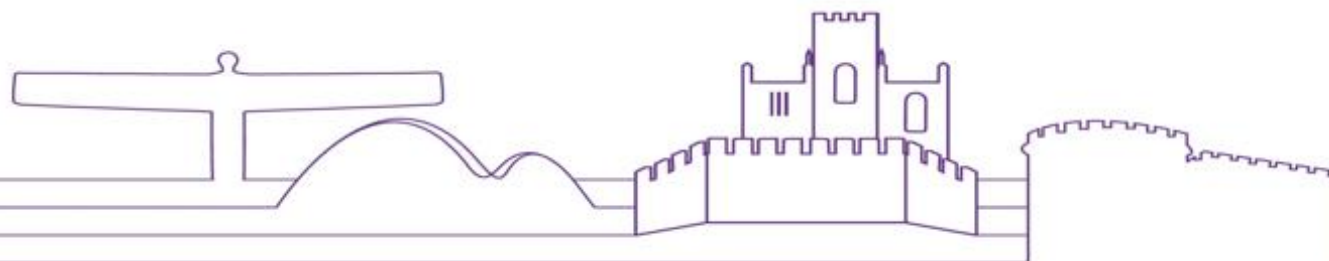


North East North Cumbria Aseptic Manufacturing Production Hub (NENC AMPH)

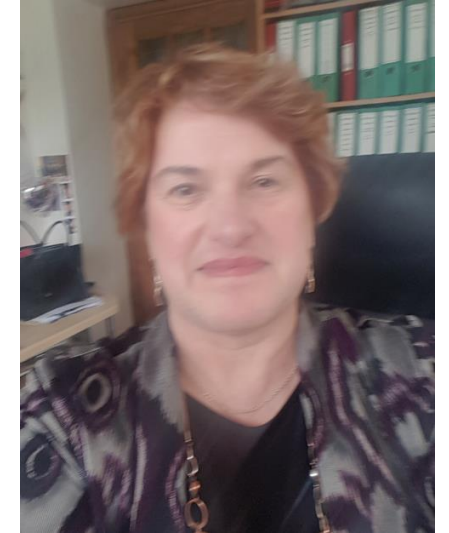
#MadeInSeaton



NENC AMPH – Meet the Team



North East and North Cumbria
Provider Collaborative



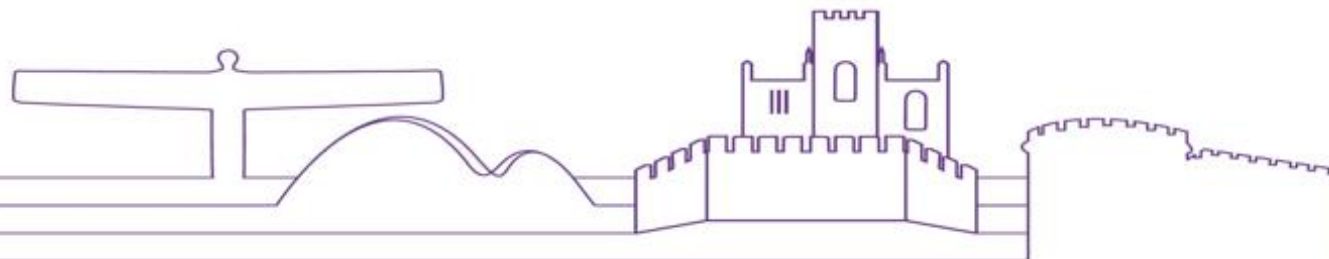
Kyle Winn
Head of Production

Dr Laura Davies
Head of QA QC

Adam Walker
Interim Head of QA QC

Craig Muller
Project Manager

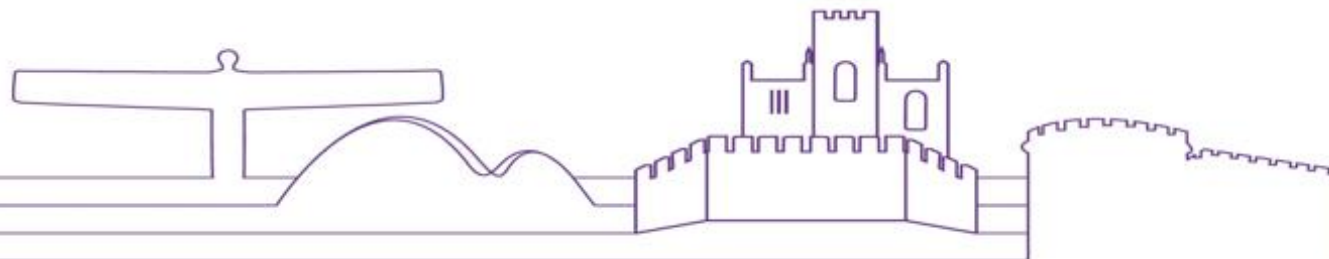
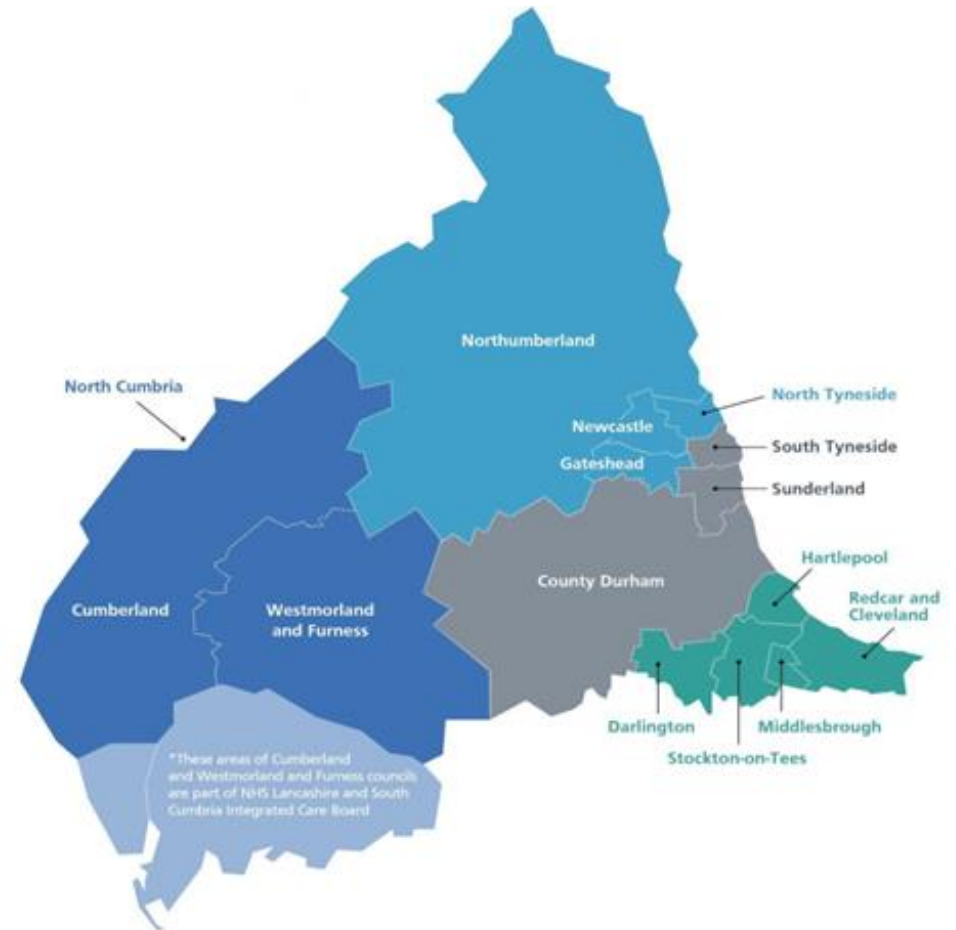
Helen Delahaye
Consultant Project
Director



NENC AMPH – Limited Liability Partnership

Limited Liability Partnership (LLP) owned by 8 Foundation Trusts.

