



**The Pharmaceutical Quality Group**

**Pharmaceutical Supplier  
Auditor Certification Scheme  
'The PS Scheme'**

**Note:** This document must be read in conjunction with the current IRCA document 602 '*Certification as a Quality Management Systems 2000 (QMS 2000) Auditor*'. (<http://www.irca.org/downloads/IRCA602.pdf>)

The Pharmaceutical Quality Group (PQG) [www.pgg.org](http://www.pgg.org) is a Special Interest Group (SIG) of the Institute of Quality Assurance (IQA) [www.iqa.org](http://www.iqa.org)

The information detailed within this document was correct at the time of publication.

# Pharmaceutical Supplier Auditor Certification Scheme

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# Pharmaceutical Supplier Auditor Certification Scheme

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## 1. INTRODUCTION

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### ■ Background

Suppliers to the Pharmaceutical Industry (pharmaceutical suppliers) may now be certified by the PQG to PS 9000:2000 for Pharmaceutical packaging materials and PS 9100:2002 for Pharmaceutical excipients. Certification follows a successful audit by a certified Pharmaceutical Supplier auditor and approval by a certification body.

Pharmaceutical suppliers are defined as.

- Organizations manufacturing, processing or supplying materials for use in pharmaceutical manufacturing. Materials may be purchased or produced under contract. Examples are chemical raw materials (excipients), medical devices and packaging materials such as containers, closures or printed materials.

Pharmaceutical supplier auditors must be certified by the Pharmaceutical Quality Group (PQG). This certification assures that auditors are competent in applying the requirements of the PS supplier standards. Suppliers may then be confident that they are being audited by a properly trained individual.

Certification within the PS Scheme is available, without restriction, to all individuals worldwide who satisfy the certification requirements: the register of PS certified auditors on the PQG website shows all currently certified auditors.

**Note:** training organizations are certified by IRCA and the PQG to carry out training of Pharmaceutical Supplier auditors according to document IRCA/PQG 2235.

### ■ Who is it for?

The PS Scheme is intended for:

- quality auditors who audit suppliers to the pharmaceutical industry

### ■ The Purpose of this document

This document provides new applicants and existing PS certified auditors with information and instructions that are additional to those requirements laid down by IRCA 602 'QMS 2000'.

## 2. CERTIFICATION GRADES

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The PS Scheme has two grades of certification:

- PS Auditor
- PS Lead Auditor

These are equivalent to IRCA QMS 2000 certification grades.

### 3. REQUIREMENTS FOR INITIAL CERTIFICATION

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To be eligible for PS Scheme certification, applicants must be certified as an IRCA QMS 2000 Auditor, Lead Auditor or Principal Auditor or meet the requirements for such certification: applicants currently certified as IRCA Internal and Provisional Auditor grades will not meet the requirements.

The PQG will evaluate applications based on demonstration of the additional Good Manufacturing Practice (GMP) competencies needed for effective audit of quality management systems in the pharmaceutical supplier industry. These competencies can be demonstrated through a combination of education, work experience, auditor training and audit experience.

**Note:** the IRCA QMS 2000 Principal Auditor grade will be accepted as being equivalent to the PS Scheme Lead Auditor grade.

**Note:** The term GMP (Good Manufacturing Practice) is used in this document. Auditors need to be aware that the term cGMP (current Good Manufacturing Practice) may also be used by regulators and industry. The auditor must make sure that, in a given context, they know exactly what is meant by the term being used and the GMPs to be applied.

#### ■ PS Scheme auditing competencies additional to those of QMS 2000

For both grades successful demonstration of:

- The application of the fundamental competencies to pharmaceutical supplier audits in relation to the PS standards.
- 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.

#### ■ Education & Work Experience additional to QMS 2000

For both grades 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.

