CATAPULT
Cell and Gene Therapy

Preparing for commercial GMP manufacture; areas for consideration

Daria Popova, Lead Technical Scientist
Gina Basman, Validation Manager
Doli Patel, Head of Quality Control

Preparing for GMP manufacture

Daria Popova, Lead Technical Scientist

CGT Catapult manufacturing centre

The centre provides access to the expertise, skills, facilities and equipment as the stepping stone needed for organisations to develop new technologies and systems for large scale manufacturing.

- Quality control
- Qualified persons
- Operating policies
- Warehouse management
- Development assistance

Managed warehouse with delivery to your manufacturing space

Flexible quality control options

Collaborating companies

Autolus

"CGT Catapult's unique operational model allows us to grow our manufacturing capacity, while accessing a range of services provided by the centre." **Jim Faulkner, SVP and Head of Product Delivery**

FREELINE THERAPEUTICS

"We are delighted to establish this collaboration for our next generation AAV gene therapy platform for chronic systemic disease." **Jan Thirkettle, Chief Development Officer**

Cell Medica

"We are looking forward to an important collaboration with CGT Catapult scaling-up GMP manufacturing strategies for commercial production." **Gregg Sando, CEO**

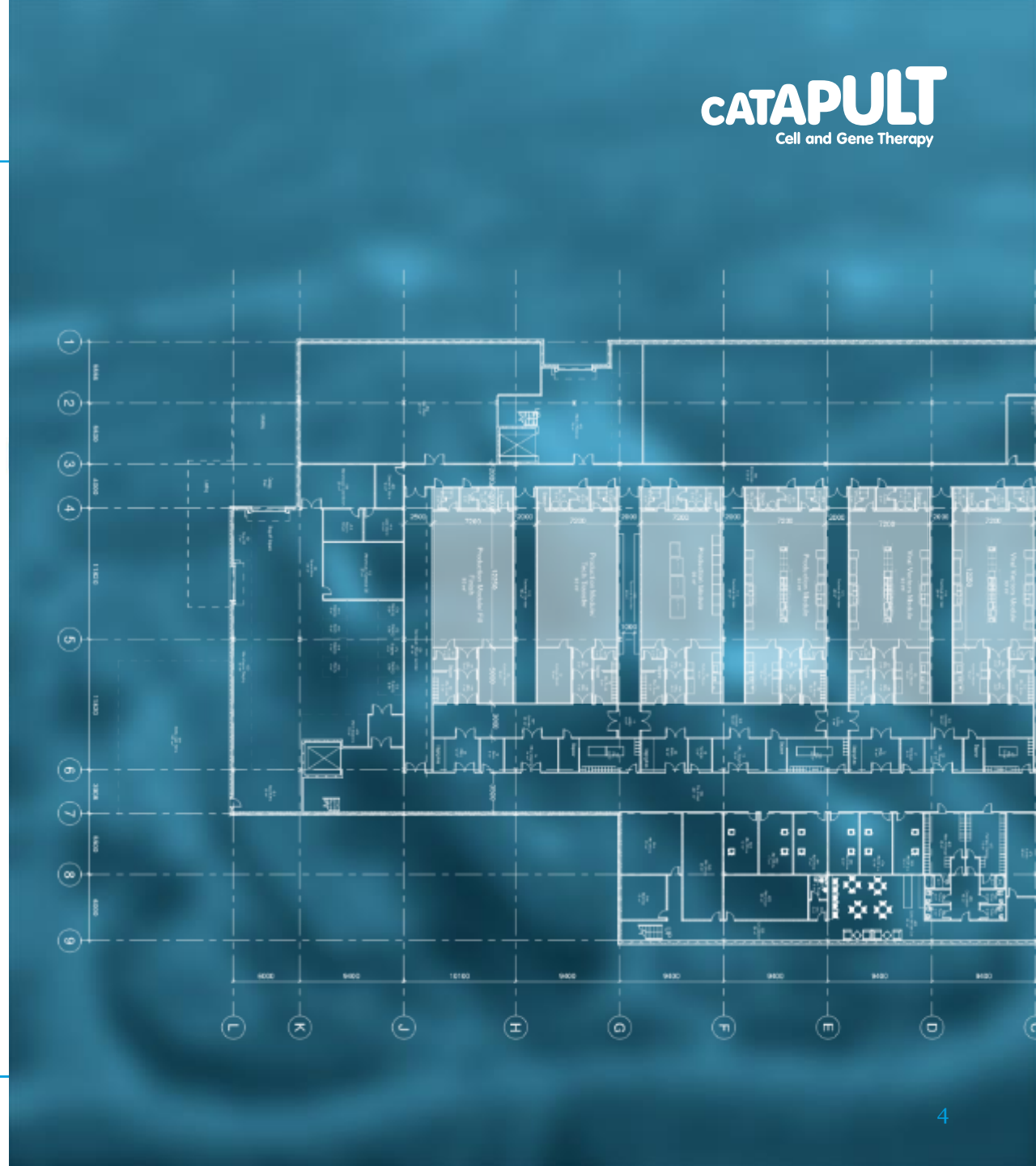
Adaptimmune
TRANSFORMING T CELL THERAPY

"With our own vector manufacturing capability at the Catapult facility, we will extend vector supply capacity beyond 2020." **James Noble, CEO**

TCR² THERAPEUTICS

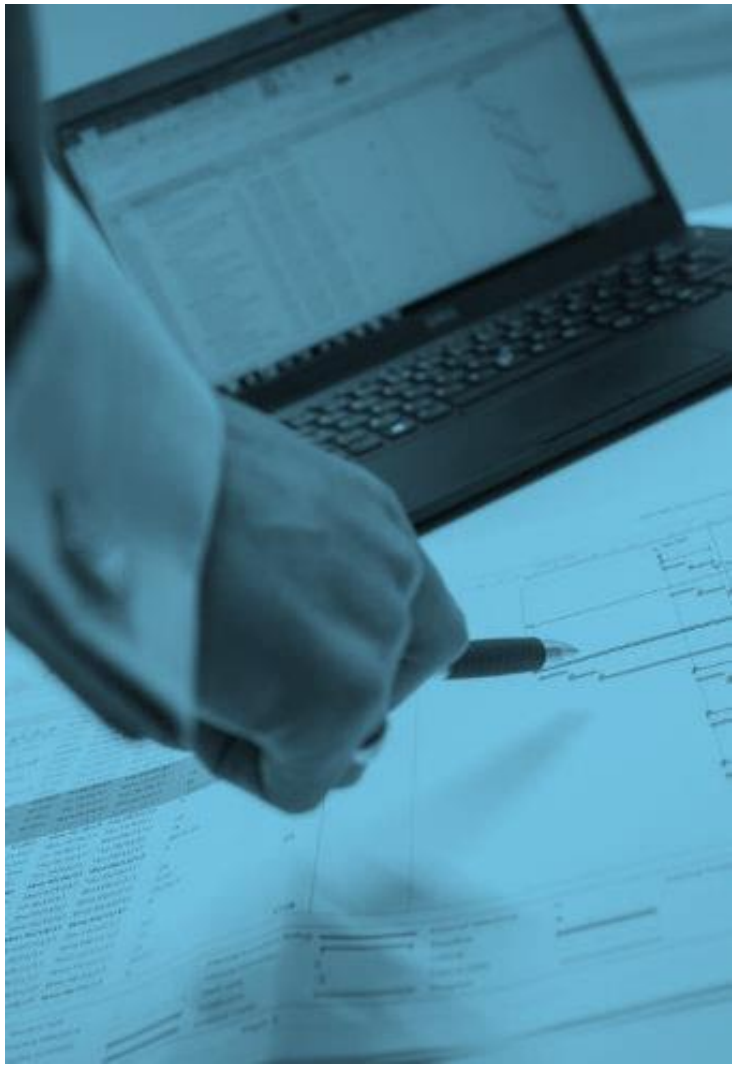
"The agreement with CGT Catapult enables us to meet our immediate clinical trials needs and have the flexibility of both our own dedicated manufacturing space" **Garry Menzel, Ph.D., President and CEO**

CATAPULT
Cell and Gene Therapy



Preparing for GMP manufacture

- Cleanroom Design & Set up Considerations
- Path to GMP Readiness: Operational Perspective
- Scheduling & Planning Challenge
- Waste Management Challenge
- Summary



Design considerations

Consumables

Reagents

Patient/Starting Material

Equipment

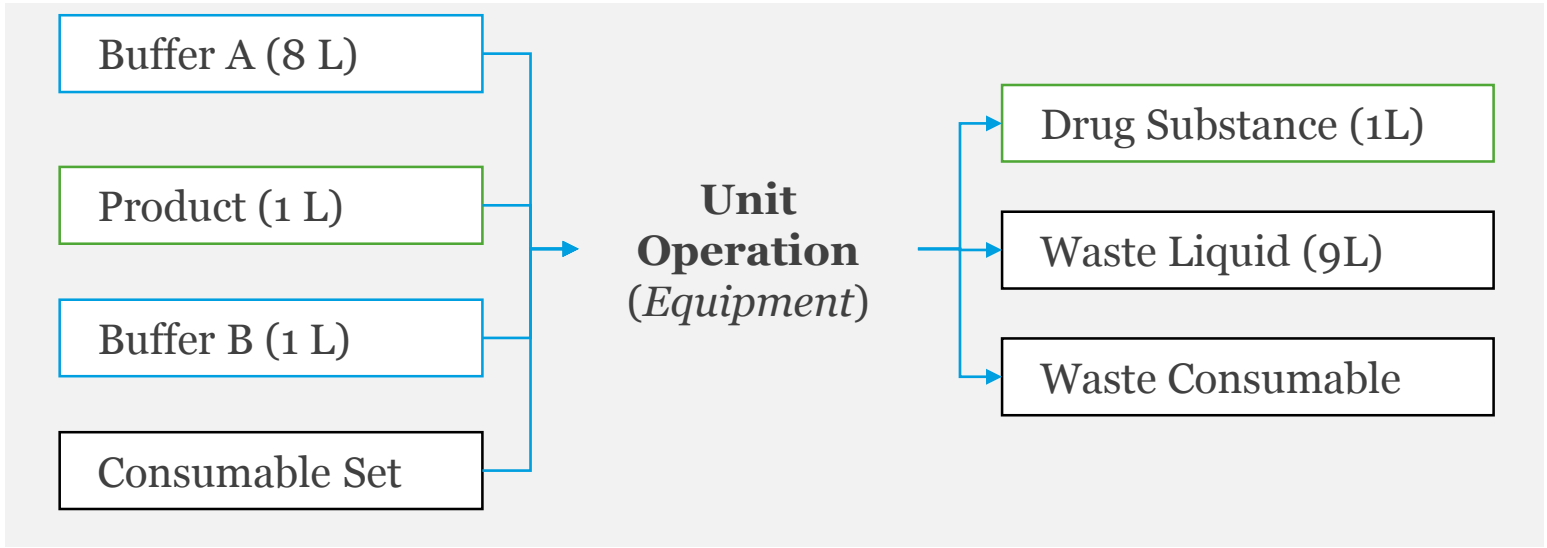
Waste Consumables

Waste Liquids

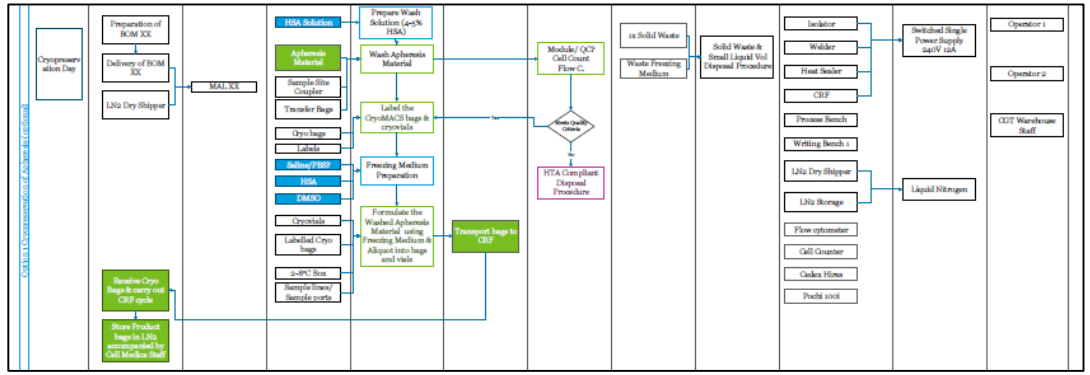
Product

Rejected Product/Starting Materials

Process mapping and mass/volume balance



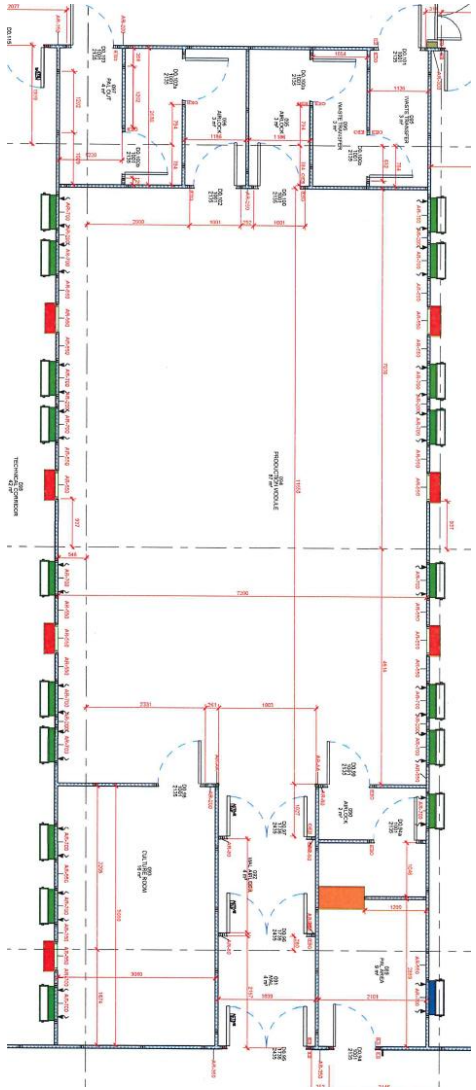
Visual Tool



Excel/Calculation Tools

No	Rev	Materials /Consumables In	Volume In		Vol Intermediate or product		Process Step	Step Time		Cumulative Time		Solid Waste	Liquid waste out
1													
2													
3		Seed vial	0.01	L			Thawing of vial and inoculation into 0.5L shake flasks	0.04	day	0.04	day	Seed vial	
4		Media	0.09	L	0.10	L						Pipette	
5		Shake Flasks											
6		Pipette											
7													
8													

