

Listed below are minimum requirements for Rx-360 auditors.

For providers of auditing services, each auditor used in an Rx-360 audit must meet these requirements.

Requirement	Description
EDUCATION	Has, as a minimum, a Bachelor's Degree from an accredited university (a minimum of three years).
PROFESSIONAL EXPERIENCE	Has a minimum of five years of GMP operational pharmaceutical experience with a minimum of 3 years of that experience in a quality related function. Operational experience includes those skills and competencies gained while working within a pharmaceutical GMP environment.
REGULATORY KNOWLEDGE	<p>Is knowledgeable about pertinent regulatory and best-practices requirements (e.g. ICH Q7 for APIs, CFRs for USA, IPEC guidelines for excipients). The training and assessments must be fully documented.</p> <ul style="list-style-type: none"> ◆ API ◆ Excipients ◆ Basic Chemical/Raw Material ◆ Packaging ◆ Chromatography Resins ◆ GDP
AUDITOR TRAINING	<p>The provider of auditing services the auditor is associated with has a quality systems approach that includes training and refresher training of auditors.</p> <p><i>Note:</i> Good communication and interpersonal skills are a “must” and are included in this category.</p>
AUDIT EXPERIENCE	<p>Had involvement in at least five audits of the relevant supplier/audit type, including leadership of at least one relevant audit. [See also the maintenance requirement (<i>i.e.</i>, at least three audits of the relevant supplier/audit type in the last 12 months)].</p> <p><i>Note:</i> Professional experience may impact the amount of audit experience required.</p>
ACCREDITATION/ CERTIFICATION	Auditors is accredited/certified by a program recognized by Rx-360 e.g., ASQ, ISO17020, IRCA, or APIC. Exceptions to external accreditation will be evaluated on an as-needed basis and justified appropriately.



MAINTENANCE OF QUALIFICATION	The auditor is up-to-date on Good Manufacturing Practices (GMPs) (this means, at a minimum, annual refresher training on relevant GMPs) and currently performing audits (at least three audits of the relevant supplier/audit type in the last 12 months).
RECORDS OF QUALIFICATION	The provider of auditing services the auditor is associated with maintains a formal recordkeeping system of auditors' qualifications. The system includes information concerning each auditor's areas of expertise.
LANGUAGE	The auditor is able to communicate with Rx-360 in written and spoken English. In addition, the auditor is able to communicate effectively (e.g., via planned use of interpreters internal to auditee or contracted as necessary) and demonstrate sensitivity to or experience with the local culture.
WORK HISTORY	A) The auditor was not an active employee of the firm to be audited in the past 5 yrs.
	B) The auditor does not have a full time job inside the pharmaceutical industry.
	C) The auditor is not employed in any matter that would create a conflict of interest.