Quality Assurance of Aseptic Preparation Services: Standards

Update to 6th edition

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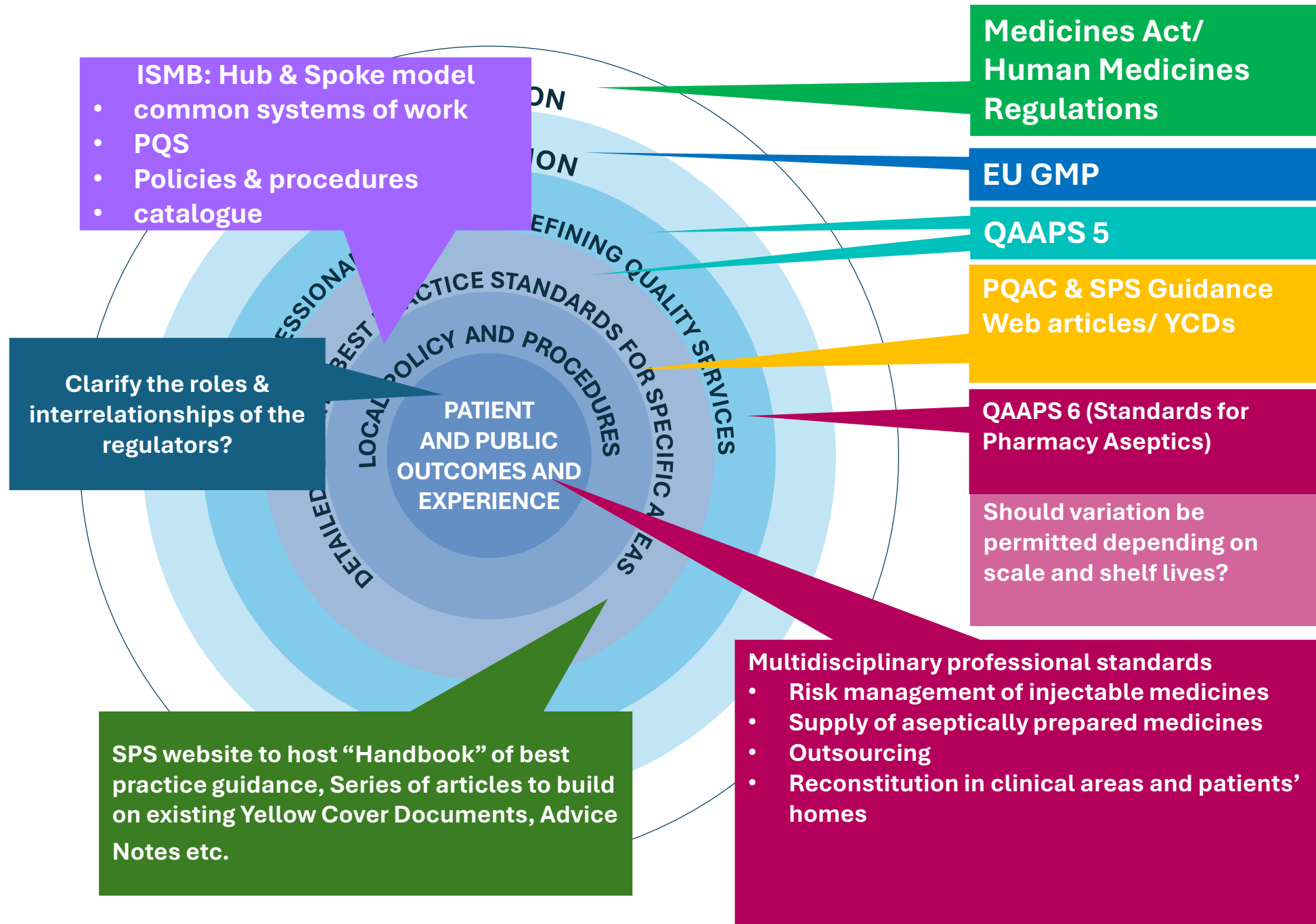
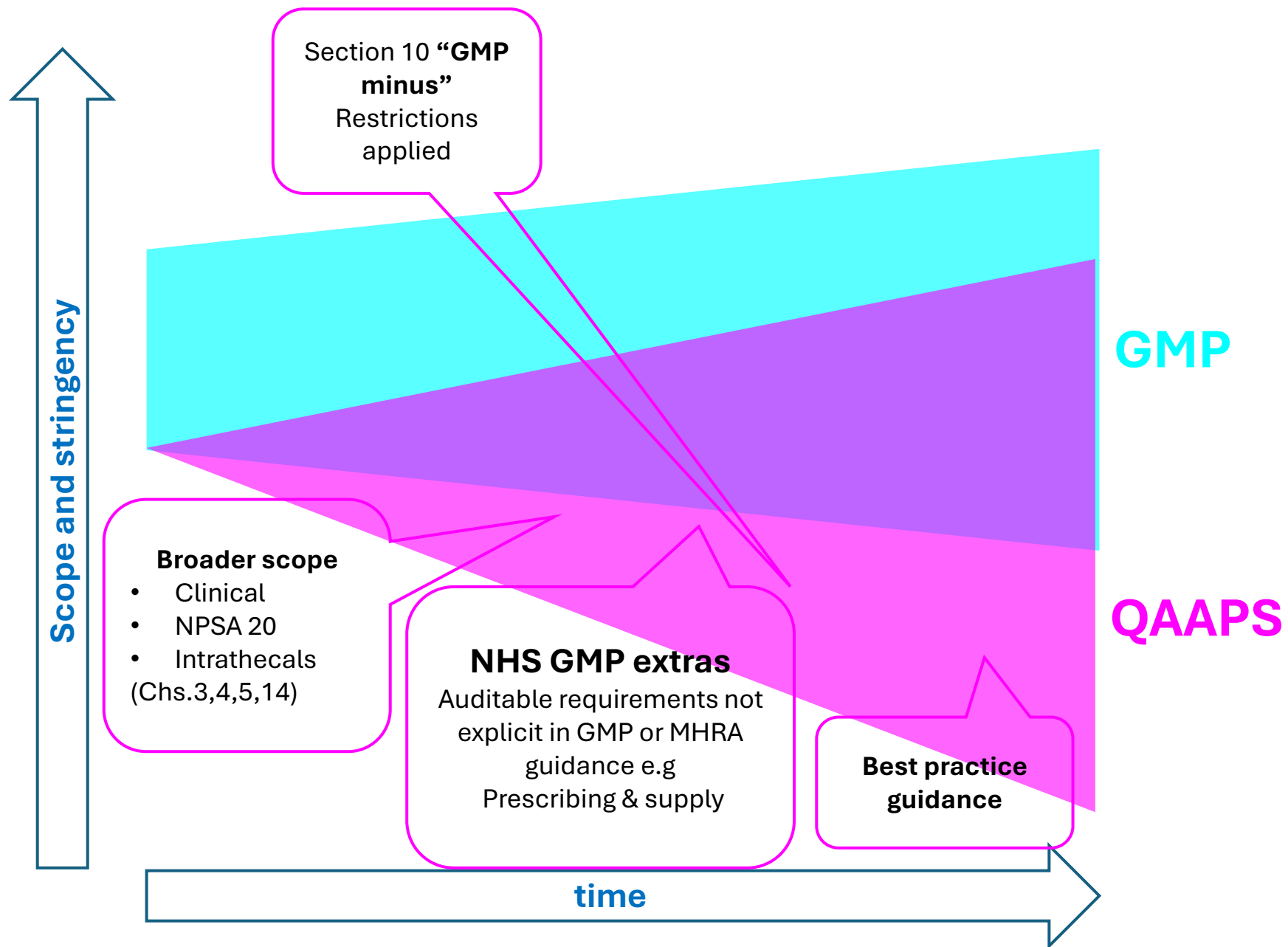Lynn Morrison, Regional QA Pharmacist/UK QA Committee Chair