- Northumbria Healthcare
- Newcastle Hospitals
- Gateshead Health
- County Durham and Darlington
- North Tees and Hartlepool
- South Tees Hospitals
- South Tyneside and Sunderland
- North Cumbria Integrated Care

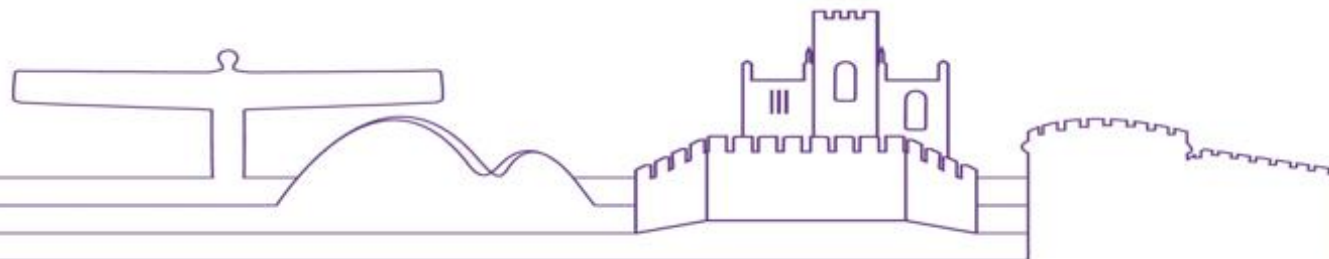


NENC AMPH – Project overview

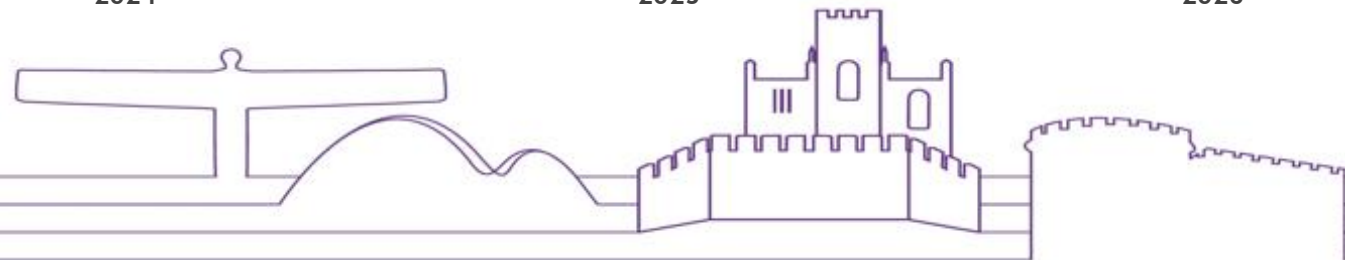
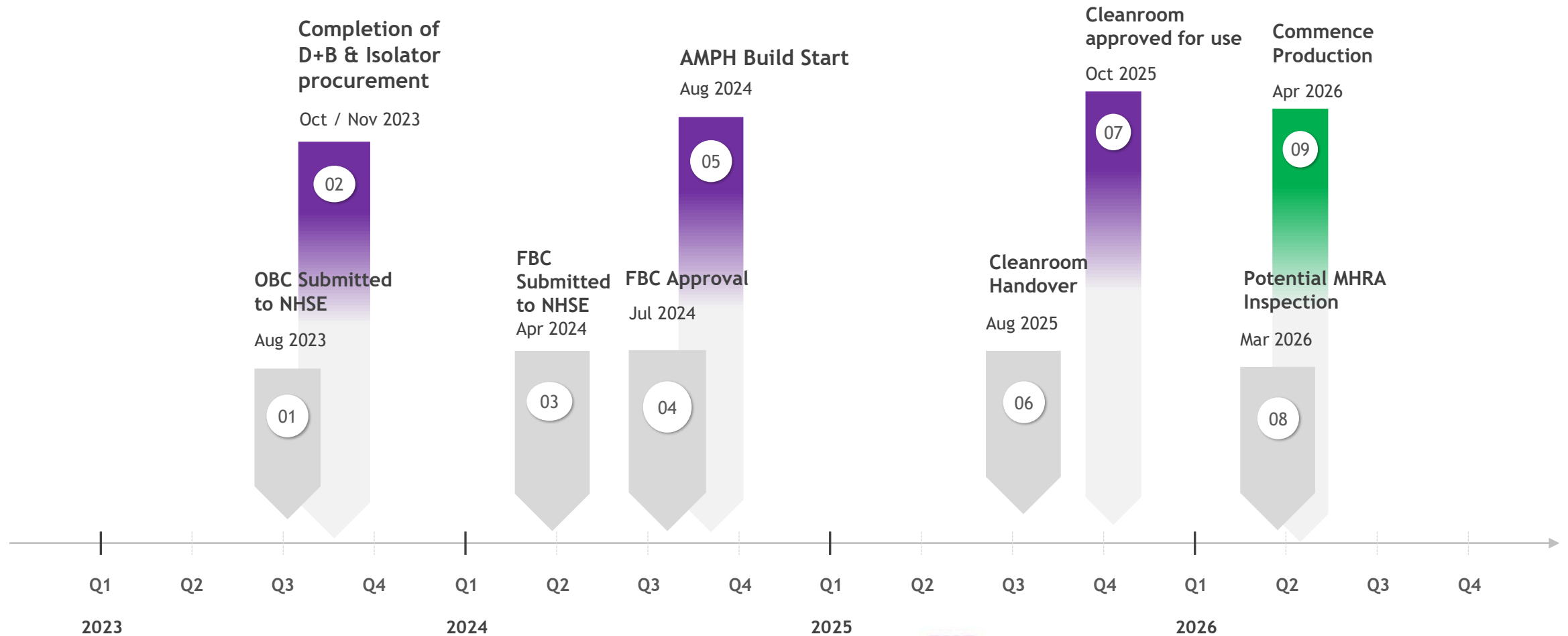
- Output of > **1,300,000** units per annum
 - Ready To Administer (RtA)
 - Systemic Anti-Cancer Treatments (SACT)
 - Over-labelled products

- Site Location

- 3 – 4 cleanroom suites
- VHP Isolator Technology
- Automation / Semi Automation
- QC Lab (Micro + Chemistry)
- MS Licenced + WDA
- Brand new workforce

