The need for development of new analytical solutions for quality testing of ATMPs throughout manufacture

Beata Surmacz-Cordle[1], Juan Jose Guijarro-Leach[1], Stephen Shapka[1], Nuno Leitão[2], Alexander Anderson[2], Damian Marshall[1]

[1] Cell and Gene Therapy Catapult, Guy's Hospital, Great Maze Pond, London SE1 9RT; [2]Synthace Limited, The Westworks, 195 Wood Lane, W12 7FQ London

Contact: beata.surmacz-cordle@ct.catapult.org.uk

Background

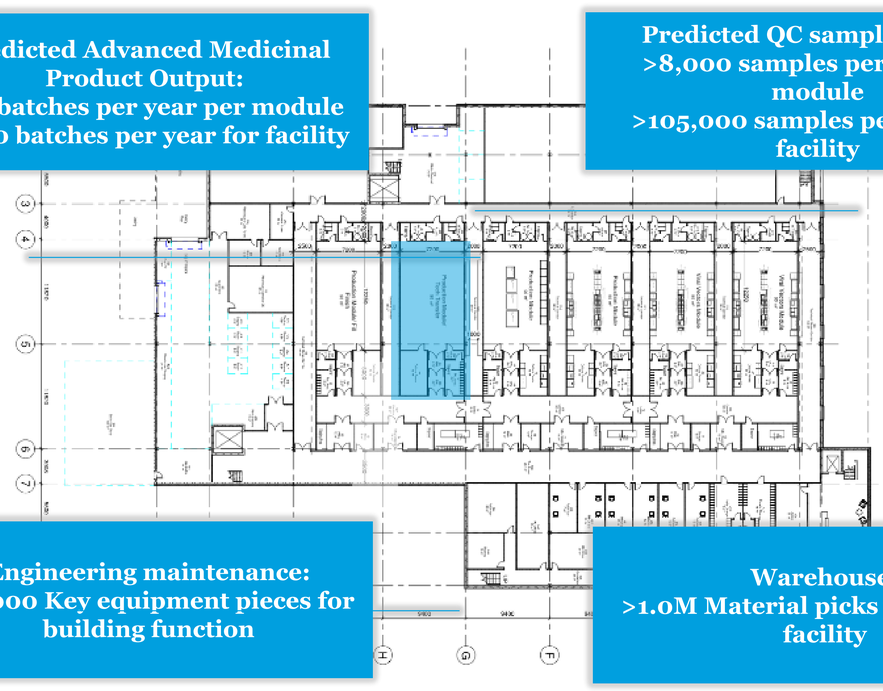
- The global market for ATMPs has seen continual year on year growth with over 900 cell and gene therapy companies and over 1000 clinical trials to date;
- Many of the therapies are looking to advance from phase 2 to phase 3 and commercialisation. With an increase in the number of patients predicted to be treated, a concurrent expansion of GMP manufacturing sites has been apparent across the continents;
- Greater demand on analytical throughput for in-process and release quality testing to GMP compliance is expected;
- It is anticipated that analytical throughput will become a bottleneck, slowing the ability of companies to release products and hindering commercial success;
- Obviating this will require a step change in QC provision, opening up opportunities for both automation and new disruptive technologies

Challenge

- It is currently predicted that autologous therapies will produce as much as 500 batches of products a year with expected increase to 1000's of batches in the coming years;
- Analytical methods used to assess the quality of the batches are complex, timely and performed manually utilising highly trained operators;

Predicted Advanced Medicinal Product Output:
528 batches per year per module
5,280 batches per year for facility

