QAAPS 6: Update and next steps

Quality Assurance of Aseptic Preparation Services

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Project aims, objectives and drivers

Aim: Update QAAPS to support safe and effective aseptic preparation in Section 10 services.

Drivers since the 5th edition

Legislative amendments : Supervision

Regulatory landscape : GMP Annex 1

Guidance replacing EL(97)52 and similar strategies in devolved nations

NHS aseptic transformation programme

New therapies: ATMPs and clinical trials

Updated Chief Pharmacist Standards

Prevention of future deaths reports

iQAAPS development

Objectives

Reflect current GMP requirements

Align with current regulation, including revised Annex 1.

Review the standards

Review every Part A standard and relevant Part B content.

Make requirements clearer

Separate mandatory standards from guidance and remove duplication.

Improve structure and usability

Follow the service process with clear, auditable statements.

Project Pathway

Analysis of project need, finance, stakeholder etc.

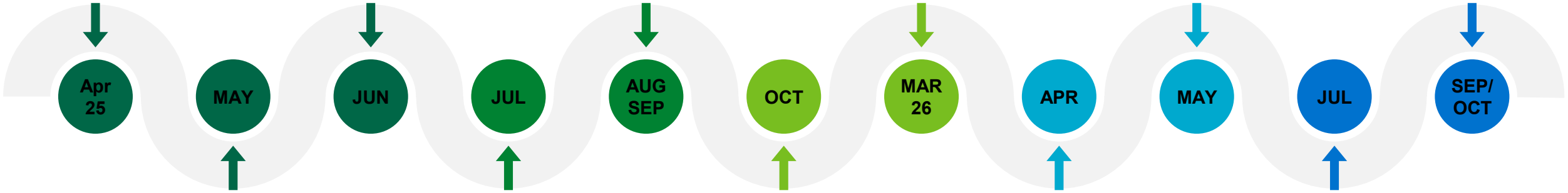
Start recruitment end of June

Finalise Lead author, chairs and working group members

Target end date for working groups

QA review

QA review, legal opinion



Delivery group agree project design

Writing job specs, project goals, formalising funding

End recruitment – 4-week period

6-month lifespan for working groups

Lead author month for initial editing

Editing
Royal College Standard format

Q1

Stakeholder engagement and project design

Q2

Recruitment and targeted stakeholder involvement

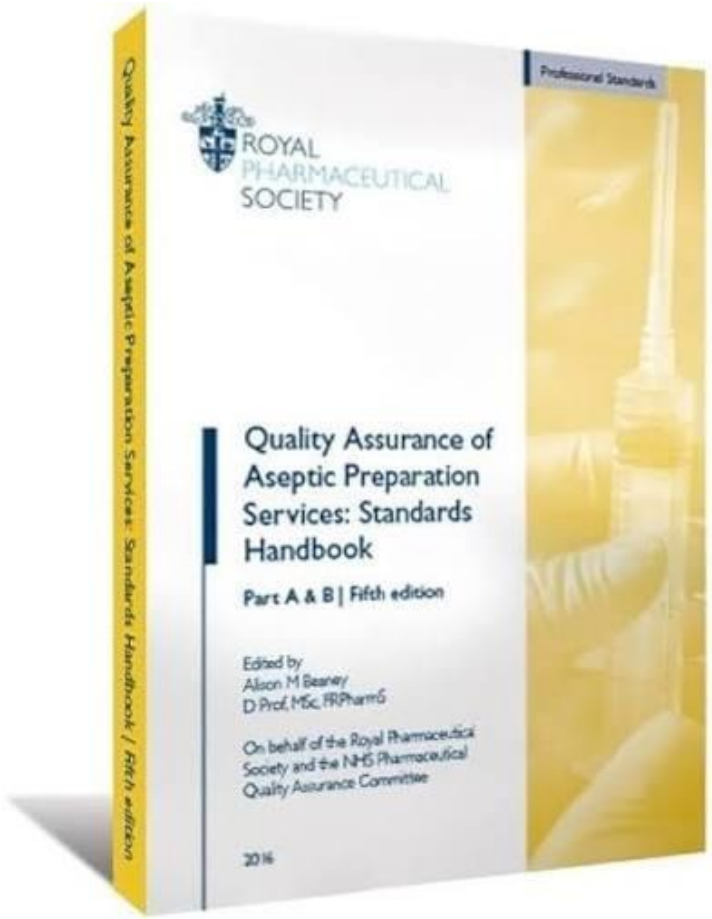
Q3/4

Working stage, updating contents and references

Q5/6

Lead Author editing period, QA review, seek legal opinion

What has been happening?