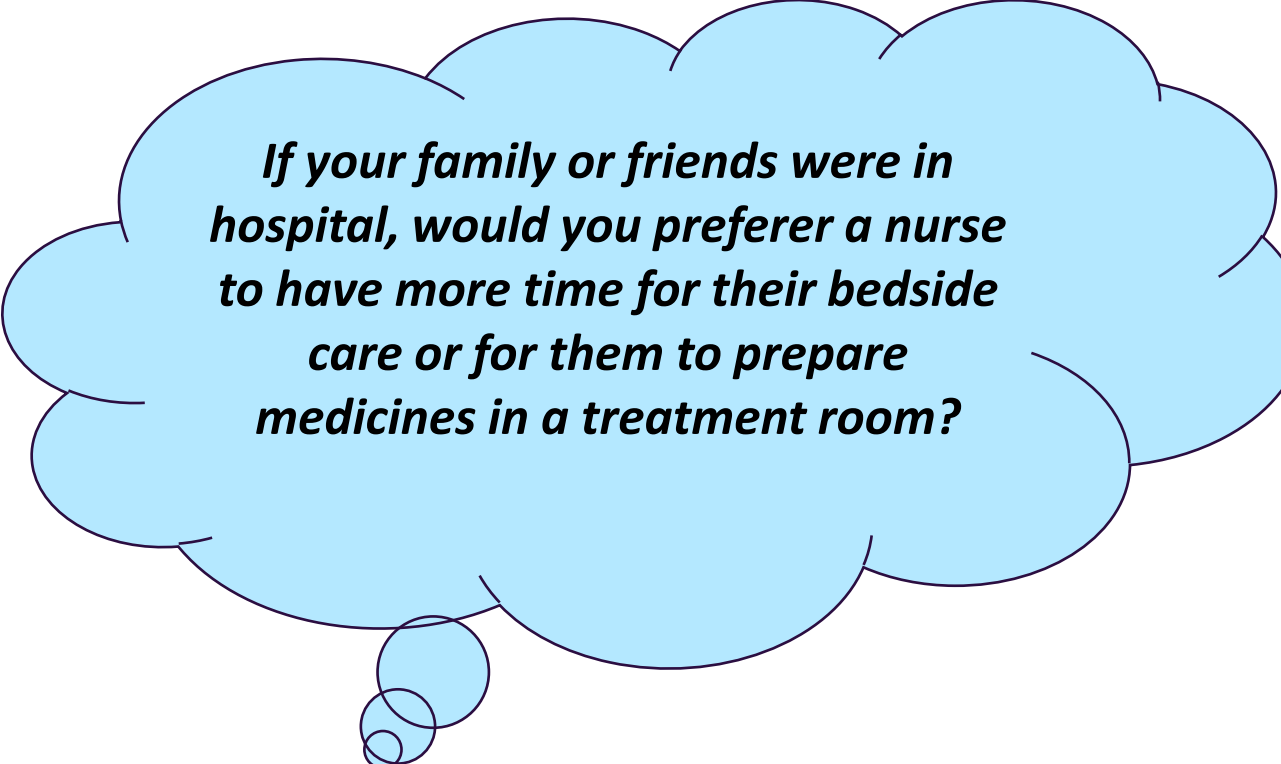


NENC AMPH – Timeline

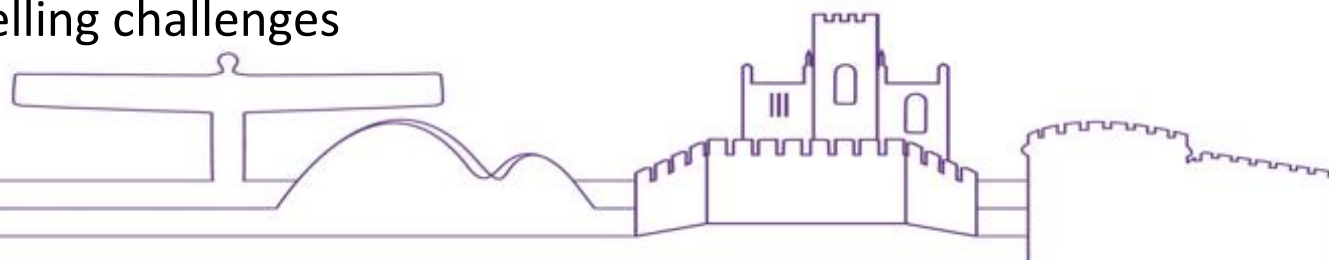


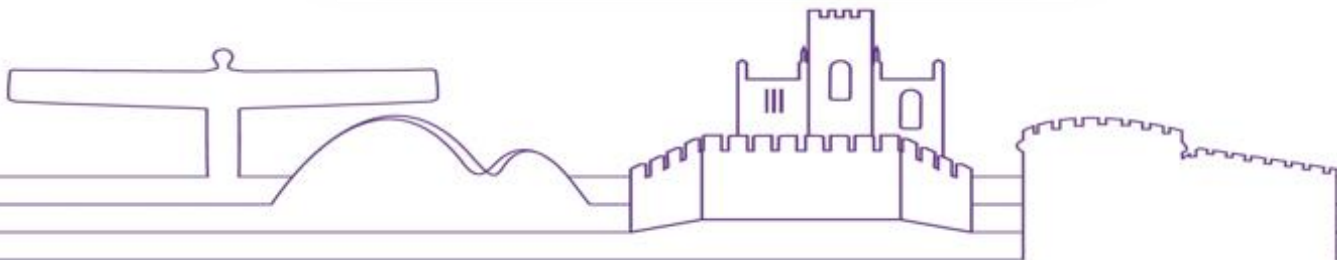
NENC AMPH – Ready To Administer (RtAs)

- What are RtAs?
 - Antibiotics such as Piperacillin Tazobactam
 - OPATs such as Flucloxacillin
- What are the benefits of RtAs
 - Improved patients care
 - Increased nursing capacity
 - Improving patient experience
 - Increased patient safety
 - Increased productivity via standardisation
- Challenges of implementing RtAs
 - Trust / Finance buy in
 - Economic modelling challenges



If your family or friends were in hospital, would you prefer a nurse to have more time for their bedside care or for them to prepare medicines in a treatment room?





WYAAT Pharmacy Aseptic Collaboration



- Airedale** NHS Foundation Trust
- Bradford Teaching Hospitals** NHS Foundation Trust
- Calderdale and Huddersfield** NHS Foundation Trust
- Harrogate and District** NHS Foundation Trust
- The Leeds Teaching Hospitals** NHS Trust
- The Mid Yorkshire Hospitals** NHS Trust



Programme Overview | Transformation of Aseptics Services

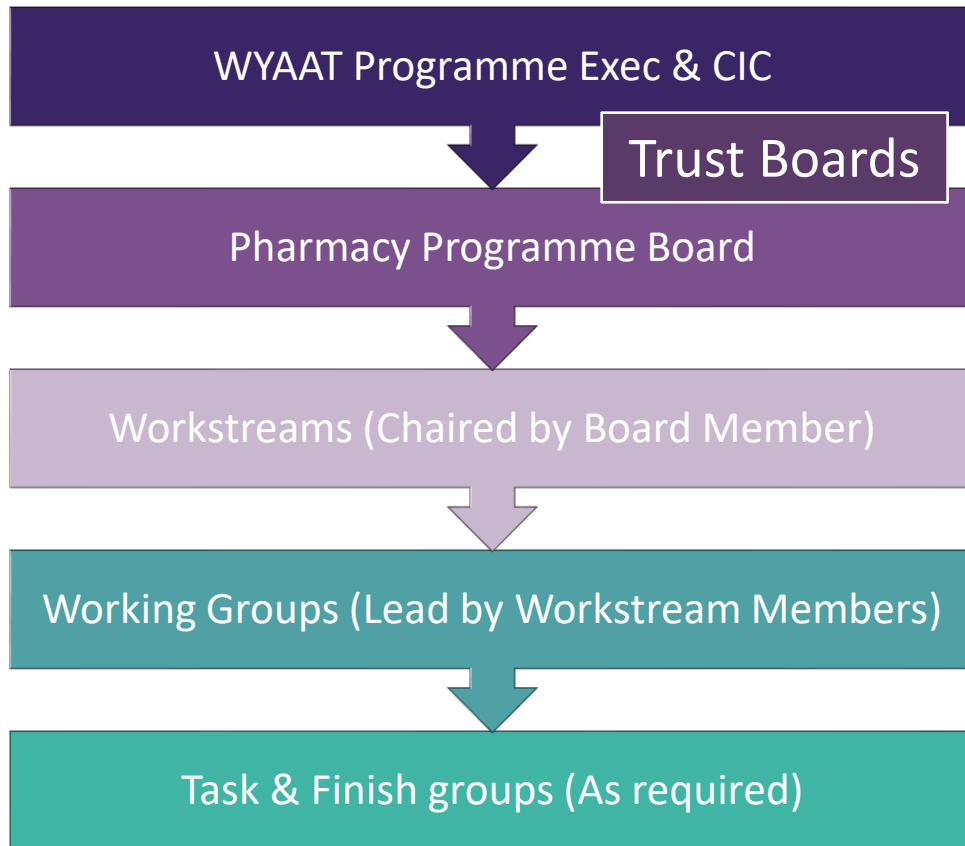
Aim

To design and implement a regional pharmacy aseptic manufacturing capability across the six WYAAT trusts concerning ready-to-administer injectable medicines

Objectives and Benefits

- Increased capacity: satisfy current and future demand of ready to administer aseptic infusions
- Release nursing time to care: currently estimated at 78 WTE across WYAAT
- Cost avoidance: increased efficiency through leveraging economies of scale
- Enhance resilience: Increased capacity for manufacture of RTAs
- Patient safety: reduce prescribing risk, administration errors, missed doses and infection risk
- Product and dose standardisation: reduce risk of errors and increase efficiency
- Utilise novel workforce: maximise career pathways and reduce reliance on traditional pharmacy workforce to prevent destabilisation
- Align with other West Yorkshire & Harrogate workstream e.g. WY&H Cancer Alliance Non-surgical Oncology project

WYAAT Pharmacy Aseptic Collaboration | Governance Structure



Implementation Project Board

Delivery of the new aseptic hub and transfer of existing services

Workforce

Develop and implement workforce plan for new hub facility

Governance & Finance

Develop and implement contract between hub and the 6 organisations, outlining governance structure, accountability and finance mechanism.

