Terms of Reference /Technical Specification Clauses

I. Procurement Title: Platelet Additive Solution (PAS) for Platelet Concentrate Storage

II. Background/ Purpose

Platelet Additive Solutions (PAS) are used to improve platelet concentrate storage conditions and to significantly reduce adverse transfusion reactions by allowing storage of platelets in a reduced plasma volume. PAS minimizes exposure to plasma proteins, including isoagglutinins, thereby reducing immunologic, allergic, and transfusion-associated circulatory overload reactions.

PAS covered under this TOR is intended for **training and validation purposes**, in collaboration with internationally recognized blood establishments, namely the **Swiss Red Cross** and the **French Blood Establishment (EFS)**, supporting LRC-BTS platelet production implementation and competency development.

III. Objective / Scope of Work

The objective is to procure a **validated Platelet Additive Solution** suitable for routine preparation and storage of platelet concentrates in compliance with EDQM and international regulatory standards.

The scope includes supply, testing, training, documentation, accessories, transport, and implementation support.

IV. Detailed Specifications / Requirements

a. Functional Requirements

- PAS shall enable platelet storage with **minimal residual plasma content** while maintaining platelet viability and function.
- PAS shall be compatible with platelet concentrates prepared by buffy coat pooling.
- PAS must be suitable for **training use by Swiss Red Cross or EFS**, and for validation activities within LRC-BTS.

b. Technical Specifications

- Regulatory compliance: **FDA approved** and **CE marked**.
- Storage performance: Maintains platelet viability and function for **up to 7 days at 20–24 °C**.
- Residual plasma: **< 35% residual plasma content** after PAS addition.
- pH requirement: **pH > 6.4 at end of 7-day storage**, in accordance with **EDQM**.
- Platelet quality parameters at day 7 (as per EDQM):
  - Platelet content per final unit: **> 2×10^{11}**
  - Volume: **> 40 mL per 60×10^9 platelets**
  - Residual leukocytes: **< 1×10^6 per final unit**
  - Acceptable platelet count, mean platelet volume, morphology score, and extent of shape change.

Supplier Sign and Stamp: _____

- Metabolic and activation parameters: Maintenance of acceptable limits for:
  - pO_2, pCO_2
  - Bicarbonate ion
  - Glucose consumption
  - Lactate accumulation
  - ATP levels
  - P-selectin expression
  - LDH release
  - Beta-thromboglobulin

- Microbiological safety: PAS shall **not increase the risk of bacterial contamination** beyond accepted standards.
- Shelf life: Minimum **2 years from date of manufacture**, under manufacturer-specified storage conditions.

c. Composition: PAS shall contain, at minimum:
- Sodium chloride
- Sodium acetate trihydrate
- Sodium citrate dihydrate
- Sodium dihydrogen phosphate
- Disodium hydrogen phosphate
- Potassium chloride
- Magnesium chloride

d. Data Management & Compliance
- All supporting validation, stability, and performance data shall be provided.
- PAS use shall be compatible with LRC-BTS quality system documentation and validation protocols.
- Traceability and batch documentation shall be ensured.

e. Training Requirements
- The supplier shall provide **technical training** to LRC-BTS technologists on:
  - PAS handling and storage
  - PAS addition to platelet concentrates
  - Critical control points
  - Impact on platelet quality and safety
- Training shall continue until users are fully competent.

f. Accessories

Any accessories required for PAS preparation or use shall be identified, recommended, and supplied by the company.

V. Submission Requirements

Suppliers shall submit:

- Technical datasheet and brochure
- Provision of free-of-charge samples for evaluation.
- Declaration of compliance with this TOR
- Warranty and after-sales service details
- Delivery timeline
- Financial quotation (clearly itemized)
- References from similar installations (if available)
- **Completed LRC BTS Supplier Qualification Form:** The official form must be fully completed, signed, and stamped.

VI. Evaluation Criteria & Scoring

Any vendor failing to comply with **any technical, functional, or regulatory requirement** specified in this Terms of Reference shall be **directly excluded from the evaluation process**, and its offer shall **not proceed to financial evaluation**.