#### ■ Auditor Training additional to QMS 2000

For both grades successful completion of:

- An IRCA/PQG certified Pharmaceutical Supplier Auditing Course or recognised alternative.
- This training should be completed within the 3 year period immediately prior to application for certification. Training completed prior to this period may be accepted if evidence is provided of recent, relevant work experience, and currency of your auditing skills.

Please refer to the PQG website for a current listing of all PQG approved training organizations offering IRCA/PQG certified Pharmaceutical Supplier auditor training courses.

## Pharmaceutical Supplier Auditor Certification Scheme

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### ■ Auditing Experience additional to QMS 2000

For both grades successful demonstration that:

- All audits are of pharmaceutical suppliers.

### ■ General Guidance on Acceptance of Audits

For both grades as IRCA 602 with the additional requirement:

- Audits must be in accordance with PS 9000 Annex E or PS 9100 Annex B. Any deviation should be justified in the application. We must be able to verify all audit experience you submit in your log sheets. Please make sure you include detailed information of the audits you perform and provide sufficient contact details so that we able to perform the verification.
- We will only accept audits that have been performed in suppliers to the pharmaceutical industry. We must be able to verify the nature of business of the audited organizations.

## 4. HOW TO APPLY

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### ■ What you do

Complete and submit the PS Auditor Certification application form and supporting documents. The application form can be downloaded from the PQG website [www.pqg.org](http://www.pqg.org).

Send the application with the fee to the PQG assessor as directed on the form.

### ■ What we do

We usually take about four weeks to process each application. But that time may vary depending on the time required to verify the information submitted with the application.

Technical evaluation, certification, offer and award of certification are performed in accordance with IRCA 602.

Your details are then added to the PQG register of certified auditors and we will send you your certificate.

## 5. FEES

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Details of current fees are available from the PQG website.

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### 6. REQUIREMENTS FOR RENEWAL OF CERTIFICATION

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The process for renewal of certification is in accordance with IRCA 602. The additional requirements for the PS Scheme are:

#### ■ Continuing Professional Development (CPD) (See Appendix 1)

The additional requirements for the PS scheme are:

- At least 25 hours of appropriate CPD must concern GMP or specific PS 9000 series requirements for the pharmaceutical supplier industry. The 25 hours CPD may be structured, semi-structured or unstructured in accordance with IRCA guidance on CPD.

#### ■ Audit Experience

Copies of the audit log sheets for renewal of QMS 2000 (IRCA/106) or equivalent evidence must be supplied to the PQG.

The additional requirements for the PS scheme are:

- These audits must be of the pharmaceutical supplier industry.

#### ■ Declaration of Complaints

As IRCA 602

#### ■ Compliance with the Code of Conduct

As IRCA 602

### 7. HOW TO REGRADE

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You can apply to be regraded to the PS Scheme Lead Auditor grade at any time; a copy of a IRCA regrade application with supporting documents may be used.

Please contact the PQG through the website if you need further advice on how to regrade.

### 8. OTHER INFORMATION

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#### ■ The Certification Period

As IRCA 602

#### ■ QMS Standards other than ISO 9001:2000 and PS series

As IRCA 602 but PS 9000 Pharmaceutical packaging materials and PS 9100 Pharmaceutical excipients are the preferred standards.

#### ■ Certificates and the Register

As IRCA 602 but the certificate is your evidence of PS certification. Although the certificate is issued to you, it remains the property of the PQG and must be returned if asked for.

We maintain and routinely update the PS certified auditor register on the PQG website.

#### ■ Appeals and Complaints

As IRCA 602

#### ■ Enforcement of Certification

As IRCA 602

#### ■ Confidentiality

As IRCA 602

#### ■ Legal Status

As IRCA 602

### 9. APPENDIX I - GUIDANCE ON CONTINUING PROFESSIONAL DEVELOPMENT (CPD)

As IRCA 602

### 10. APPENDIX II - DEFINITIONS

As IRCA 602

### 11. APPENDIX III - CODE OF CONDUCT

As IRCA 602