

**Workshop on Plasma Management in Eastern Europe and Nearby Countries**  
**12-14 November 2026, Kalyon Hotel, Istanbul**

| <b>PROVISIONAL WORKSHOP PROGRAM</b>      |                                                                                                                                                                                                                                                     |
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| <b>DAY 1: THURSDAY, 12 NOVEMBER 2026</b> |                                                                                                                                                                                                                                                     |
| <b>08:30 – 09:00</b>                     | <b>Registration</b>                                                                                                                                                                                                                                 |
| <b>09:00 – 10:00</b>                     | <b>I. Introductory session</b>                                                                                                                                                                                                                      |
| 09:00 – 9:10                             | Welcoming statements from ISBT and WHO                                                                                                                                                                                                              |
| 09:10 – 09:25                            | Concept of a regional approach to advance utilization of domestic plasma to provide safe plasma proteins                                                                                                                                            |
| 09:25 – 09:30                            | Goals for the workshop                                                                                                                                                                                                                              |
| 09:30 – 09:40                            | Remarks from the Republic of Türkiye Ministry of Health                                                                                                                                                                                             |
| 09:40 – 10:00                            | Keynote addresses <ul style="list-style-type: none"> <li>• Clinical importance of essential PDMPs</li> <li>• Global Insufficiency of PDMPs</li> </ul>                                                                                               |
| <b>10:00 – 10:30</b>                     | <b>Coffee / Tea Break</b>                                                                                                                                                                                                                           |
| <b>10:30 – 11:00</b>                     | <b>II. International Perspective on Patient Access to PDMPs</b>                                                                                                                                                                                     |
|                                          | <ul style="list-style-type: none"> <li>• Optimal utilization of plasma as part of public health</li> <li>• Concepts of national and regional self-sufficiency in PDMPs</li> <li>• Model of emerging plasma cooperation in Western Europe</li> </ul> |
| <b>11:00 – 12:30</b>                     | <b>III. Review of Survey Responses</b>                                                                                                                                                                                                              |
|                                          | <ul style="list-style-type: none"> <li>• Analysis of “landscaping” survey and pre-workshop questionnaire with use of the PESTELE framework</li> <li>• Open discussion</li> </ul>                                                                    |
| <b>12:30 – 13:30</b>                     | <b>Lunch Break</b>                                                                                                                                                                                                                                  |
| <b>13:30 – 15:30</b>                     | <b>IV. Selected Country Presentations on Progress Towards Plasma Fractionation</b>                                                                                                                                                                  |
| 13:30 – 14:15                            | <ul style="list-style-type: none"> <li>• Self-sufficient and functional settings</li> </ul>                                                                                                                                                         |
| 14:15 – 15:00                            | <ul style="list-style-type: none"> <li>• Partial and developing settings</li> </ul>                                                                                                                                                                 |
| 15:00 – 15:30                            | <ul style="list-style-type: none"> <li>• Open discussion</li> </ul>                                                                                                                                                                                 |

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| <b>15:30 – 16:00</b>                   | <b>Coffee/Tea Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>16:00 – 16:30</b>                   | <b>V. Panel Discussion on Pathways from Plasma Collection to PDMPs</b>                                                                                                                                                                                                                                                                                                                                                                           |
|                                        | <ul style="list-style-type: none"> <li>• Round table discussion</li> </ul>                                                                                                                                                                                                                                                                                                                                                                       |
| <b>16:30 – 17:30</b>                   | <b>VI. Q/A and General Discussion</b>                                                                                                                                                                                                                                                                                                                                                                                                            |
|                                        | <ul style="list-style-type: none"> <li>• Q/A with speakers and panelists</li> <li>• Reflection on the survey findings and use of the PESTELE framework</li> <li>• Open discussion</li> </ul>                                                                                                                                                                                                                                                     |
| <b>DAY 2: FRIDAY, 13 NOVEMBER 2026</b> |                                                                                                                                                                                                                                                                                                                                                                                                                                                  |
| <b>09:00 – 10:30</b>                   | <b>VII. Standards for Plasma Collection and Quality Control</b>                                                                                                                                                                                                                                                                                                                                                                                  |
|                                        | <ul style="list-style-type: none"> <li>• Plasma Collection Methods and Quality Assurance <ul style="list-style-type: none"> <li>– Whole blood separation versus plasmapheresis</li> <li>– Protections for donor health and safety</li> </ul> </li> <li>• Documentation, traceability, and quality control during handling, storage, and transport</li> </ul>                                                                                     |
| <b>10:30 – 11:00</b>                   | <b>Coffee/Tea Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                          |
| <b>11:00 – 12:30</b>                   | <b>VIII. Technologies and Viral Safety Measures for Plasma Fractionation</b>                                                                                                                                                                                                                                                                                                                                                                     |
| 11.00 – 11:45                          | <ul style="list-style-type: none"> <li>• Common fractionation methods (Cohn fractionation, chromatographic methods)</li> </ul>                                                                                                                                                                                                                                                                                                                   |
| 11:45 – 12:30                          | <ul style="list-style-type: none"> <li>• The Safety Tripod for PDMPs <ul style="list-style-type: none"> <li>– Donor Selection <ul style="list-style-type: none"> <li>* Viral testing of donations and plasma hold periods</li> <li>* Viral testing of plasma pools</li> <li>* Robust virus inactivation and removal technologies</li> </ul> </li> <li>– Lessons learned from 10 years of failures and 25 years of success</li> </ul> </li> </ul> |
| <b>12:30 – 13:30</b>                   | <b>Lunch Break</b>                                                                                                                                                                                                                                                                                                                                                                                                                               |

