



# Equipment Required for Training Cell and Gene Therapy Technicians

# Industry Subject Matter Experts Recommendations for Equipment Required for Training Cell and Gene Therapy Technicians

## Equipment Essential for Both Cell and Gene Therapy Courses

### UPSTREAM

- Cell culture equipment
- Incubators
- Biosafety Cabinets
- Freezer/refrigerators
- Single use bioreactors
- Rocker bioreactors for mammalian cell culture (these are single use)
- Single use technologies including aseptic connector and tube welders
- Suspension cell bioreactors
- Adherent cell bioreactors
- Appropriate control units for fermentors, bioreactors
- Microscope
- Bioprocess analyzer for analyte measurement (such as a Bio HT system)
- Cell counter (such as a Vi-CELL or fluorescent nuclear staining model)

### DOWNSTREAM

- Centrifuge for cell recovery/clarification; disc-stack unit would be preferable
- Depth filtration system for clarification
- Tangential flow microfiltration equipment for clarification
- (Bulk) Final filling equipment (many options here)
- Conductivity meters
- pH meters
- Bench-top centrifuge
- Freezers/refrigerators
- UV/Vis spectrophotometer

### PROCESS SUPPORT

- Mixers (these could be stainless steel or single use, with single use being preferable)
- Buffer storage equipment – the need for this would depend on scale of operations
- Filter integrity tester
- Autoclave
- Glasswasher

### ANALYTICAL

- Gel electrophoresis system
- Plate reader
- qPCR system
- Various smaller miscellaneous items for measurements such as endotoxin, bioburden, ELISAs, protein quantification, host cell protein quantification, host cell DNA quantification, etc.

## Equipment Essential for Cell Therapy Course

### UPSTREAM

- The use of antibodies to identify particular cell populations – Flow Cytometer
- Cell Type Separator technology

### ANALYTICAL

- Flow Cytometry – Analytical
- Fluorescence Activated Cell Sorter

## Equipment Essential for Gene Therapy Course

### UPSTREAM

- Insect cell cultivation for the production of some virus vectors
- Stirred tank bioreactors for mammalian cell culture

### DOWNSTREAM

- Chromatography system for product purification
- Tangential flow ultrafiltration system for product concentration, formulation

## Optional Equipment for Cell and Gene Therapy Courses

### UPSTREAM

- Electroporators
- Fermentors for microbial fermentation

### DOWNSTREAM

- Homogenizer for cell lysis (other lysis options are available)

### FILL-FINISH

- Fill machine – many sizes and varieties
- Isolator
- Freeze dryer
- Differential scanning calorimeter

### PROCESS SUPPORT EQUIPMENT

- Clean-in-place equipment (the need would depend on scale)

### ANALYTICAL

- High performance liquid chromatography system (HPLC)