processes related to the integrity of the healthcare supply chain and the quality of materials within the supply chain.

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Rx-360 Audit Programs

Membership

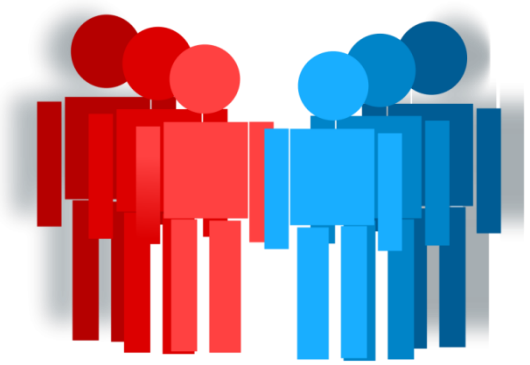
Broad and Inclusive

- Global
- Small and large companies
- Suppliers and manufacturers
- Branded and generic
- Regulatory agencies, standard setting bodies, and industry organizations participate as Observers

How We Are Organized

Operating Model

- 501(c)(6) nonprofit organization
- Volunteer based
- Companies are members not individuals
- Not intended to replace regulatory systems or oversight
- Designed to meet competition law requirements; on-going and comprehensive antitrust compliance



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About BSI

- BSI was the World's first National Standards Body and Globally recognized as champions of best practice
- Play a Key Role in Standards Development and Leading Supply Chain Risk and Compliance Based Solutions.
- Preferred EU Notified Body Co-Regulator for 23 of the World's Top 25 Global Medical Device Manufacturers
- Focused on High Risk Class III Medical Devices
- Leading Supply Chain Risk Management and Compliance Provider to Pharmaceuticals

Rx-360 Audit Programs

SUPPLIER AUDITING

The Challenge and a Solution

Rx-360 Audit Programs

The Challenge	It is becoming more difficult for manufacturers and suppliers to meet the growing requirements for audits.
Drivers	Increased Regulatory expectations and concern in Supply Chain Security and Compliance Global sourcing
Impact	Manufacturers: May not conduct audits, resulting in lack of knowledge of supplier compliance Suppliers: May not be able to accommodate all audit requests

Rx-360 AuditPrograms

The Rx-360 Joint Audit Program

Multiple Sponsors

One Audit

One Report

Shared Cost – Fewer Audits - Compliance

Rx-360 Audit Programs

Rx-360 Joint Audit Program

- ✓ Audits are conducted on behalf of members using third party auditing service providers
- ✓ Audit costs are equally divided amongst audit sponsors
- ✓ Prior to conducting an audit suppliers can exclude specific companies (i.e., competitors) from viewing the audit reports
- ✓ Audits may be requested by both manufacturers and suppliers

Rx-360 Audit Programs

Key Benefits of Rx-360 Joint Audits

- ✓ Reduce the number of audits at a supplier site while increasing the effectiveness of the audits performed
- ✓ Utilize a standardized audit approach and report template
- ✓ Improve transparency of audits and improve ‘collective’ assessment of supplier QMSs
- ✓ The report can then be licensed (with supplier approval) in lieu of conducting an on-site audit

Rx-360 Audit Programs

Rx-360 Audit Licensing Program

- Audit reports originating from the Joint Audit Program may be licensed to both members and non-members for a fee
- A list of reports available for licensing can be found on the Rx-360 website
- Suppliers determine which organizations may license an audit report through an addendum to the original CDA
- Members are provided access to the reports and corresponding materials through auditsPLUS

Rx-360 Audit Programs

Rx-360 Audit Guidelines

API and Registered Intermediates
- Adopted from ICH Q7 with additional TSE/BSE text

Excipients
- Adopted from EXCiPACT GMP standard for excipients

Basic Chemicals/Raw Materials (including Chromatography Resins Index)
- Based on IPEC/PQG excipients audit guide

Packaging/Printed Materials
- Adopted from ISO 15378 standard

GDP
- Applicable Global GDP Regulations

Rx-360 Audit Programs

Observations

- Rx-360 Audit reports use two types of Observations

Potentially Critical	A deficiency that indicates a critical system failure that may pose an immediate risk to patient safety or health, or may result in adverse impact to the safety, identity, strength or purity of a product.
Other	A deficiency against the Rx-360 audit standards, guidelines, checklists, but that are not potentially critical

