QA TECHNICAL SYMPOSIUM

Building Successful Partnerships for QC Services

“You can outsource the services, but not the responsibility.”

Liam Harvey & David Caulfield

4th Nov 2026

Today: from regulation to partnership

A practical roadmap for the next 30 minutes

30 MINUTES

01 — 08 MIN

WHY IT MATTERS

Partnership success
Chapter 7 + QAAPS 5

→

02 — 06 MIN

THE OPERATING REALITY

UK post-Brexit
One laboratory, many clients

→

03 — 13 MIN

THE PRACTICAL MODEL

QTA + URS + SPM
An example and governance

→

04 — 03 MIN

THE TAKEAWAY

Five lessons
Questions and discussion

Define accountability → Agree operational expectations → Monitor and improve delivery

What makes a QC partnership successful?

Compliance

GMP-compliant testing, complete records, appropriate investigation and data integrity.

Reliability

Predictable sample receipt, capacity, turnaround and escalation.

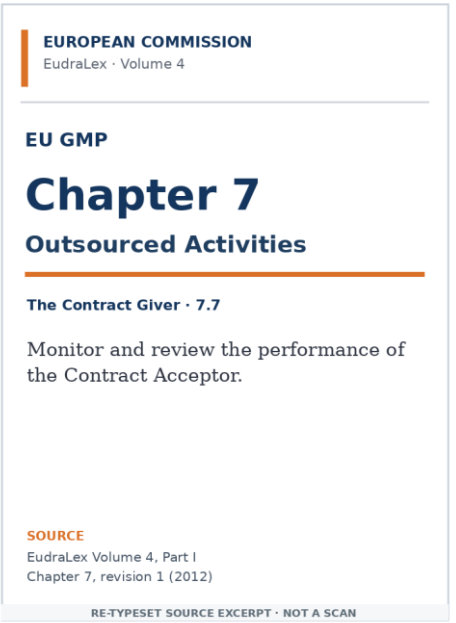
Confidence

Clarity over responsibilities, transparent communication and early identification of risk.

Chapter 7: the non-delegable responsibility

The contract giver retains responsibility for the control and review of outsourced activities.

- **7.4–7.5** Qualify the provider and maintain risk-based control
- **7.6–7.8** Share critical knowledge, monitor performance and review results
- **7.14–7.17** Define responsibilities, records, communication and audit rights



EUROPEAN COMMISSION
EudraLex · Volume 4

EU GMP

Chapter 7

Outsourced Activities

The Contract Giver · 7.7

Monitor and review the performance of the Contract Acceptor.

SOURCE
EudraLex Volume 4, Part I
Chapter 7, revision 1 (2012)

RE-TYPESET SOURCE EXCERPT · NOT A SCAN

Chapter 7 source-page extract

Source: EudraLex Volume 4, Part I, Chapter 7 (2012 revision)

From regulatory expectations to effective oversight

EU GMP Chapter 7

Control and review of outsourced GMP activities rests with the contract giver.

§7.4–7.8, §7.14–7.17

QAAPS 5th edition

Define outsourced responsibilities, resource oversight and ensure laboratory competence.

§8.2.9.1–2; Ch. 11, II.8.4–5



2016 standards

OUR PRACTICAL RESPONSE

QTA

Define accountability

URS appendix

Make expectations measurable

SPM

Monitor delivery and improvement

Regulations define the duty. These three tools provide the operating model.

Post-Brexit: a more complex operating environment

- EU–UK agreement recognises GMP inspection outcomes — not blanket equivalence of batch testing
- UK QC batch release testing no longer accepted in the EU
- Consolidation of testing by pharma to EU test labs

Implication: Fewer commercial QC UK, significant drivers to find efficiencies for those that remain.

The laboratory perspective: one lab, many clients

Methods

Pharmacopoeial versus client-specific methods; validation, verification and transfers.

Quality systems

Different deviations, OOS/OOT triggers, notification thresholds and report templates.

Service demands

Routine versus urgent, stability and environmental monitoring; variable volume and lead times.
Resource planning.
Do users always compare like with like.

Where relationships strain: specifications lag behind change

The trigger is often change — the risk is that agreed technical requirements do not evolve with it.

