



Terms of Reference / Technical Specification Clauses

I. Procurement Title: Pooling set of the octopus type intended for the preparation of platelet concentrates

II. Background/ Purpose

The Lebanese Red Cross Blood Transfusion Services (LRC-BTS) aims to introduce standardized and validated platelet concentrate preparation by buffy coat pooling, in alignment with international best practices. This TOR supports capacity building and technology transfer through collaboration with internationally recognized blood establishments, specifically the Swiss Red Cross and the French Blood Establishment (EFS), which provide technical training and validation support.

III. Objective / Scope of Work

The objective of this procurement is to supply a **validated octopus-type pooling set** for the preparation of leukocyte-depleted pooled platelet concentrates.

The scope includes supply, testing, training, documentation, accessories, transport, installation, and setup of the system in compliance with regulatory and quality requirements applicable to blood establishments.

IV. Detailed Specifications / Requirements

A. Functional Requirements

- The pooling set shall enable pooling of multiple buffy coat units and additive solution into a central pooling bag.
- The system shall allow subsequent transfer to a platelet storage bag equipped with an **integrated leukocyte reduction filter**.
- The system shall support preparation of **leukocyte-depleted platelet concentrates** suitable for storage and clinical use.
- The bag system must be **currently used by the Swiss Red Cross or the French Blood Establishment (EFS)** for platelet preparation and training purposes.

B. Technical Specifications

- Regulatory approval: **FDA approved and CE marked**.
- Manufacturer certification: **ISO accredited and GMP certified**.
- Materials:
 - Flexible, biocompatible, sterilizable materials compatible with blood components.
 - Pyrogen-free.
- Design: Octopus-type configuration with **six tubing ends** radiating from a central pooling hub/bag.
- Each tubing end shall include:
 - o Sterile connection device
 - o Clamp
 - o Access port
- Pooling bag capacity: **up to 600 mL**.
- Platelet storage bag:
 - Manufactured from **PVC-BTHC**.

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- High gas permeability to ensure optimal platelet viability.
- Integrated **sample pouch**.
- Leukoreduction filter:
 - Integrated, gamma-irradiated.
 - Made of **non-woven polyester fiber** with non-ionic coated fiber surface.
 - Residual leukocytes: **$< 0.1 \times 10^6$ per unit**.
 - Platelet recovery: **$\geq 90\%$** .
 - Filtration time: **approximately ≤ 3 minutes**.
- Storage performance: Platelet viability and function maintained for **up to 7 days at 20–24 °C**.
- Shelf life: Minimum **2 years** from date of manufacture.

C. Data Management & Compliance

- All supplied products shall comply with applicable international standards for blood component preparation.
- Batch traceability, labeling, and documentation shall support LRC-BTS quality system and validation requirements.
- Supporting validation and performance studies shall be provided.

D. Maintenance & Support

- The supplier shall ensure technical support related to product use and troubleshooting during implementation and validation phases.
- Any specific handling or storage requirements shall be clearly documented.

E. Training Requirements

- The supplier shall provide **comprehensive technical training** for LRC-BTS technologists.
- Training shall cover:
 - System setup and use
 - Platelet pooling workflow
 - Leukoreduction filtration
 - Critical control points and troubleshooting
- Training shall continue until technologists are fully competent and confident in using the system.

F. Accessories

Any accessories required for optimal use of the pooling set shall be clearly identified, suggested, and supplied by the company.

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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

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**.

Supplier Sign and Stamp: _____