QAAPS 5th edition

Standards review

Four specialist workstreams reviewed all Part A standards and relevant Part B content.

Drafting and editorial work

The lead author completed the first edit. The Project Board and SPS QA produced a second edit.

Review and assurance

QA Committee consultation is complete. Legal and regulatory review is in progress.

Workstream setup and process-flow approach

Specialist working groups

Four task and finish groups combined specialist expertise from across the UK.

Groups reviewed standards over six months from September 2025.

Members used meetings and Monday.com to share documents and comments.

The lead author brought the drafts together, with editing queries routed through group chairs.

Process-flow approach

Review organised around the aseptic service process.

Four workstreams: Management & Infrastructure, Clinical Interface, Production and Quality Control.

QAAPS 6 Workstreams

Management & Infrastructure



Ensuring the aseptic unit is effectively resourced & maintained

Facilities & Equipment

Workforce capacity & capability.

Regulatory compliance

Ch 5: Management
Ch 7: Facilities & Equipment
Ch 9: Personnel

Clinical Interface



Right Medicine

Clinical verification

Product formulation

Good clinical practice with injectable medicines

Appropriate use of aseptic capacity

Ch 3: Risk Management
Ch 4: Prescription Verification
Ch 6: Formulation & Stability

Production



Production activities

Processes designed for safety (human factors)

Contamination control

GMP

Ch 10: Aseptic Processing
Ch 12: Cleaning
Ch 13: Starting Materials
Ch 15: Storage & Distribution

