



# Development of PS 9000

Initial Meeting – PAGB, London 11th May 2009

Pharmaceutical Quality Group



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# Meeting agenda



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## 10.00 Welcome & Introductions

10.15 Background to PQG, project & process so far

10.45 The target – PS 9000:2010

11.30 Identify source documents

12.00 Consider breakdown into subprojects

12.30 Lunch

13.15 Project team, governance & benefits

13.30 Project ways of working

14.00 Define initial tasks/ teams

14.30 Summary and next steps

15.45 Conclusions & Close

## Norman R

Steve

Steve/Normans

Norman S/Steve

Norman S

Steve/Normans

Norman S

Norman S

Steve/Norman S

Norman R



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# PQG & Partners Team



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## Chartered Quality Institute

### Pharmaceutical Quality Group – committee

#### PQG Partners - steering committee

Norman Randall (Chairman), Ashley McCraight, David Mogg, Steve Moss,  
Ian Richardson, Justin Ahern

#### PQG Partners Team

Steve Moss (Leader), Tony Harper, Jill Jenkins, Linda Nield, Justin Ahern, Norman Sadler

#### PQG Partners Project teams



# PQG Partners Team



## **Aims & objectives**

The Pharmaceutical Quality Group Partners Team will promote the application of appropriate GMP for suppliers to the pharmaceutical industry through:

- developing, publishing and maintaining standards and guidance
- collaborating with other organisations with similar aims on projects for standards and guidance
- maintaining a process for certification of suppliers against PQG standards
- maintaining a process for assessment of training in PQG standards and guidance
- certification of auditors used by certification bodies for assessing suppliers against PQG standards



# Partners Team - record



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1990 & 1995 Pharmaceutical Supplier Codes of Practice  
2000 - PS 9000 Pharmaceutical packaging materials  
2002 - PS 9100 Pharmaceutical excipients  
2004 - PS 9004 Guidance for implementing PS 9000

1991 – Auditor and Training course standards designed

## Contribution

2005 EFfCI GMP Guide for Cosmetic Ingredients  
2006 - ISO 15378 Primary packaging materials  
2006 – IPAC/RS Materials for inhalation products

## Collaboration

2006 - IPEC/PQG Excipients GMP Guide  
2008 – IPEC/PQG Excipients GMP Audit guide



# Partners Team - record



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Packaging materials suppliers certified to PS 9000:

- 54 UK
- 18 Overseas (Eire 13; Sweden 3; Malta 1; China 1)
- 72 Total

Excipients suppliers certified to PS 9100 = 2

Auditors certified to PS scheme = 12



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# Current PQG Partners projects



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<b>PQG Partners project</b>	<b>Leader</b>
<b>Risk Management in the Supply Chain</b> Guidance for pharmaceutical industry and their suppliers	Jill Jenkins
<b>IPEC/PQG Excipients GMP standard</b> For certification schemes proposed in Europe & USA	Steve Moss
<b>Common Questionnaires</b> Minimise supplier time responding to multiple customer formats	Linda Nield
<b>ISO 15378 developments</b> Extension to secondary packaging & guidance	Tony Harper



# PQG PS Scheme



## **The PS Scheme**

PS 9000:2001

PS 9100:2002

PS 9004

PS supplier certification scheme

PS auditor training (IRCA variant)

PS auditor certification scheme

## **Related**

IPAC RS incorporates PS 9001:2001

ISO 15378 primary packaging

IPEC-PQG Excipients GMP guide 2006, & audit guide 2008

# Why is development required?

1. There are differences between ISO 15378 & PS 9000 on primary packaging requirements
2. Uncertainty on timescales for the development of a possible ISO standard for suppliers of secondary packaging materials.
3. Updates to PS 9000 & PS 9100 are overdue (particularly PS 9000 for developing technology)
4. IPAC-RS Guide (for Orally Inhaled and Nasal Drug Products) includes good additional content
5. Supplier certification audit requirements need updating
6. Competence and training requirements for PS Auditors
7. New excipients GMP standard developed jointly with IPEC Europe & IPEC Americas will replace PS 9100 part 1



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# Differences: ISO 15378 - PS 9000



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## Clauses where ISO 15378 contains more than PS 9000

- 4.2.4 Control of records. There are two extra requirements
- 5.5.1 Management responsibility. There are two extra requirements.
- 5.5.3 Internal communication. There are two extra requirements
- 6.2.2. Competence, Awareness and Training. There are two extra requirements.
- 7.4 Purchasing. There are 8 new requirements
- 7.5.1 Cleanliness of Product and Contamination.
- 7.5.1 Change control
- 7.5.2. Validation of processes for Production.
- 7.5.5 Preservation of product. There are two extra requirements
- 8.3. Control of non-conforming product.