Equipment placement

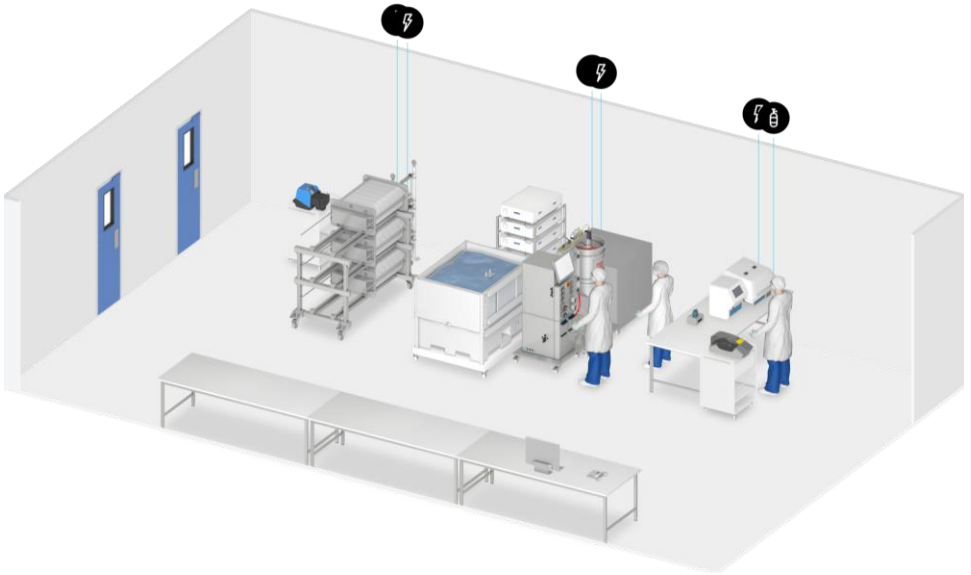


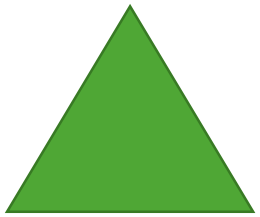
- **HVAC type & supply**
- **Utility provision**
  - Power supply (UPS/generator/non-essential)
  - Gas supply
  - Chilling capacity
- **Environmental monitoring**
  - Connection
  - Cabling route
- **Identify clear zones**
  - air outlets
  - equipment access routes
  - Material, product & people movement routes

Operational Considerations

-Segregation of unit operations

- Space & movement of auxiliary materials e.g., buffers/medium/welding stations/mobile equipment

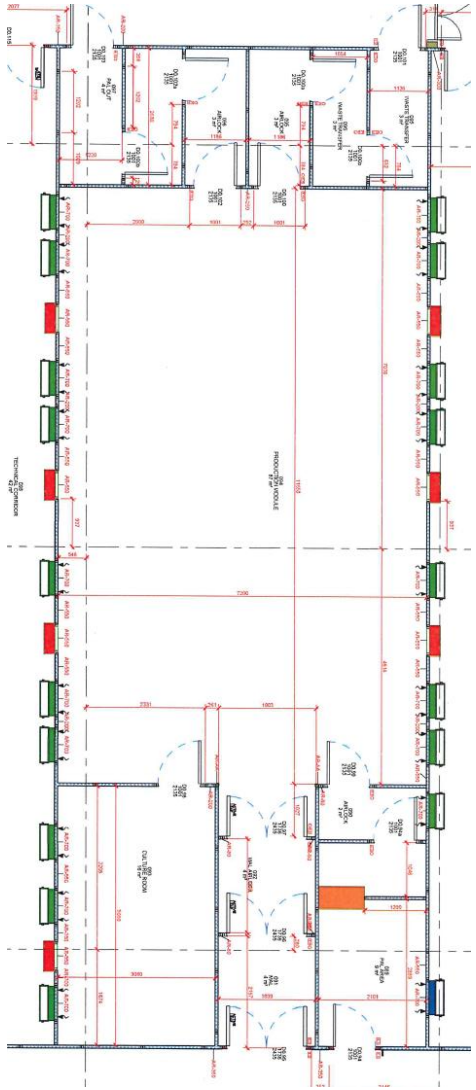




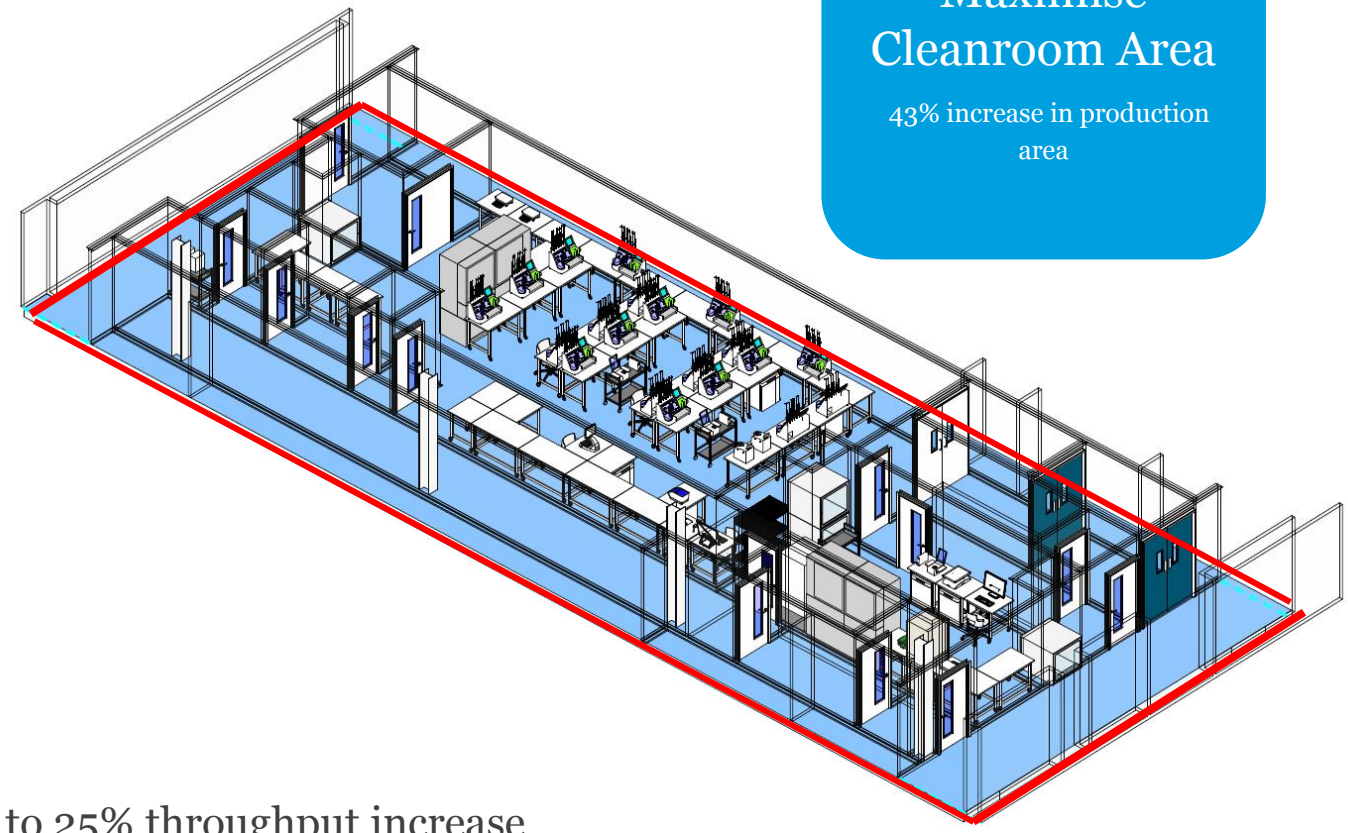
Operational quality
Process efficiency
Process robustness
Operator safety
Cross- containment

Contamination risk
Cross- contamination risk
Operator error
Unnecessary movement

Material, product and people flow



Maximise Throughput

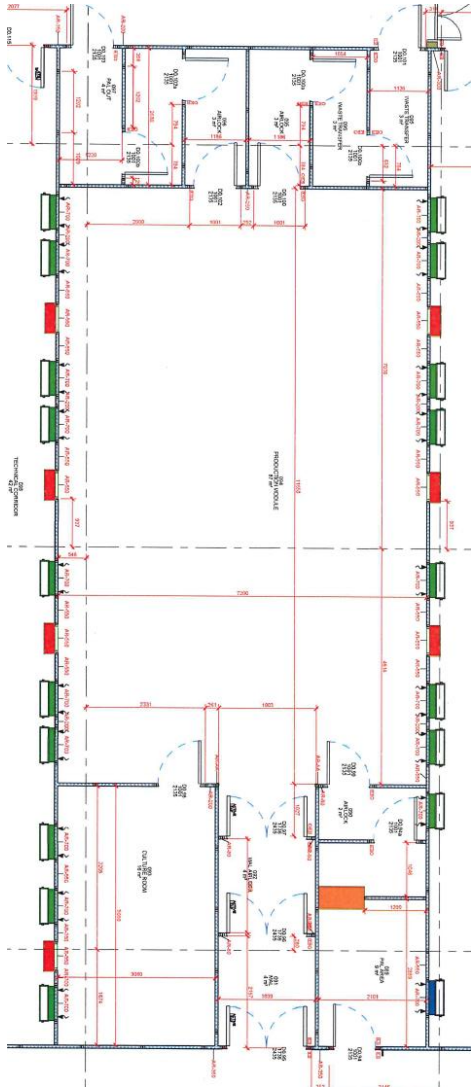


Maximise Cleanroom Area

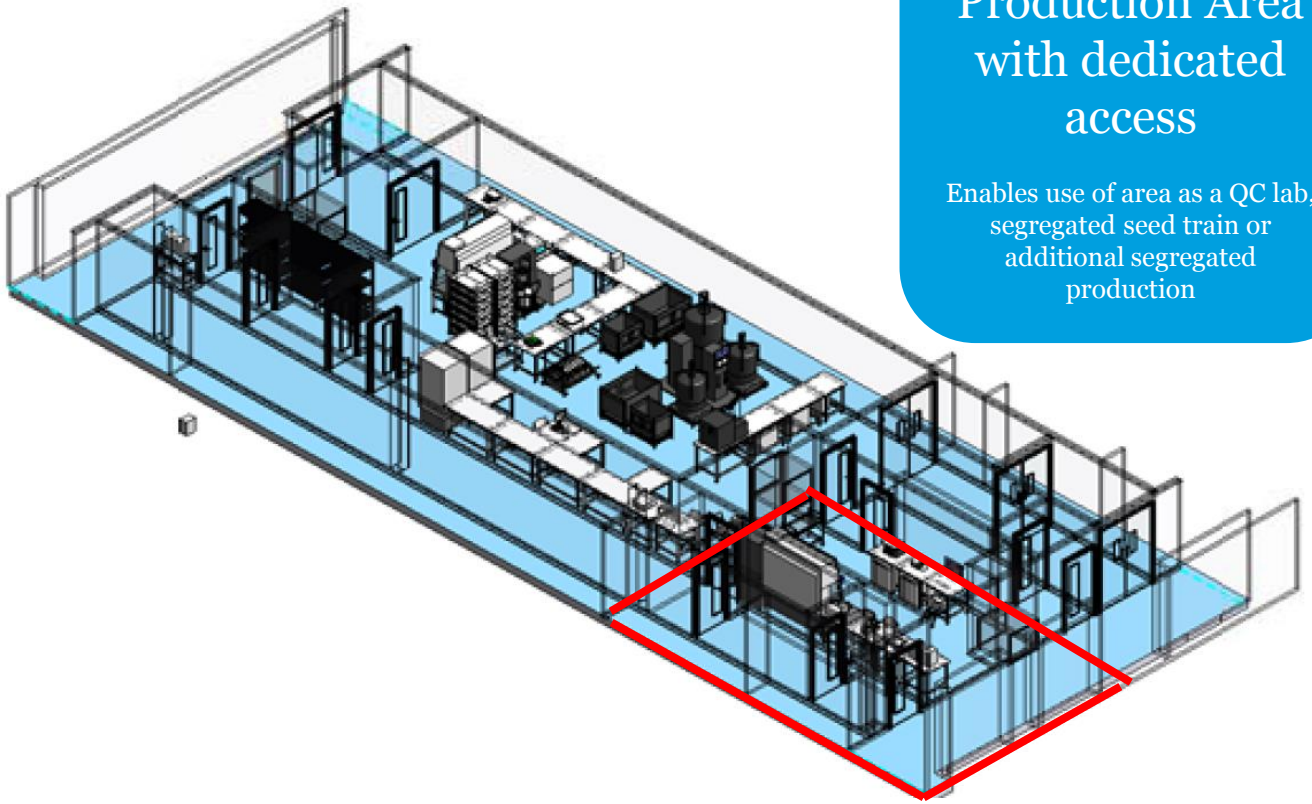
43% increase in production area

Autologous: up to 25% throughput increase

Material, product and people flow



Maximise Throughput

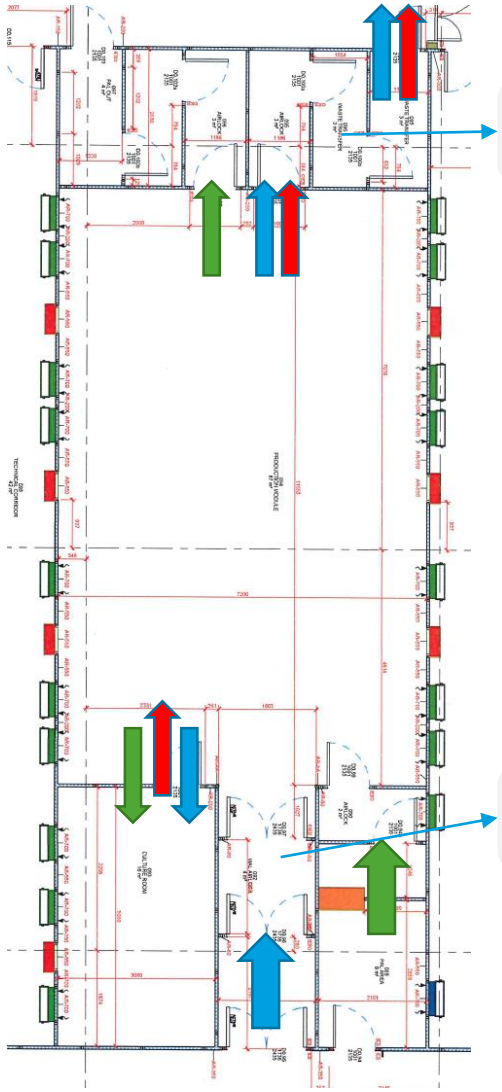


Segregated Small Production Area with dedicated access

Enables use of area as a QC lab, segregated seed train or additional segregated production