Quality Control



Quality Control activities

Maintaining state of control

Validation & self inspection

Product approval

Ch 8: PQS
Ch 11: Monitoring
Ch 14: Product Approval
Ch 16: Audit

Workstream outputs

QAAPS 5

Part A

Every standard reviewed

Part B

Relevant sections reviewed



QAAPS 6

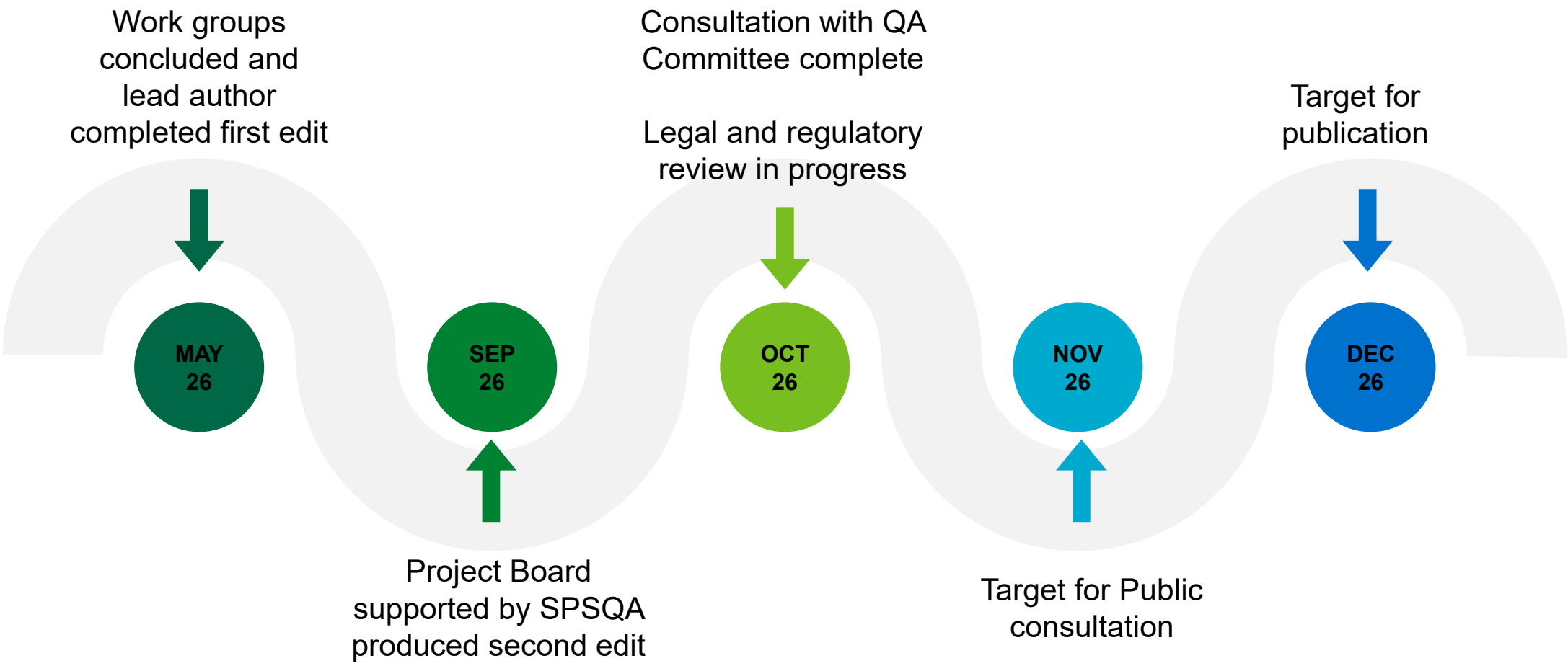
Updated standards

GMP and current regulatory requirements

Guidance

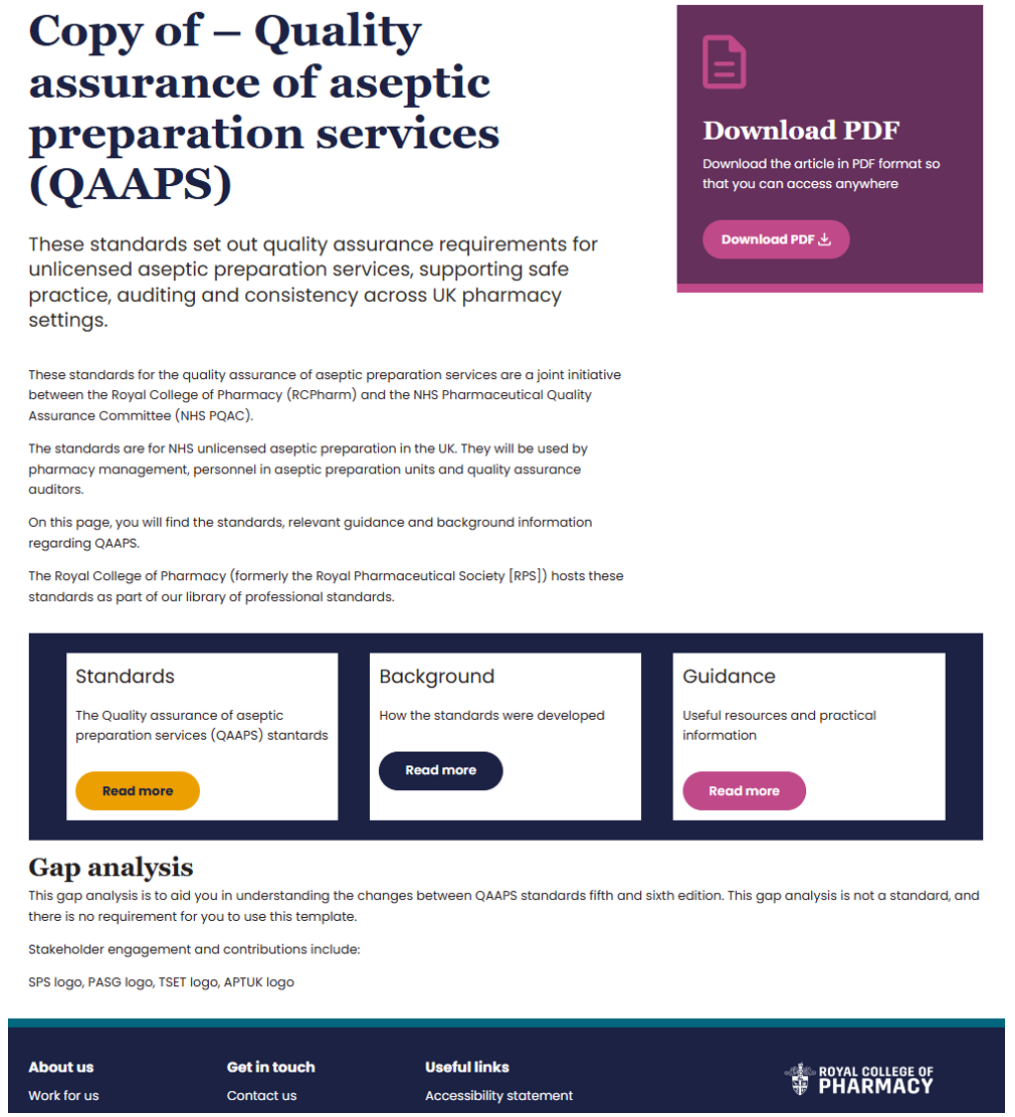

Are we nearly there yet?

