Newcastle Specials
Pharmacy Production and Quality Control Unit

The Challenge

- **Enabling Safe Cross-Boundary Aseptic Supply Under Section 10 Constraints**

The Problem

- Oncology patient required Epcoritamab treatment.
- On-site NHS aseptic unit could not safely provide the product due to workforce and capability limitations.
- Delaying treatment created a genuine patient risk.
- Proceeding without appropriate governance arrangements created patient safety, legal and regulatory risks.

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Challenges

Patient	Organisation	Regulatory	Quality
Time-critical treatment required	Different Trusts	Section 10 Constraints	Product preparation
	Different Accountable Pharmacists	Not mutual aid	Transport
	Different governance responsibilities	Accountability needed to be clearly defined	Dispensing
			Stability
			Traceability

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What we did

Governance First Approach

- Engaged Regional Quality Assurance specialists.
- Reviewed Royal Pharmaceutical Society guidance.
- Conducted formal risk assessments.
- Implemented Change Control within both organisations.
- Developed and signed a formal Quality Technical Agreement.
- Defined responsibilities for:
  - preparation
  - transport
  - dispensing
  - accountability
  - quality management

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The Outcome

Results

✅ Treatment delivered on time.
✅ Patient remained under local care.
✅ No transfer to another organisation required.
✅ Governance fully maintained.
✅ Quality assurance standards upheld.
✅ Clear accountability established.
✅ Framework available for future situations.

Wider Benefits

- Built capability within the receiving unit.
- Shared technical expertise.
- Strengthened regional collaboration.

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Key Learning

What this taught us

1. Governance should enable care, not block it.
2. Urgency should not override patient safety.
3. Cross-organisational collaboration can solve complex service problems.
4. Quality Agreements are powerful tools for enabling safe shared working.
5. Similar frameworks could support future regional resilience planning.

Final takeaway

A governance-led solution to a patient-centred problem.