**User Requirement Specification**

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| **Description of the application** | | | |
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| **Basic performance requirements** | | | |
| Sample | □Vaccines: Inactivated vaccines, live vaccines, recombinant genetic engineering vaccines, etc.  □ Antibody (monoclonal antibodies / bispecific antibodies / ADCs)  □ Hormones: Insulin / Growth hormone  □Cell therapy (CAR-T cell therapy, stem cell therapy) / Gene therapy – viral vectors (mainly including lentivirus [LV], adenovirus [ADV], retrovirus, adeno-associated virus [AAV], etc.) / Gene therapy – non-viral vectors (mainly including naked DNA, liposomes, nanocarriers, etc.)  □ Blood products: Coagulation factors, immunoglobulins, albumin  Interferons  □ Fusion proteins  □ Cytokines  □ Extracellular vesicles (exosomes) | | |
| Filter | □ Hollow Fiber  □ Membrane | Area of Membrane  If use membrane |  |
| Processing | □Clarification  □Ultrafiltration (Concentration)  □Diafiltration  □Harvest | | |
| Working Flow Rate |  | Processing Time |  |
| Working pressure |  | | |
| Initial volume for processing |  | Final volume after processing |  |
| **Scalability requirement** | | | |
| pH detector | □Yes □No | Location of the pH detector (Retentate/Permeate/Other) |  |
| Conductivity detector | □Yes □No | Location of the conductivity detector (Retentate/Permeate/Other) |  |
| Ultrasonic flowmeter | □Yes □No | Location of the flowmeter  (Retentate/Permeate/Other) |  |
| UV detector | □Yes □No | Location of the UV detector  (Retentate/Permeate/Other) |  |
| Cassetter Holder | □Yes □No | The membrane brand and size |  |
| **Document Requirements** | | | |
| IQ / OQ | □Yes □No | FAT | □Yes □No |