QAAPS 6 progress summary 4 November 2026



About the new standard

- Professional standard for medicines preparation
- Continuing alignment with GMP
- Style alignment with other RCPharm standards
- Positive statements describing what a patient can expect from our services
- Web based (with a print option)



Copy of – Quality assurance of aseptic preparation services (QAAPS)

These standards set out quality assurance requirements for unlicensed aseptic preparation services, supporting safe practice, auditing and consistency across UK pharmacy settings.

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These standards for the quality assurance of aseptic preparation services are a joint initiative between the Royal College of Pharmacy (RCPharm) and the NHS Pharmaceutical Quality Assurance Committee (NHS PQAC).

The standards are for NHS unlicensed aseptic preparation in the UK. They will be used by pharmacy management, personnel in aseptic preparation units and quality assurance auditors.

On this page, you will find the standards, relevant guidance and background information regarding QAAPS.

The Royal College of Pharmacy (formerly the Royal Pharmaceutical Society [RPS]) hosts these standards as part of our library of professional standards.

Standards

The Quality assurance of aseptic preparation services (QAAPS) stantards

Read more

Background

How the standards were developed

Read more

Guidance

Useful resources and practical information

Read more

Gap analysis

This gap analysis is to aid you in understanding the changes between QAAPS standards fifth and sixth edition. This gap analysis is not a standard, and there is no requirement for you to use this template.

Stakeholder engagement and contributions include:

SPS logo, PASG logo, TSET logo, APTUK logo

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ROYAL COLLEGE OF PHARMACY

Style preview

Section 4.: Pharmaceutical Quality System

Section outcome

An effective and well-maintained Pharmaceutical Quality System (PQS) fosters a culture of continuous improvement to assure product and service quality, patient safety and regulatory compliance.

4.1. PQS structure and principles

The PQS is supported by defined policies and associated documents, with risks to product quality, patient safety, and service delivery managed through a documented risk management process. All required PQS elements are integrated into an effective framework that promotes continuous improvement and the ongoing control of quality risks.

4.1.1. A Pharmaceutical Quality System is established, maintained and reviewed in accordance with recognised Good Manufacturing Practice (GMP) quality management and quality risk management principles.

4.1.2. The structure of the PQS is fully documented in formal policies and associated documents, including but not limited to:

- Quality System summary (for example, a Site Master File or Quality Manual)
- Validation Master Plan
- Contamination Control Strategy
- Capacity plan
- Training programme
- Contingency plan
- Risk management