Viral Vector: up to 6 fold throughput increase

Material, product and people flow

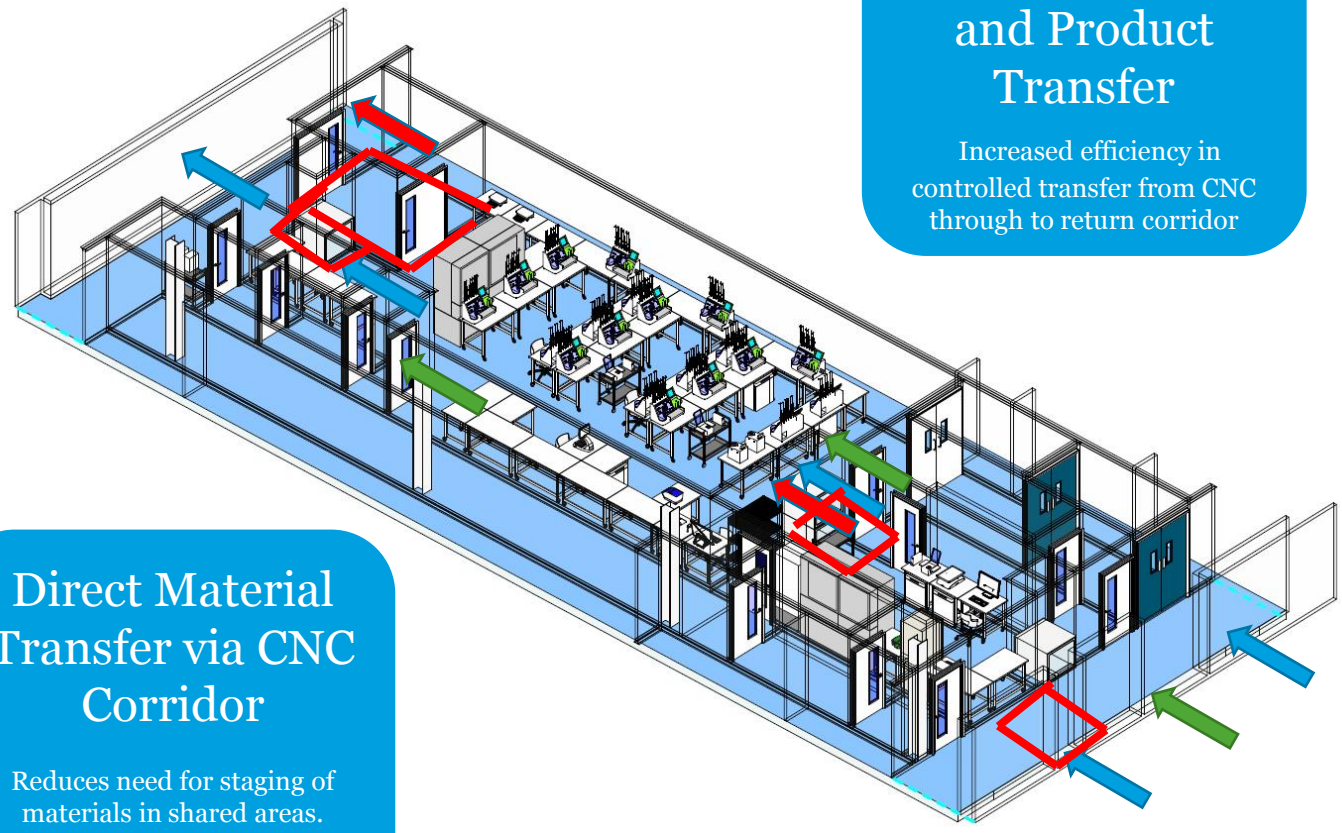


Materials Clean Down

Maximise Throughput

Optimise Flows

Materials Clean Down



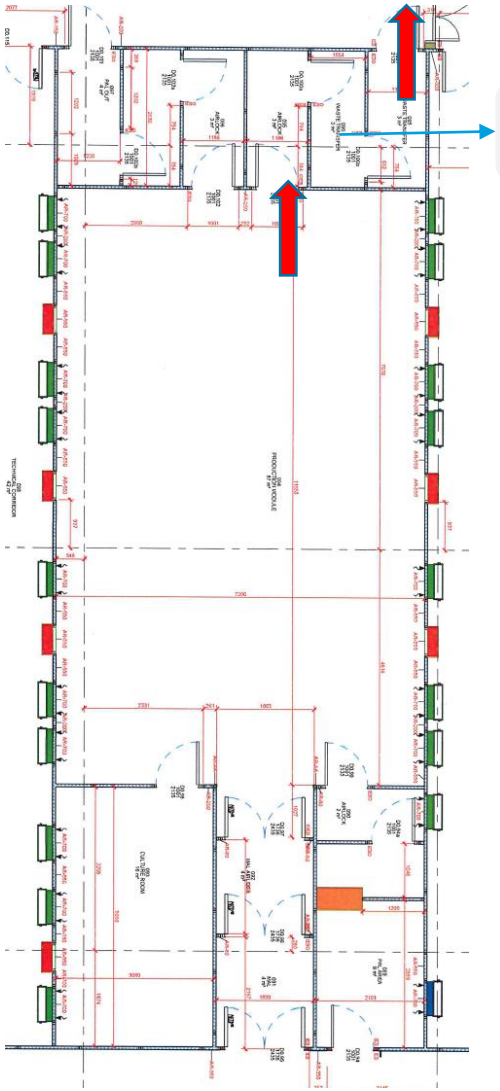
Segregated Material, Sample and Product Transfer

Increased efficiency in controlled transfer from CNC through to return corridor

Direct Material Transfer via CNC Corridor

Reduces need for staging of materials in shared areas. Enables delivery directly to module.

Material, product and people flow

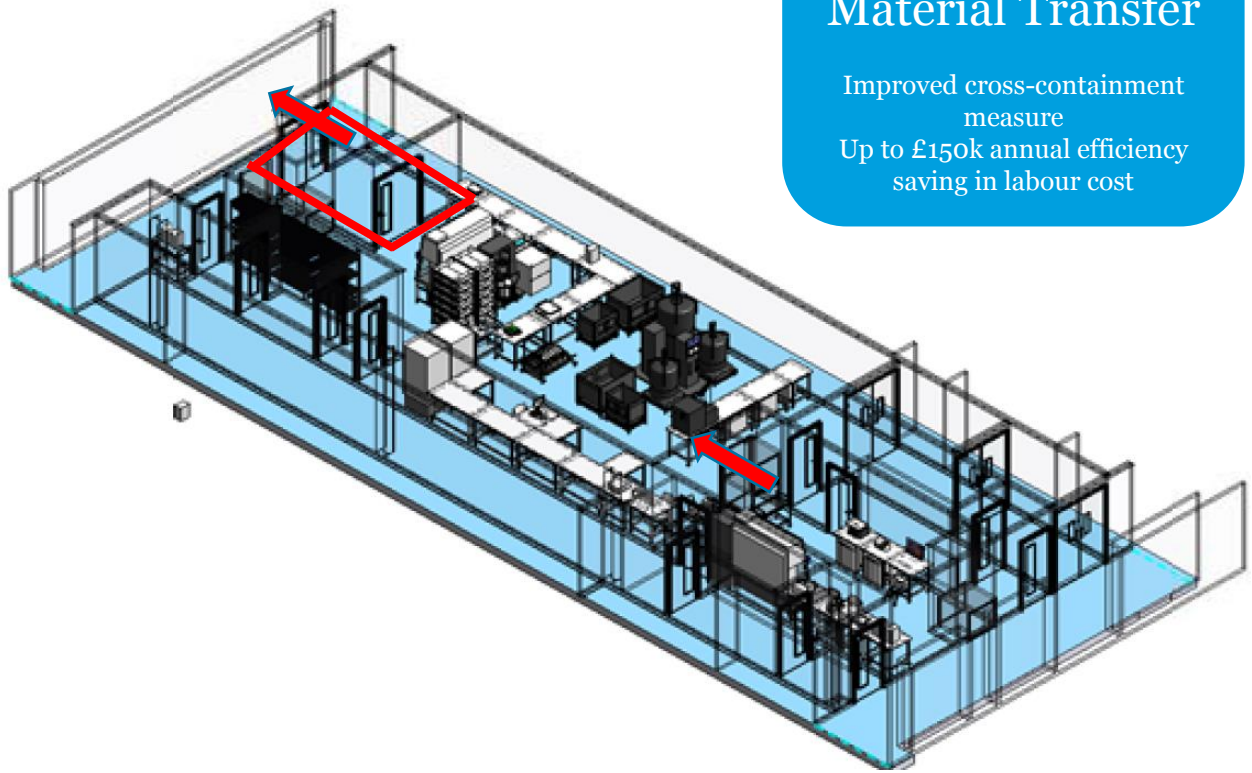


Materials Clean Down

Maximise Throughput

Optimise Flows

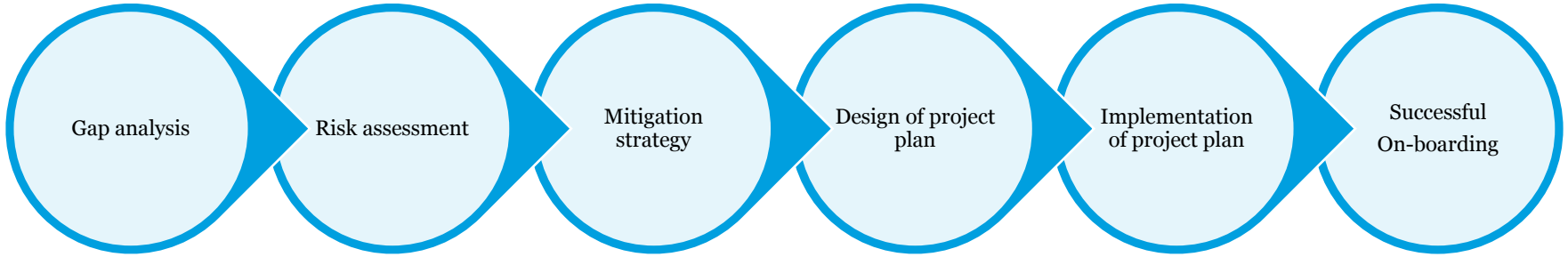
Decrease Labour

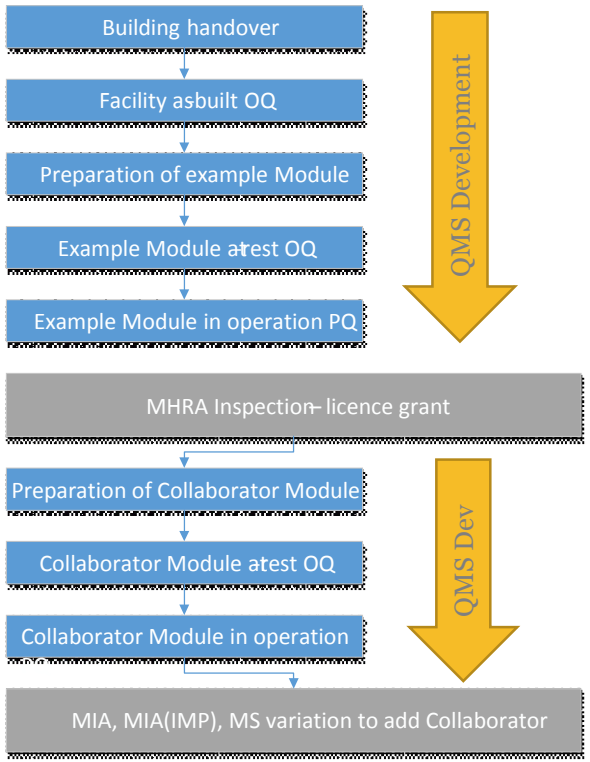


Fumigation Chamber for Material Transfer

Improved cross-containment measure
Up to £150k annual efficiency saving in labour cost

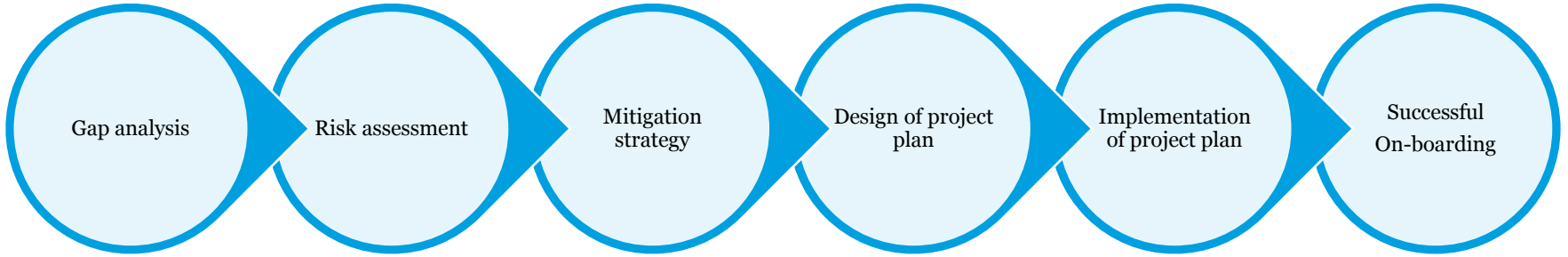
Path to GMP readiness: Operational perspective