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Rx-360 Audit Programs

AUDIT PROCESS

Audit Scheduling & Monitoring

In 2014 Rx-360 introduced auditsPLUS, a new custom audit database

- Members enter audit requests into auditsPLUS
- The database matches like requests
- BSI monitors the database and sends audit requests to suppliers
- The audit is tracked, viewed and made available to members through the database

Audit Process

- Audit requests are entered into auditsPLUS
- Matching process
- Scheduling
- Audit Performance
- Reporting
- Reviewing
- CAPA management
- Report Finalized
- Audit Closed

Overview

- Supplier
- Location
- Timing
- Special requirements

- Scheduling
- CDA
- Audit prep
- Draft Report
- Supplier/Sponsor Reviews

- Point in Time overview
- Observations
- CAPAs

The Sponsors incorporate the report into their internal Supplier Management Program

Rx-360 Audit Programs

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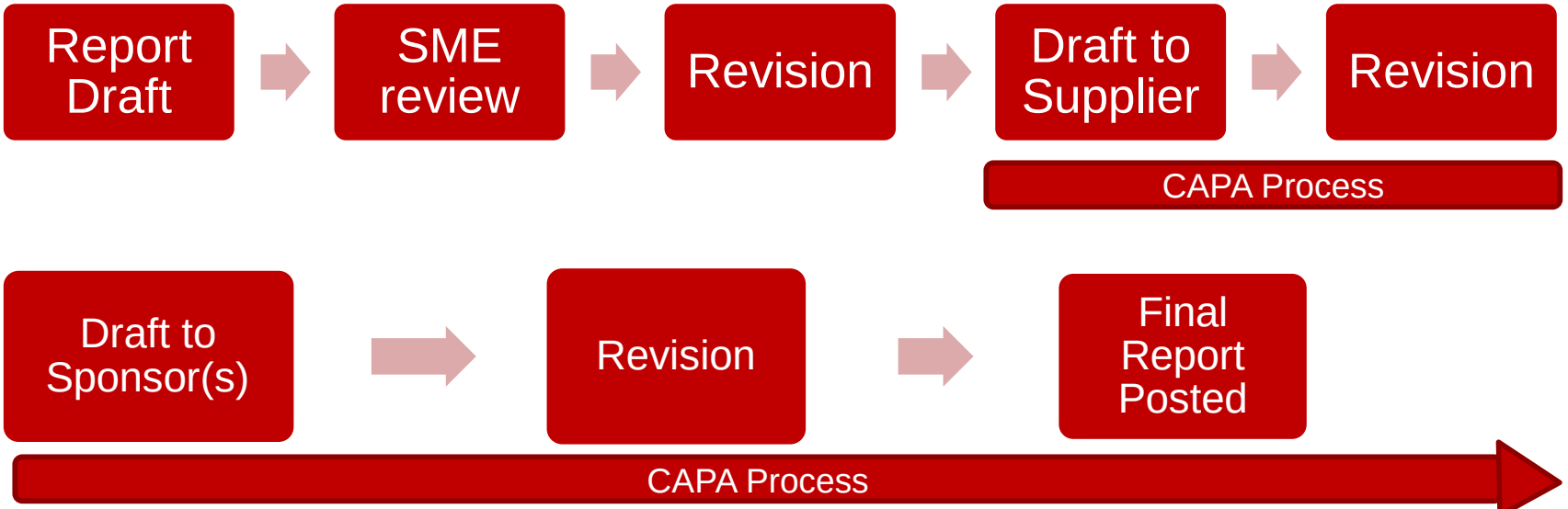
BSI

- BSI assigns auditors based on experience
- Auditors are trained on Rx-360 process
- BSI provides auditor information to Sponsor(s)



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Rx-360 Audit Programs

Membership

Requirements

Any legal entity may join Rx-360 provided that it meets the following criteria:

> Its activities relate to the research, development, manufacture, or distribution of pharmaceutical, biotechnology, or medical device products, including (i) research-based pharmaceutical companies, generic pharmaceutical companies, biotechnology companies, and medical device companies, (ii) suppliers of ingredients and components of pharmaceutical, biotechnology, and/or medical device products, and (iii) suppliers of services relating to the quality or safety of the pharmaceutical, biotechnology, and/or medical device supply chain, including distributors and wholesalers.

Excerpt from Rx-360 Bylaws, Article IV: Membership; Section 4.01 (A): Membership Criteria

Rx-360 Audit Programs

Contact Information

For further information on Rx-360 and the audit programs, please contact Ben Mills of BSI using the information below.

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Rx-360 Audit Programs