



The International
Pharmaceutical
Supply Chain
Consortium

The Benefit of the Rx-360 Membership and the Joint Audit Program[®]

June 2024

Author: Anonymous

Opportunity Identified: Joint Audit[®] Program

Value to Suppliers

Value by the Numbers

When evaluating the benefits of any program the first question is usually “What is the Return On Investment (ROI)?”. The table below outlines the numbers accumulated over the course of 2023 for our company.



Item Reviewed	Amount	Quantity
Membership Dues (Annual)	\$6,957.00	
Cost of Sponsoring Audits (2023 combination of sole and co-sponsorship)	\$34,290.24	3
Credits Earned Due to Licensing of Sponsored Audits 2023	\$34,676.23*	N/A
Savings from Licensing Audits	\$425,000.00**	85
Rx-360 Working Group Participants and Savings	\$8000.00***	8
Total Savings Associated with Rx-360 Membership	\$427,428.99	

* Some credits earned in 2023 were as a result of 2022 license acquisitions

** ** Assuming \$5000.00 savings per onsite audit

*** Assuming \$1000.00 per employee in annual education budget

Sponsoring 1 Audit through the Joint Audit Program®

Freed Up 57 Work Days for Other Tasks



85 Audit Reports Licensed

= \$425,000

in savings & licence acquisition



In 2023 the Supplier recognized 85 audit reports licensed, resulting in an estimated savings related to having an audit done by Rx-360 and subsequent license acquisition of \$425,000.00. Taking into consideration the annual membership fees of \$6957.00, the cost of sponsoring 3 audits, and keeping steady with 8 Supplier employees involved in Working Groups and those benefits a total savings of 427,428.99 was realized in 2023.

It is important to note that Rx-360 has not raised it's membership fees in 15 years, further highlighting the benefit of this Supplier's membership as the ROI has significantly increased year-over-year (YOY).

The benefit seen by the numerous Supplier sites varies dependent on the number of audits licensed by customers. In 2023 the number of audit reports licensed per site audited ranged from 2 to 21, for an estimated savings of \$10,000 - \$105,000, assuming \$5000.00 savings per onsite audit not hosted.

However, estimated cost is not the only benefit of the Rx-360 Audit program. The commentaries below speak to some real-life identified benefits.



Site A:

The obvious benefit is that it frees up our resources: customer audits are hosted by 2 quality managers and 1 quality engineer and if you look at the previous audit report, it was licensed 17 times in its first year, plus the audit sponsors, that's 57 (wo)man-days that we were able to spend on other activities than customer audits. And that's not even counting the time spent on customer audit scheduling, preparation, and responding to audit observations. It's definitely a huge plus.

Ahead of the audit, it was very useful to receive the list of "sponsor needs". This was new compared to a previous Rx-360 audit in 2020 and it was a great tool to prepare for the audit and make sure we had the right records ready for the auditors.

Finally, getting the opportunity to review the audit report before it gets sent to the sponsors makes the process more interactive than your typical customer audit and it allowed the site to catch a few mistakes and inaccuracies, which has the benefit of resulting in a more accurate report and represents an increased value for the customers who license it.



Site D:

Our site completely agrees with the comments above. Our site continues to host ~30 customer audits a year yet there are still many requests that we cannot accommodate. The Rx-360 audit only occurs every 3 years (to be relevant) and satisfies many customers who are not able to get on our schedule.



Site M:

Rx-360 had appropriate expectations coming into the audit which were communicated in a clear and timely manner. It was communicated that the audit would be focused on ISO 9001 compliance and the following Rx-360 audit checklist guides: Basic Chemicals/Raw Materials and Supply Chain Security. The auditor stayed within the scope of the audit and demonstrated an understanding of our business and the requirements of our products.

A Continuous and Evolving Relationship

The Rx-360 organization and its programs have demonstrated significant progress over the past 6 years, becoming a key partner to Manufacturers and Suppliers in the Pharmaceutical and related industries. The scope of the RX-360 audit program continues to grow and provide additional benefit in an increasing budget conscience world.

While the program is very positively received, there are opportunities for continuous improvement, which is communicated through the Supplier sites and Rx-360 representative. Some examples we are looking at to expand and improve upon in the future are the following:



Site J:

There was a fair bit of back and forth during the audit report review to ensure specific customer requests for detail were met. Eventually all parties were satisfied, and the report was finalized. This could be improved upon going forward to reduce the time commitment after the completion of the audit.



