QATS 2026

Aseptic Preparation Audit - Compliance Management

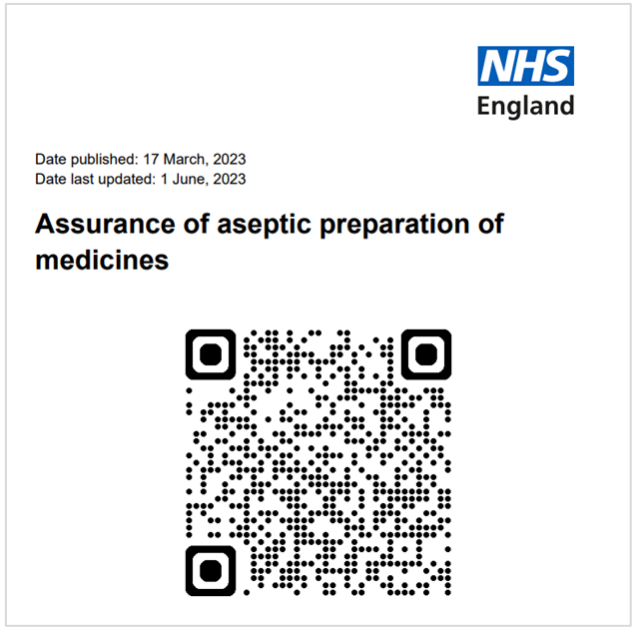
Mark Jackson SPS QA Function Lead

The first stop for professional medicines advice

04/11/2026

Compliance Management

- Triggers
  - High Risk Rating at Audit
  - Loss of control
- Two stages
  - Enhanced oversight (CM1)
  - Escalation (CM2)
- Led by SPS QA
  - ➢ Monthly CM meetings with sites
  - ➢ Additional support provided to units
  - ➢ Reporting to RCPs
  - ➢ Oversight by CMOG


NHS England

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Assurance of aseptic preparation of medicines

Aims of Compliance Management

- Ensure immediate risks are communicated and controlled
- Maintain safe continuity of supply
- Ensure a robust recovery plan is in place
- Secure support and commitment from the Trust, integrated care board and region
- **Return the service to compliance**



High-Risk Audit Rating









Product Quality:

Contamination risk

Product Quality:

Error risk

Missed doses:

Service continuity risk

Common Problems





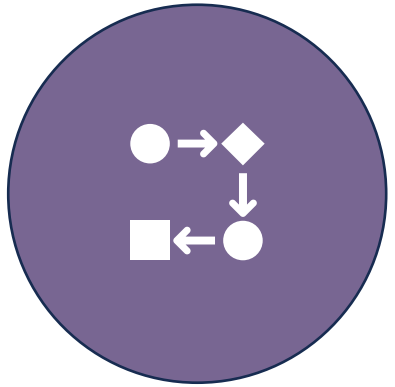
Capacity



Premises

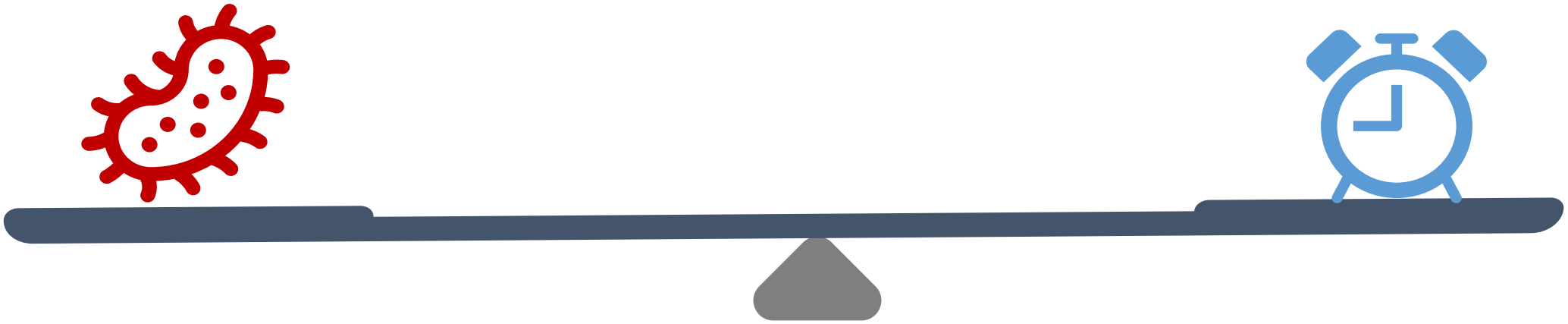


Capability



Processes

Balancing Patient Risks



Medicine Quality

Delayed Treatment

MAKE SAFE

Compliance Management Exit Pathway

1. Make Safe

Can the service operate safely?

Interim measures to control patient safety risks and enable safe operation

2. Demonstrate control

Can the service show the interim controls are working?

On-going evidence to demonstrate control

3. Recovery plan

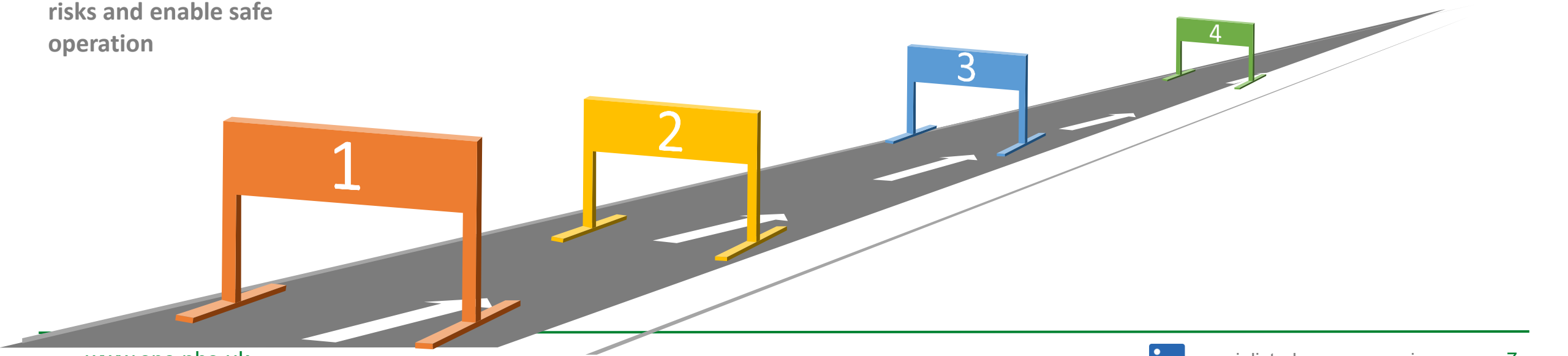
Do the team understand the root cause(s) and how to address them?

Sustainable plan established

4. Secure Commitment

Has the organisation committed the resources needed to deliver the improvements?

Evidence of organisational approval



Questions

