



Regulatory Insights on Third-Party Audits

The FDA on Third-Party Audits

FDA regulations explicitly require manufacturers to conduct supplier qualification ([FDA 21 CFR §820.50](#)). Audits are recognized by regulators as a tool for qualifying suppliers. Regulators do not distinguish audits conducted by a third party versus an internal auditor.

Global Regulatory Positions - Beyond the FDA

Other global regulatory frameworks—including EU GMP and PIC/S—recognize and even rely on third-party audits as an acceptable mechanism for supplier qualification, while maintaining manufacturer accountability. For example, the European Medicines Agency (EMA), explicitly acknowledges that third-party audits are acceptable when conducted with independence and rigorous standards ([EMA](#)), reinforcing their importance in modern supplier qualification systems.

Policymakers and regulators around the world have consistently highlighted the need for greater transparency, independent verification, and coordinated oversight across pharmaceutical supply chains. For example, U.S. legislators have emphasized that we lack full visibility into where and how our essential medicines are made ([Congressperson Doris Matsui](#)). Global health authorities such as the United Nations Office of Drug and Crime and the World Health Organization have called for coordinated efforts across stakeholders to mitigate systemic risks ([UNODC and WHO](#)). Together, these perspectives demonstrate broad support for the underlying principles of third-party auditing—even as formal frameworks for their use in pharmaceuticals remain underdeveloped.

Third-party auditors are your regulatory friends across the globe, especially when they're from a non-profit organization.

What Rx-360 Says

Our nonprofit mission to protect patient safety together with our 135-plus strong global member consortium make us the ideal compliance partner. Our Joint Audit Program® handles coordination of confidential, blinded, multi-sponsor third-party audits through to corrective and preventive action closure and licenses all audit reports to reduce redundancy and waste.

We acknowledge regulatory gaps that indicate a need for formal standardization, recognition, and governance structures to ensure consistency, independence, and scalability of third-party auditing across the pharmaceutical supply chain.

Join us in working to raise awareness and driving solutions to address these gaps. Contact us at info@rx-360.org.