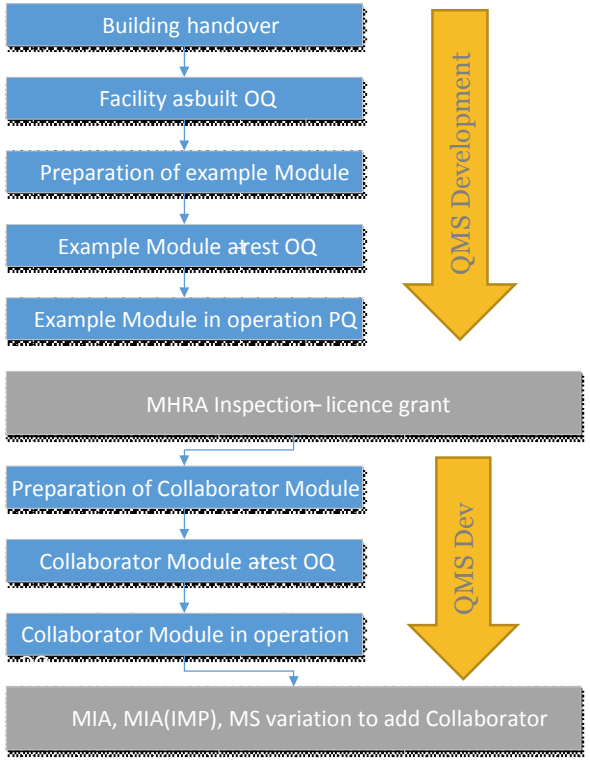




1. Equipment
2. Facility Adjustment/Modifications
3. Supply Chain & Logistics
4. Validation
5. Quality Assurance
6 Quality Control
7. EHS
8 Operations

Path to GMP readiness: Operational perspective





1. Equipm

2. Facility

3. Supply

4. Validat

5. Quality

CATAPULT Cell and Gene Therapy

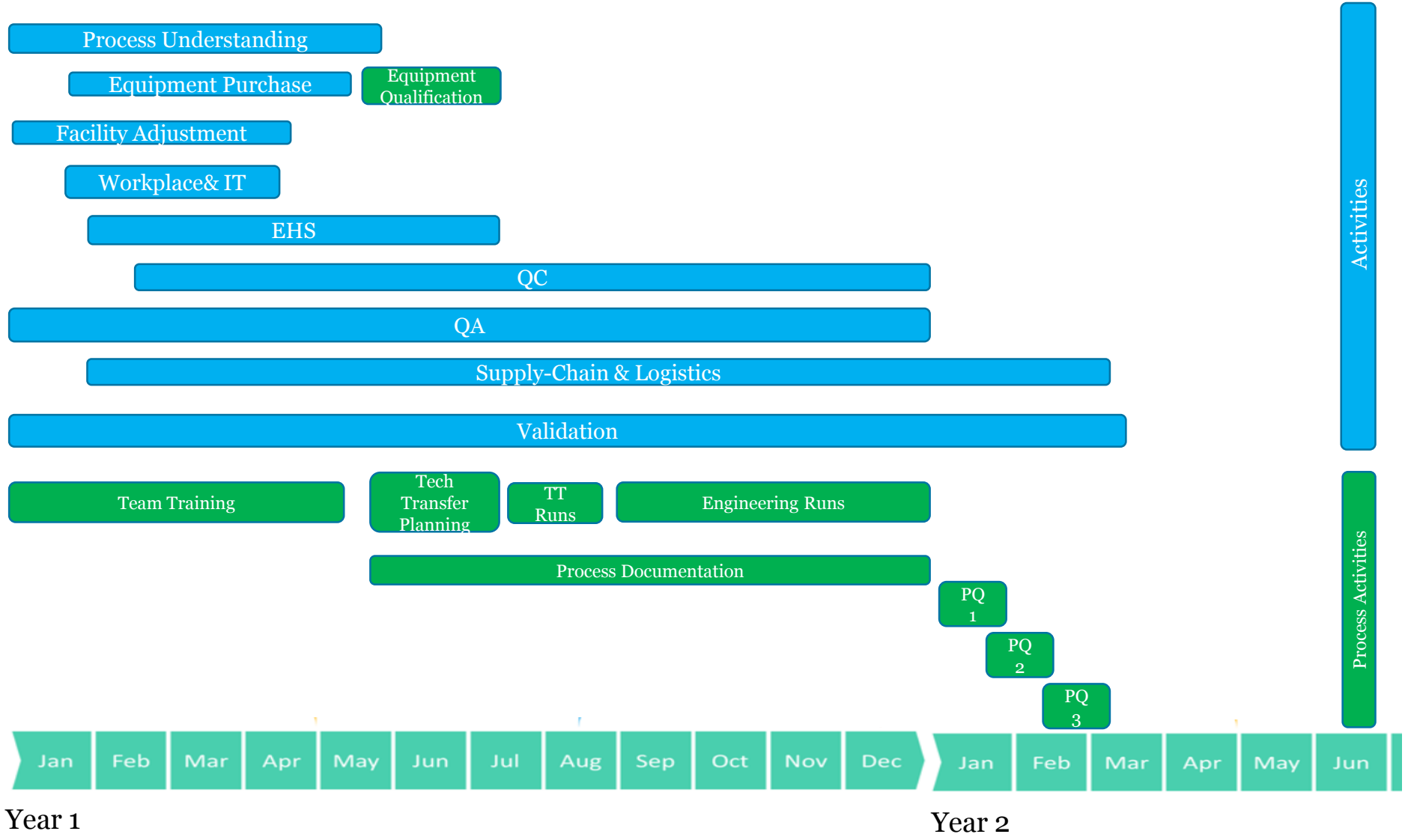
READINESS TO SUBMIT A VARIATION TO ADD A COLLABORATOR TO CGT MIA OR MIA(IMP)

MC-

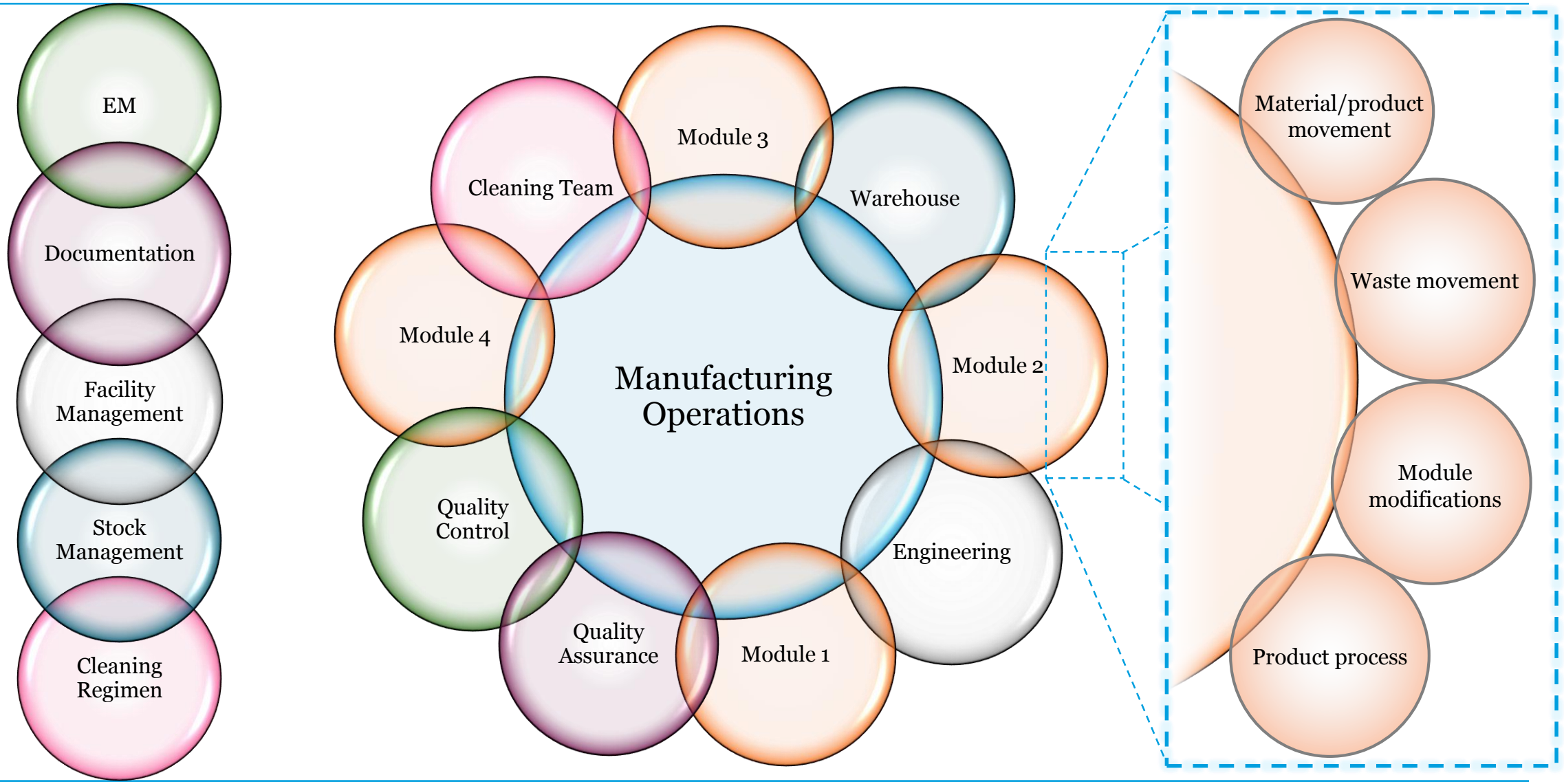
3 Facilities and Equipment

	Question	Res
3.1	Do you have an approved validation master plan compliant with section Annex 15 – Qualification and Validation?	
3.2	Have you performed an assessment of qualification requirements of your production and QC equipment?	
3.3	Have you qualified your production and QC equipment, as appropriate for your activities? Where qualification is not complete, do you have list of qualifications that need to be completed and the appropriate protocols in place for completion of the qualification activities?	
3.4	For computerised systems that generate critical data, does the validation include an assessment of compliance with data integrity principles?	
3.5	Do you have a mechanism for setting and managing equipment calibration frequencies?	
3.6	Has all your equipment been calibrated in line with your PQS requirements, and are all calibration certificates available on request?	

Path to GMP readiness: Operational perspective



Scheduling and planning challenge



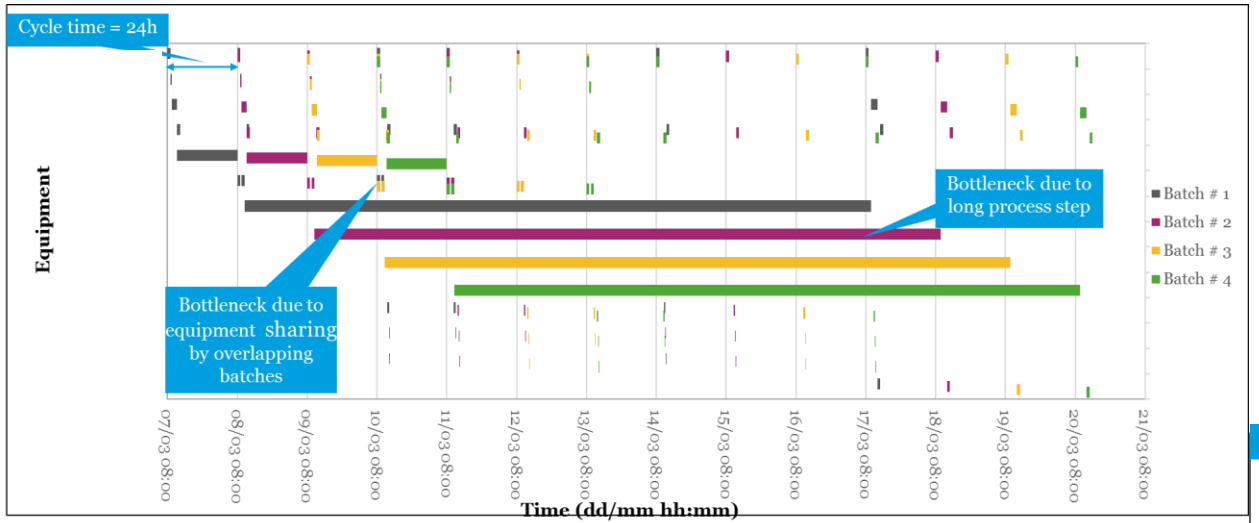
Scheduling tool

	Week	13									
	Date	26-Nov-18		27-Nov-18		28-Nov-18		29-Nov-18		30-Nov-18	
	TIME	Mon		Tue		Wed		Thu		Fri	
Module X	7:00 AM	Process	Biological material movement	EM	Process	Weekly Clean	Process	Process	Eng's on site	Process	Product movement
	9:00 AM										
	11:00 AM				Material movement				Material movement		
	1:00 PM										
	3:00 PM		Waste Movement					clean	Waste Movement		Waste Movement
	5:00 PM										
	7:00 PM										

- Modules and MC common areas
- Maps Activities
- Rules
- Accessible to all facility teams

