

Annex 6: Auditor Competency requirements

1. Auditors must comply with the requirements of the IRCA 1000 auditor grade plus additional PQG requirements.

The IRCA 1000 auditor requirements are available from the IRCA website:

<https://www.quality.org/file/3459/download?token=T20rdGPe>

Note: IRCA Internal and Provisional Auditor grades do not meet the applicable requirements.

2. The additional PQG auditor requirements are as follows (these may be updated from time to time. Changes will be advised to the Certification Body):

a. Auditing competences - successful demonstration of:

- The application of the fundamental competencies to pharmaceutical supplier audits in relation to the PS standard.
- The understanding and application of GMP principles applicable to the supplier.
- The understanding of the importance of managing hazards and risks relevant to suppliers to the pharmaceutical industry.

b. Education & Work Experience - successful demonstration of:

- The additional requirement for at least 3 years of the IRCA general work experience to be in the pharmaceutical or pharmaceutical supplier industry.
- The additional requirement for the 2 years of the IRCA quality work experience to be replaced by at least 4 years in quality assurance related activities with evidence of auditing in the pharmaceutical or pharmaceutical supplier industry.

c. Auditor Training - successful completion of:

- An IRCA/PQG certified Pharmaceutical Supplier Auditing Course or recognised alternative such as internal Certification Body training.
- This training should be completed no more than 3 years prior to any certification audits unless supported by recent, relevant work experience, and currency of the auditor's auditing skills.

d. Continuing Professional Development (CPD)

- The additional requirements for the PS scheme are:

At least 25 hours of appropriate CPD must concern GMP or specific PS 9000 requirements for the pharmaceutical supplier industry. The 25 hours CPD may be structured, semi-structured or unstructured in accordance with the IRCA guidance on CPD. The IRCA CPD requirements are available from the IRCA website: <https://www.quality.org/article/cpd-guidance-irca-auditors>