

Supplementary Data

The necessity of automated manufacture for cell-based immunotherapies: a cost-based analysis

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Supplementary Table 1										
Unit costs of reagents and consumables included in the model.										
Item	Cost per unit		Manual		Bolt-Together		Integrated		High Throughput	
	Cost	Units per batch	Cost	Units per batch	Cost	Units per batch	Cost	Units per batch	Cost	Units per batch
Anti-CD4+ Selection Kit (Antibodies)	£2,500.00	each	1	£2,500	1	£2,500	1	£2,500	1	£2,500
Anti-CD8+ Selection Kit (Antibodies)	£2,500.00	each	1	£2,500	1	£2,500	1	£2,500	1	£2,500
Selection kit buffer	£38.00	L	4	£152	2	£76	2	£76	2	£76
DPBS	£70.00	500mL	4	£280	1	£70	1	£70	1	£70
Human Albumin Solution	£100.00	100 mL	1	£100	1	£100	1	£100	1	£100
Basal Media	£145.00	L	3	£435	1	£145	1	£145	0.2	£29
Human AB Serum	£100.00	100 mL	2	£200	1	£100	1	£100	0.1	£10
IL-2	£100.00	vial	0.1	£10	0.1	£10	0.1	£10	0.1	£10
Vector	£1,000.00	10 ⁸ IU	4	£4,000	1	£1,000	1	£1,000	1	£1,000
Polymeric activation agent	£2,600.00	4 mL	1	£2,600	1	£2,600	1	£2,600	1	£2,600
Cryopreservant	£200.00	100 mL	1	£200	1	£200	1	£200	1	£200
1L cell differentiation bag	£66.00	each	1	£66	-	-	-	-	-	-
Stirred tank bioreactor (250 mL)	£265.00	each	-	-	1	£265	1	£265	1	£265
Automated wash, concentrate kit	£500.00	each	-	-	2	£1,000	-	-	-	-
Magnetic cell selection kit	£1,500.00	each	1	£1,500	1	£1,500	-	-	-	-
Cryopreservation bag	£20.00	each	2	£40	2	£40	2	£40	-	-
Integrated - complete tubing Kit	£2,500.00	each	-	-	-	-	1	£2,500	-	-
Parallel Processing - Isolation Kit	£1,600.00	each	-	-	-	-	-	-	1	£1,600
Parallel Processing - Formulation Kit	£750.00	each	-	-	-	-	-	-	1	£750
Wafers	£2.00	each	150	£300	20	£40	10	£20	10	£20
Auxiliary plastics	N/A	each	-	£300	-	£250	-	£200	-	£200
Total cost per batch for each automation level				£15,183		£12,396		£12,326		£11,930

Quantities employed are shown by automation level.
*Estimated cost

Supplementary Table 2

Unit costs of QC tests and production review activities included in the model.

Item	Cost per unit		Units per batch	Cost
QC				
IPCs*	£100	each	3	£300
Identity (FACS)*	£500	each	1	£500
Potency*	£800	each	1	£800
pH	£400	each	1	£400
VCN/Integration Site Analysis Assays	£3,000	each	1	£3,000
Endotoxin	£500	each	1	£500
Mycoplasma	£1,000	each	1	£1,000
Sterility	£500	each	1	£500
Production Review				
BMR review and sign-off	£2,000	each	1	£2,000
Total cost per batch for each automation level				£9,000

*Tests performed "in-house" and therefore costs reflect materials only (labour is captured within the scheduling module of the model). All other tests are outsourced and therefore include material and labour costs.

Supplementary Table 3					
CAPEX unit cost and numbers of each equipment employed within each manufacturing suite, per automation level.					
Item	Price per unit	Manual	Bolt-Together	Integrated	High Throughput
Isolator	£78,000	2	1	1	1
Incubator, 37 °C	£9,000	6	0	0	0
Refrigerator	£1,000	2	1	1	1
Freezer -20 °C	£1,000	2	1	1	1
Freezer -80 °C	£6,000	2	1	1	1
Trolley	£5,000	0	8	8	8
Centrifuge	£10,000	4	0	0	0
Automated Cell Processing System	£60,000	0	6	0	0
Automated Magnetic Cell Separation	£28,000	2	6	0	0
Bioreactor Controller (250 mL)	£20,000	0	18	0	0
Integrated Manufacture System	£150,000	0	0	24	0
Parallel Processing Manufacture System	* £350,000	0	0	0	10
Formulation System	£50,000	0	3	4	0
Tube Sealer	£8,000	4	2	4	4
Tube Welder	£12,000	4	2	4	4
Plasma Expressor	£1,000	4	0	0	0
Balance	£5,000	4	0	0	0
Dry thawer	£8,000	2	1	1	1
Controlled Rate Freezer	£11,000	1	1	1	2
Flow Cytometer	£86,000	2	2	2	0
Auto. Cell Counter	£33,000	2	1	1	0
Total CapEx cost for each automation level		£691,000	£1,428,000	£4,230,000	£3,736,000
*Estimated Costs.					