Benefits Realisation / Releasing Nursing Time to Care

Ensure all organisations are realising benefits as set out in the business case

Hub Operational Plan

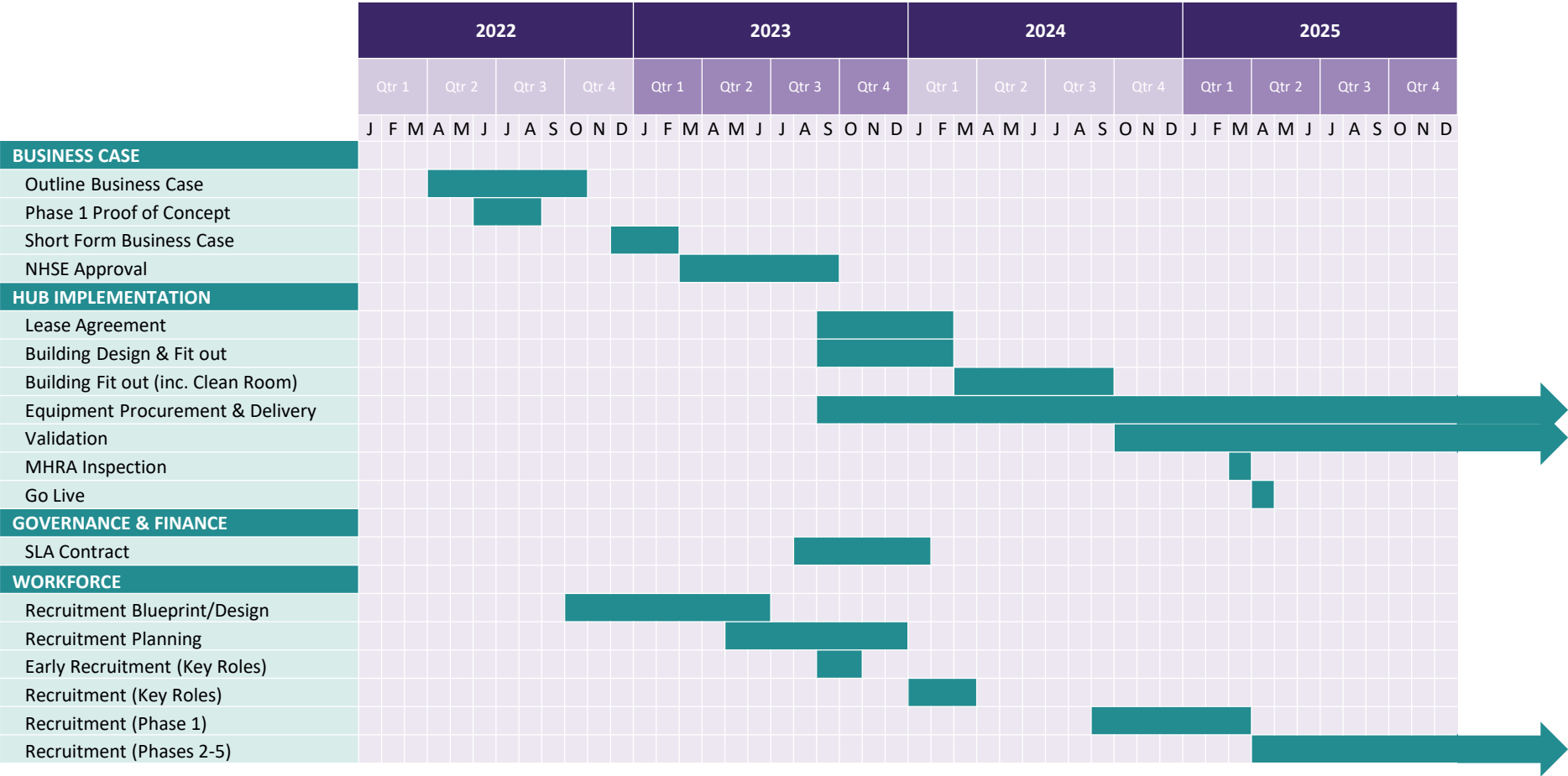
Facility

- 6,500m² leased site
- Clean Room Suite with 4 manufacturing rooms capable of producing over 700,000 products per year
- QA/QC department with Microbiology and Chemistry service
- Flexibility between product types
- Co-located with Leeds Pharmacy Store (WDA) and existing overlabelling/repacking service (MS)

Equipment

- Dual system gassing isolators (VHP)
- Semi-automated processing
- Scope for future fully automated systems

