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# **User Requirement Specification Document**

### Purpose

Cell Therapy Catapult requires an automated process and preparative chromatography system intended for method and process development, as well as scalable development of bioprocessing operations associated with the viral vectors. The system should be high throughput with integrated Design of Experiments (DoE) providing maximum information from a minimum number of experiments. The system must have an automated buffer preparation capability helping to optimise the suitable buffer composition and conditions in minimum timelines. An end fraction collector will be required and will need to be protected from contamination and should be maintained at 2-8°. The system must also be compatible for use on a lab bench and incorporate full software support. The main features required for the system are listed below:

### Product Specification

### Dimensions

* Overall size: width <100cm, depth <80cm, height <75cm

### Configuration

* Must be compatible with UK mains electricity, 230V/50Hz
* All equipment must be supplied complete with UK 3 pin plug(s)
* The quotation must state all utilities required to operate the system

### Operating features

**System must incorporate the following components**:

* Integrated Design of Experiments (DoE) functionality
* Advanced control software
* Must have a capacity of no more than 150mL/ min flow rate and 20M Pa pressure limit
* automated on-line buffer preparation
* Cold, integrated fraction collector
* Capable of operating in a room maintained between 15 and 30OC
* Comprehensive software support for system operation and study analysis

### Operational support

* The Supplier must provide installation and commissioning services by a trained engineer. Installation and commissioning to take place at the Client’s facility at a time to be agreed post award.
* The Supplier must provide a copy of the Installation and Commissioning protocols and associated documentation for review and approval by the Client. Any changes will be incorporated by the Supplier and sent back to the Client for approval prior to execution.
* A suitable installation and operation manual (electronic/paper-free), including routine maintenance activities, a trouble-shooting guide and a list of common faults/alarm messages must be provided.
* Comprehensive training must be included in the quote for at least 2 operators. Training module may be amended to the installation and commissioning activities, or provided as a standalone session. All support literature to be sent to the Client prior to training commencing for review and approval.
* The Supplier must include pricing for at least 1 year’s warranty, commencing from the date of installation and commissioning.

### Timescales

* The unit must be delivered to site and invoiced by 21st March 2016