Requirements for CQI/PQG Certified Supplier status

1.1 The organisation

The organisation (pharmaceutical supplier company/certification body client) shall:

a) Set up its quality system and procedures to meet the requirements of a PS 9000 Standard.

b) Seek certification to the PS 9000 certification scheme from a PQG recognized accredited certification body.

c) Maintain its quality system and procedures to meet the above requirements.

d) Supply copies of third party certification body audit reports (initial, surveillance and re-certification audits) as requested by customers and the PQG.

e) If appropriate, participate in meetings and make proposals for improving the PS 9000 certification scheme.

f) If appropriate, provide feedback on the PS 9000 certification scheme's effectiveness.

1.2 The Pharmaceutical Quality Group (CQI/PQG)

CQI/PQG shall publish the requirements for training courses for QMS + PS 9000 auditors/lead auditors. See CQI/PQG website: www.pqg.org

1.3 The auditor

The auditor (third party certification audits) shall:

a) Meet the PS 9000 certification scheme requirements

b) Ensure experience/familiarity with the technology of the pharmaceutical supplier organisation concerned.

c) Ensure experience in, and understanding of, the requirements of the pharmaceutical industry particularly the GMP requirements associated and relevant to a particular material and/or component.

d) Carry out audits in a professional manner according to the IRCA Code of Conduct.

e) Include positive attributes and opportunities for improvement using ISO 9001:2015 quality management principles, as appropriate, in audit reports.

f) Seek clarification and advice, as required, from the PQG.

g) As appropriate, participate in meetings and make suggestions for improving the PS 9000 certification scheme.

h) As appropriate, provide feedback on the PS 9000 certification scheme's effectiveness.

1.4 The accredited certification body

The accredited certification body shall:

a) Sign an agreement with CQI/PQG to meet the PS 9000 certification scheme requirements including.

- all certification audits (initial, transition, surveillance/ periodic and re-certification audits) shall be carried out by one of the QMS + PS 9000 certification auditors/lead auditors meeting the PQG requirements
- the GMP requirements of PS 9000 shall be examined, at every audit, even if they represent only a small part of the business of the supplier

• surveillance/periodic audits shall be carried out at six monthly intervals; the period between audits shall not be greater than seven months unless there are exceptional circumstances agreed with the CQI/PQG

b) Carry out all audits in accordance with the above requirements and to the PS 9000 audit timescales; also complying with accredited certification requirements.

c) Ensure PS 9000 pharmaceutical supplier auditors are experienced and familiar with the technology of the pharmaceutical supplier company/client concerned.

d) Ensure PS 9000 pharmaceutical supplier auditors are experienced in, and understand the requirements of, the pharmaceutical industry particularly the GMP requirements associated and relevant to a particular material and/or component.

e) Seek clarification/advice from the PQG as necessary.

f) Participate, as appropriate, in the development of the PS 9000 certification scheme.

g) Provide feedback on the PS 9000 certification scheme's effectiveness.

h) Issue certificates referring to PS 9000 in the scope of an UKAS or equivalent accredited Certificate or as the Standard in a non-accredited Certificate.

i) Notify the PQG of new companies certificated to/withdrawn from PS 9000.

2. PS 9000 Registration/certification requirements

2.1 The accredited certification body

The accredited certification body shall:

a) Issue certificates referring to PS 9000 using the full title(s) and issue reference.

b) Provide copies of certificates, including appendices, to the CQI/PQG as and when certificates are issued/updated to client companies.

c) Advise CQI/PQG when new Certifications to PS 9000 have been issued together with the dates, duration and the name(s) of the auditor(s).

d) Advise CQI/PQG if certification is suspended or withdrawn

e) Provide an annual return of PS 9000 organisations audited to include dates, duration and name(s) of auditor(s).

2.2 The CQI Pharmaceutical Quality Group (PQG)

The PQG shall:

a) Administer the PS 9000 certification scheme and set up agreements with interested parties.

b) Publish the PS 9000 pharmaceutical supplier certification scheme requirements.

c) Develop and publish the PS 9000 pharmaceutical supplier Standards.

d) Issue CQI/PQG certified supplier logo origination and rules to certification bodies and certified companies.

e) Maintain and publish the list of CQI/PQG pharmaceutical supplier certified companies.

f) Carry out accreditation activities to verify that the PS 9000 certification scheme rules have been followed.

See PQG website: www.pqg.org

3. PS 9000 Third party certification audit timescales

The timing in Table F.1 are based on the International Accreditation Forum Mandatory Document for the Duration of QMS and EMS Audits (IAF MD 5:2009) and the consistent application of ISO/IEC 17021:2011 for audits of quality and environmental systems. The audit durations have been increased to allow for auditing the good manufacturing practices in PS 9000:2016. In accordance with IAF guidance, certification bodies should allow sufficient time for each audit, based on the complexity of the organisation and other relevant factors including the language of the audit.

The total times allow for all administration, audit planning and follow up.

Table 1. Relationship between effective number of personnel and audit duration.

Certificated company: Effective Number of Personnel	Initial assessment (auditor days)		Annual surveillance (auditor days per annum) – audits at 6 monthly intervals		Re-certification / transition to PS 9000:2016 (auditor days)	
	Total min	On-site	Total per annum	On-site	Total min	On-site
1 – 5	2.5	1.5	1.5	1	2	1
6 – 10	3	2	1.5	1	2	1.5
11 -15	3.5	2.5	2	1.5	2.5	2
16 – 25	4	3	2	2	3.5	3
26 – 45	5	4	2	2	4	3
46 – 65	6	5	3	2	4.5	3.5
66 – 85	7	6	3	2	5	4
86 – 125	8	7	4	3	6	5
126 – 175	9	8	4	3	6	5
176 – 275	10	8	5	4	6	5
276 – 425	11	9	5	4	7	6
426 – 625	12	10	6	5	8	7
626 – 875	13	11	6	5	8	7
876 – 1,175	14	12	7	5	9	8
1,176 – 1,550	15	13	7	5	10	8
1,551 – 2,025	16	14	8	6	12	10

3.1 Surveillance and re-assessment

The guidance for initial assessment is relevant for surveillance and re-assessment. In these circumstances, where a supplier has demonstrated to the certification/registration body during assessment and following surveillance(s) that its quality system has reached maturity and fully conforms on a continuing basis with all the requirements of the standard, the certification/ registration body could be justified in reducing (up to a maximum of 25%) the amount of time applied to surveillance visits and re-assessment. In such cases, where less time than that specified above is used, the reasons shall be recorded on each occasion.

3.2 Multiple Site Certifications

Where an organisation has multiple sites operating under a common quality system and procedures, the requirement to audit each site every 6 months may be modified subject to documented justification and prior agreement with the CQI/ PQG.

3.3 Organisations with minimal PS 9000 activity

The requirement to audit each site every 6 months may be modified subject to a mature system, documented justification and prior agreement with the CQI/PQG.

3.4 Transition

Transition auditor days are for transition from an ISO 9001:2015 Certificate to PS 9000:2016 or for transition from PS 9000:2011 to PS 9000:2016

F.3.5 Transition from PS 9000:2011 to PS 9000:2016

The audit days for transition from PS 9000:2011 to PS 9000:2016 may be reduced (up to 30%) for organisations already certified to ISO 15378:2015. The reduction shall be justified based on the level of risk management and validation implemented and the justification recorded.

Transition from PS 9000:2011 to PS 9000:2016 shall be completed by 15 September 2018 after which date Certificates to PS 9000:2011 will no longer be valid.