

Trusted and Confidential Audit Licensing

The Rx-360 Joint Audit Program®



What is a licensed report?

A licensed report is the product of an audit performed by Rx-360 that covers materials produced at a facility. The audit covers the site's Quality Management System, production, testing, and supply chain security.

What does the document package contain?

The document package contains the audit agenda, auditor CV, report, CAPA Plan, and evidence of CAPA closures. Upon completion of all the CAPAs, a Closure Letter is also provided.

COMPANY	LOCATION	DATES	AUDIT METHOD	GUIDELINES USED
			Onsite	Basic Chemicals / Raw Materials
			Remote	Single Use Systems
			Onsite	Excipient
			Onsite	API
			Onsite	Primary Packaging Materials
			Remote	Excipient
			Onsite	Basic Chemicals / Raw Materials
			Onsite	Single Use Systems
			Remote	API
			Onsite	Basic Chemicals / Raw Materials



Additional License Program Benefits

- Audit reports that provide a depth and breadth of information to protect the supply chain. Reports are narrative and include audit of Quality Management System, production, in-house testing and supply chain security.
- Audit reports provide full access to auditee CAPA Plan and evidence of CAPA completion.
- Audit reports provide access to redacted Cover Page prior to licensing commitment.
- Rx-360 maintains the ownership of all audit reports. License requests are approved by the auditee, on a case-by-case basis, to protect confidentiality.
- Licensing also protects the distribution of the report versus purchasing which could be perceived as ownership. Rx-360 does not offer the purchasing of audit reports.

A Licensing Case Study

1 Year View from a Supplier Perspective

Supplier Site	Number of Audit Report Licenses Acquired in 2023	Cost Savings for Each Joint Audit Program® Audit
Site A	31	\$155,000
Site B	20	\$100,000
Site C	5	\$25,000
Site D	5	\$25,000
Site E	3	\$15,000
Site F	1	\$5,000
Site G	1	\$5,000
2023 Audit Deflection Savings	66	\$330,000

Each supplier site had an audit conducted in last 15 months making the available licensable audit report within an industry accepted 2 to 3-year window.

Each audit conducted took on average 1.5 days to complete + preparation and follow-up time.

Through the Joint Audit Program® model, this supplier was able to save on the resources associated with 66 onsite audits and realize savings of **\$330,000**.

Also expedites cycle time to supply.

Joint Audit Program® Model Value to Industry in 2023

Reducing the Cost Burden Through Licensing

	~# of Licenses Issued in 2023	Cost Per EA	Financial Impact
Biomanufacturer Cost to Audit	~800	~\$12,000	~\$10M
LESS: Cost Per License	~800	~\$2,500	~\$2M in Cost
NET Benefit to Biomanufacturers			~\$8M in Savings
+Supplier Savings via Audit Host Deflection	~800	~\$12,000	~\$10M
Net Financial Benefit to Industry in 2023	~800		~\$12M

Utilizing a Joint Audit model allows a pharmaceutical supplier save on expenses associated with hosting onsite audits and in building strong quality-based relationships with their manufacturer customers.

The average cost in some scenarios are that hosting an audit can cost a supplier \$5000 a day in expenses. This does not include the expense burden being absorbed by the manufacturer, which could be as much as \$25,000 in some cases.

Through a Joint Audit Program® a supplier can provide permission for a manufacturer business partner to license a recently conducted audit report for a fee that is a fraction of conducting an onsite audit. In some cases, the savings of licensing versus conducting is 90%. The supplier could then save up to the previously referenced \$5000 per day, through that audit license transaction.

"Just in 2022, we've saved \$110,000 in potential audit expenses because customers have licensed our audit reports through Rx-360. Self-sponsoring audits pays for itself in no time when factoring in the number of times our audit reports have been licensed. We could have had 29 onsite audits this year, but because of Rx-360, we only had to have 18."

Chris Boytim
Supplier Quality Manager, New Age Industries

For more information on the Rx-360 Joint Audit Program® and how it can benefit you, as well as how you can join the Rx-360 consortium, please contact us at info@rx-360.org.