Project Timeline | High Level Overview



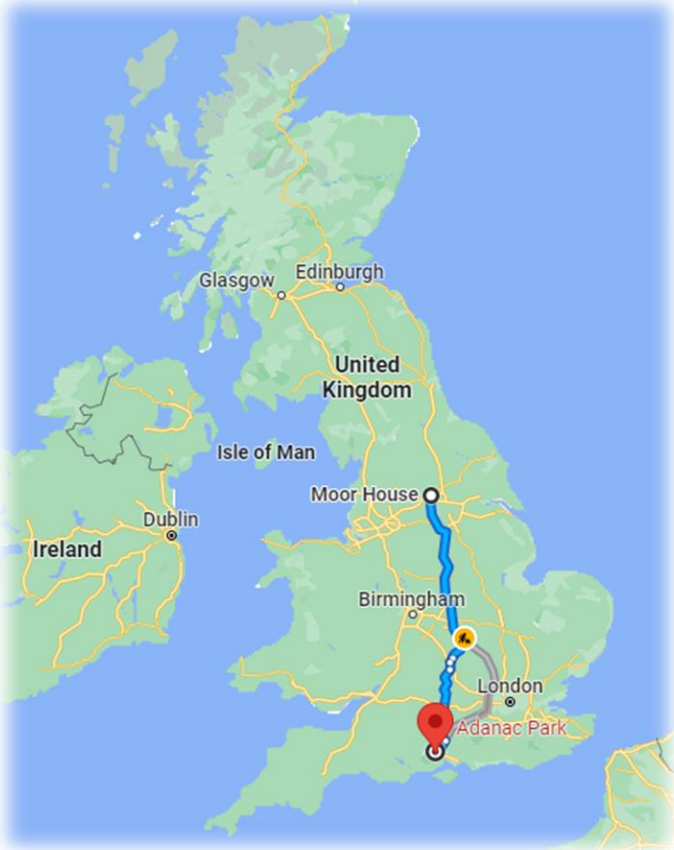
✉ WYAATProgramme@nhs.net

☎ 0113 2065684

🌐 wyaat.wyphpartnership.co.uk

🐦 @WYAAT_Hospitals

Thank You | UHS & HIOW



✉ WYAATProgramme@nhs.net

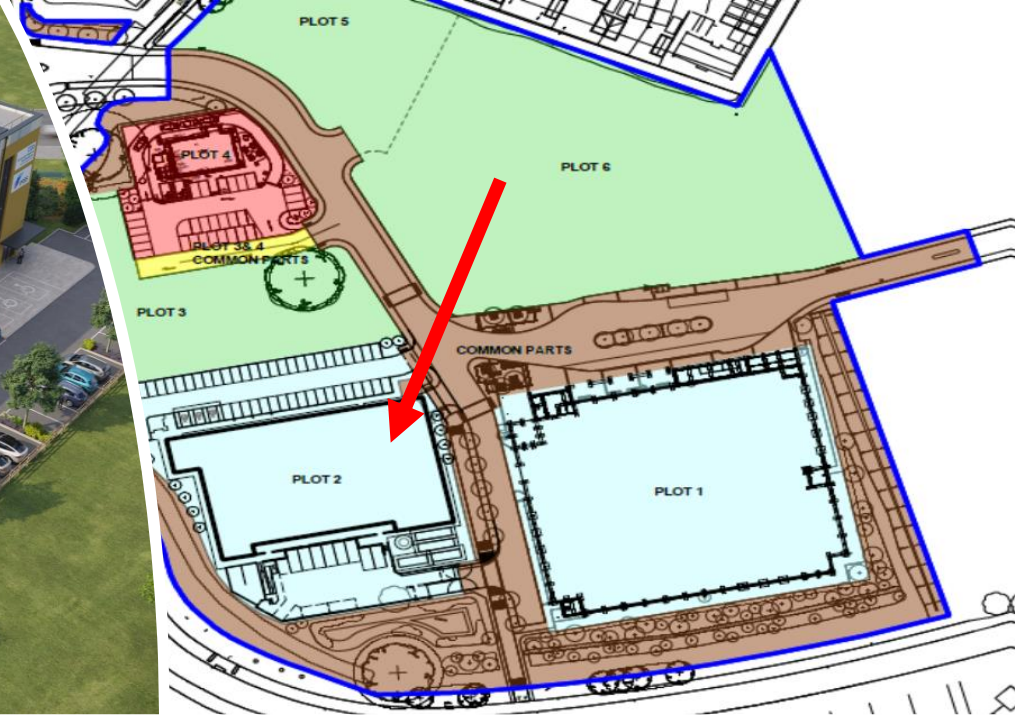
☎ 0113 2065684

🌐 wyaat.wyhpартnership.co.uk

🐦 @WYAAT_Hospitals

UHS Adanac Park Development

- 6,599m² building
- 3 floors comprised of
 - Sterile services
 - Aseptic Suite
 - Offices
- Initial development aimed to replace on-site aging aseptic production facility
- National aseptic capital allocated to support fit-out of aseptic floor providing significant capacity uplift



Adanac Park – On location

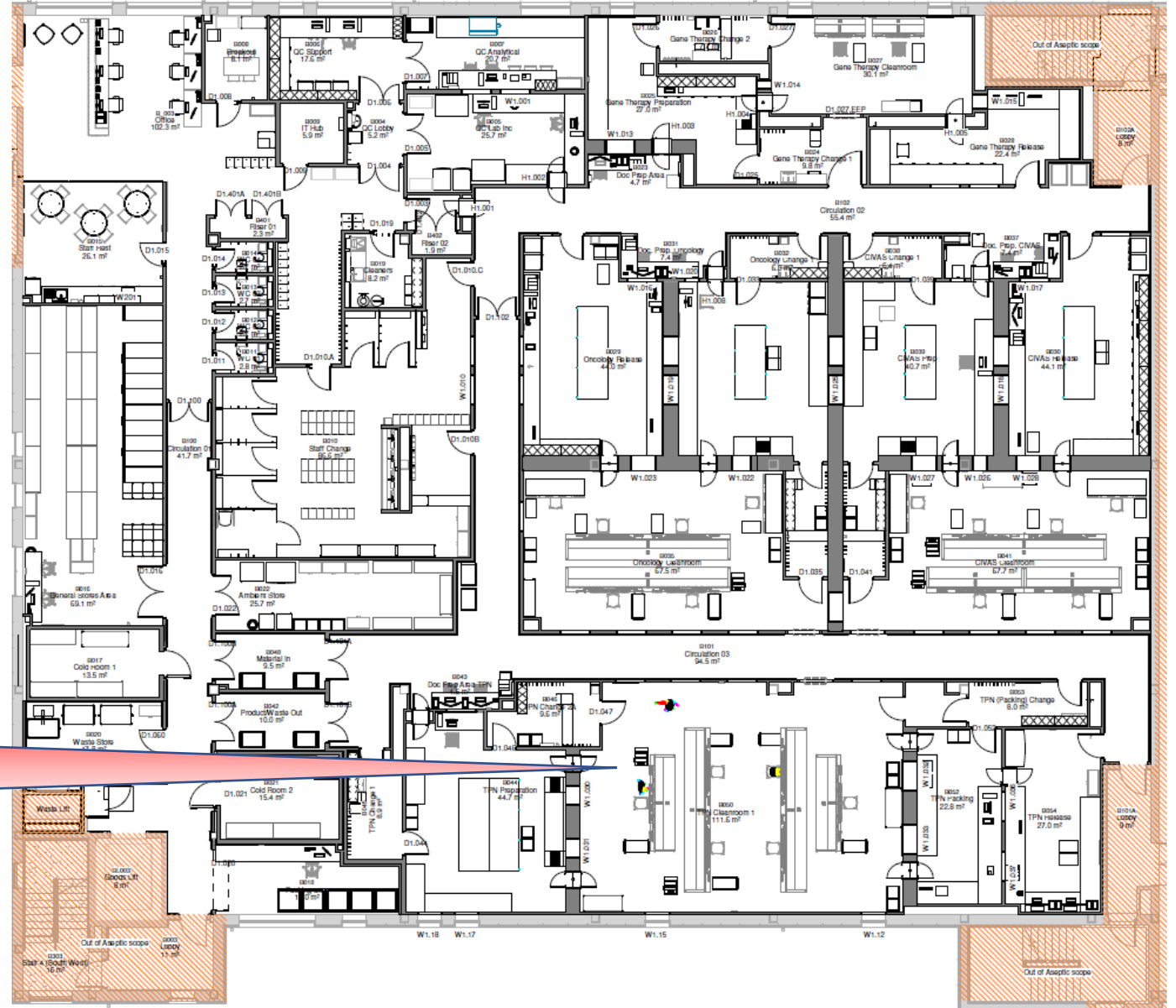
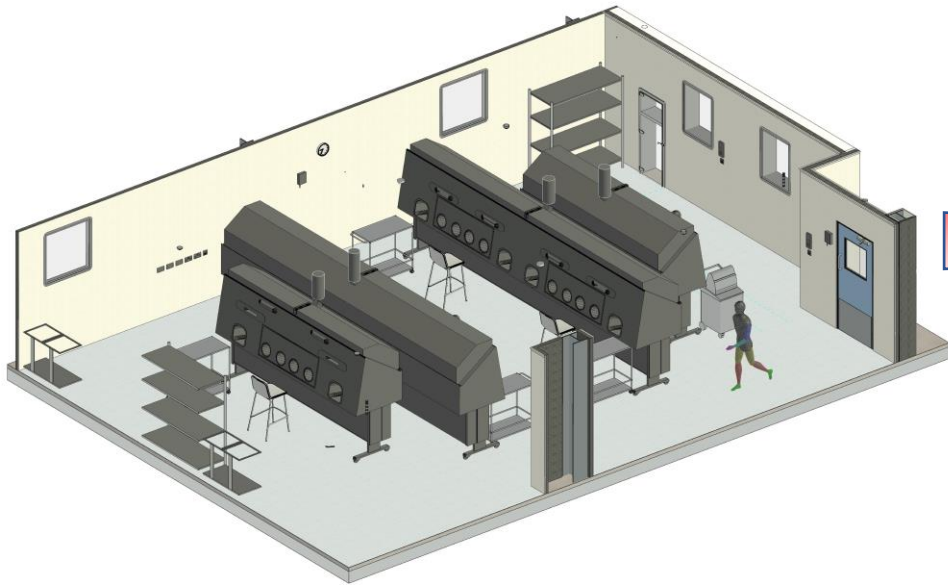


- Adanac Park site (red) will provide base for new aseptic facilities.
- Excellent transport links and infrastructure