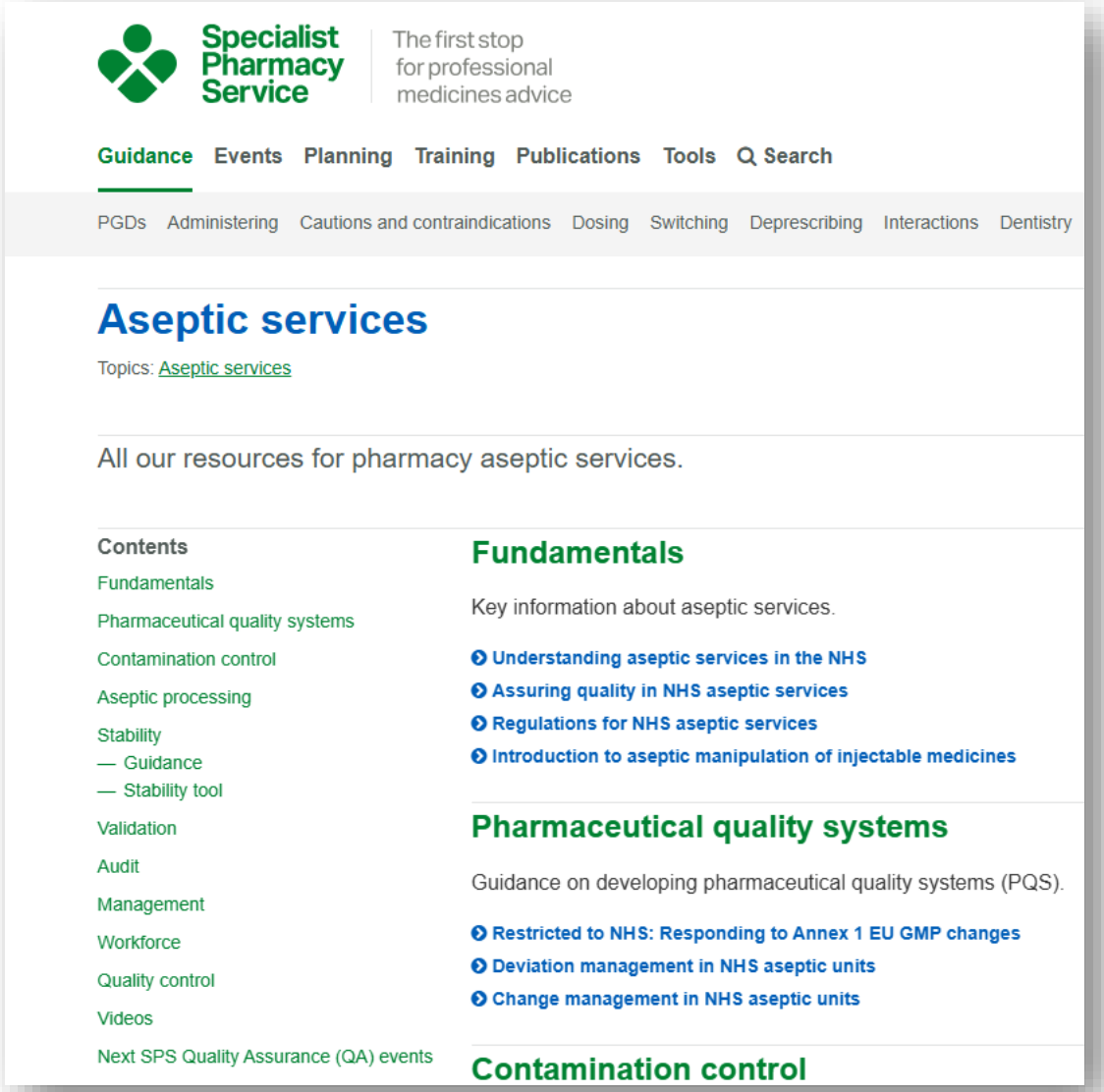
Outcome statement for section

Descriptors, with auditable descriptor outcomes

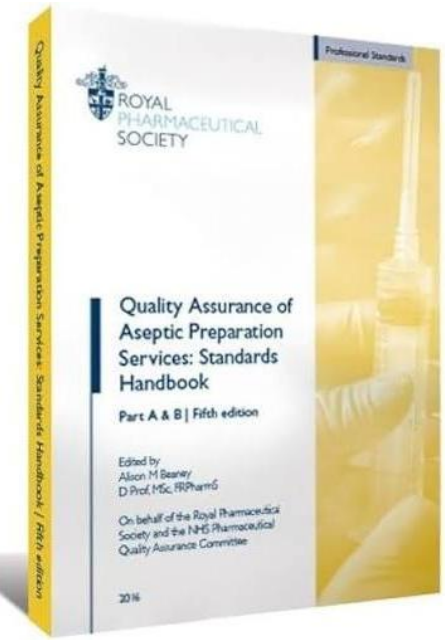
Individual auditable standards

QAAPS 6 is not…

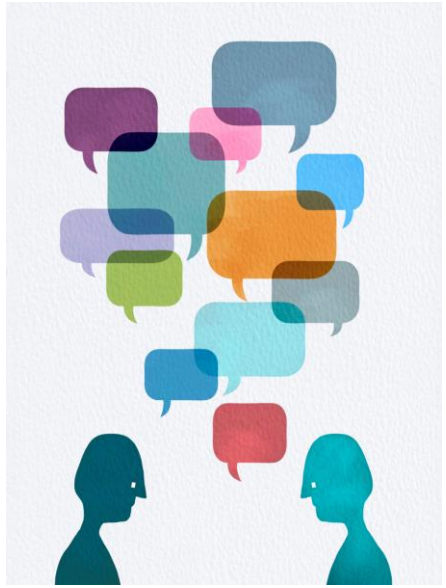
- Aspirational
  - full compliance is expected
  - non-compliances to be managed as deviations
- A “how to” guide
  - Supporting guidance will continue to be developed



First draft


Professional Standards
ROYAL PHARMACEUTICAL SOCIETY
Quality Assurance of Aseptic Preparation Services: Standards Handbook
Part A & B | Fifth edition
Edited by
Alison M Beaney
D Prof, MSc, FRPharmS
On behalf of the Royal Pharmaceutical Society and the NHS Pharmaceutical Quality Assurance Committee
2016
Quality Assurance of Aseptic Preparation Services: Standards Handbook / Fifth edition