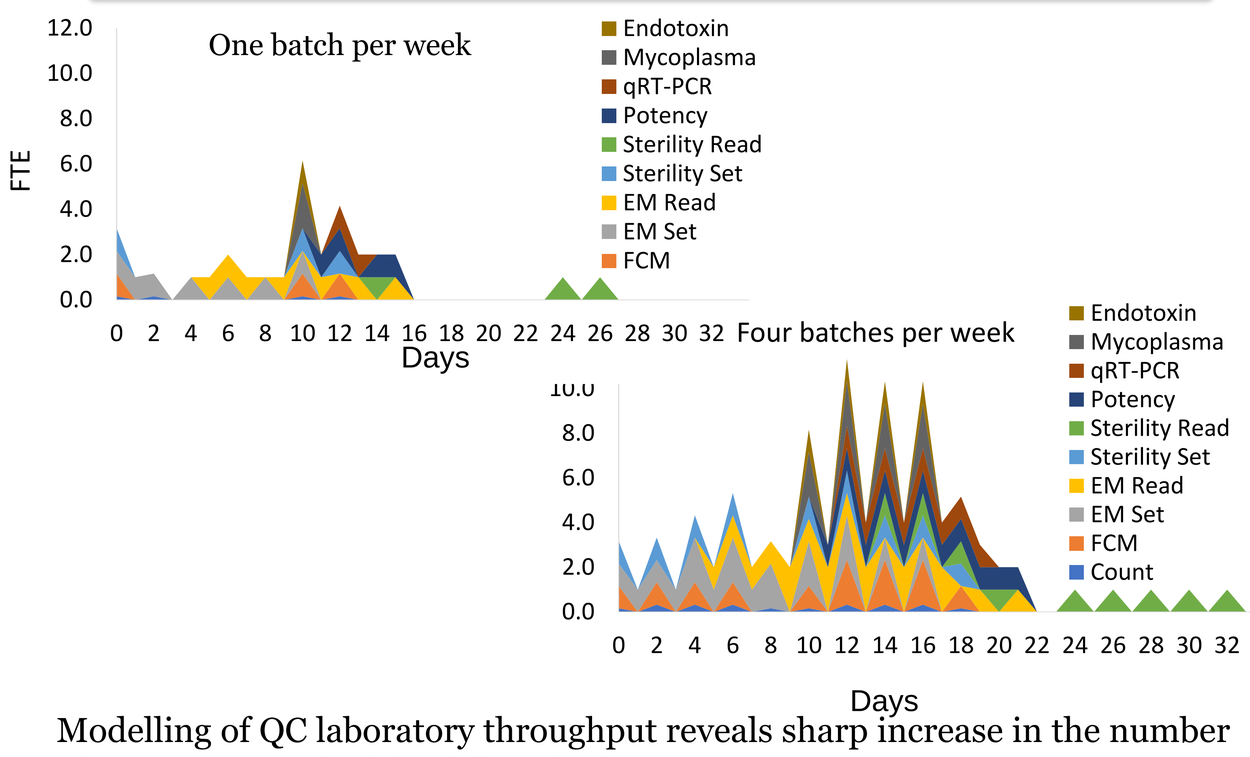
Predicted QC sample output:
>8,000 samples per year per module
>105,000 samples per year for facility



Engineering maintenance:
>3,000 Key equipment pieces for building function

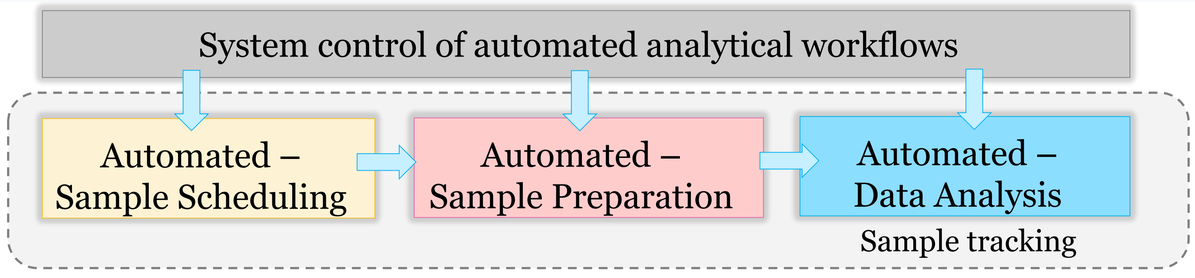
Warehouse:
>1.0M Material picks per year for facility

QC capacity modelling tool



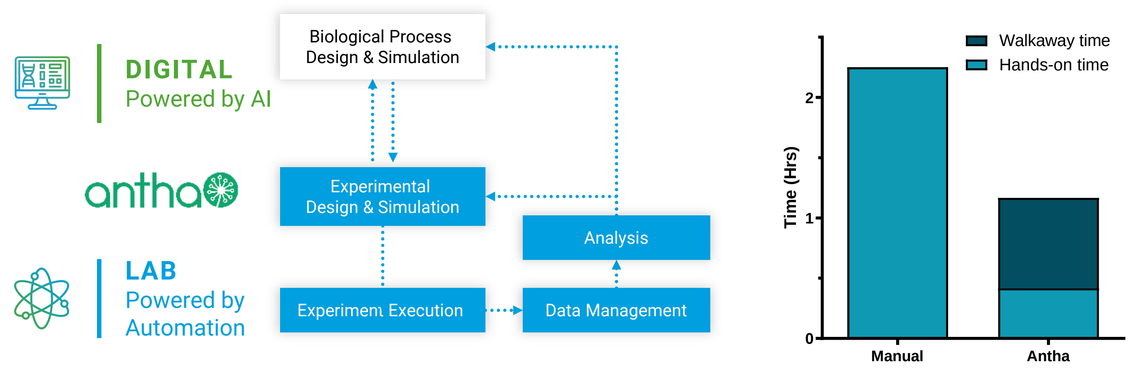
Modelling of QC laboratory throughput reveals sharp increase in the number of operators required for QC analysis