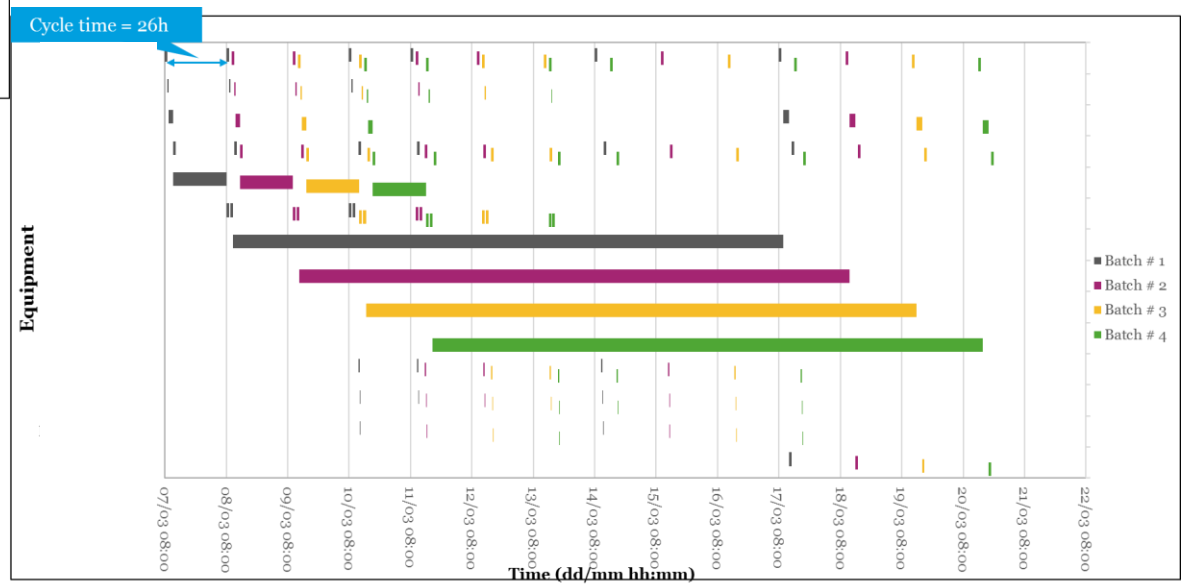
Scheduling tool: Process specific

Detailed process schedule automated tool example

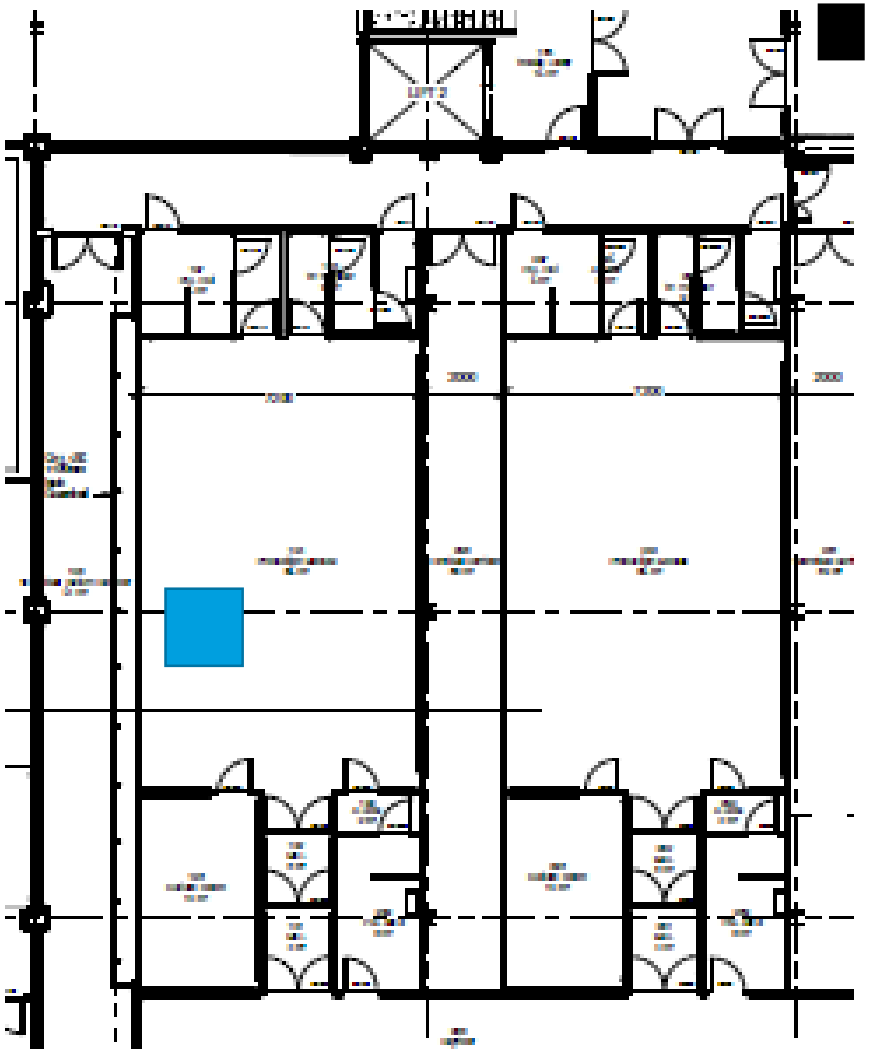


- Automated calendars for each piece of equipment
- In-built process step length
- Defined process step sequence to allow for automated schedule generation
- Visual and numerical outputs

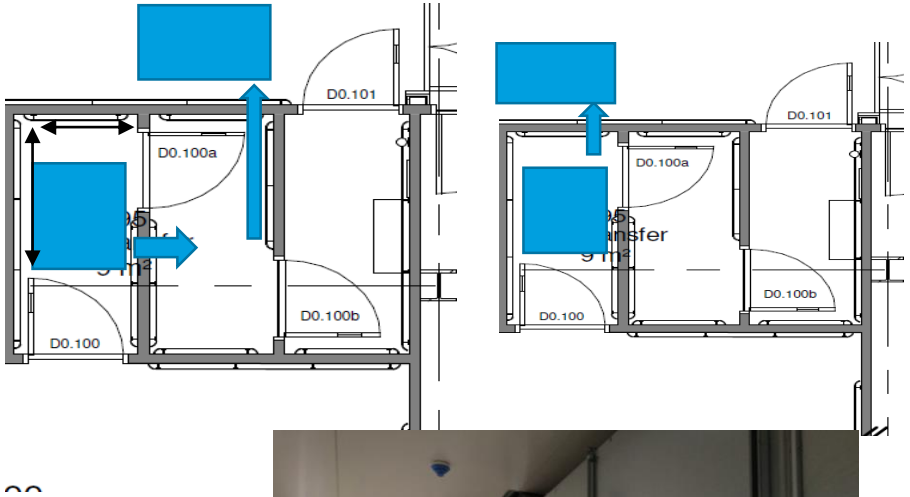
- Allow to determine rules for maximum capacity schedule
- Reduce operational risk
- Assist scheduling and decision making in detailed and high level planning



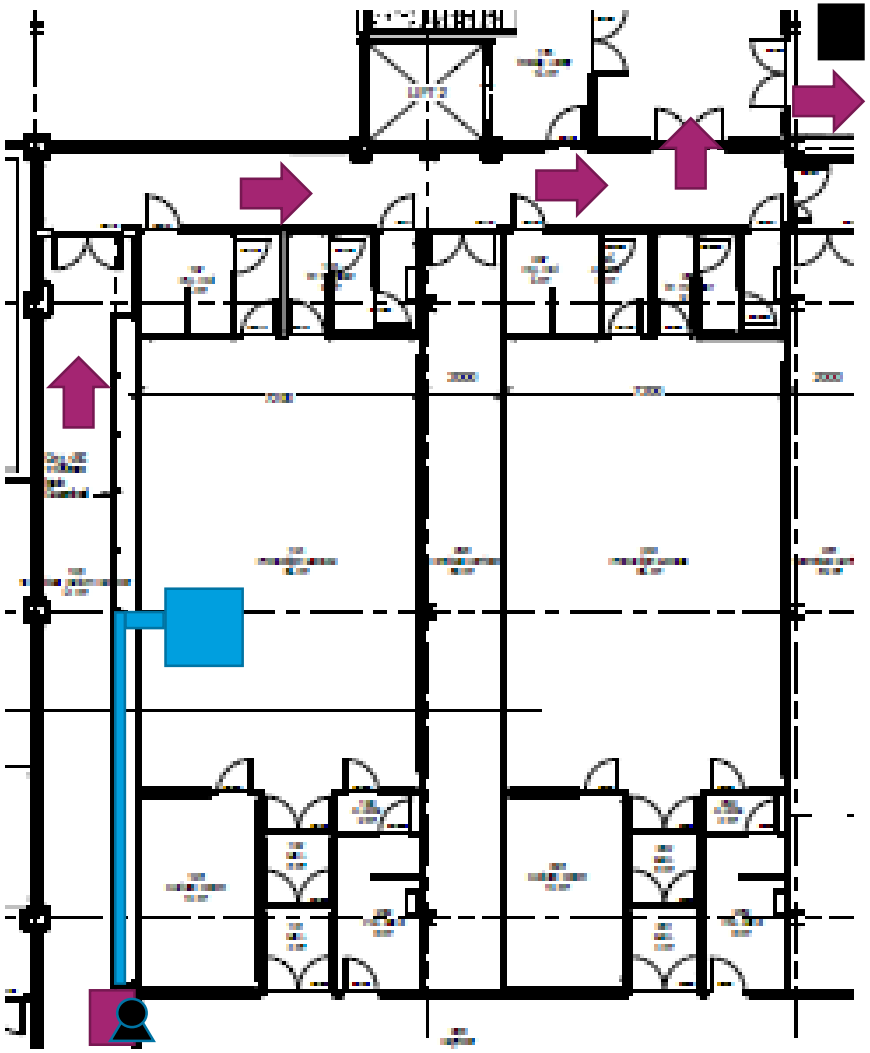
Waste management challenge



1. Brainstorm
2. Options Analysis
3. Risk Assessment



Waste management challenge

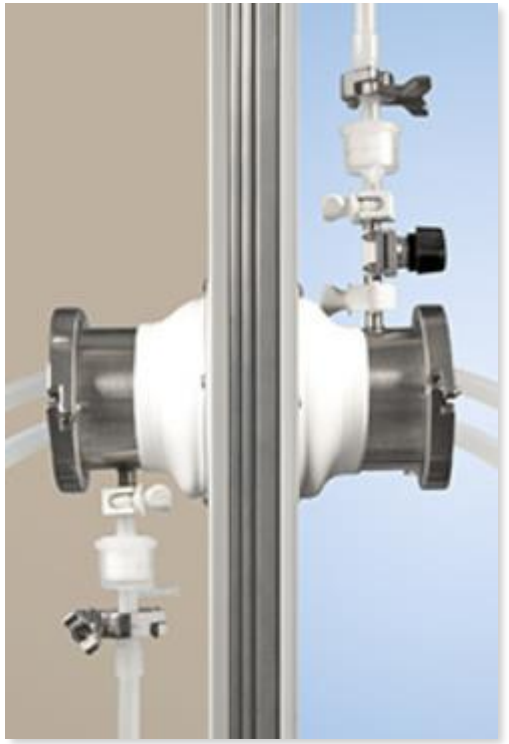


Collection Tank Movement Out

Inner Tank

Collection Tank

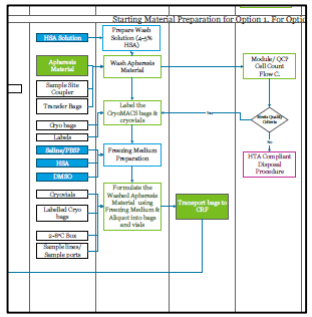
Drain



AdvantaPass

Inactivation of biological process waste streams

Preliminary study



Assess:
Volumes
Composition
Conditions

Inactivation Agent Candidate Panel

Representative Matrices

Design Experiment

Work to **component** level of detail

Consider Agent Inhibitory Factors:
- Temperature conditions
- pH
- Salt concentration
- Buffering capacity
- Protein content

Consider:
- Waste Removal Route
- Waste Contractor
- Suitability for Drain
- Handleability
- Efficacy (available data)
- Need for pre-treatment prior to disposal
- Acceptance criteria

Consider:
- Contaminated stream (bacterial & fungal)
- Range of inhibitory materials
- Range of operating conditions
- Worst case vs DoE approach
- Matrix stability

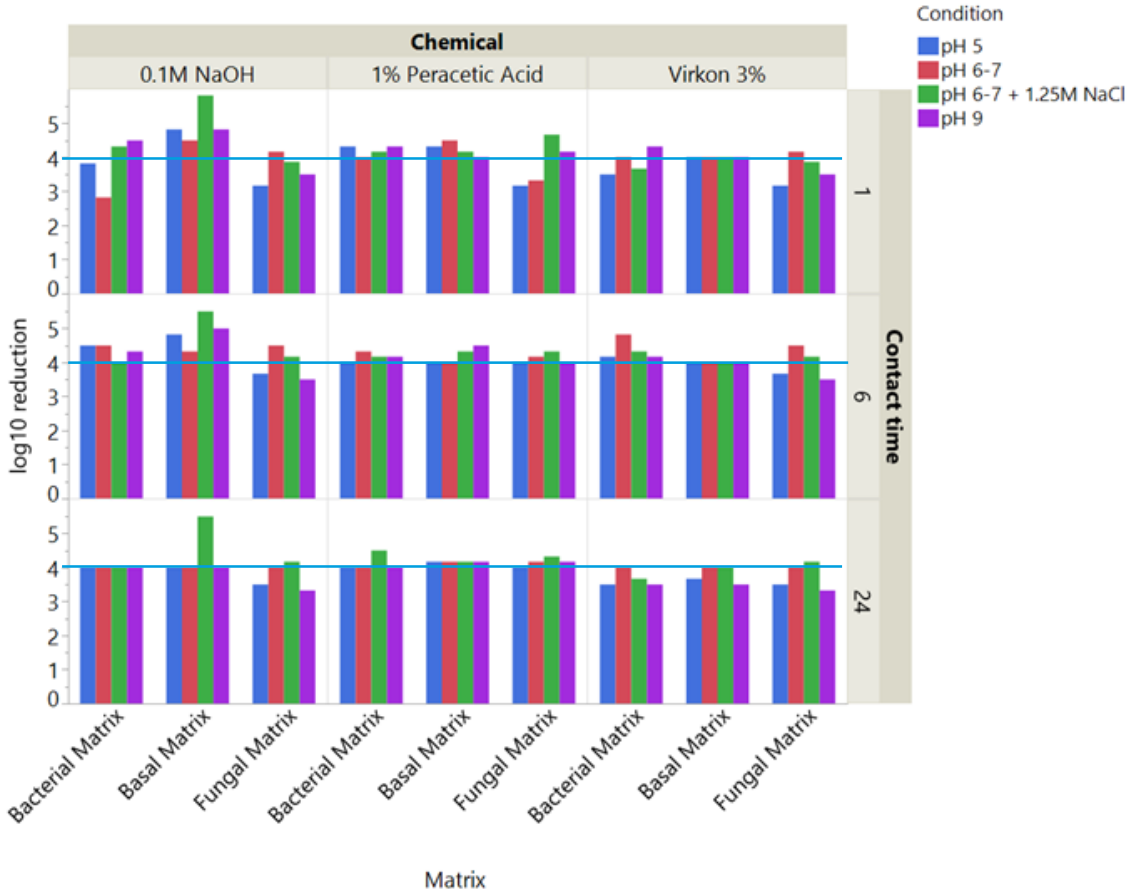
Consider:
- Contracting out vs inhouse
- Type of study - validation vs informative package
- One vs multiple studies
- Order of experiments
- Timeline

