

Development of the PS 9000/9100 Supplier Certification scheme

Notes from a meeting held on 19th November 2008 at CQI Headquarters, London

Present:

Ashley McCraight	- PQG Chairman
Steve Moss	- PQG Partners Group
Norman Randall	- PQG Partners Steering Group Chairman
Jane Smith	- PQG Events Co-ordinator
David Abraham	- MY Packaging
Richard Bream	- Chesapeake
David Crome	- Niche Generics
Michael Grunow	- Fisherprint
Tony Harper	- BVC and DNVC.
John Lee	- BSI
Julie Noonan	- Sessions of York
David Parsons	- Labelsco

Summary of the meeting

This proved to be a very useful meeting with many good inputs which will assist in developing the strategy for the future of PQG's PS Certification Scheme.

The main points were:

- **a recognition of the benefits of the scheme and also the need for change**
- **opportunities were put forward for improved control systems & promotion**
- **PS 9000 proposal (annexes) prompted many varied opinions which need careful consideration (e.g. annexes or one document; inclusion of guidance or pure standard; risk assessment approach; timescales)**
- **PS 9004 proposal (keep as is) could be developed by website updates including 'interpretations'**
- **Supplier Certification needs to be clear yet flexible and not add excessive assessment hours. Updated scheme definition (to include transition plan) can be on website**
- **Auditor Accreditation scheme requires review, particularly regarding competency requirements/assessments**

Feedback to the proposals from the breakout discussions at the meeting is shown below:

1. General feedback on the Scheme

Positive:

- A good benchmark – useful globally
- Useful for marketing – provides differentiation between companies
- A condition for quoting in UK and ROI – though less pressure now, more a 'nice to have'
- Pharma auditors are helpful - using PS 9000 as aid for QMS development, FMEA, OCR (optical character recognition)

Negative:

- Out of date
- Lack of knowledge/awareness of PS 9000 in small pharma companies
- Very British
- Companies working for total service (£ + Quality + delivery) - customers aiming to move costs into suppliers
- BRC – food industry guidelines are better promoted

Note: QAPP & Certipharm in use in France/Germany

2. General feedback on the Certification process

- OK - defined
- Multisite – can have one certification but not clear that this applies for PS.
- Need feedback on changes
- Credibility high – well recognised
- No revalidation process – depends on updates to PSs
- Difficult to find a Certification Body that can do 14001, 9001, PS, ISO 15378 etc. – can be 30 days auditing for all certifications!

3. Reaction to PS 9000 proposal – issue Annexes for latest requirements (see presentation slides 15 & 16)

- Long timescale – why 2 years when it is out of date now?
- ISO 9001:2008 – drives need to update as well as requirements such as Braille
- Why not upgrade to PS 9000:2008 - looks out of date as PS 9000:2000.
- Are resources available to drive preparation of documents and implement?
- Annexes difficult to use – would rather see additional requirements embedded

- OK to use Annexes separate from PS 9000
- Annexes allow flexibility for updates for new requirements (Braille, e-Pedigree) and technology advances
- Could have current updates on website - assuming version control by approved process - with communication
- Need to be clear what each Annex covers - overlap potential between Annex 1 and 2 e.g. blisters/sachets printed
- Cut out ISO text altogether but leave clause numbers
- Keep ISO text in one document - CD is available
- Would like complete review of all requirements - move some guidance out e.g. pest control
- Could move to CEN/ISO standard, rather than PS, on similar timescales, however, PQG do not control these development processes

(ISO 9004 is under revision – expected 2009)

General comments:

- Low awareness of ISO 15378
- Main difference may be print requirements & also specifics for product contact e.g. bioburden.
- Need to explain why the requirement is there
- Need appropriate level of standards e.g. computer validation
- Can use risk assessment to vary requirements i.e. multilayer requirements

4. Reaction to PS 9004 proposal – leave as is (see presentation slide 17)

- Could insert content into revisited PS 9000 – leave out the ISO Changes to PS 9000 would benefit from guidance anyway
- Could ‘donate’ to ISO 15378 development process
- Could put cases on PQG website
- Useful at introduction/development stage for companies - less so in maintenance of standards
- Could PS 9004 be linked to something on web like FAQs to provide up to date interpretations of the guide? (Similar to automotive standards interpretations). Also parallels by pharma regulators, Orange Guide & EMEA website FAQs

General comments:

- PQG website – currently has no tab
- Some not aware that it is available free
- Publicity needed
- Has good content
- Supports discussions with top management
- Possibly not widely used except by enthusiasts

5. Reaction to PS Supplier Certification and Auditor Accreditation Schemes proposal (see presentation slides 35 & 36)

Supplier Certification:

- Agree with it!
- Need to be prepared for requests for certification to either standard
- How do we do it? suggestion: Revise Annex E and publish on PQG website + email
- Don't want multiple audits, adding cost – define what incremental audit time is required to add extra standard.
- Must be practical
- Need transition process for Annexes e.g. BSI transition checklist – audit identifies gaps for closure before end of transition period.
- Need to ensure no conflict between standards for 1y and 2y packaging and ensure it is clear which standard applies
- What to do when both standards apply – higher or lower requirement?
- Matrix of requirements i.e. 1y, 2y, 15378, PS 9000 etc. may be useful

Auditor Accreditation:

- Need to review competency requirements for scheme auditors
- How do you determine competence of auditors? 17024 part 2 under development, knowledge
- Renewal/CPD
- There should be a revision process (target <3years)

Next steps

The Partners Steering Committee will revise and further develop proposals before implementation. This will include PS 9000, PS 9004, Supplier Certification and Auditor Accreditation (A replacement standard for PS 9100 is already underway in collaboration with IPEC).

N.B. All volunteers will be warmly welcomed for work on the standards!