Site L:

The primary agenda was received well in advance. However, one of the co-sponsors attempted to expand the scope a week prior to the start date which resulted in additional back-and-forth between the site, Rx-360, and the co-sponsor. The communication between Rx-360 and the site was clear and timely. We are not sure why there was a disconnect with the co-sponsor, but it would be helpful if this could be avoided in the future to reduce time and frustration.

There were technical issues with sharing documentation via MS Teams due to complications of having this specific auditor already within the site's systems for previous, unrelated audits. Lesson learned: Verify access prior to the day of the audit.

Summary

The relationship with Rx-360 has proven to be invaluable to this Supplier. While the majority of this case study has focused on the Joint Audit Program®, the additional benefits of belonging to the international consortium are likewise important: knowledge sharing, development of whitepapers and standards around topics of key concerns and the benefit of being part of a community of life-science and medical device thought leaders committed to driving positive change within the industry.

Learning more about Rx-360

Rx-360 is a nonprofit international consortium which addresses pharmaceutical and medical device supply chain security in relation to public health concerns and patient safety. It is a community of life-science and medical device thought leaders committed to driving positive change within the industry.

Rx-360 has a mission to protect patient safety by sharing information and developing processes to improve the integrity of the health care supply chain and the quality of materials within the supply chain. One of the ways this is accomplished is through the Joint Audit Program®.



The Rx-360 Joint Audit Program® is designed as a unique approach to executing audits using our Joint Audit Program® as well as licensing already completed audit reports. The program is specifically designed by Rx-360 members to help reduce audit costs industry-wide and be adjunctive to your own supplier audit program.

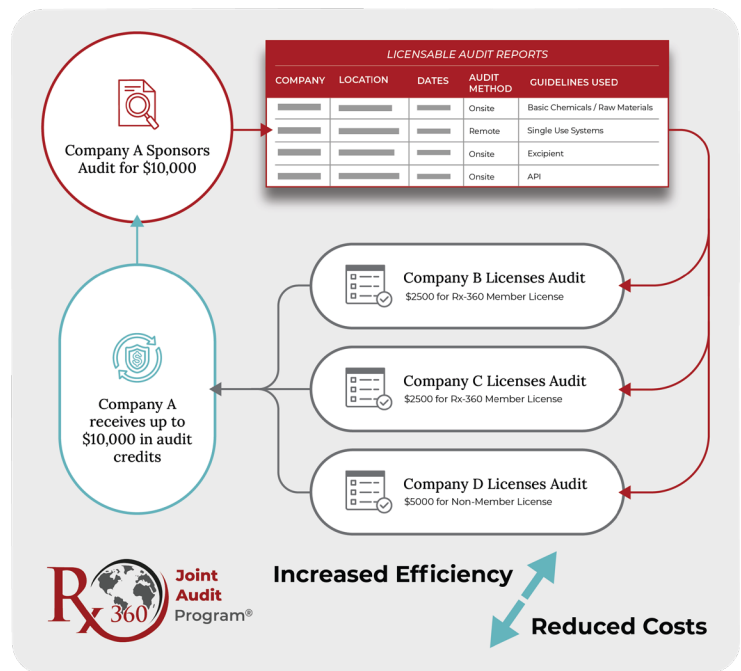
Rx-360 as a non-profit follows a very defined step-by-step approach within the Joint Audit Program®. The approach ensures that confidentiality between all parties is protected and that all audit stakeholders are aligned on the audit specifics and process. In most cases due to that approach, it is very difficult to expedite an audit. Rx-360 however will always research opportunities to meet our member needs.

Rx-360 has a mission within the audit program, to reduce industry burden and

costs associated with supplier auditing. The Rx-360 Joint Audit Program® can match sponsors confidentially for a specific audit. The sponsors 'join' together to have a single collaborative audit conducted, while Rx-360 maintains confidentiality for the sponsors. This allows for the cost of the audit to be shared among the sponsors, reducing cost burden for them, as well as overhead and time burden for the auditee.

In addition, as part of the non-profit mission, Rx-360 offers a unique credit program to members that allows for audit expense to be greatly reduced through program utilization. The program offers members who sponsor audits the chance to recoup their spend in credits.

As a member of Rx-360 one can take advantage of all aspects of the Joint Audit Program®. However, this case study will focus on the audit portion of the program and the cost and resource efficiencies that we, a supplier and as a member have gained.



Ready to Have a Seat at The Table?

Visit Rx-360.org to learn more.

For more information on our cost-effective member pricing and how our consortium can benefit your organization, please contact us at info@rx-360.org.