Develop appropriate rationale for acceptance criteria: e.g., EN 14476

Inactivation agent selection

Inactivation Agent	Concentration	Inactivation Time (h)	Pass/Fail
Virkon	3%	6 hours	Pass
NaOH	0.1M	6 hours	Pass
Peracetic Acid	1% v/v	6 hours	Pass

- Additional considerations include:
  - Practical handling of reagents
  - Storage, use and disposal
  - Cost and supply reliability
  - Compatibility with trade effluent consent limits



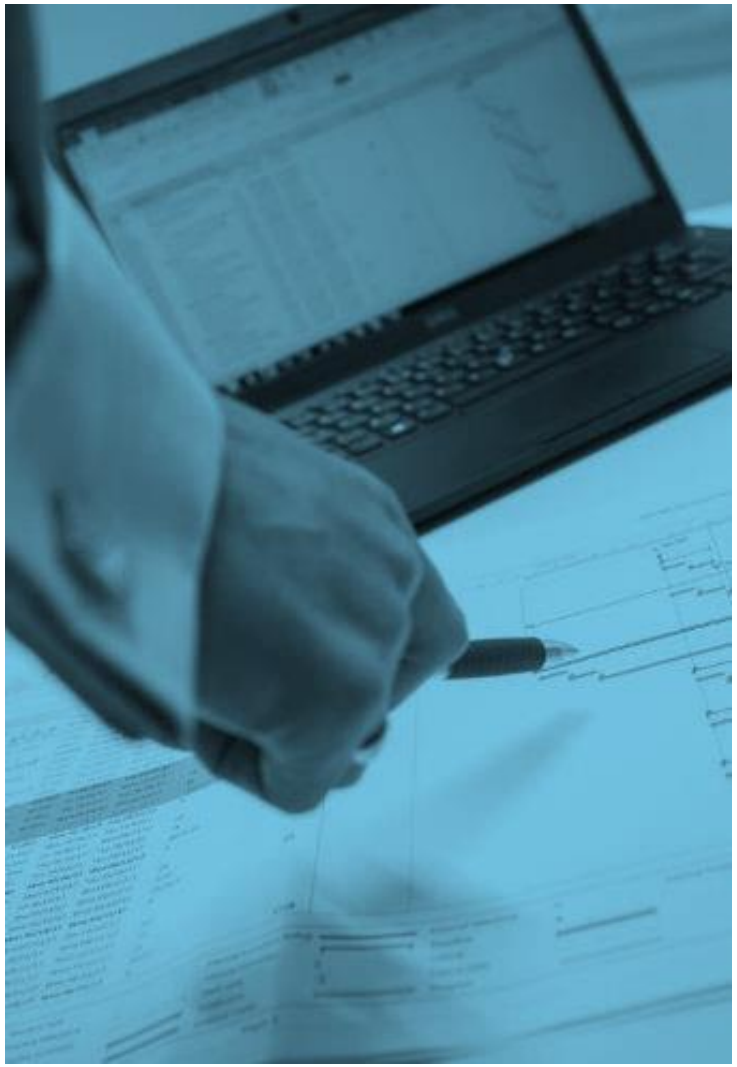
Summary

Process mapping and varying complexity of design tools are available to aid cleanroom design and fit out.

Quality, operations and project management collaborative approach is key to timely delivery of GMP readiness.

Activity scheduling can be a challenge during operational set up, the solution needs to be appropriate for the level of planning required.

Inactivation studies take time and effort. Not all waste can go down the drain.



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Kasia Averall
Julie Kerby
Kwok Pang
Jon Halling
James Biggins

Validation considerations

Establishing a cell and gene therapy manufacturing centre

Gina Basman, Validation Manager

Validation Considerations

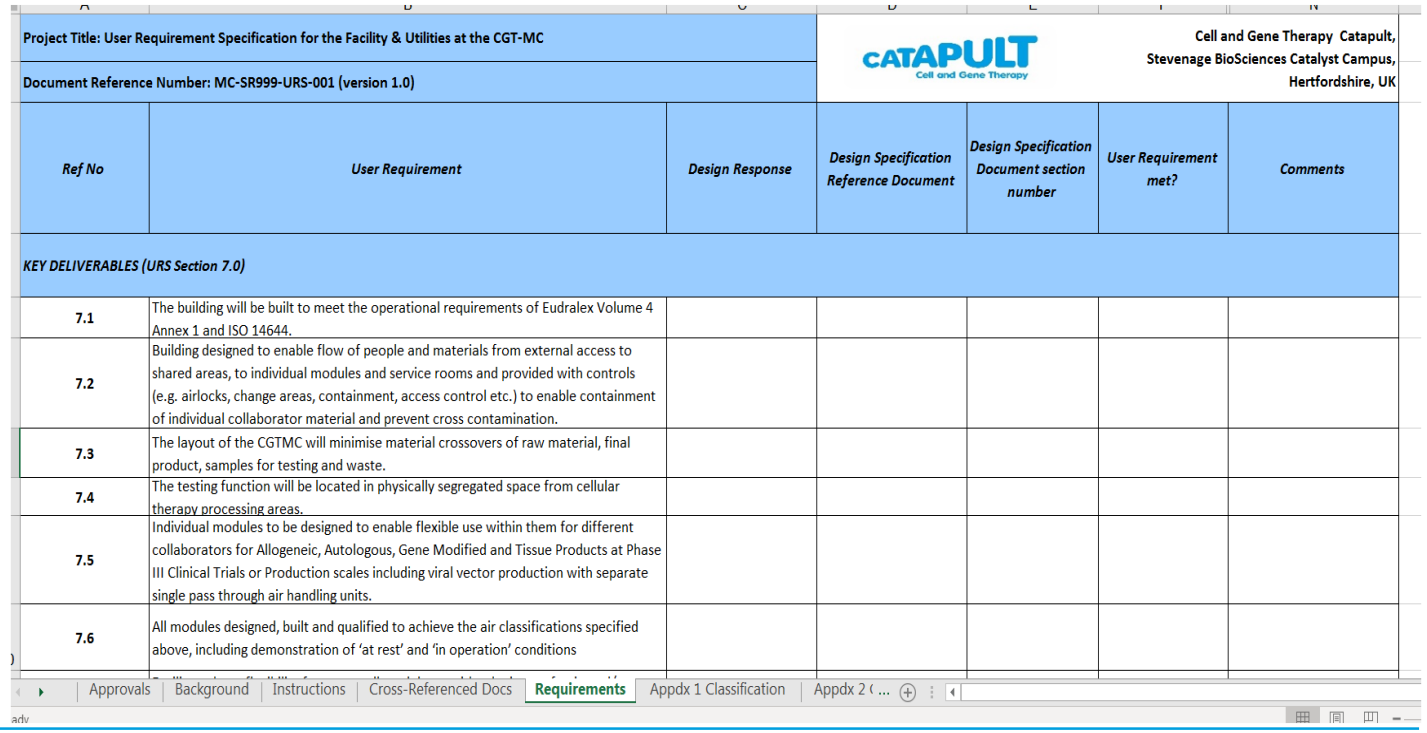
Regulating Medicines and Medical Devices

Validation Considerations

User Requirement Specification → Validation Master Plan → Design Qualification → Commissioning, Offsite (FAT) / On Site (SAT) Testing

Regulatory expectation: *"The manufacturer, or- as appropriate- the sponsor or marketing authorisation holder should define the specifications for the premises and equipment."*

- Define scope, and
- deliverables for quality,
- engineering, IT and
- business compliance



Project Title: User Requirement Specification for the Facility & Utilities at the CGT-MC						Cell and Gene Therapy Catapult, Stevenage BioSciences Catalyst Campus, Hertfordshire, UK
Document Reference Number: MC-SR999-URS-001 (version 1.0)						
Ref No	***User Requirement***	***Design Response***	***Design Specification Reference Document***	***Design Specification Document section number***	***User Requirement met?***	***Comments***
KEY DELIVERABLES (URS Section 7.0)						
7.1	The building will be built to meet the operational requirements of Eudralex Volume 4 Annex 1 and ISO 14644.					
7.2	Building designed to enable flow of people and materials from external access to shared areas, to individual modules and service rooms and provided with controls (e.g. airlocks, change areas, containment, access control etc.) to enable containment of individual collaborator material and prevent cross contamination.					
7.3	The layout of the CGTMC will minimise material crossovers of raw material, final product, samples for testing and waste.					
7.4	The testing function will be located in physically segregated space from cellular therapy processing areas.					
7.5	Individual modules to be designed to enable flexible use within them for different collaborators for Allogeneic, Autologous, Gene Modified and Tissue Products at Phase III Clinical Trials or Production scales including viral vector production with separate single pass through air handling units.					
7.6	All modules designed, built and qualified to achieve the air classifications specified above, including demonstration of 'at rest' and 'in operation' conditions					

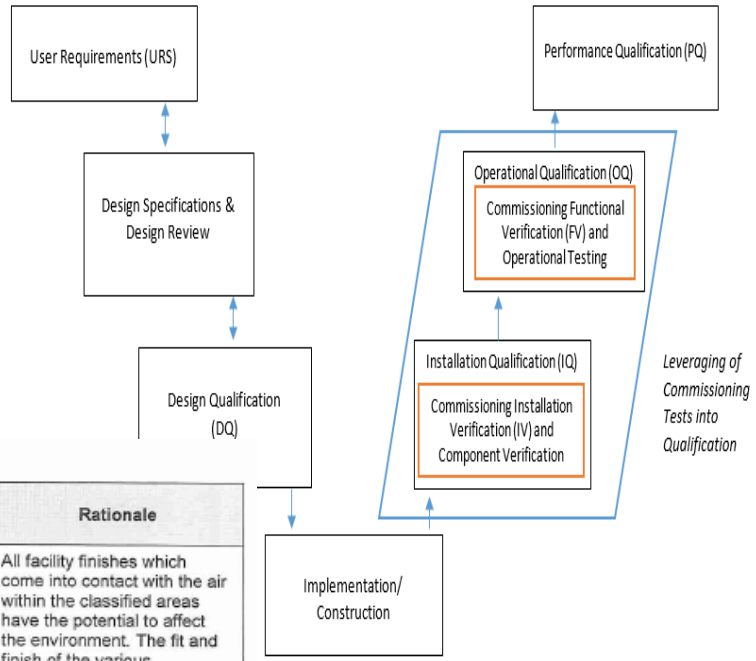
Approvals | Background | Instructions | Cross-Referenced Docs | Requirements | Appdx 1 Classification | Appdx 2 (...

Validation Considerations

User Requirement Specification → **Validation Master Plan** → Design Qualification → Commissioning, Offsite (FAT) / On Site (SAT) Testing

Regulatory expectation: *"The key elements of the site qualification and validation programme should be clearly defined and documented in a validation master plan (VMP)."*

- Validation Scope and Strategy
- Deliverables
- Roles and Responsibilities
- System Criticality Assessment



4. SLIA – SYSTEM LEVEL IMPACT ASSESSMENT.

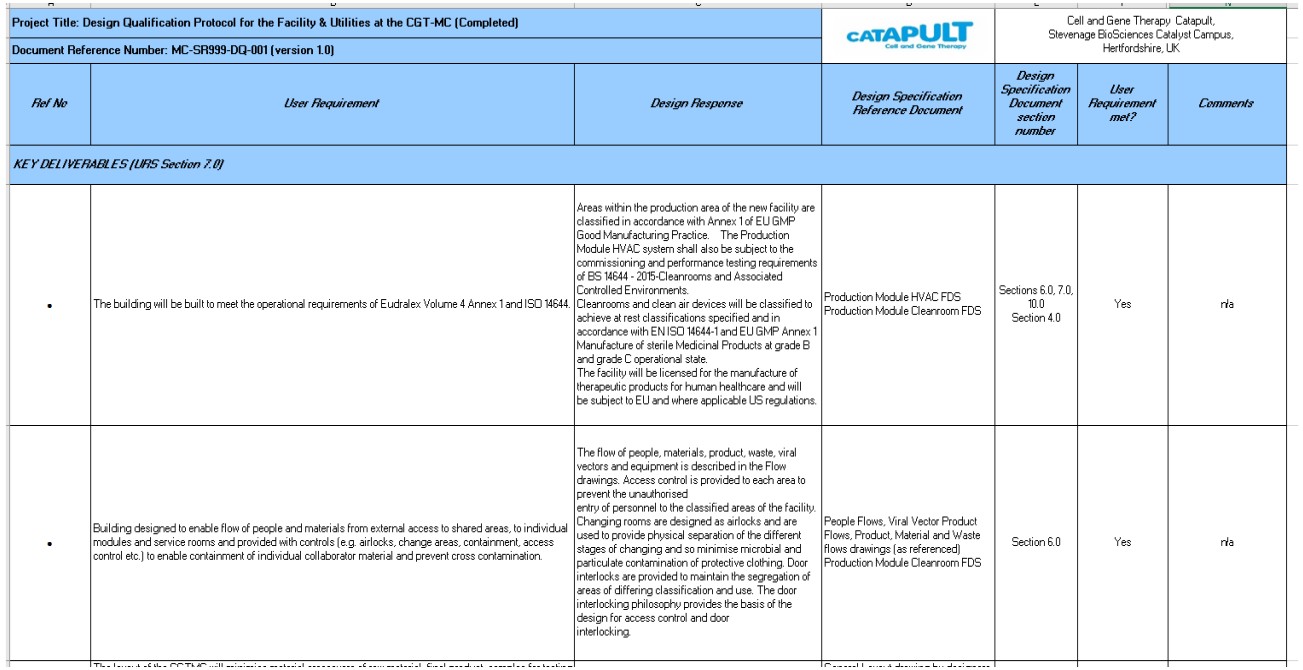
System	Description	Assessment Criteria							Impact	Required Testing	Rationale
		1	2	3	4	5	6	7			
Cleanroom Module 7	Floor, wall and ceiling finishes, light fittings, doors and interlock systems, fixtures and fittings which form classified or GMP areas	N	N	N	Y	N	N	N	Direct	Commissioned and Qualified	All facility finishes which come into contact with the air within the classified areas have the potential to affect the environment. The fit and finish of the various components is key to producing an easy to clean, crevice free envelope. Doors and interlock systems play a key role in controlling the specified pressure cascades and environments. Each module will have access control.
Cleanroom Module 8		N	N	N	Y	N	N	N			
Cleanroom Module 9		N	N	N	Y	N	N	N			
Cleanroom Module 10		N	N	N	Y	N	N	N			
Cleanroom Module 11		N	N	N	Y	N	N	N			
Cleanroom Module 12		N	N	N	Y	N	N	N			