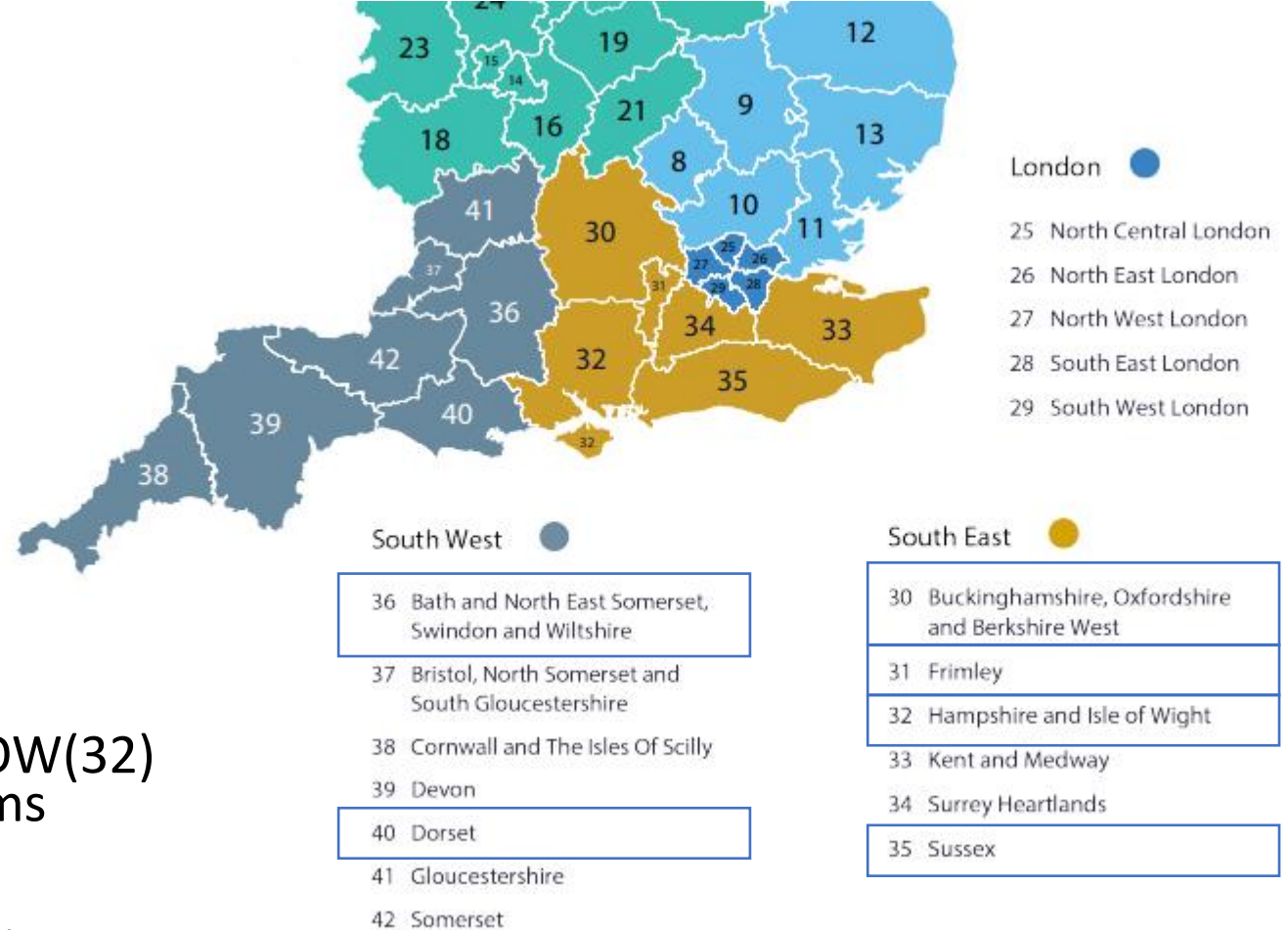


Aseptic Unit Layout

- Design team comprised of UHS, developers and specialist consultants has reached RIBA stage 4/5.
- Primary (awarded) aseptic contractor Enbloc.
- Ex MHRA inspector input has been incorporated into the design and specification decision.
- Unit includes
 - Dedicated gene therapy/AT(I)MP clean room
 - Flexible capacity with oncology and CIVAS areas
 - TPN suite with semi-automated compounding capacity
 - Multiple air-handling units and interchangeable rooms to ensure business continuity



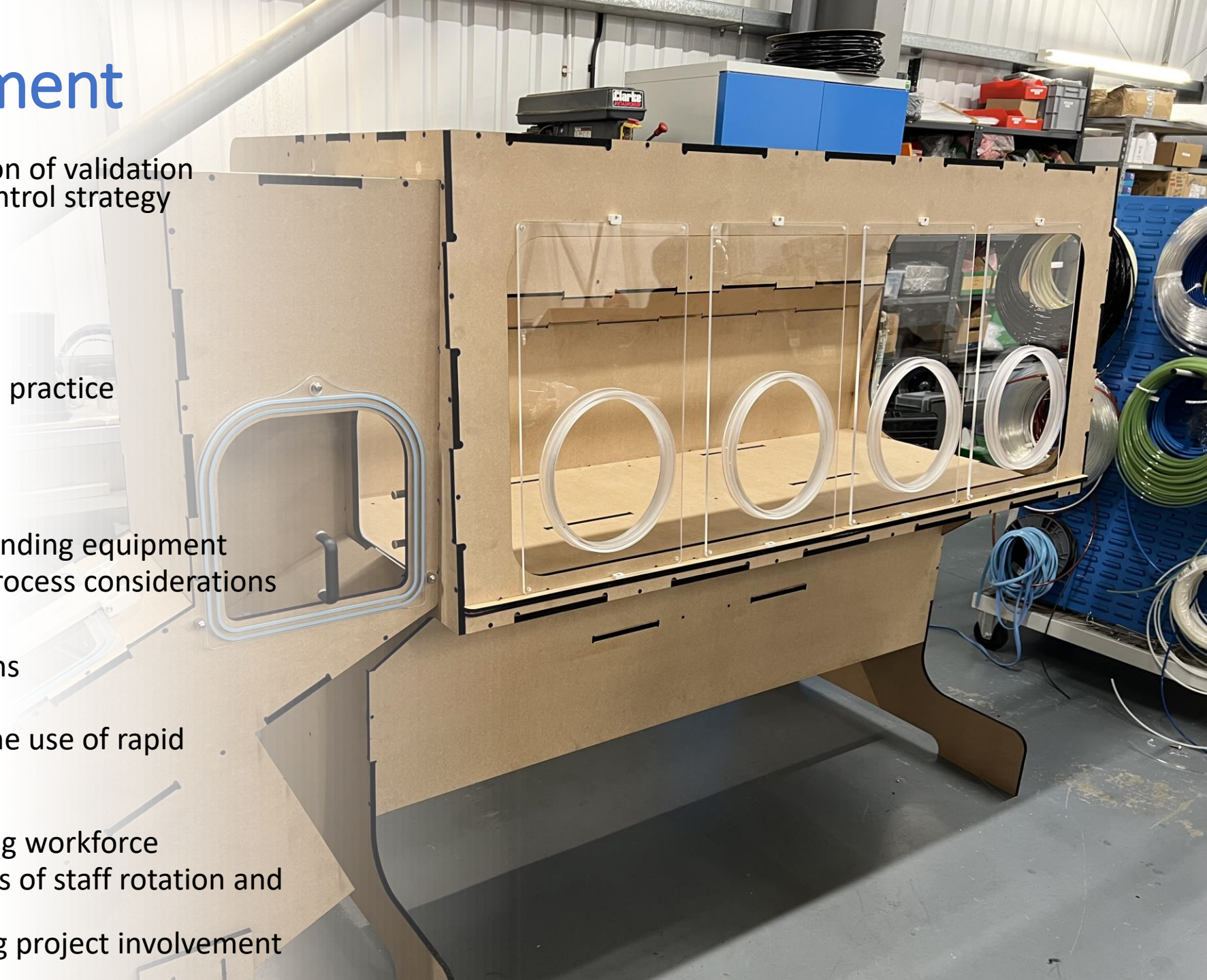
Local Geographical Coverage



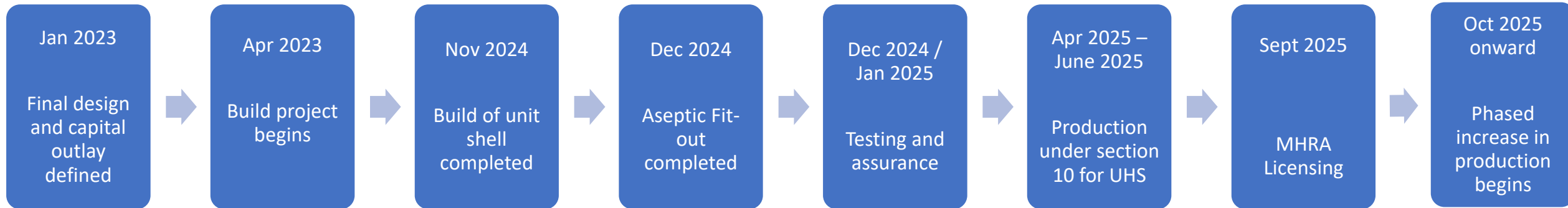
- Well positioned to support HLOW(32) and several surrounding systems
- Confirmed link with Dorset (40) system aseptic lead
- Opportunity to further support other neighbouring systems (30, 31, 35, 36 - red boxes)