Why is there a need for a new edition?

Changes & Drivers since the 5ᵗʰ edition

- New GMP Annex 1
- New MHRA guidance
- NHS aseptic transformation Programme
- New Guidance replacing EL(97)52
- iQAAPS
- New therapies – ATMPs, Clinical trials
- Regulator landscape (CQC, MHRA, GPhC)
- Updated Chief Pharmacist Standards
- Prevention of future deaths reports
- Supervision legislation
- Brexit
- Devolved Nations Strategies

ISMB: Hub & Spoke model
- **common systems of work**
- **PQS**
- **Policies & procedures**
- **catalogue**

Clarify the roles & interrelationships of the regulators?

Medicines Act/ Human Medicines Regulations

EU GMP

QAAPS 5

PQAC & SPS Guidance Web articles/ YCDs

QAAPS 6 (Standards for Pharmacy Aseptics)

Should variation be permitted depending on scale and shelf lives?

Multidisciplinary professional standards
- **Risk management of injectable medicines**
- **Supply of aseptically prepared medicines**
- **Outsourcing**
- **Reconstitution in clinical areas and patients' homes**

SPS website to host "Handbook" of best practice guidance, Series of articles to build on existing Yellow Cover Documents, Advice Notes etc.

PATIENT AND PUBLIC OUTCOMES AND EXPERIENCE

LOCAL POLICY AND PROCEDURES

BEST PRACTICE STANDARDS

PROFESSIONAL STANDARDS

DEFINING QUALITY SERVICES FOR SPECIFIC AREAS

DETAILED

Design of the project

Scope of the Project

- Commissioned by NHS England, Scotland and Wales

- Joint project – NHSPhQAC and RPS

- To update Part A of the Quality Assurance of Aseptic Preparation Services: Standards Handbook.