EXTERNAL CHANGE

Revisions to Annex 1 or QAAPS; new pharmacopoeial or regulatory expectations

INTERNAL CHANGE

Changes in ownership, leadership or key staff; changes to service or testing scope

If the QTA, URS and laboratory procedures are not reassessed together...

Technical mismatch

Test methods, sample plans, specifications or verification expectations diverge.

Regulatory ambiguity

Investigation triggers, identification, acceptance criteria or reporting are unclear.

Lost accountability

Approvals, communication, knowledge transfer and escalation become uncertain.

Response: joint change assessment → update URS / QTA → implement & verify → monitor via SPM

A QTA is necessary — but is it sufficient?

What the QTA does

Defines GMP obligations, responsibilities, quality events, change notification, records and audit rights.

What it may not fully define

Detailed regulatory requirements / testing specifications, sample logistics, critical turnaround expectations, service interfaces, reporting detail.

The practical gap

Sample retentions, approval for hypothesis testing, responsibility for regulatory surveillance for changes in test methods.

An Audit Deficiency

Neither the QTA or analytical record provided the sufficient lack of detail to determine whether the testing performed was sufficient and in compliance with regulatory expectations.

Our practical model: three layers of control

QTA

WHO is accountable

Quality responsibilities, GMP governance, rights and escalation

URS

WHAT good service requires

Defined expectations, interfaces, timing and outputs

SPM process

HOW delivery is monitored

Issue capture, triage, action, trend and review

URS : turn assumptions into requirements

Inputs & scope

Sample types, methods, specification versions, test quantities, stability, acceptance criteria and special handling.

Especially important when regulatory standards have changed.

Service interfaces

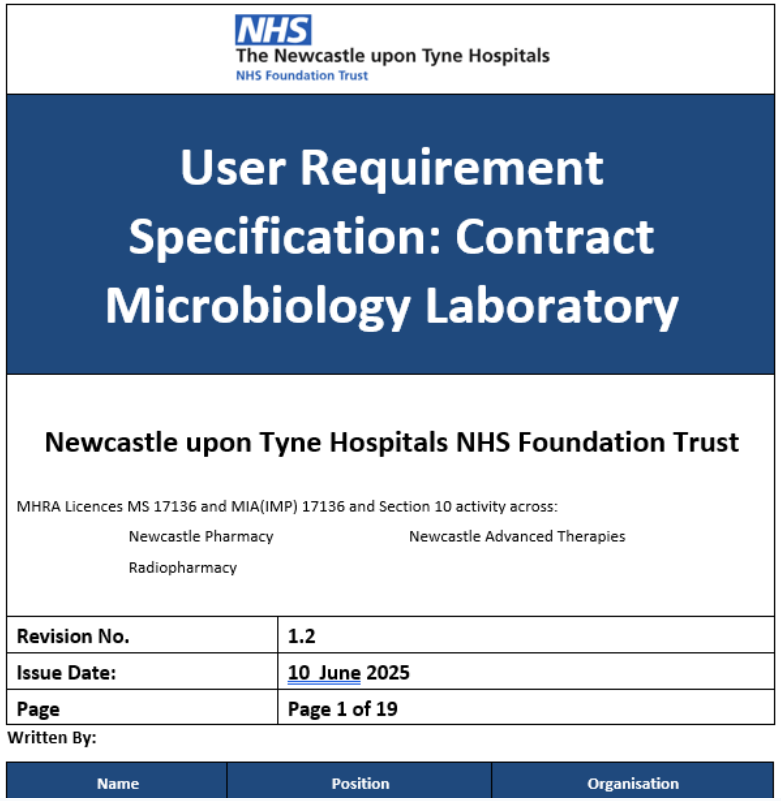
Booking / forecasting, sample acceptance, chain of custody, priorities, turnaround definitions and reporting routes.

Quality expectations

Immediate critical-event alerts, investigation handoffs, data package, method changes, oversight and contingency.

Case study: defining expectations with a microbiology URS

A controlled URS appendix turns the needs of multiple services into agreed laboratory expectations.



