**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, albuminInterferons□ Fusion proteins□ Cytokines□ Extracellular vesicles (exosomes) |
| Filter | □ Hollow Fiber□ Membrane | Area of MembraneIf 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 |