Lab Set Up Challenges and UK Regional Requirements

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Bioanalysis Immunogenicity and Biomarkers

In Vs Out Strategy

PK
Soluble Biomarkers
Cellular Biomarkers
ImmGen (US only)

In →

Candidate Selection studies
Clinical (FTiH to Phase 2a)

Out ↓

TK
Late Phase Clinical

Clinical main internal focus
Fast Turnaround key deliverable for PK

Key Challenge – Virus (Airborne, Contact Surfaces)

A New Vista for Business Continuity Planning

What Decisions (Ghosts) Might Come to Haunt You?

PAST

HBS workflows agreed with EHSS (mix of Lab bench and Class II BSC)

PRESENT

Define and adapt to new ways of working

Aerosolisation and contact surfaces

Redefine automation needs

YET TO COME

Designs for new lab recently completed (based on '*old normal*')

How many Class II BSCs?
Lab pinch points
Flow of lab staff

PAST

- Several Bioanalytical Risks Assessments permitted work on lab bench if aerosolisation risk was low (e.g. low sample volumes).
  - Including walkaway automation

- Steps in place to manage risks from bloodborne infections arising from potential needle/sharps injuries

PRESENT

- EHSS re-evaluation of risks associated with potential airborne infections
- More lab activities re-classified to be conducted in Class II BSCs
- Class II BSC capacity becomes '*prime real estate*'
  - Lots of shared labs at STV, primarily non-regulated
  - Requests for additional BSC capacity coming from multiple lab lines (Research, GCP, GMP)
- Most workflows at least partially automated
  - How many are still deployable in BSC?

PRESENT

RISK ASSESSMENTS FOR LAB INSTRUMENTATION (ELLA as an example)

Scan barcode

Add samples and wash buffer

Run cartridge

Typical Sample Volumes: ≤ 25 µL per sample, total number of samples depends on type of plate used

Pre-Treatment: <u>Within the Class 2 BSC</u>: 50 µL pipetted into the 'sample well' of the ELLA plate – this equates to 2.5-25 µL neat sample mixed with ELLA buffer.

System Operation:

- Plate transferred to the ELLA
- The run is activated
- Within the ELLA, samples/reagents run through microfluidic channels and detected; runs are completed in ~90 min
- Once completed the plate is disposed in the biohazard waste stream

Possibility for aerosol generation/release during normal operation?