NHS
The Newcastle upon Tyne Hospitals
NHS Foundation Trust

User Requirement Specification: Contract Microbiology Laboratory

Newcastle upon Tyne Hospitals NHS Foundation Trust

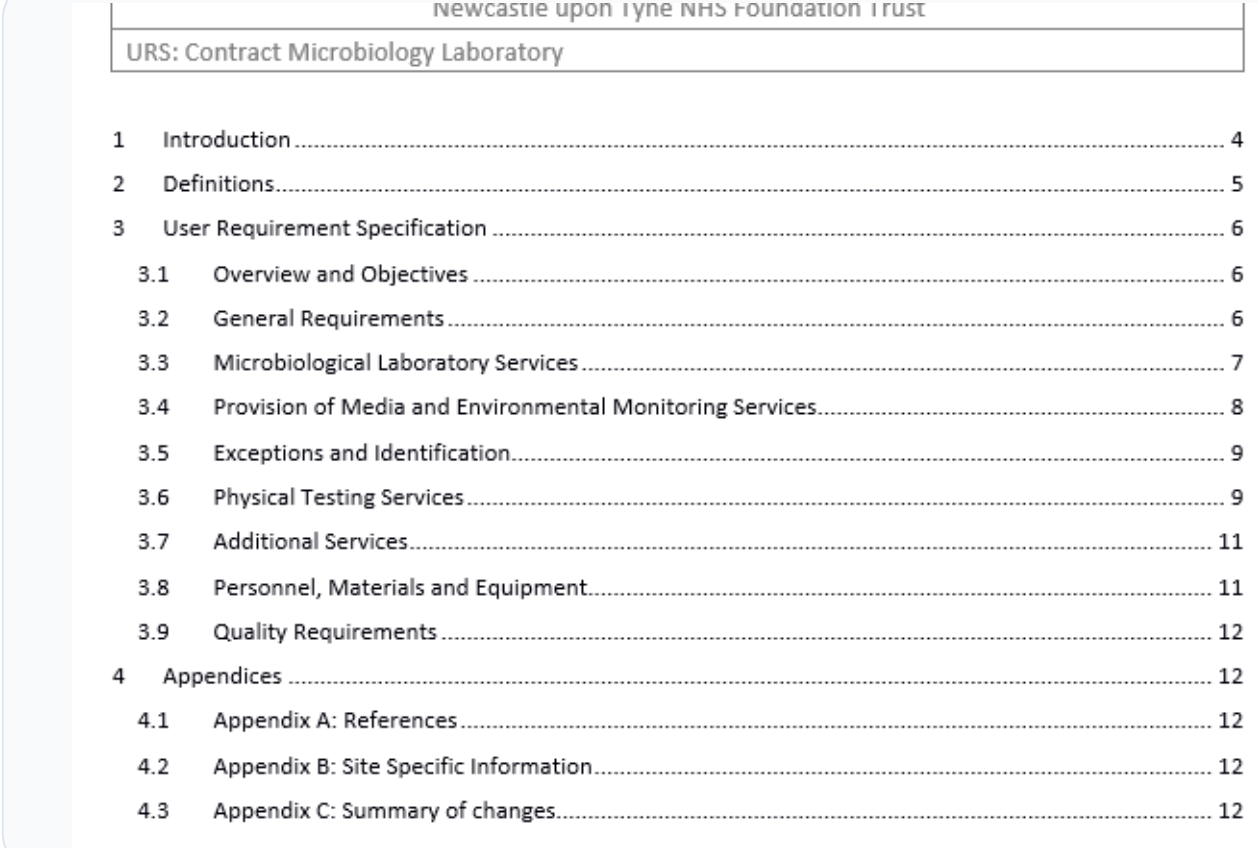
MHRA Licences MS 17136 and MIA(IMP) 17136 and Section 10 activity across:

Newcastle Pharmacy | Newcastle Advanced Therapies | Radiopharmacy

Revision No.	**1.2**
Issue Date:	**10 June 2025**
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Written By:

Name	Position	Organisation



Newcastle upon Tyne NHS Foundation Trust

URS: Contract Microbiology Laboratory

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Supplier Performance Monitoring

A five-stage, auditable route from issue identification to evidenced close-out

01

RECORD

Identify & log

Capture event type, dates, details and evidence.

