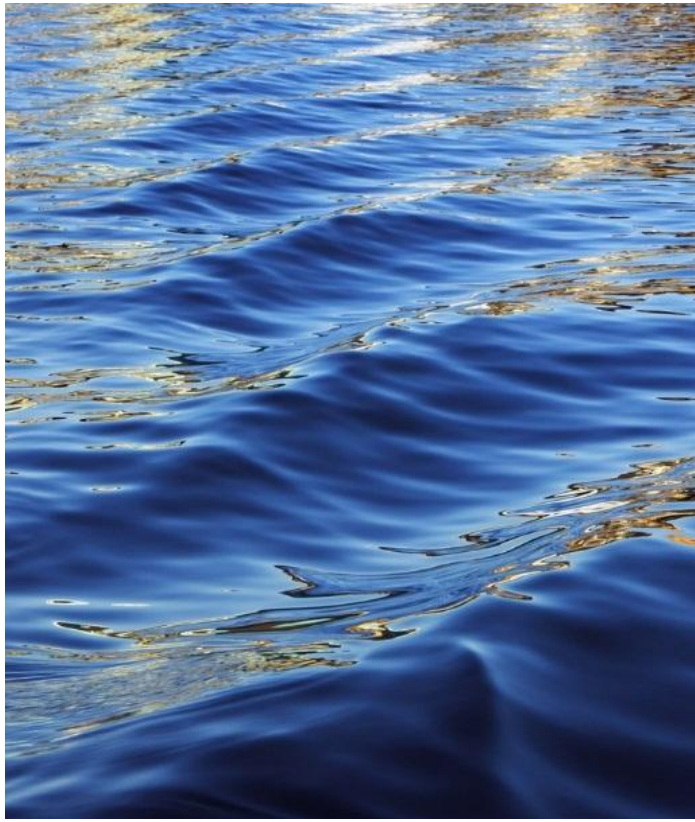
Guy's Radiopharmacy



From IAG to Inspection readiness

Our Experience of MHRA Compliance Monitoring





NHS
Guy's and St Thomas'
NHS Foundation Trust

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Context and Background

- Radiopharmacy Service
  - Specials Manufacturer's Licence (MS)
  - Supply to multiple NHS and Private hospitals

Inspection History

- MHRA inspection 2013
- Outcome: 1 Major deficiency
- Planned inspection cycle disrupted by organisational factors, COVID-19 and inspectorate capacity
- Next full inspection: 2023

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MHRA inspection 2023

The 2023 inspection followed a prolonged period without a full Radiopharmacy inspection and occurred during a time of operational pressure and change.

Inspection outcome

- 2 Critical deficiencies
- 2 Major deficiencies
- Referred to MHRA Inspection Action Group (IAG)

Themes identified by inspectors

- Environmental monitoring and microbiology oversight
- Aseptic process controls
- Capacity and resource management
- Data integrity and Pharmaceutical Quality System (PQS)weaknesses
- Lack of senior management oversight

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MHRA inspection 2023 fallout

Contributing factors

- Significant increase in workload
- Staffing vacancies and sickness absence
- Ageing facilities
- Growing PQS backlog

Option to Join Compliance Monitoring Programme

- Enhanced regulatory oversight following referral to IAG
- Structured programme to deliver and verify remediation
- Demonstration of sustainable GMP compliance

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Compliance Monitoring Programme

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Company expectations	Compliance Monitor expectations
• Commitment	• Available to the company for the required time
• Communication • Open and honest	• Open dialogue with inspector and IAG

• Drive remediation
  • Company ultimately responsible
	• Engagement with company
	  • Both on site and remote

• Make sustainable changes • Independent of reliance on specific personnel	• Review the report on deliverables according to the timelines in the protocol
• Have adequate resource • Doesn't introduce further risk	• Ensure changes to the protocol are reported to the IAG and Inspector as soon as identified
• Report to timelines	• Confirm that they agree company is ready for inspection
• Report changes	• Ensure no conflict of interest

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Compliance Monitoring Programme - Process

- Select suitable CM approved by MHRA
  - Inspector with the MHRA for >15 years and has extensive experience of the NHS and Radiopharmacies
- Agreed remediation plan – the protocol
- Regular progress reviews
- Submission of objective evidence
- Site visits and document reviews
- Independent challenge and support
- Verification before closure of actions

Key point: It is not simply reporting progress. Evidence must demonstrate that improvements have been implemented, embedded and are effective.

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Compliance Monitoring Programme - Experience

- Having a dedicated Compliance Monitor ensured:
  - Supportive and constructive process
    - Honest discussions and opportunity to test proposed solutions
  - Regular engagement-maintained momentum
  - Improved inspection readiness and quality culture
    - Confidence that remediation was aligned with MHRA expectations
  - Clear expectations and rapid feedback
    - Biggest benefit to our unit due to a period of reduced capacity and lack of regional supply
- Not simply about closing deficiencies; it was about demonstrating that improvements were effective, sustainable and embedded within the quality system.

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Compliance Monitoring Programme - Outcome

- After 12 months agreed with Compliance Monitor that unit was ready for reinspection
  - Due to being on the programme inspection was prioritised

- April 2024 – reinspected by MHRA
  - 0 Critical deficiencies
  - 1 Major deficiency
  - Significant progress acknowledged by inspectors
  - Removed from IAG oversight
  - Risk rating improved from II to III
  - Moved to Compliance Management Team (CMT)

  - Capacity restrictions removed and output increased



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