# Differences: ISO 15378 - PS 9000



## Clauses where PS 9000 contains more than ISO 15378

- 7.2.3. Customer communication. It is more specific.
- 7.5.1. Line Clearance. It is more demanding.
- 7.5.2. Validation of processes for production. There is one extra requirement.
- 9.1.2. Facilities, equipment and operating conditions.  
There are additional requirements for segregation.
- 9.2. Environmental conditions. There are specific requirements.
- Annex C: Additional requirements for certificates
- Annex D: Additional guidance on types of bar codes.



# PQG position on PS 9000 scheme



- To meet its aims and objectives, PQG must ensure that its PS Supplier Certification scheme is supported with current standards, guidance and control of supplier certification, auditor training and auditor certification.
- In the long term ISO documents may be developed to cover all GMP requirements and guidance for primary and secondary packaging materials. However these developments are out of the control of PQG.
- Collaboration with other organisations has mutual benefits in broadening the inputs and extending the scope of potential application of PQG standards and guidance.



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# Development process



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1. Need for review of PQG PS Scheme identified
2. Input from Partners and Steering Committee Mar 08
3. Steering Committee develop strategy proposals Apr 08
4. Certification Bodies meeting – discuss proposals June 08
5. Suppliers meeting – discuss proposals Nov 08
6. Steering Committee updated strategy Dec 08
7. Steering Committee discuss with other organisations Dec 08
8. Steering Committee finalise strategy Q1 09
9. Implementation planning Q1 09
10. Implementation Q2 09 - Q4 10



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# Proposal 1. PS 9000



<b><u>Current</u></b>	<b><u>Future = realistic plans within 1-2 years</u></b>	<b><u>Vision = ideal 3-5 years</u></b>
<b>PS 9000:2001 standard/guide</b>	<b>PS 9000:2010 standard/guide</b>	<b>Potentially not needed if ISO 15378 covers all requirements</b>



# Proposal 1. PS 9000



**PS 9000:2010 standard/guide** Issue new document including latest requirements – both certification standard and additional guidance. To include:

Additional specific requirements for 1y packaging materials over ISO 15378 (source PS 9000 and updates, also include requirements in ISO 15378 and not in PS 9000 i.e. risk, validation)

Requirements for 2y packaging materials (updated + new inputs; paraphrased ISO text)

Updated IPAC-RS specific requirements/ guidance for inhalation products [Subject to discussions with IPAC-RS]



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# Proposal 1. PS 9000



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“ **PS 9000: 2010**” clearly setting out **Standard + Guidance** within one new document

“**PS 9000:2010**” **Standard** will be precise on what requirements apply where different standards are possible for difference classes of components and risks

**ISO 9001 text** – not included, will be paraphrased

**International** – development to involve overseas inputs (including PS certified suppliers) to be seen as more than just ‘British’

**Download free** – main aim is to make freely available – so download from website

**Printed** – cheap hardcopy will be provided for sale



# PS 9000:2010 target dates



Project plan draft - Jul 2009

URS draft - Aug 2009

Project plan - mid Sept 2009 including budget for SC approval

URS - mid Sept 2009 for SC approval

Initial outline document - end Nov 2009 (scope/format) for SC comment

Draft document - Mar 2010 for SC approval prior to issue for comment

**Final document - Sept 2010** for SC approval prior to publication as pdf and printing

**Launch of PS 9000:2010 - Nov 2010**

Team needs to be happy with achievable interim dates in the project plan



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# Potential source documents



PS 9000:2001

ISO 9001:2008; ISO 9004:2009

ISO 15378; other ISO standards

IPAC – RS

PS 9004?

PS 9100; IPEC/PQG Excipients GMP guide?

draft PQG Supply Chain Risk Management Guide?