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| <b>13:30 – 15:30</b>                     | <b>IX. GMP Standards and Quality Control</b>                                                                                                                                                                                                                                                                                                             |
| 13:30 – 14:30                            | <ul style="list-style-type: none"> <li>GMP Compliance Essentials for Plasma Fractionation <ul style="list-style-type: none"> <li>Key GMP requirements for production facilities</li> <li>Process validation, environmental monitoring, and documentation</li> </ul> </li> </ul>                                                                          |
| 14:30 – 15:30                            | <ul style="list-style-type: none"> <li>Quality Control Measures and Analytical Methods: Physicochemical characterization, purity, potency, and stability testing</li> </ul>                                                                                                                                                                              |
| <b>15:30 – 16:00</b>                     | <b>Coffee/Tea Break</b>                                                                                                                                                                                                                                                                                                                                  |
| <b>16:00 – 17:00</b>                     | <b>X. Adapting large-scale fractionation processes to stepwise intermediate scale approaches to optimize plasma usage into safe plasma proteins</b>                                                                                                                                                                                                      |
| 16:00 – 16:20                            | <ul style="list-style-type: none"> <li>Options for preparation of fibrinogen and normal immune globulin and strategies for preparation of hyperimmune globulins including donor immunization</li> </ul>                                                                                                                                                  |
| 16:20 – 16:40                            | <ul style="list-style-type: none"> <li>Production of anti-RhD Immune Globulins</li> </ul>                                                                                                                                                                                                                                                                |
| 16:40 – 17:00                            | <ul style="list-style-type: none"> <li>Preparation of hyperimmune globulins for COVID-19</li> </ul>                                                                                                                                                                                                                                                      |
| <b>17:00 – 17:30</b>                     | <b>XI. Q/A and Open Discussion</b>                                                                                                                                                                                                                                                                                                                       |
| <b>DAY 3: SATURDAY, 13 NOVEMBER 2026</b> |                                                                                                                                                                                                                                                                                                                                                          |
| <b>09:00 - 10:30</b>                     | <b>XII. Facility Registration and Regulatory Requirements</b>                                                                                                                                                                                                                                                                                            |
| 09:00 – 09:45                            | <ul style="list-style-type: none"> <li>Facility registration and product market authorization <ul style="list-style-type: none"> <li>International regulatory frameworks and harmonization efforts <ul style="list-style-type: none"> <li>* WHO GBT Plus Blood</li> </ul> </li> </ul> </li> <li>Overview of regulatory requirements for PDMPs</li> </ul> |
| 09:45 – 10:30                            | <ul style="list-style-type: none"> <li>Preparing a Plasma Master File: comprehensive product registration dossiers, including documentation and clinical research considerations</li> </ul>                                                                                                                                                              |
| <b>10:30 – 11:00</b>                     | <b>Coffee/Tea Break</b>                                                                                                                                                                                                                                                                                                                                  |

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| <b>11:00 – 12:30</b> | <b>XIII. SWOT Analysis on Progress Towards Fractionation</b>                                                                                                                                                                                                                                                                                 |
|                      | <ul style="list-style-type: none"> <li>• Facilitated SWOT analysis</li> <li>• Open discussion</li> </ul>                                                                                                                                                                                                                                     |
| <b>12:30 – 13:30</b> | <b>Lunch Break</b>                                                                                                                                                                                                                                                                                                                           |
| <b>13:30 – 15:00</b> | <b>XIV. Key Elements for Development of a Common Roadmap</b>                                                                                                                                                                                                                                                                                 |
| 13:30 – 14:15        | <ul style="list-style-type: none"> <li>• National development <ul style="list-style-type: none"> <li>– MoH engagement</li> <li>– Plasma policy and plan</li> <li>– Regulatory framework</li> <li>– Infrastructure Investment</li> <li>– Sustainable support</li> <li>– Movement towards Contract Plasma Fractionation</li> </ul> </li> </ul> |
| 14:15 – 15:00        | <ul style="list-style-type: none"> <li>• Opportunities for regional cooperation <ul style="list-style-type: none"> <li>– Adoption of common plasma standards</li> <li>– Mutual regulatory recognition</li> <li>– Possibility of plasma pooling</li> </ul> </li> </ul>                                                                        |
| <b>15:00 – 15:30</b> | <b>Coffee/Tea Break</b>                                                                                                                                                                                                                                                                                                                      |
| <b>15:30 – 16:30</b> | <b>XV. Possible Next Steps:</b>                                                                                                                                                                                                                                                                                                              |
|                      | <ul style="list-style-type: none"> <li>• General discussion</li> <li>• Request for volunteers to develop draft document</li> </ul>                                                                                                                                                                                                           |
| <b>16:30 – 17:00</b> | <b>Closure of the meeting and Group Photograph</b>                                                                                                                                                                                                                                                                                           |