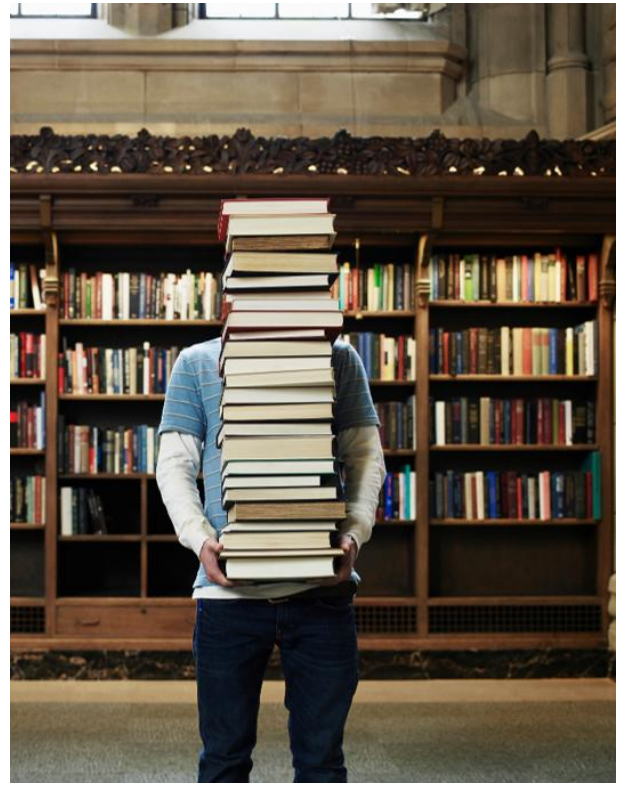
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Editorial task

- Separate standard (mandatory) from guidance (best practice)
- Remove (minimise) duplication and overlap
- Remove health and safety (this has its own legislation and guidance)
- Harmonise style – positive statements and plain English

"*There must be a standard operational procedure in place that defines…*"

becomes

"*A standard operational procedure defines…*"



Preview of QAAPS 6 structure

1. Management of Aseptic Services
2. Personnel and training
3. Facilities and equipment
4. PQS
5. Product initiation and lifecycle
6. Working in cleanrooms
7. Decontamination
8. Validation and monitoring
9. Starting materials, consumables & components
10 . Aseptic services verification, worksheets and labels
11. Aseptic processing
12. Product release
13. Distribution

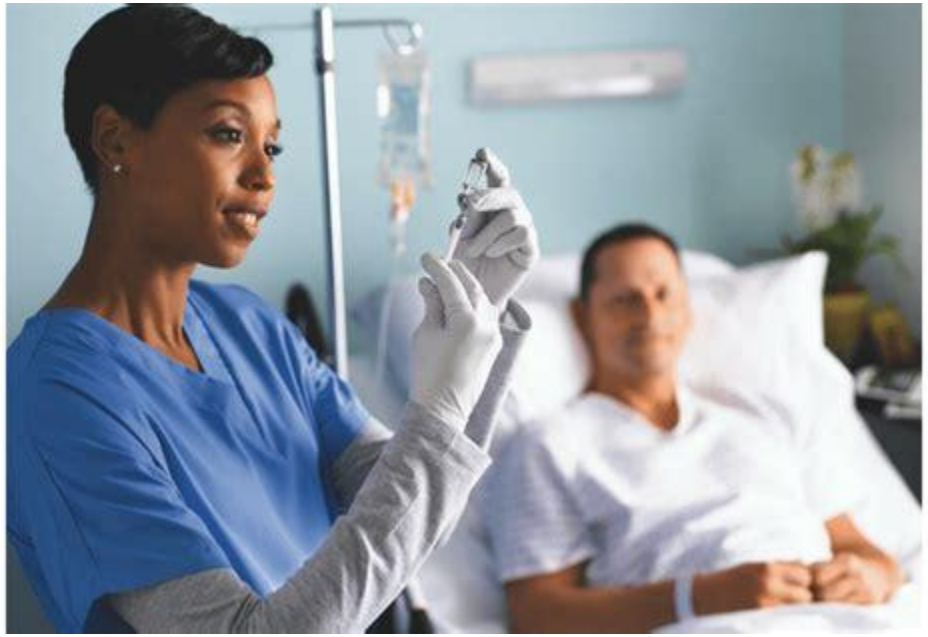
- Chapters replaced by sections
- More logical flow and overlaps removed
  - Some titles have changed
  - Some content has moved
- Some new content (regulatory change)