Specialist standards/guides - Braille? CQI Digital? Origination guide?

Other draft/issued industry guides?

Company standards?

Etc etc



# Potential source documents



Confirm / identify availability of all source documents

- Hard copy
- Electronic



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# Subproject plans

Are there any obvious streams of activity that are best handled as subprojects by small teams with task leader?

May need to start to brainstorm some of the key tasks



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# PS 9000:2010 governance



A PQG partners team project, leader reports to Partners Team for details on scope, URS, coordination with other projects, guidance, deliverables, launch etc.

A project charter may be helpful.

Will need to build a budget for approval by PQG committee.



# PS 9000:2010 governance



Governed by PQG Partners Steering Committee for overall direction on funding (by PQG Committee) & financial implications, PS Scheme implications, collaboration with other organisations, approval for key stages (e.g. formal consultation; publication).

Usually Partners team leader reports on project to SC.



# Project team benefits



Great opportunity to develop contacts & work with other professionals with similar interests.

Update your current knowledge by discussion with industry experts.

Take part in developing industry best practise. Get your name in the book! Include it in your CV!

Many companies allow some time for contributions, and essential travel costs.

PQG can help with essential UK travel costs where agreed.

PQG will pay the core development team a small bonus.



# PS 9000:2010 Team



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## Who?

Meeting attendees!

Interested but unable to attend meeting:

James Brown (EthiPrint)

Godwyn Pace (Lewis Press)

Davaki Khurjekar (Chesapeake)

Sandra Routledge (Alcan)

David Pethick (PPF)

John Lee (BSI)

Jeff Monk (JMT)

Tracey Keen (Benson)



# PS 9000:2010 Team



Who else will we need?

Any key names missing?

or what other  
skills/expertise/representation do we  
need to involved at this initial stage..?

...or later?

Related activities (Translation, RFID etc)?

Input from regulators?

Wider than UK?



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## Maximising benefit of interactions

### Balancing

- time commitments,
- individual workload,
- level of detailed work required,
- small active teams
- larger review team (s)

## Minimising travel time & costs



# Project ways of working



One team vs sub teams:

Face to face meetings:

- Preferred location
- Any company facilities on offer?
- Initial & subsequent frequency?

Teleconferences:

- Any company facilities on offer?
- MS Live meeting/alternative collaboration tool

Other communications



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# Initial plans



Getting started....

Any specific topic/subgroup interests?

Volunteers for specific tasks etc?

Focus on initial plans:

- subject topics
- project plans, URS, charter etc



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# Next steps



Initial telecon...?

When?

Attendees

Topics

- Feedback on initial reviews

- URS

- Team charter

- Agree topics/teams

- Outline project plans



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# PQG & Partners Team



## Reference slides



# Certification bodies 13<sup>th</sup> June



AJA, Jeff Monk

BSI, Doug Peacock

BVQI,

DNV, Tony Harper

LRQA,

NQA, Steve Durston

NSAI,

SGS Y, Ann Elton



# Certification bodies 13<sup>th</sup> June



## Main points from discussion:

1. Validation model examples for pack material suppliers helpful.
2. New version of ISO 9001 no concern, as no requirements change.
3. A few 'unregulated' certifications of suppliers to ISO 15378.
4. Potential for wider certification of suppliers to ISO 15378 – e.g. Far East.
5. CBs need to see true demand and prepare business plans etc to develop certification to ISO 15378.
6. CBs must comply with ISO 17021 requirements for auditors.
7. Wider communication of PS scheme and benefits welcomed.
8. Certification to ISO 15378 superior to certification to PS 9000.



# Certification bodies 13<sup>th</sup> June



9. Dual certification by PQG (PS 9000 and ISO 15378) proposed in a PQG paper 2/2/06, has not been taken up.
10. Approach for recertification assessments would need to be defined (for dual PS certification, and/or CB certification). Could be similar to scope extension.
11. IPAC-RS includes both guidance and standard. A certifiable annex would be useful to assist in certification.
12. Early submission of an ISO work item for IPEC/PQG draft standard would encourage interest and save time.
13. PQG primary focus is on making standards widely available, rather than ensuring widespread take up of certification.