Anticipated solutions



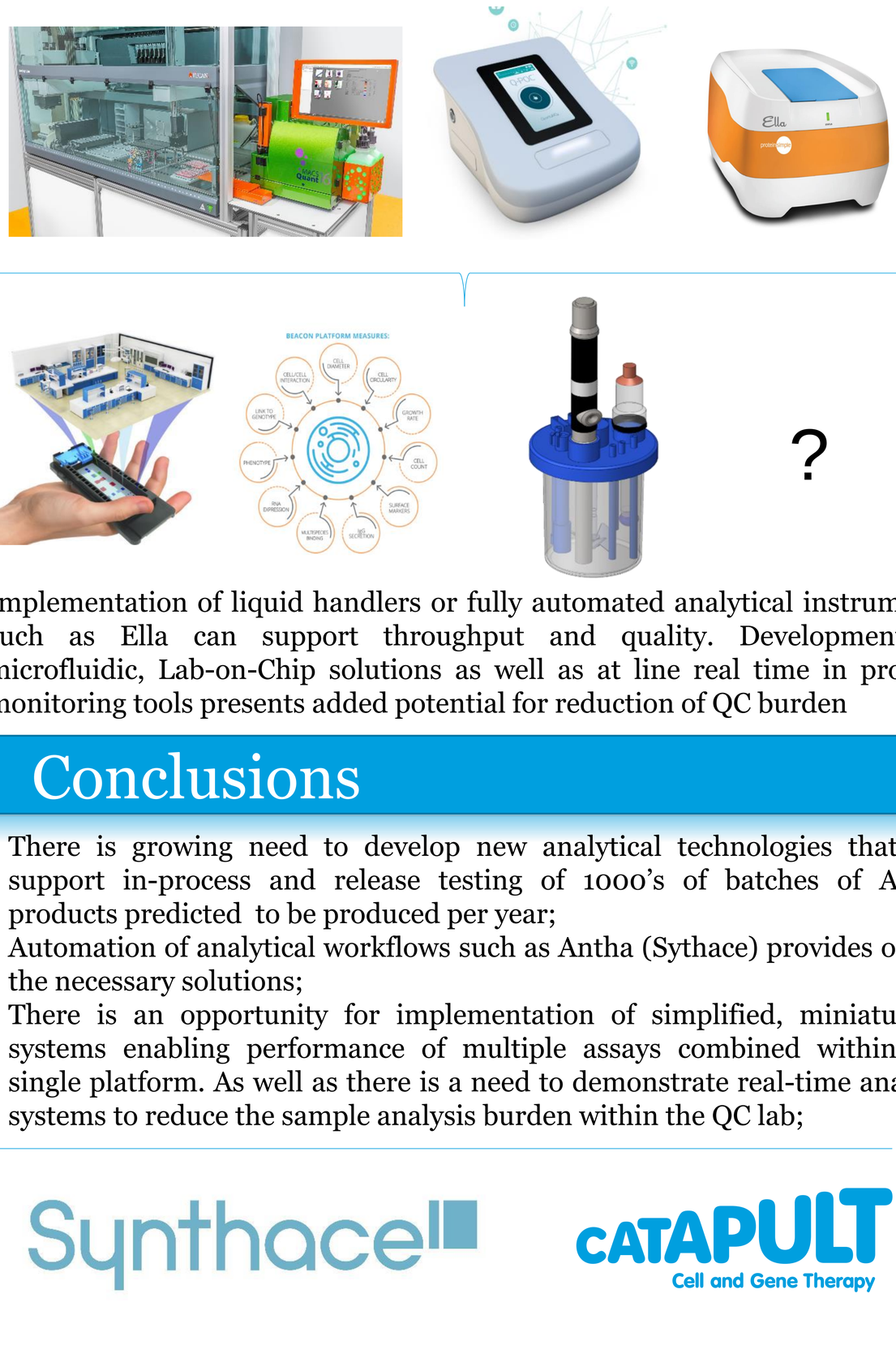
Automation of lab and data processes

- Automation has the potential to increase facility throughput and make QC faster, less error-prone, more reproducible, and more GMP compliant;
- Synthace is developing Antha, a software platform that connects processing equipment such as bioreactors, liquid handlers, and analytical devices, automating experimentation and collecting data outputs to create structured data sets. This mitigates user error during execution and data handling, saves time, and enables rapid process insight.



Comparison of operator hands-on for manual and automated qPCR plate prep. The hands-on time for the operator was reduced by 81%, from 2h15m to 25m per plate.

Development and Integration of new technologies



Implementation of liquid handlers or fully automated analytical instruments such as Ella can support throughput and quality. Development of microfluidic, Lab-on-Chip solutions as well as at line real time in process monitoring tools presents added potential for reduction of QC burden

Conclusions

- There is growing need to develop new analytical technologies that will support in-process and release testing of 1000's of batches of ATMP products predicted to be produced per year;
- Automation of analytical workflows such as Antha (Sythace) provides one of the necessary solutions;
- There is an opportunity for implementation of simplified, miniaturised systems enabling performance of multiple assays combined within one single platform. As well as there is a need to demonstrate real-time analysis systems to reduce the sample analysis burden within the QC lab;

We work with Innovate UK

Cell and Gene Therapy Catapult
12th Floor, Tower Wing, Guy's Hospital, Great Maze Pond, London SE1 9RT
+44 (0) 203 728 9500 | info@ct.catapult.org.uk | ct.catapult.org.uk