None, only risk of spillage when samples are being loaded the system

PRESENT

AUTOMATION

CAPACITY

- ADA Testing
- multi-parameter optimisation, DoE

QUALITY

- Meth Dev / Val
- Sample Testing
- Protein MS

TIME SAVING

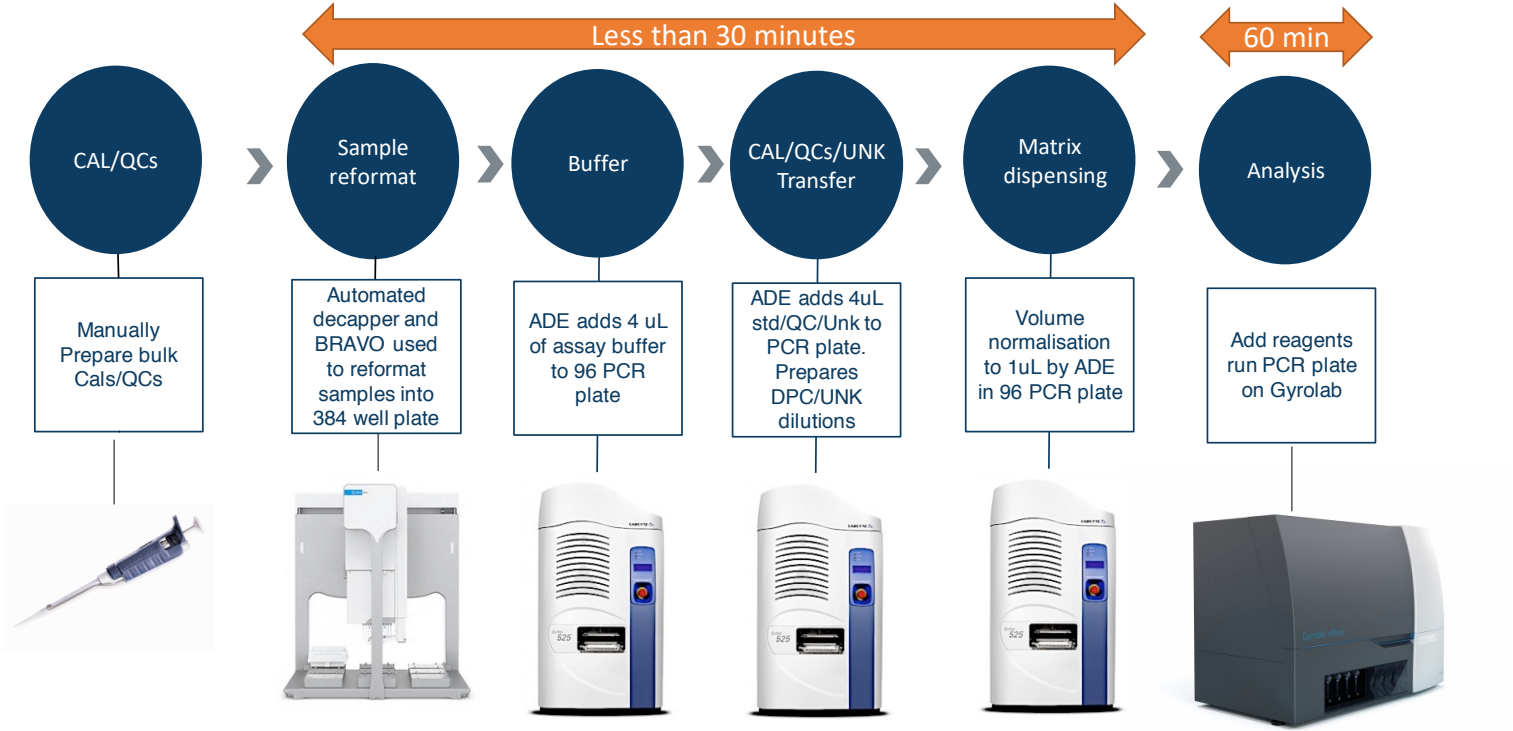
- FTiH (f/t)
- Histology Inventory
- Compound Inventory
- Reagent Workflows

COST

- Ultra-high sensitivity LBA
- T-Cell Response

PRESENT

ADOPTING HIGHLY AUTOMATED WORKFLOWS



PRESENT

SMALL FOOTPRINT AUTOMATION

- Minimise time of staff working in cramped BSC environment
- Readily deployable in BSC or on workbench
- Deactivation steps (in BSC). Combine with larger footprint instrumentation on bench

FUTURE

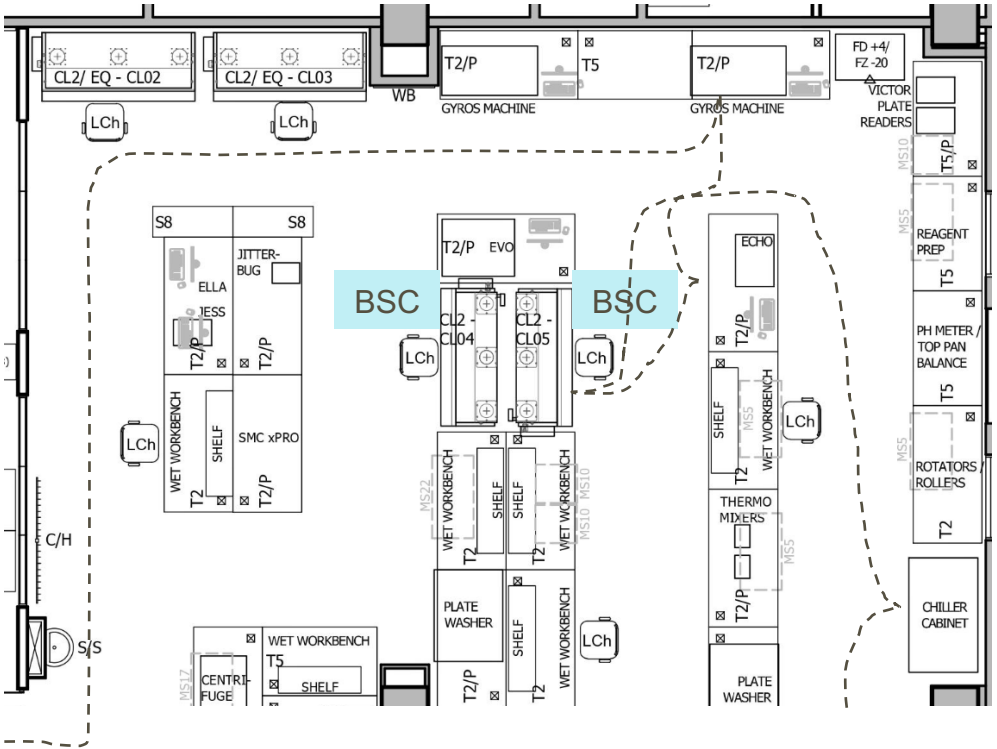
- Multi-million pound new facility in final design phase