Change Management

- Quality by design - early preparation of validation master plan and contamination control strategy
- Moving to licensed service
 - Annex 1 gap analysis
 - Ex MHRA Consultant advice
 - Review of workforce and local practice
- Preparation of process validation
 - Staff training – mock isolator
 - Early purchase of key compounding equipment
 - Gas cycle development and process considerations
- Increase in capacity vs existing plans
 - Semi-automation
 - Increasing capacity through the use of rapid transfer
- Additional considerations of moving workforce
 - Beginning to build foundations of staff rotation and cross department training
 - Staff consultation and ongoing project involvement



High Level Timelines



Phase 1 Workforce Plan

- Development of training programme for conversion to licensed unit
- Recruit additional (QA) posts

Phase 2 Workforce Plan

- Training of existing staff
- Recruitment of first wave of new assistants
- Establish relationship with higher education supplier

Phase 3 Workforce Plan

- On-site recruitment with phasing and training across licensed and spoke sites
- Training for bespoke areas of manufacture (gene therapies)

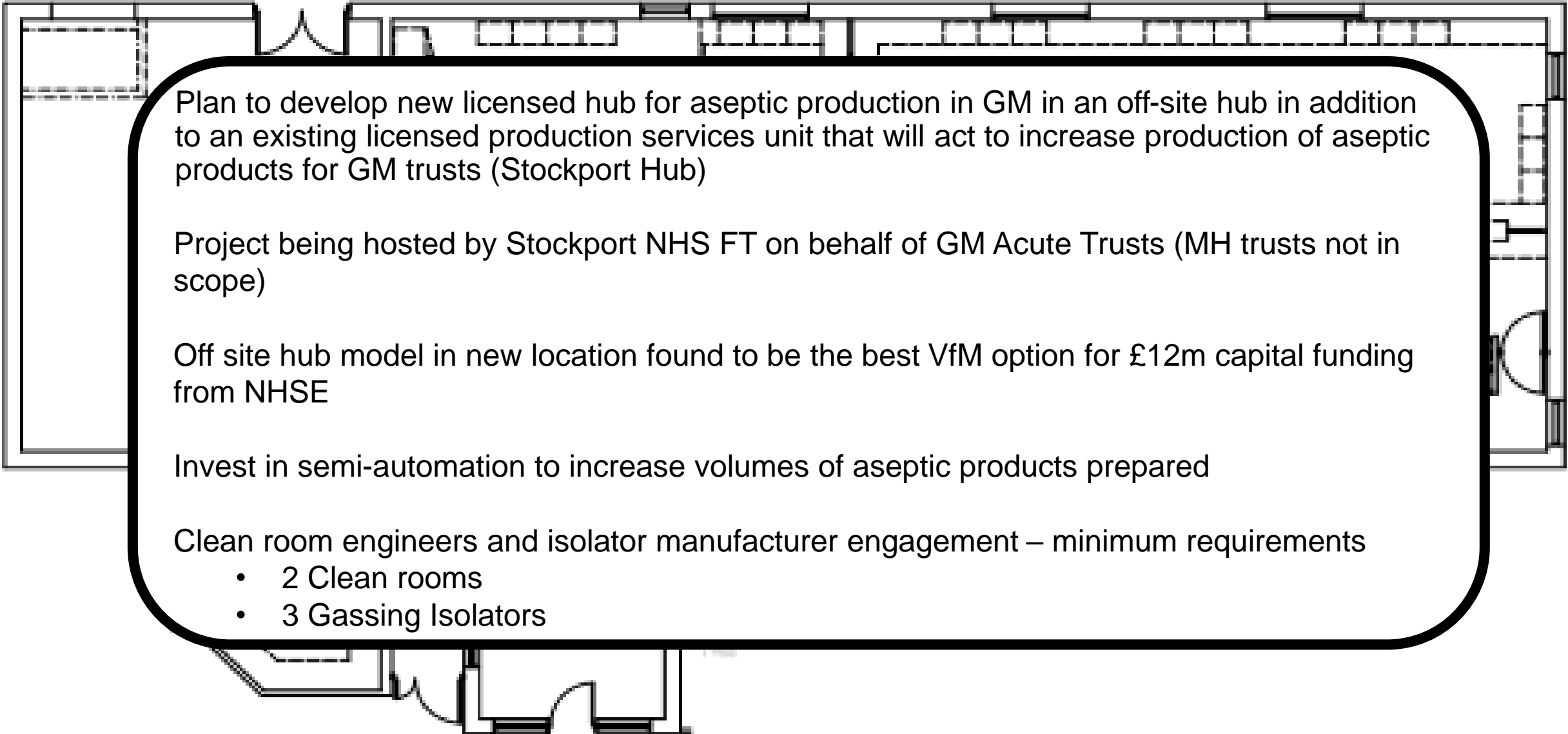
HIOW & Other ICS Production Planning

Product portfolio & capacity planning

Dose Standardisation



Greater Manchester Aseptics Hub project

A black and white architectural floor plan of a facility is shown in the background. A large, rounded rectangular text box is overlaid on the plan, containing project details. The plan shows various rooms, corridors, and structural elements.

Plan to develop new licensed hub for aseptic production in GM in an off-site hub in addition to an existing licensed production services unit that will act to increase production of aseptic products for GM trusts (Stockport Hub)

Project being hosted by Stockport NHS FT on behalf of GM Acute Trusts (MH trusts not in scope)

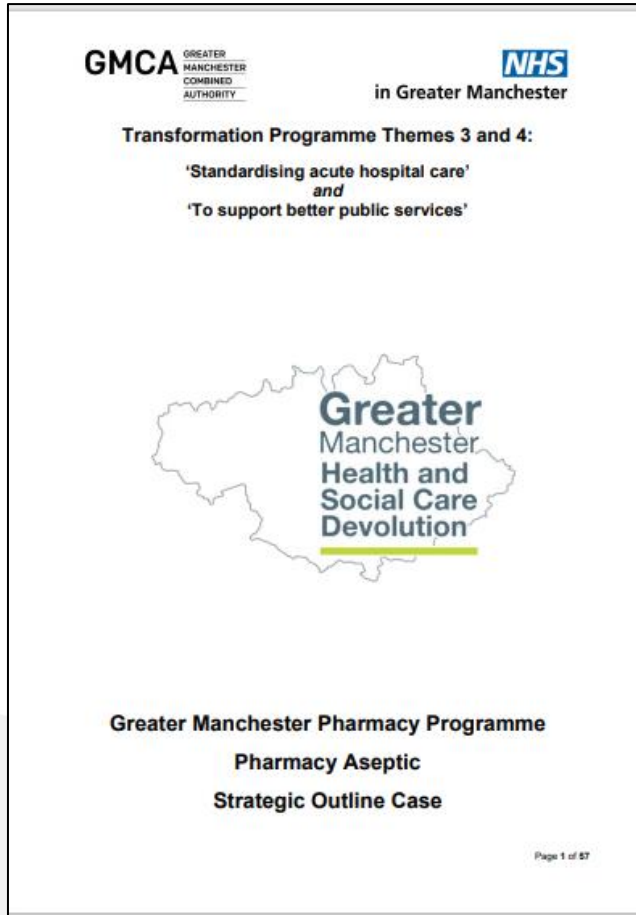
Off site hub model in new location found to be the best VfM option for £12m capital funding from NHSE