Validation Considerations

User Requirement Specification → Validation Master Plan → **Design Qualification** → Commissioning, Offsite (FAT) / On Site (SAT) Testing

Regulatory expectation: *"Compliance with user requirements should be demonstrated."*

- Design Specifications
- Design Review
- Design Freeze
- Change Management
- Design Qualification Protocol



Project Title: Design Qualification Protocol for the Facility & Utilities at the CGT-MC (Completed)			CATAPULT Cell and Gene Therapy	Cell and Gene Therapy Catapult, Stevenage BioSciences Catalyst Campus, Hertfordshire, UK		
Document Reference Number: MC-SR999-DQ-001 (version 1.0)						
Ref No	*User Requirement*	*Design Response*	*Design Specification Reference Document*	*Design Specification Document section number*	*User Requirement met?*	*Comments*
KEY DELIVERABLES (URS Section 7.0)						
•	The building will be built to meet the operational requirements of Eudralex Volume 4 Annex 1 and ISO 14644.	Areas within the production area of the new facility are classified in accordance with Annex 1 of EU GMP Good Manufacturing Practice. The Production Module HVAC system shall also be subject to the commissioning and performance testing requirements of BS 14644 - 2015-Cleanrooms and Associated Controlled Environments. Cleanrooms and clean air devices will be classified to achieve at rest classifications specified and in accordance with EN ISO 14644-1 and EU GMP Annex 1 Manufacture of sterile Medicinal Products at grade B and grade C operational state. The facility will be licensed for the manufacture of therapeutic products for human healthcare and will be subject to EU and where applicable US regulations.	Production Module HVAC FDS Production Module Cleanroom FDS	Sections 6.0, 7.0, 10.0 Section 4.0	Yes	n/a
•	Building designed to enable flow of people and materials from external access to shared areas, to individual modules and service rooms and provided with controls (e.g. airlocks, change areas, containment, access control etc.) to enable containment of individual collaborator material and prevent cross contamination.	The flow of people, materials, product, waste, viral vectors and equipment is described in the Flow drawings. Access control is provided to each area to prevent the unauthorised entry of personnel to the classified areas of the facility. Changing rooms are designed as airlocks and are used to provide physical separation of the different stages of changing and so minimise microbial and particulate contamination of protective clothing. Door interlocks are provided to maintain the segregation of areas of differing classification and use. The door interlocking philosophy provides the basis of the design for access control and door interlocking.	People Flows, Viral Vector Product Flows, Product, Material and Waste flows drawings (as referenced) Production Module Cleanroom FDS	Section 6.0	Yes	n/a

Validation Considerations

User Requirement Specification → Validation Master Plan → Design Qualification → Commissioning, Offsite (FAT) / On Site (SAT) Testing

Regulatory expectation: *"Equipment, especially if incorporating novel or complex technology, may be evaluated, if applicable, at the vendor prior to delivery."*

- Good Engineering Practices
- Agree inspection test plans
- Commissioning Master Plan
- Leveraging Matrix
- Documented Inspections
- Acceptance of pre-qualification activities
- FAT, SAT, Commissioning
- Handover

6.0 APPENDIX – Test and Commissioning Schedule

6.1 Mechanical Systems

System:	Clean Room HVAC (AHU01, AHU02, AHU03, AHU04, AHU05, AHU06)
Qualified:	Yes

Offsite / Factory Testing

Test				Test Documentation	
Description	**Carried Out By**	**Witnessed By**	**Results used in Qualification**	**Format**	**Written By**
AHU Inspection (1no. AHU only)	Mechanical Subcontractor	M+W Qualification Engineer	No	Inspection Report with Snag list.	M+W

Static / Pre-commissioning

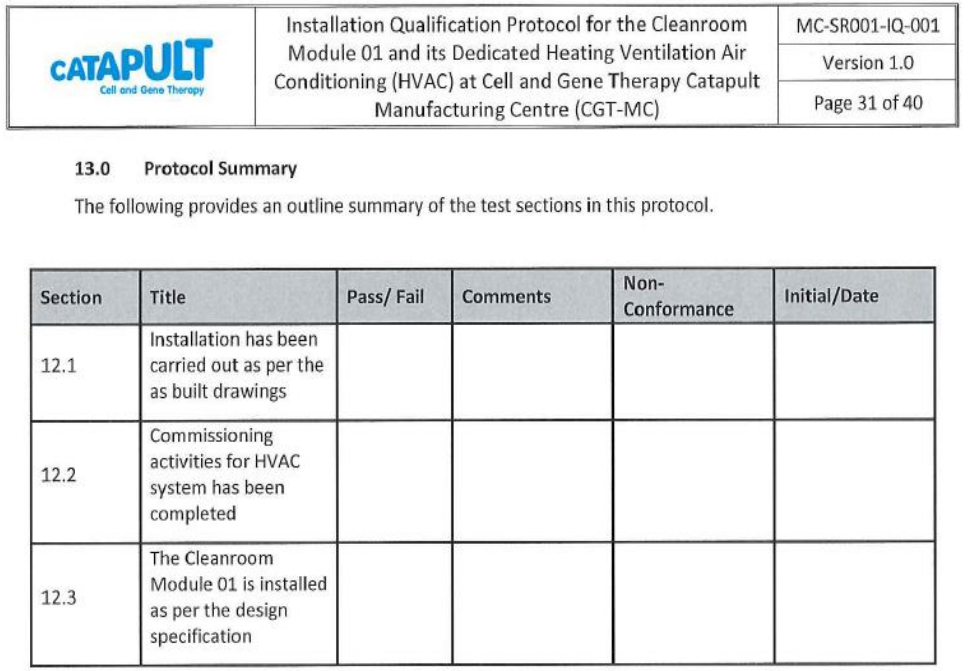
Test				Test Documentation	
Description	**Carried Out By**	**Witnessed By**	**Results used in Qualification**	**Format**	**Written By**
AHU Pressure Test	Mechanical Subcontractor	M+W Qualification Engineer	IQ	Individual Test	M+W Standard
Duct Pressure Test	Mechanical Subcontractor	M+W Qualification Engineer	IQ	Individual Test	M+W Standard

Validation Considerations

Installation Qualification → Operational Qualification → Performance Qualification → Validation Sign Off

Regulatory expectation: *"The manufacturer or- as appropriate- the sponsor or marketing authorisation holder should verify that the premises/equipment comply with the user specifications and are in line with GMP requirements."*

- Validation Protocols
- Verification of Installation and Functionality
- Leveraged Tests as per Plan
- Establishing Procedures



CATAPULT Cell and Gene Therapy	Installation Qualification Protocol for the Cleanroom Module 01 and its Dedicated Heating Ventilation Air Conditioning (HVAC) at Cell and Gene Therapy Catapult Manufacturing Centre (CGT-MC)	MC-SR001-IQ-001 Version 1.0 Page 31 of 40

13.0 Protocol Summary

The following provides an outline summary of the test sections in this protocol.

Section	Title	Pass/ Fail	Comments	Non-Conformance	Initial/Date
12.1	Installation has been carried out as per the as built drawings				
12.2	Commissioning activities for HVAC system has been completed				
12.3	The Cleanroom Module 01 is installed as per the design specification				

Validation Considerations

Installation Qualification → Operational Qualification → **Performance Qualification** → Validation Sign Off

Regulatory expectation: *"The suitability of the premises and equipment to operate consistently in accordance with the requirements of the intended manufacturing process (assuming worst case conditions) should be tested. A test with surrogate materials or simulated product is acceptable."*

- Verification of Performance
- Training
- Cleaning Qualification (where applicable)

12.0 TEST SUMMARY

The following tests will be executed under the authority of this protocol.

Test Section	*Test Title*
13	Verification of Air Cleanliness by Particle Concentration (Run 1)
14	Verification of Air Cleanliness by Particle Concentration (Run 2)
15	Verification of Air Cleanliness by Particle Concentration (Run 3)
16	Verification of Viable Concentration (Run 1)
17	Verification of Viable Concentration (Run 2)
18	Verification of Viable Concentration (Run 3)
19	Review of the Environmental Conditions Within the Cleanroom Module

Validation Considerations

Installation Qualification → Operational Qualification → Performance Qualification → Validation Sign Off

Regulatory expectation: "A formal release for the next stage in the qualification and validation process should be authorised by the relevant responsible personnel either as part of the validation report approval or as a separate summary document."

- Validation Sign Off
- Quality Approval
- Regulatory Approval

Medicines & Healthcare products Regulatory Agency — MHRA

Certificate No: UK MIA(IMP) 48152 Insp IMP 48152/16823386-0002

Medicines and Healthcare products Regulatory Agency

CERTIFICATE OF GMP COMPLIANCE OF A MANUFACTURER

Medicines & Healthcare products Regulatory Agency — MHRA

MIA(IMP) Number: MIA(IMP) 48152 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's Authorisation - Investigational Medicinal Products

Medicines & Healthcare products Regulatory Agency — MHRA

MIA Number: MIA 48152 Version: 1

MEDICINES AND HEALTHCARE PRODUCTS REGULATORY AGENCY
On behalf of the Licensing Authority under:
The Human Medicines Regulations 2012 (SI 2012/1916)

Manufacturer's/Importer's Licence

Validation Considerations

Process / Equipment Qualification → Process Validation → Validated State → Periodic Evaluation

Regulatory expectation: *"Equipment used in production or control operations should be suitable for its intended purpose and it should not present any hazard to the product."*

- Process Equipment Qualification
- Data Collection , Critical Process Parameters
- Process Development / Optimisation

Regulatory expectation: "The validation of analytical methods is intended to ensure the suitability of the analytical methods for the intended purpose."

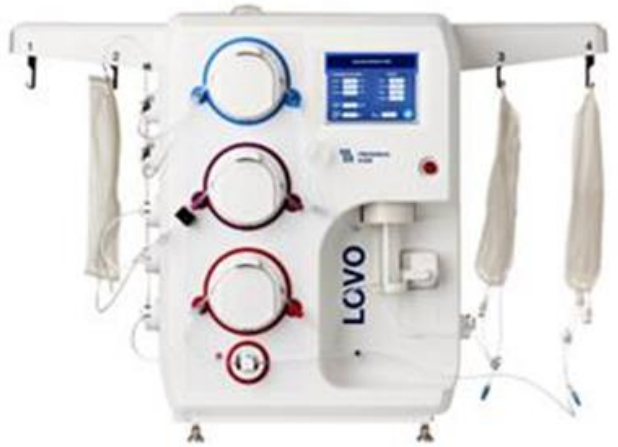
- QC Equipment Qualification
- Analytical Test Method Validation

Validation Considerations

Process Pre-qualification Runs → **Process Validation** → Validated State → Periodic Evaluation

Regulatory expectation: *"The aim of the process validation for ATMPs is to demonstrate that the finished product characteristics are within a given range (in compliance with the terms of the marketing authorisation)."*

- Validation Protocol
- Strategy to Process Validation
- Critical Process Parameters
- Critical Quality Attributes



Validation Considerations

Process Pre-qualification Runs → Process Validation → **Validated State** → Periodic Evaluation

Regulatory expectation: *"Manufacturers should monitor product quality to ensure that a state of control is maintained throughout the product lifecycle with the relevant process trends evaluated."*

- Product Process Monitoring
- Environmental Monitoring
- Calibration Program
- Preventative Maintenance Program
- Change Control Management
- Non Conformance Process

Validation Considerations

Process Pre-qualification Runs → Process Validation → Validated State → **Periodic Evaluation**

***Regulatory Expectation**: "Equipment, facilities, utilities and systems should be evaluated at an appropriate frequency to confirm that they remain in a state of control."*

- Periodic Review Schedule (risk based)
- Periodic Qualification Tests
- Temperature Mapping
- Decommissioning

CATAPULT Cell and Gene Therapy	Periodic Review Report for the CGT-MC Binder Incubators	MC-SR038-P Version 1 Page 4 of

3.0 Reference Documentation

The following table details the last approved report for the Binder Incubators:

Last Validation Summary Report No.	MC-SR038-VSR-001	**Approval Date**	15 April 2019*
Preceding Periodic Review Report No.	First review	**Review Period**	12 Months

* The review period has been taken from the approval of the PQ report conducted on the 21 Dec 17 (ref MC-SR038-PQR-001), therefore making the review date January 2018 to March 2019.

4.0 Review of Key Documentation

Key Points

- Validation is a lifecycle that begins with a conceptual design of the manufacturing process or facility and ends with system retirement.
- Validation activities and requirements are taken into account at the earliest stages of the design process.
- Risk-based approach where supplier testing is leveraged and used to reduce repetitive validation testing.
- Activities that support the manufacturing process such as analytical methods, and computer systems are adequately validated.
- The need for periodic reviews, changes to the validated system and revalidation activities are adequately addressed.