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# Suppliers meeting Nov 19<sup>th</sup> 2008



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- 
- |                |                    |
|----------------|--------------------|
| 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         |



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# Suppliers meeting Nov 19<sup>th</sup> 2008



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## 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 the 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**



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## 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

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!



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## Reaction to PS 9000 proposal – issue Annexes for latest requirements

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



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## 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



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## Reaction to PS 9004 proposal – leave as is

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



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## Reaction to PS Supplier Certification and Auditor Accreditation Schemes proposal

### 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)



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# Proposal 2. PS 9004



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<u>Current</u>	<u>Future = realistic plans within 1-2 years</u>	<u>Vision = ideal 3-5 years</u>
PS 9004:2004 guide	PS 9004:2004 guide	Potentially not needed if ISO 15378 covers all requirements

**Leave as is – do not develop.** Reason – little/no demand

However - FAQs/Updates on interpretation of PS 9000 – needs to be developed linked to clause numbers and available on line, with email updates to certificated suppliers & auditors, and training organisations.



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# Proposal 3. PS 9100



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<b><u>Current</u></b>	<b><u>Future = realistic plans within 1-2 years</u></b>	<b><u>Vision = ideal 3-5 years</u></b>
<b>PS 9100 PQG standard/guide</b>	<b>IPEC/PQG PS 9100A standard  + Appendices</b>	<b>IPEC/PQG PS 9100A standard [or possibly developed to ISO standard]</b>



# Proposal 3. PS 9100



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## Standard being developed with IPEC Europe & IPEC Americas

Extra auditable requirements only

Matched to IPEC/PQG guide at foundation level

Additional annexes/levels for specific requirements for different excipient classifications - Taking note of MHRA & FDA feedback/input.

Revised certification requirements [*should be same as PS 9000 – unless collaboration with IPEC requires difference*]

### Notes

Standard to be cheap to produce/buy

Standard to be downloaded free from PQG & IPEC members areas



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# Proposal 4. PS Scheme



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<u>Current</u>	<u>Future = realistic plans within 1-2 years</u>	<u>Vision = ideal 3-5 years</u>
<p><b>Certification to PS 9000, PS 9100</b></p>	<p><b>Certification of:</b></p> <p><b>1y, 2y or Inhalation components to PS 9000: 2010 [Potential for dual certification to ISO 15378]</b></p> <p><b>Excipients to IPEC/PQG PS 9100A</b></p>	<p><b>Certification of:</b></p> <p><b>Components to ISO 15378 1y &amp; 2y std</b></p> <p><b>Excipients to IPEC/PQG PS 9100A,</b></p>



## 4. Supplier certification



**Certification to PS 9000:2010 – would cover requirements of cert to ISO 15378 for primary components and IPAC-RS for inhalation components.**

**PS 9000:2010 standard will be precise on what requirements apply where different standards are possible for difference classes of components and risks.**

**Revised certification requirements should be issued on website (so can be changed).**

**Where Certification bodies are not using PQG certificated auditors need controls to ensure appropriate standards for auditors are maintained.**

<u>Current</u>	<u>Future = realistic plans within 1-2 years</u>	<u>Vision = ideal 3-5 years</u>
<p><b>Includes:</b></p> <p><b>PS 9000:2001</b></p> <p><b>IPAC-RS</b></p> <p><b>PS 9100</b></p> <p><b>IPEC/PQG audit guide</b></p> <p><b>ISO 15378 1y std</b></p>	<p><b>Includes:</b></p> <p><b>PS 9000:2010</b></p> <p><b>IPEC/PQG PS 9100A</b></p> <p><b>IPEC/PQG audit guide</b></p>	<p><b>Includes:</b></p> <p><b>ISO 15378 1 &amp; 2y std &amp; guide</b></p> <p><b>IPEC/PQG PS 9100A</b></p> <p><b>IPEC/PQG audit guide</b></p>



# 5. Auditor training & certification



## **TRAINING**

To include PS 9000:2010, which covers requirements for ISO 15378 (primary) and IPAC-RS.

Periodic PQG audits of training providers (against IRCA variant requirements) needed.

## **CERTIFICATION**

To include PS 9000:2010, will cover requirements for ISO 15378 (primary) and IPAC-RS.

Periodic “re-validation” of auditors required – every 3 years - auditor CPD specifically on updates to PS –relevant standards