Aston University 750 yds
Aston Triangle 800 yds
Aston Science Park 1/2 mile
Law Courts 750 yds
Police Station 775 yds
Dental Hospital 1/2 mile
Children`s Hospital 1/2 mile
Blood Donor Centre 650 yds
Civic buildings 725 yds
Central Library 1 mile
Convention Centre/NIA
Snow Hill Station
St Philip`s Cathedral
Shopmobility
Jewellery Quarter
1 mile
Martineau Place
Post Office
NHS Walk-in Centre
Moor St Station
New Street, Toilets
Welcome/ Tourism Centre
The Mailbox/BBC
Bull Ring/Markets
St Martin`s Church 650 yds
Thinktank at Millennium Point 3/4 mile

Minimising Risk with Injectable Medicines



- Governance arrangements critical to patient safety
- Relevant to all hospitals, not just those with a Section 10 aseptic unit
- Extracted from QAAPS 6
- New, separate standard to go on RCPharm website



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- Strengthened governance & leadership requirements including management of the PQS
- Clarified supervision & delegated authority arrangements
- Roles, responsibilities & accountabilities for key personnel
- Pharmacy Technicians in professional lead & supervisory roles
- Increased emphasis on capacity, service resilience & business continuity

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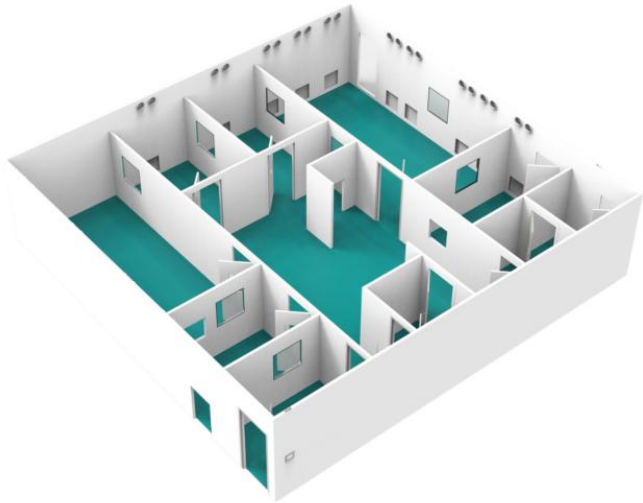
- Role-specific competencies for all personnel
- New section for staff performing PQS tasks
- Increased emphasis on demonstrating competence



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- Focus is design and maintenance
- Greater alignment with Annex 1
- Move to barrier technology
- Qualification, validation and monitoring in other sections



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- Scope and structure of PQS clarified
- Consolidation of PQS elements from other QAAPS 5 Chapters
- Incorporates self inspection

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- New section
- Replaces *Formulation, stability and shelf life*
- Considers whole lifecycle of product
  - New product assessment
  - Formulation and stability
  - Master worksheets
  - Review and change control

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- New section
- Incorporates elements of QAAPS 5 *Personnel, training and competency assessment* and *Facilities and equipment*
- Covers cleanroom behaviour and gowning



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- New umbrella term “decontamination”, incorporates cleaning and disinfection.



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- Qualification and validation of facilities and equipment moved to this section



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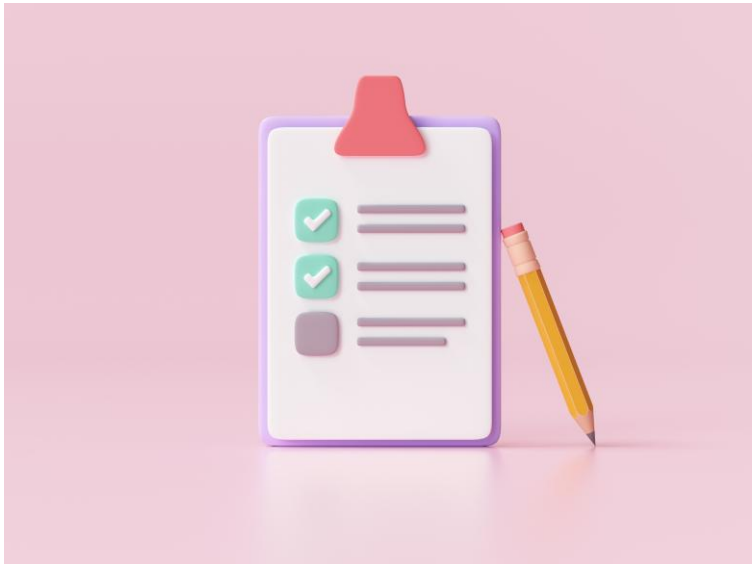
- No significant content changes



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- Separated from clinical check
- Includes preparation of individual product worksheets and labels