Section 1

02

RESPOND

Engage contractor

Notify the provider; agree actions and timescales.

Section 2

03

ASSESS

Evaluate impact

Review product, process, facilities and patient risk; check trends.

Section 3

04

FOLLOW UP

Track & escalate

Monitor actions and deadlines; record extensions, escalation or contract review.

Section 4

05

CLOSE

QA sign-off

Confirm outcome and completed actions; authorise closure.

Section 5

↺ **LEARNING LOOP** Trends and escalations feed supplier reviews, improvement actions and QTA / URS updates.

Workflow adapted from SOP U-19-02 Appendix 1 (Monitoring of Outsourced Activity report form).

What a useful SPM dashboard might show

Turnaround reliability

On-time versus agreed test-specific commitment

Notification timeliness

Time from event detection to contract-giver notification

Recurring issues

Open / overdue SPM issues and repeated categories

Investigation effectiveness

Age of joint investigations and recurrent causes

Verifying what was requested was delivered

The Newcastle upon Tyne Hospitals NHS Foundation Trust — Pharmacy Production and Quality Control Unit

SAFE- Service Acceptance for Facilities + Equipment

SQC: ZONE 6 AM Suite Checklist

SOP U-03-42 Appendix 2f AM-Q

QUARTERLY — SQC No:

Equipment / Facility Location:

Licensed Production Area: ~~Z3 NS~~ | ~~Z4 TS~~ | Z6 AM✓ | ~~Store~~

~~Unlicensed Production Area~~: ~~Z5 PN~~ | ~~Z5 AD~~ | ~~Z5 CYT~~ | ~~NCCC~~

~~Lab~~: ~~QC~~

~~Plant~~: ~~WFI~~ | ~~AHU~~

Outsourced activity to be Performed By:

Company *(Outsourced activity contract holder)*

Stockton Quality Control Laboratory

Date of visit:

PTW Register: PPU | QC | NCCC | PS

PTW No:

Details of outsourced activity performed + corresponding interval

Environmental Testing

Quarterly✓ | ~~Annual~~ | ~~At rest~~ | In use✓

SCHEDULED TESTING – SQC Staff to indicate areas / equipment + testing completed

i) ROOMS

Zone 6 AM Suite

ROOM reference

Expected tests = All as listed

P1.603 AM Isolator room ☐

Expected tests = Pressure differentials only

P1.601 AM change ☐ P1.602 AM Support room ☐

Expected tests:

Microbial air test [QC Limits] ☐	Microbial surface test [QC Limits] ☐	Particle test [QC Limits] ☐
Clean up rate [c GMP] ☐	No. of A/c per hour [QC Limits] ☐	Temperature ☐
Relative Humidity ☐	Noise levels [Isolators running] ☐	Light levels ☐
Room checks ☐		

ROOM Pressure differentials [measured from indicated Room]

601 AM change ☐ 602 Support Rm ☐ 603 Iso Rm ☐

604 Stock Room ☐

Trolley Transfers: 605 [TT] ☐ 606 [TT] ☐ 607 [TT] ☐

ii) EQUIPMENT LOCATION: AM Isolator room [P1.602]

PROCESS Isolator	Serial No:	Asset ID:	PROCESS Isolator	Serial No:	Asset ID:
P1 ☐	2099	133479	P2 ☐	2102	133477
P3 ☐	2103	133480	P4 ☐	2101	133478
P5 ☐	2100	133481			

Expected tests:

Microbial air test [c GMP] ☐	Microbial surface test [c GMP] ☐	Particle test [c GMP] ☐
Average air velocity [c GMP] ☐	Air changes per hour ☐	Noise levels ☐
Light levels ☐	Pressure differentials ☐	Isolator checks ☐
Airflow pattern ☐		

The Newcastle upon Tyne Hospitals NHS Foundation Trust — Pharmacy Production and Quality Control Unit

SAFE- Service Acceptance for Facilities + Equipment

SQC: ZONE 6 AM Suite Checklist

SOP U-03-42 Appendix 2f AM-Q

QUARTERLY — SQC No:

i. **ROOM:** Summary of expected testing according to interval

[P1.601] AM Change

Test performed	Test standard	Test Limits / Required Standard	TEST STATUS PASS [P] / FAIL [X]	Additional Comment
Pressure differential ROOM				
• AM change [601] → Outer corridor [117]		15 – 50 Pa		

