Mission Statement

“Transforming the lives of patients with cancer by developing off-the-shelf CAR-NKT cell therapy”

Planning for Success in ATMP Manufacturing

Planning – begin with the end in mind
Understanding – process & impact
People – knowledge exchange & common language
Planning – begin with the end in mind

**World Leading Research & Partnerships**
- Baylor College of Medicine
- University College London

**Process Development**
- Transforming academic cell therapy discoveries into early phase clinical trials processes
- Closed-system processing
- Design of Experiments
- Critical Process Parameter identification
- Analytical Development
- Product Characterization

**Manufacturing Process Design and Scale-up**
- Scale-up of processes for manufacturing & commercialization
- Development of scalable and robust process
- Development of platform technologies for multiple products lines
- Cost of Good Modelling
- In process control strategies

**Manufacturing Operation**
- Execution of manufacturing processes and QC assays
- 90m² cleanroom module flexible to Grade B/C
- 15m² QC Laboratory
- Facilities, utilities, warehousing, QC & regulatory collaboration with CATAPULT
PLANNING FOR SUCCESS IN ATMP MANUFACTURING

Planning – begin with the end in mind

Transforming the lives of patients with [cancer] by developing “profitable” [off-the-shelf CAR-NKT] cell therapy

Commercialisation
Clinical Safety & Efficacy
Manufacturing Operations
Process Development & Manufacturing Design
Patient Treatment
Research

Quality
- Deviations & Risk Assessments
- Validation
- Change controls

Regulatory
- Submissions
- Comparability
- Phase I – II – III strategy

Supply Chain
- Material availability
- Storage requirements
- Licences
Understanding – Process Decisions & Impact

- **Scalability** – “Make sure the product can reach many people not just a few”
  - Know your process parameters that impact product quality
  - Design for manufacture

- **Reproducibility** – “Make the same over and over again”
  - Simplicity
  - Variability

- **COGS** – “Make the product affordable”
  - Understand the impact of early decisions on COGS
  - Choose the right manufacturing partner
People - Knowledge Exchange and Common Language

How the Client describes it
How the Project Manager understands it
How the Structural Engineer designs it
How the Architect designs it
How the Contractor describes it

How the Reports describe it
How the Quantity Surveyor describe it
What the Client is billed
How field workers build it
What the Client really wants
Thank You

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