- The update will review the contents of Part A. The 6th edition will set a standard and not a '*how to*' guide e.g., '*a unit will have a risk assessment*' not '*a unit must have a quantitative risk assessment with 10 risks*'. Units must have flexibility to achieve the standards.

- To incorporate relevant changes since 2016 with a practical mindset on implementation within NHS aseptic units.

- The working groups and lead author will be able to incorporate new and remove old standards from the 5th edition.

- To have a complete review of references ensuring that the new guidance is using up to date evidence, legislation and guidance.

Structure of the Project
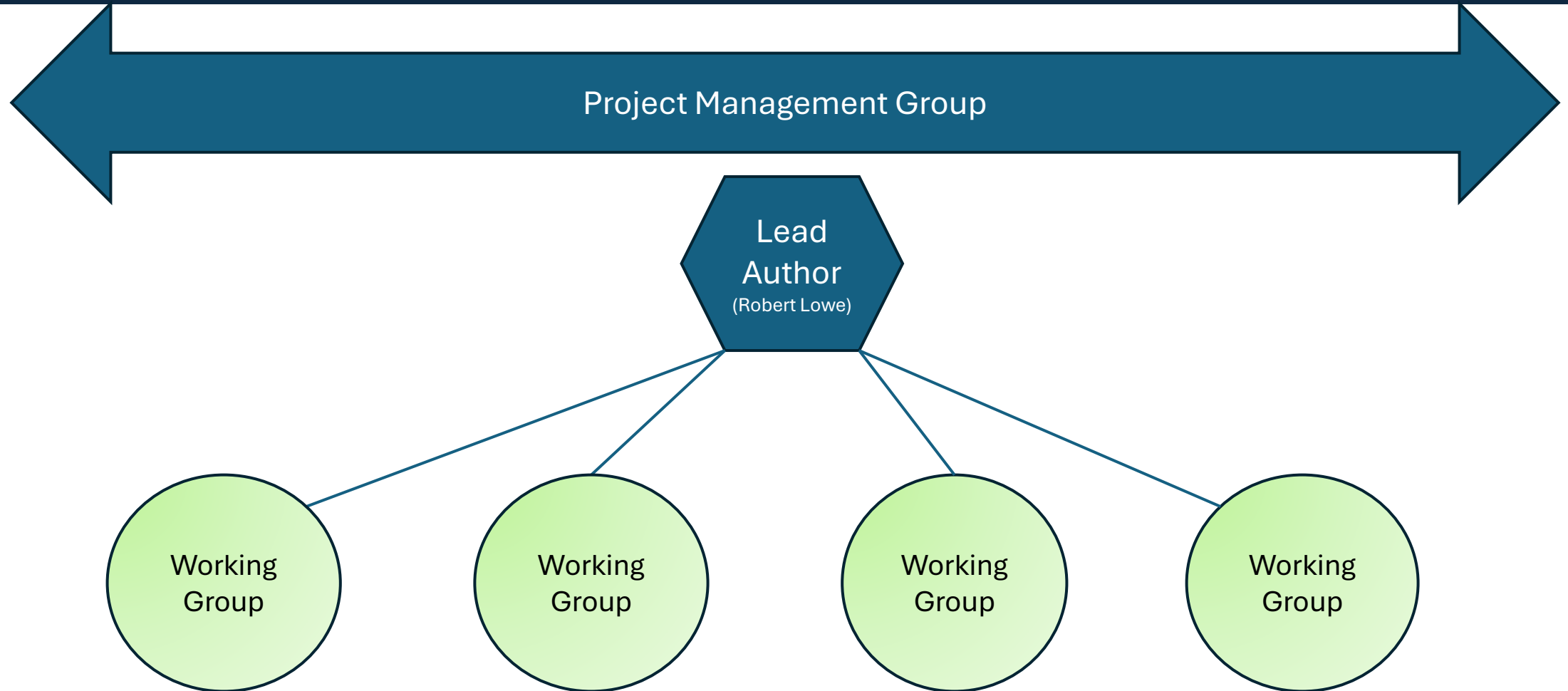
Structure of the Project

- **Project Management Group**
- Governance – RPS,QA,Lead Author, Co-chairs
- Project scope
- Selection process – over 160 applicants
- Define roles and responsibilities
- Forum for resolution of any debate
- Forum for collating innovation and best practice

- **Workstreams**
- 2 Co-chairs
- 15 members
- Aseptic, QA, Radiopharmacy, Education specialists etc.