- Instrument dense lab focusing on clinical (PK, soluble biomarkers, cellular biomarkers)
  - Current and future platforms
  - LC-MS, Protein MS, LBA, Flow Cytometry, PCR, Western Blot…..*ad infinitum*

- Requirement to adapt lab design during at the height of maximum uncertainty

FUTURE

WET LAB

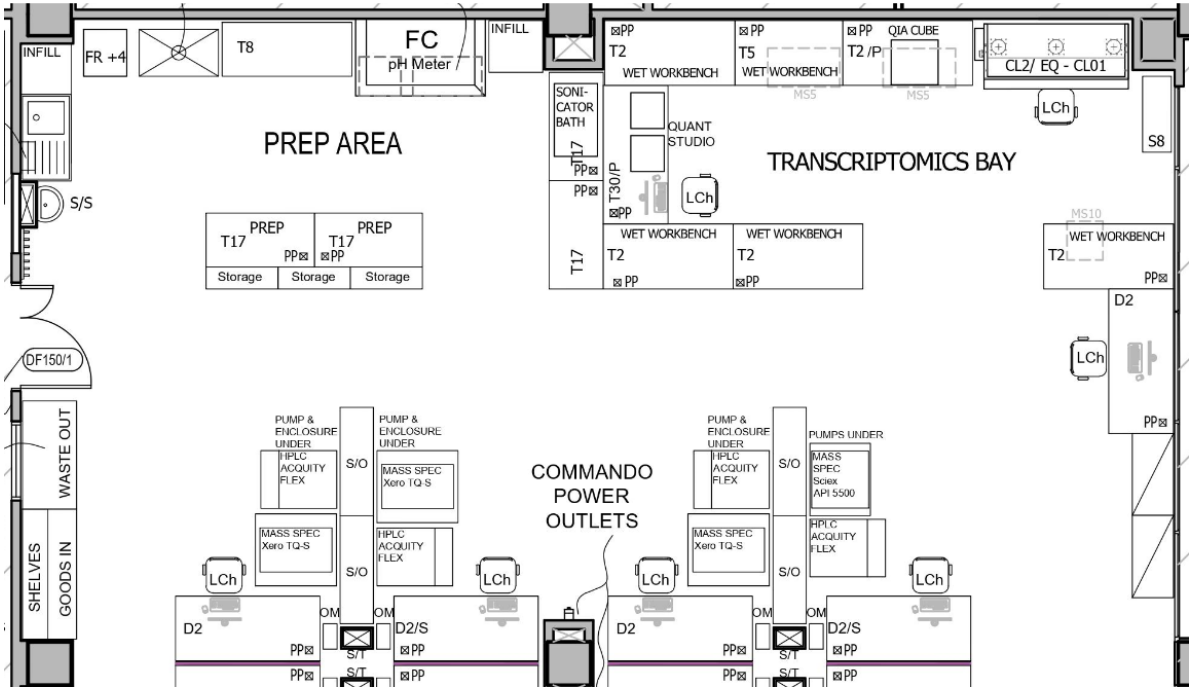


- “Spaghetti” diagrams to understand movement of people, lab layout and pinch points
- Optimise placement of BSCs
- Minimise face-to-face work areas (e.g. while seated)

FUTURE

MS LAB

- Position MS systems to reduce proximity of adjacent seating
- Perspex barriers for opposite seating
- **Better understanding of the movement of people, lab layout, and how we can optimise these alongside optimising workflows to facilitate safe and efficient work practices**



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"EVERY CLOUD HAS A SILVER LINING"

- Inspiring us to think differently about bioanalysis and what new ways of working could open up for us
- More small footprint automation = more flexibility to change workflows and throughput as needed
- Increased use of BSCs can mean more efficient working (as scheduling becomes more of a requirement)
- Seeing the strong safety culture in action (lab and home-based work)

Summary

- ~~SILO: What's in it for me?~~
- ENTERPRISE: What's in it for us?

THANK YOU

- Steve White
- Arun Sen
- Alex Georgiou
- Farjana Mahammed
- Joanne Thompson
- Matt Barfield