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SPECIFICATION

1. Scope

This specification describes the requirements for a liquid chromatography based protein purification system (hereinafter referred to as 'the System') for the purification of proteins. This system will be used specially to purify monoclonal antibodies produced from hybridoma cells. It will also be used to purify recombinant proteins produced by bacterial and eukaryotic cell cultures.

The system is intended for research purposes at Animal Production and Health Laboratory (APHL), International Atomic Energy Agency, Seibersdorf, Austria (hereinafter referred to as 'the end user').

2. Definitions, Acronyms, and Abbreviations

The following definitions, acronyms, and abbreviations shall apply throughout this Specification unless defined otherwise hereinafter:

APHL: Animal Production and Health Laboratory of International Atomic Energy Agency

FPLC: Fast Protein Liquid Chromatography System

3. Requirements

3.1. Functional and Performance Requirements

The System shall meet the following functional and performance requirements:

3.1.1. Shall be a protein purification system at laboratory scale level

3.1.2. Shall be able to perform gel filtration, ion exchange, and affinity chromatography.

3.2. Technical Requirements

The System shall meet the following technical requirements:

3.2.1. An automated system

3.2.2. The system shall fall within the category of FPLC

3.2.3. The system shall be optimized for monoclonal antibody purification

3.2.4. The system shall be able to function with chromatography columns from various different manufactures and affinity columns that have been prepared in house.

3.2.5. The contractor shall supply minimum of twenty five (25) columns for monoclonal antibody purification that can be used with the system

3.2.6. The system shall be pre-programmed and user friendly.

3.2.7. The system shall provide the associated computing hardware with preinstalled software for data visualization

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3.2.8. The power requirements shall meet the standards in Austria

4. Marking

The System shall have all safety markings in English language.

5. Packing

The System shall be packed in accordance with international standards that are applicable for the shipment to the end-user for this kind of equipment.

6. Quality Requirements

6.1. The System shall be manufactured, shipped and installed in accordance with the Contractor's ISO quality assurance system or an equivalent quality assurance system.

6.2. The Contractor shall document the compliance with this quality assurance system.

7. Testing and Acceptance

The System, prior to shipment, shall be tested for conformance of the System with manufacturer's performance specifications and the minimum requirements specified herein.

The System, after installation, shall be tested by the Contractor together with the IAEA to demonstrate that the performance meets the manufacturer's performance specifications and the minimum requirements specified herein as determined by the IAEA.

The results of the testing of the System shall be documented by the Contractor in an acceptance protocol that shall be signed by the IAEA.

8. Installation and Training

The Contractor shall install the System at APHL.

The Contractor shall provide two day training for up to three staff of the End-User in the operation and maintenance of the System at the End-User's location immediately after the installation of the System.

9. Maintenance

The Contractor shall provide full service contract that includes a maintenance services for a period of at least 5 (five) years, which shall include a minimum of 1 (one) visit per year to perform preventive maintenance of the System, with the option of additional visits, if and when required by the IAEA. The Contractor shall

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coordinate with the IAEA on the dates and the period of the preventive maintenance services.

The Contractor during such visits shall bear the cost of parts that expect to be replaced regularly and are prone to wear.

10.Warranty

The Contractor shall provide one (1) year warranty after the system installation and acceptance by the IAEA.

11.Deliverable Data Items

The Contractor shall provide two complete sets of operation and servicing manuals and technical drawings in the English language.