- Opportunity to reach out to other specialists as required

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
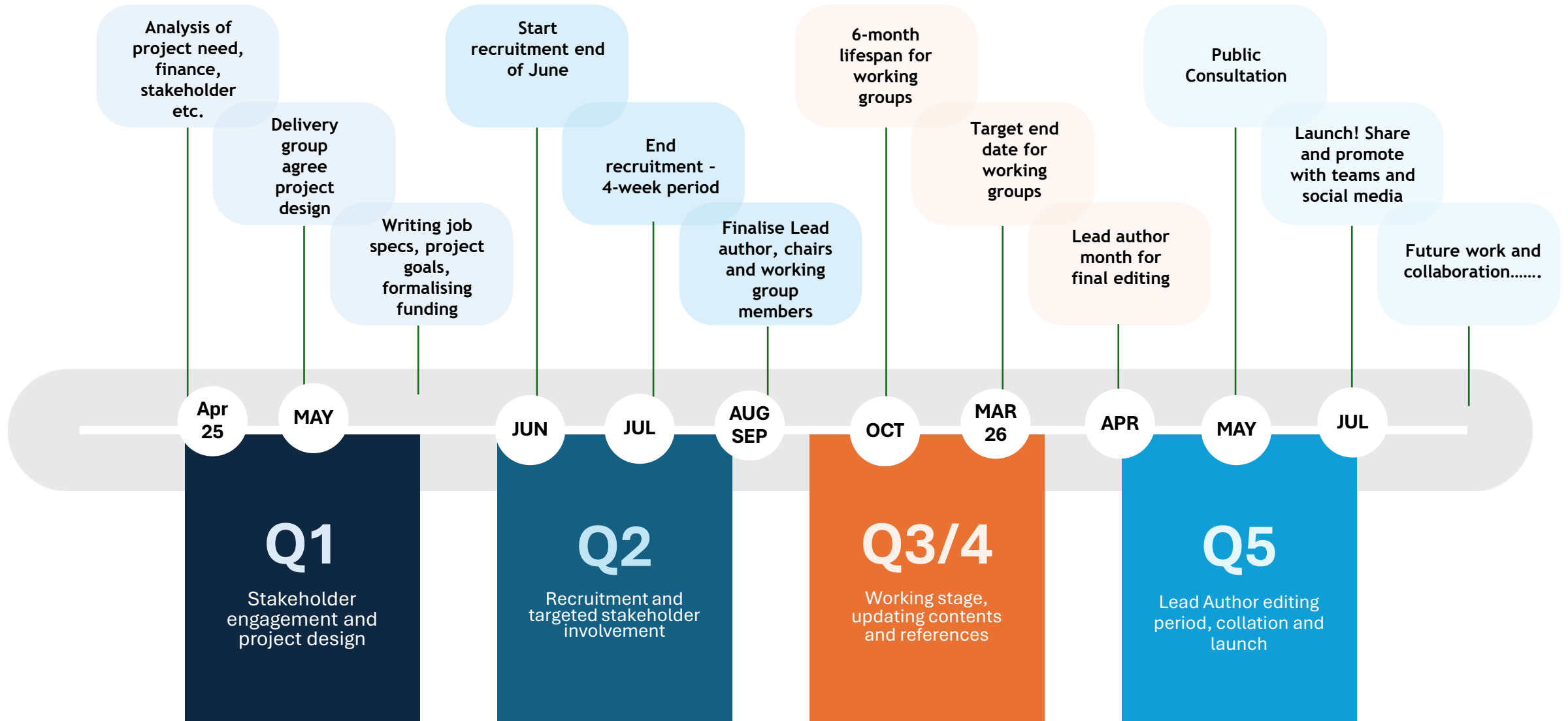Ch 13: Starting Materials
Ch 15: Storage & Distribution

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

Project Timescales

Analysis of project need, finance, stakeholder etc.

Delivery group agree project design

Writing job specs, project goals, formalising funding

Start recruitment end of June

End recruitment - 4-week period

Finalise Lead author, chairs and working group members

6-month lifespan for working groups

Target end date for working groups

Lead author month for final editing

Public Consultation

Launch! Share and promote with teams and social media

Future work and collaboration.......

Apr 25 | MAY | JUN | JUL | AUG SEP | OCT | MAR 26 | APR | MAY | JUL

Q1 — Stakeholder engagement and project design

Q2 — Recruitment and targeted stakeholder involvement

Q3/4 — Working stage, updating contents and references

Q5 — Lead Author editing period, collation and launch

Up-to-Speed, Where we are now?

- RPS have completed legal and financial contracts. RPS will continue to support the project, financially, editorially, publication and media.

- Project governance - Project Management group

- Lead author has been selected and appointed

- Workstream co-chairs and members have been selected

- Initial meeting with Project Management Group, Lead Author and Co-chairs

Thank You
Any Questions?