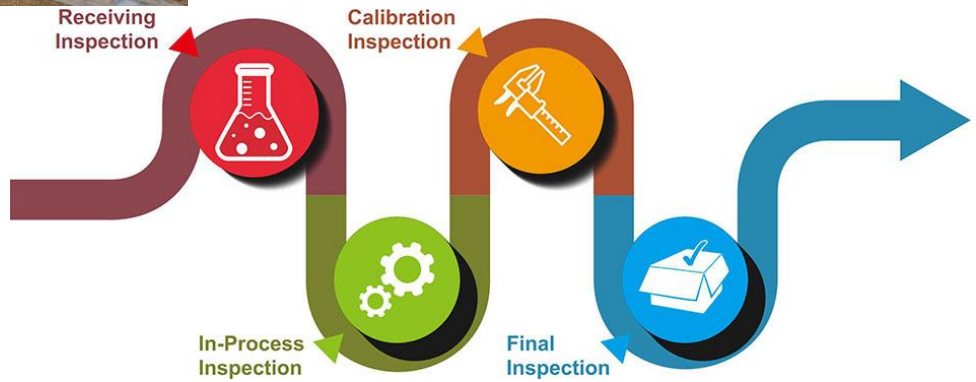
References

1. The principles of Orange Guide 'Rules and Guidance for Pharmaceutical Manufacturers and Distributors' (MHRA)
2. EU EudraLex Vol 4 -
   - Annex 15: Qualification & Validation
   - Annex 1: Manufacture of Sterile Medicinal Products
   - Annex 11: Computerised Systems
   - Part 4: GMP Requirements for Advanced Therapy Medicinal Products
3. International Conference on Harmonisation (ICH) Q9 Quality Risk Management and Q10 Pharmaceutical Quality Systems guides will be used to support the validation studies.
4. International standards, such as ISO 14644
5. ISPE GAMP 5 : Compliant GxP Computerised Systems
6. ISPE Baseline Guide Vol 5: Commissioning and Qualification
7. The Genetically Modified Organisms (Contained Use) Regulations 201
8. FDA Guidance for Industry Process validation: General Principles and Practices

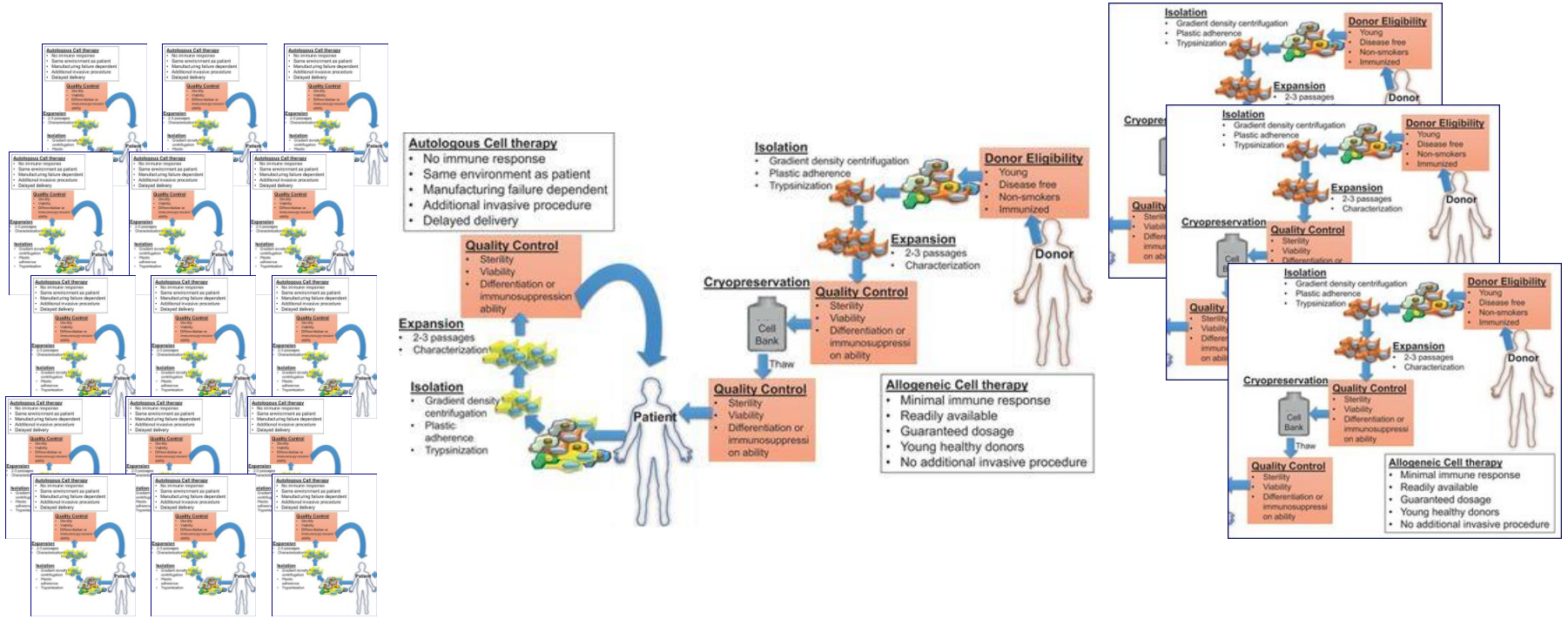
Quality control considerations

Doli Patel, Head of Quality Control

Quality Control Considerations

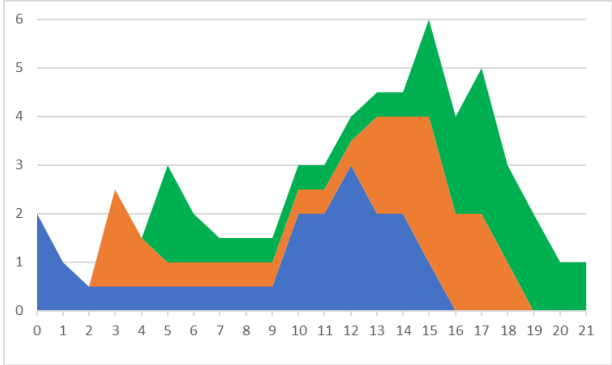


QC load Vs. Process Model



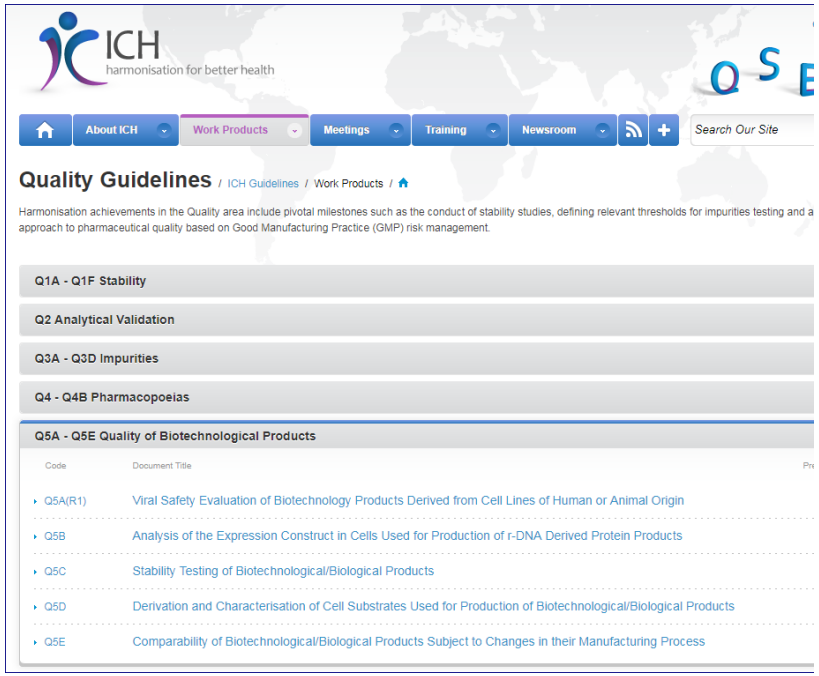
QC provision

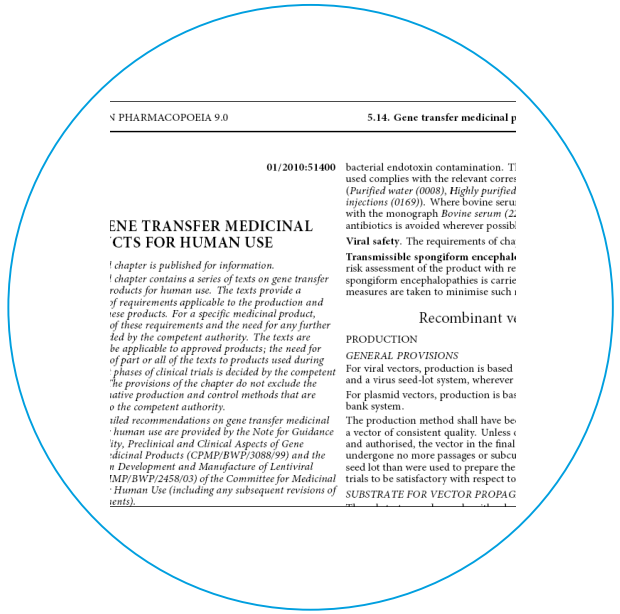
- Approximately half of all cell therapy products under clinical development are autologous therapies
  - *Product release - several complex assays*
  - *manual and time consuming*
  - *Each individual patient treatment is a separate batch that requires product release*
- Significant strain on its way for a QC facility - can limit the number of products that can be released



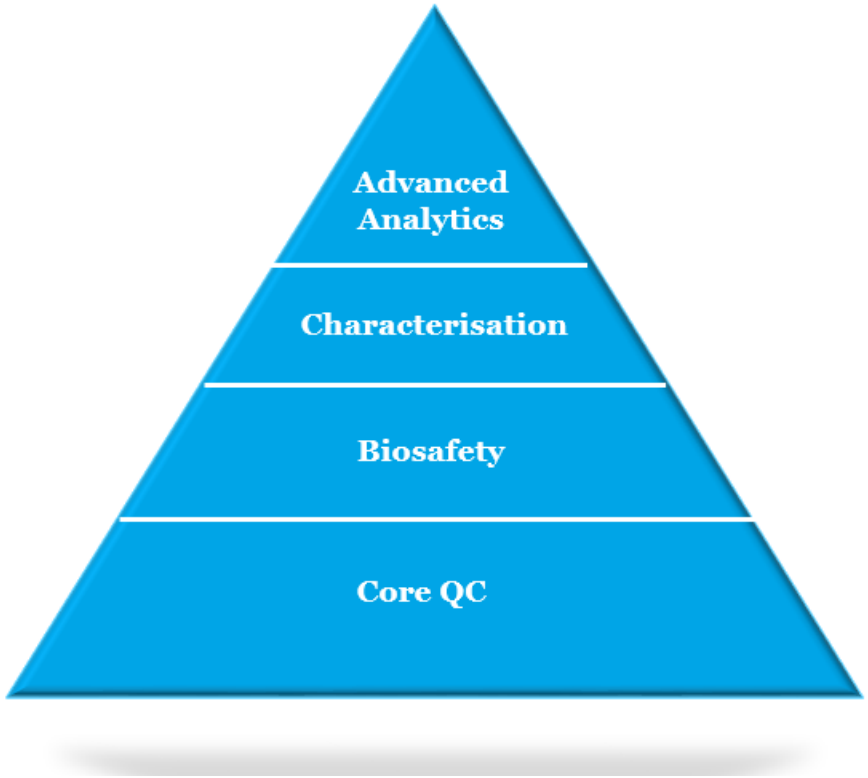
As companies strive to improve manufacturing processes to increase throughput the ability to release products will become an industry bottleneck

QC profiling



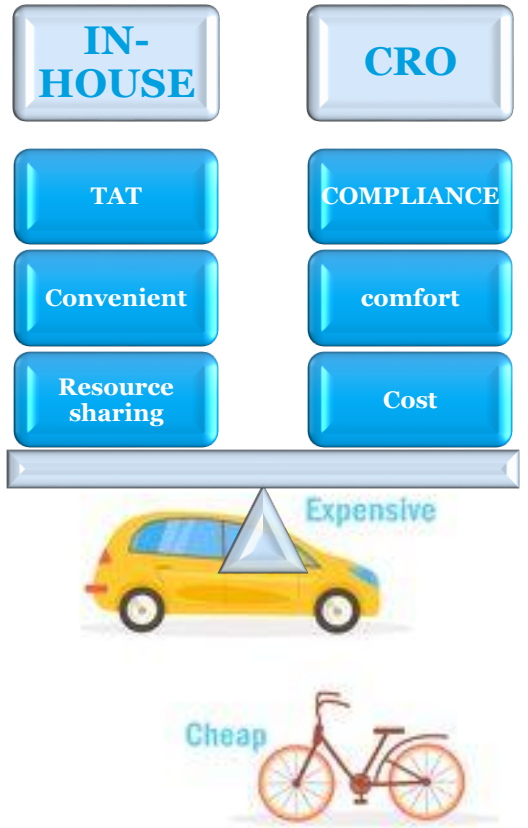


Quality Control – Strategy and Delivery



QC delivery – Building an affordable model

- Date integrity
- Validation cycles
- Staff Training
- Staff Availability
- Assay life cycles
- Modernization
- Capital Investment



References

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   Annex 15: Qualification & Validation
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   Annex 11: Computerised Systems
   Part 4: GMP Requirements for Advanced Therapy Medicinal Products
3. International Conference on Harmonisation (ICH)
   Q2 Validation of Analytical Procedures
   Q9 Quality Risk Management
   Q10 Pharmaceutical Quality Systems guides will be used to support the validation studies.
4. The Genetically Modified Organisms (Contained Use) Regulations 2014
5. European Pharmacopoeia

CATAPULT
Cell and Gene Therapy

12th Floor Tower Wing
Guy's Hospital
Great Maze Pond
London SE1 9RT

info@ct.catapult.org.uk
ct.catapult.org.uk
Twitter: @CGTCatapult

Cell and Gene Therapy Catapult is committed to ensuring high standards of research integrity and research best practice in the activities we carry out. We subscribe to the principles described in the UK concordat to support research integrity.

We work with Innovate UK