[P1.602] AM Support Room

Test performed	Test Limits / Required Standard	TEST STATUS PASS [P] / FAIL [X]	Additional Comment
Pressure differential ROOM			
• AM Support [602] → AM change [601]	10 – 50 Pa		
• AM Support [602] → AM Trolley transfer [607]	–		
• AM Trolley transfer [607] → Outer corridor [117]	–		
• AM Trolley transfer [606] → AM Support [602]	> 0 Pa		

[P1.603] AM Isolator Room — **Room - IN USE**

Test performed	Test standard	Test Limits / Required Standard	TEST STATUS PASS [P] / FAIL [X]	Additional Comment
Microbial air test				
• Near Change [601]	[c GMP]	≤ 200 cfu/m³, Grade D		
• Far end		≤ 200 cfu/m³, Grade D		
Microbial surface test	[QC Limits]			
Near Change 601:				
• Floor		≤ 50 cfu		
• Bin		≤ 25 cfu		
• Bench		≤ 25 cfu		
• Trolley		≤ 25 cfu		
• Top of Sanitising Isolator	*(S1 or S2)*	≤ 50 cfu	S1 S2	
Far end of room 603:				
• Floor		≤ 50 cfu		
• Bench		≤ 25 cfu		
• Chair		≤ 25 cfu		
• Top of Process Isolator	*(P3 or P4)*	≤ 50 cfu	P3 P4	
• Heat sealer		≤ 25 cfu		
Middle of room 603:				
• Inside half suit		≤ 50 cfu		

Governance: prevent the QTA becoming a shelf document

- Operational check-ins: capacity, samples, open issues and short-term priorities
- Periodic quality reviews: SPM trends, deviations, CAPA, changes and audit actions
- Joint improvement decisions: record owner, date, effectiveness and residual risk
- Periodic refresh of the URS and QTA when service scope or risk changes

An example discussion: a delayed sterility result

Lab reports completion later than the date the manufacturing team expected.

- QTA: who communicates, investigates and decides batch impact?
- URS: was turnaround defined from acceptance, incubation start or another trigger?
- SPM: is this isolated, repeated or linked to capacity / sample logistics?
- Joint action: fix the interface, agree an owner and check sustained effectiveness

Five lessons to take back to your organisation

- Contract the service — and define how it will actually operate
- Specify critical expectations before the first sample arrives
- Recognise the constraints of a shared, multi-client laboratory
- Monitor the relationship continuously, not just at qualification or audit
- Treat issues as shared improvement opportunities, with clear accountability

You can outsource the services,
but not the responsibility.

QTA + URS + SPM

Questions and discussion

Selected regulatory sources

EU GMP Part I, Chapter 7 — Outsourced Activities

https://health.ec.europa.eu/system/files/2016-11/vol4-chap7_2012-06_en_0.pdf

EMA — EU–UK recognition of GMP inspection outcomes

https://www.ema.europa.eu/en/human-regulatory-overview/research-development/compliance-research-development/good-manufacturing-practice/international-collaboration-gmp-inspections

MHRA — Windsor Framework explanatory guidance

https://www.gov.uk/government/publications/windsor-framework-explainer/windsor-framework-agreement-on-the-supply-of-medicines-in-northern-ireland-explained

MHRA — UK-wide licensing for human medicines

https://www.gov.uk/government/publications/uk-wide-licensing-for-human-medicines/uk-wide-licensing-for-human-medicines

QAAPS, 5th ed. (2016) — §8.2.9 and Ch. 11, II.8.4–5

https://www.rpharms.com/Portals/0/RPS%20document%20library/Open%20access/Professional%20standards/Quality%20Assurance%20of%20Aseptic%20Preparation%20Services%20%28QAAPS%29/rps---qaaps-standards-document.pdf

MHRA — guidance for manufacturer use of QC laboratories (historical operational guidance)

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/482018/Guidance_for_mnfs_on_QC_labs_LG_Dec_15_version__doc.pdf