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- Emphasis on readiness checks and process controls
- Some process design elements have moved to product initiation



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- Change of name from *Product approval*
- Introduces the role of “releasing officer” for aseptic preparation



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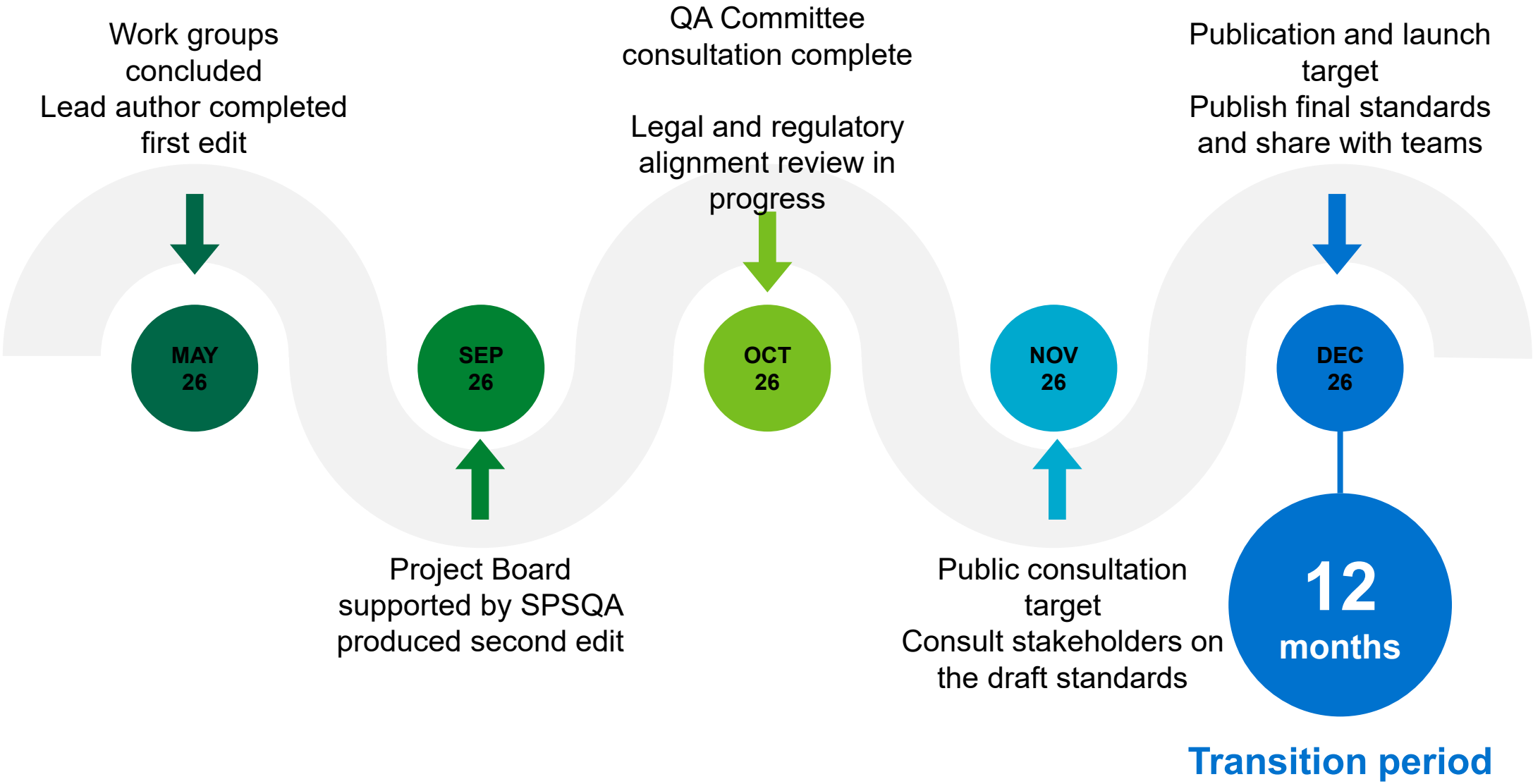
- No significant content changes
- Content on storage has moved to *Facilities and equipment* and *Validation and monitoring*




Are we nearly there yet?

QAAPS 6 progress and next steps

4 November 2026



Acknowledgements

With thanks to

Project commissioners

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UK NHS Pharmaceutical Quality Assurance Committee

Workstream members

Workstream chairs

Lead author

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GPhC/RCPharm Legal Teams

MHRA

Everyone who has contributed to the project

