



## The Rx-360 Joint Audit Program

**Audit**Programs

### **The Current Environment**

Pharmaceutical manufacturers and suppliers of pharmaceutical ingredients and components are facing unprecedented challenges in ensuring product quality. Their supply chain is global, complex and increasingly vulnerable to adulteration and counterfeiting. These challenges can only be overcome through a strong partnership between pharmaceutical manufacturers and suppliers. As you are probably aware, there is increasing regulatory pressure to ensure the integrity of the supply chain through on-site auditing.

### **The Rx-360 Consortium**

Rx-360 is a non-profit organization developed by volunteers from the biotech and pharmaceutical industry and suppliers to the industry. The mission of Rx-360 is to protect patient safety by enhancing the quality of the supply chain and authenticity of materials within the supply chain.

Rx-360 seeks to further its mission through joint audits, information sharing and other initiatives. Further details regarding Rx-360's activities, including a list of member companies, may be found at <http://www.rx-360.org/>.

### **Joint Audit Concept and Benefits**

An Rx-360 joint audit can benefit both the Rx-360 member companies who requested the audit and the audited supplier. The benefits include:

- Reducing the number of pharmaceutical audits at a supplier site while increasing the effectiveness of the audits performed.
- The Consortium's third party auditors will utilize a standardized audit approach and use a standard audit report format.
- Only the most qualified third party auditors will be utilized, ensuring that the audit is effective, efficient and audit standards are applied consistently across suppliers.
- Rx-360 member companies can reduce the number of audits they perform by utilizing this joint auditing approach.
- The audit report will be placed in an electronic database that other consortium members can access in lieu of conducting an on-site audit themselves.

As a supplier, you will have the option to restrict access to your audit report. Additional audit process details can be found in a separate list of Frequently Asked Questions.

For additional information about the program, please contact the Rx-360 Secretariat at [joint-Rx360-audits@dbr.com](mailto:joint-Rx360-audits@dbr.com).

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