Invest in semi-automation to increase volumes of aseptic products prepared

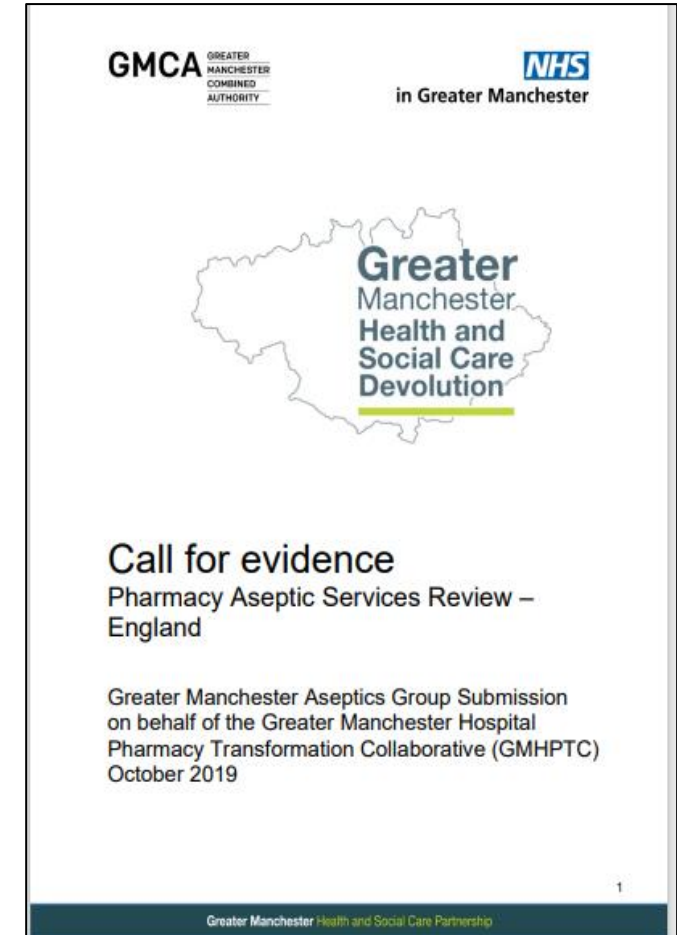
Clean room engineers and isolator manufacturer engagement – minimum requirements

- 2 Clean rooms
- 3 Gassing Isolators

Evolution of Case from 2019 - 2023



- GM Aseptics established group within GM pharmacy programme
- Secondment created by GM Chief Pharmacists at risk
- Options Appraisal - June 2019
- 'Meeting the unmet need'
- Top 5 Antibiotics in new stand alone unit
- Full automation key to case
- GM Chief Nurses supportive 'in principle'
- Call for Evidence – October 2019
- Transformative agenda working collaboratively



GM Pharmacy Project Management Team

– Key learnings

1. Rapidly developed a short form business case using core GM pharmacy project management team to outline plans and how GM would utilise capital funds to develop hub
2. Would not have been possible to meet tight deadlines without previous work from 'at risk' secondment and options appraisal from 2019 and recent PMO support
3. Resourcing requirements adaptations through next phase of project – increase in technical input and moderation in PMO support for next phase

Wider transformation and standardisation

Spoke / Outsourced unit considerations

Training – whilst not directly part of hub project will still carry on at NW level

Technical standardisation
Standardise policies and Procedures pan GM
e.g. Gowning policies to start



Clinical Standardisation will allow movement of products from spokes to hub releasing capacity

- ↑ local unit outputs
- ↑ clinical trials
- ↑ new short expiry products

Clinical Standardisation
e.g. product catalogue
biosimilars
dosing / diluents / stability



GM Aseptics Hub – Clinical Standardisation workshop

NHS

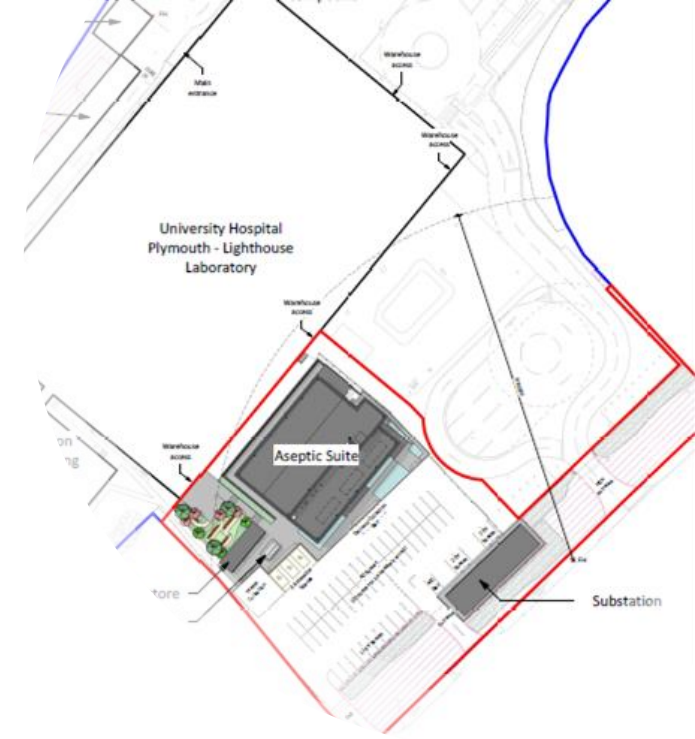
Greater Manchester
Integrated Care

- Excellent engagement from medics, nursing, microbiology, OPAT colleagues, critical care networks, aseptics managers
- Initial Product Catalogue for Day 1 of hub includes antimicrobials, monoclonal antibodies, chemotherapy agents
- Next step to map product volumes onto workforce plan and capacity tools

Project next steps

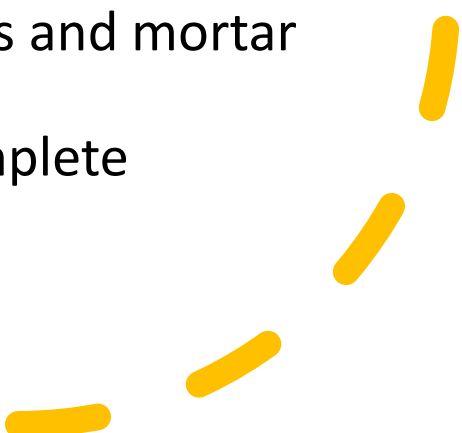
- Conclude pilot / proof of concept focussed at trusts currently in progress
- Initial URB complete and property search beginning for hub
- Further develop and conclude revenue business case for staffing required to run hub



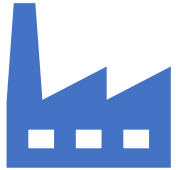


Kandarp Thakkar
Chief Pharmacist & Clinical Director of Medicines Optimisation

Setting the scene

- Largest Trust in the SW – *over* 1000 beds; nearly every specialty!
 - Current unit over 25 years old; not fit for purpose – RED (25 risk) on the Risk Register
 - Planning for a new unit been happening over 3 years – how do you change appetite to leveraging risk into something tangible?
 - OBC approval around preferred option – Feb 2023
 - FBC – finessing benefits, reviewing costs and agreeing funding model – submission expected Nov 2023
 - Concurrent system alignment/work – TWO hubs
 - Design- RIBA stage 3 completed; full bricks and mortar build
 - Isolator and EMS procurement nearly complete
 - ‘Spade in ground’ – Jan/Feb 2024
- 
- Four thick, yellow, curved lines of varying lengths and orientations, arranged in a loose, upward-curving pattern in the bottom right corner of the slide.

FBC - challenges



Maximising benefits

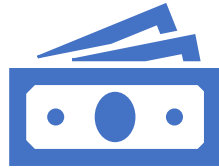
Modelling

CIVAS

R&D income

Spare capacity

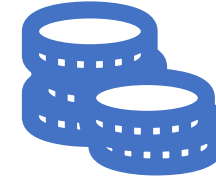
Strategic alignment



Reducing the costs

Phasing of FBC

Staffing models



Funding streams

National

What else can you do in the absence of CDEL capital – partnerships, managed service etc.

Invest in the team!



'Internal' aseptics team – thinking about wider capacity issues



Programme / Project Management



CC Tech - Project/Validation Consultants



Architects



B Braun - External Consultant (Trust 'side')



Ex-MHRA inspectors



Expertise areas - Mechanical & Electrical, IT, HR etc.

Automation

- Needs
 - Ability to fit into isolators
 - ISO27001 accreditation
 - VHP compatible
 - Ease of operator use
 - Ease of set up
 - UK Service Support
 - Data integrity
 - Defined user profiles and secure access
 - Sterile consumables
- Wants
 - WiFi / Network compatible
 - Bar code verifications (diluent, drug, container)
 - HL7 Compatible
 - Speed of filling
 - Versatile filling
 - Syringes
 - I.V. bags (inc. volume withdrawals)
 - Infusors
 - Ability to fill from vials and bulk diluent containers (simultaneously)
 - Minimal aseptic connections
 - Patient specific and batch