

**Programme of the Workshop**  
**Stepwise Access to Safe Plasma Proteins in Resource-Constrained Countries:**  
**Local Production & Pathways to Fractionation**

**Online Workshop organized by the Working Party for Global Blood Safety (GBS) of ISBT**

**Day 1. Tuesday September 21, 2021 (13:00 – 16:00 CEST)**

13:00-13:10 Introduction of the Workshop:  
Introduction and housekeeping issues: **Martin Smid, Chair ISBT WP GBS**  
Welcome from ISBT President (**Erica Wood, Australia, ISBT**)

**Unmet Needs for PDMPs in LMIC**

**Moderators: Jean-Claude Faber (Luxembourg – ISBT WP GBS) and Cesar Garrido (Venezuela - WFH)**

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13:10-13:30 Coagulation factors (FVIII, VWF, FIX, PCC, fibrinogen, others)

(**Saliou Diop, Senegal, for WFH**)

13:30-13:50 Immunoglobulins (polyvalent) (**Johan Prevot, Belgium, for IPOPI**)

13:50-14:05 Discussion/Q&A

**Options for fractionation of domestic plasma**

**Moderators: Thierry Burnouf (ISBT WP GBS - Taiwan) and Junping Yu (WHO)**

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14:05-14:25 Wastage of plasma in LMIC (**Yuyun Maryuningsih, Geneva, for WHO**)

14:25-14:45 Key steps to improve quality of plasma for further processing (**Vee Armstrong, Australia**)

14:45-15:05 Plasma fractionation technologies: benefits and limitations; technical issues (**Jan Bult, The Netherlands, for PPTA**)

15:05-15:25 Oversight of contract plasma fractionation (**Françoise Rossi, France, for IPFA**)

15:25-15:45 Country experiences: Thailand (**Narin Kijkriengkraikul, Thailand, for Thai Red Cross Society**), Nicaragua (**René Berrios, Nicaragua, for MINSA**)

15:45-16:00 Discussion/Q&A

**Day 2. Wednesday September 22, 2021 (13:00 – 16:00 CEST)**

**Options to improve access to safe plasma protein products in LMIC**

Moderators: Jean-Claude Faber (Luxembourg, ISBT WP GBS) and Jay Epstein (USA, ISBT WP GBS)

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13:00-13:20 Recruitment and retention of safe Donors (Giuliano Grazzini, FIODS, Italy)

13:20-13:40 Quarantine of plasma as a means to reduce the risk of transfusion-transmitted infection: logistics and feasibility (Pierre Tiberghien, France, for EFS)

13:40-15:20 Technologies for pathogen reduction (PR) of single-donor or mini-pools of plasma, cryoprecipitate, and immunoglobulins: experience from suppliers and users:

- Strategies to move safe plasma products into low resource areas: overview and experience with Riboflavin/UV (Jeffrey McCullough, Arizona, USA)
- Psoralen/UVA (Hans Vermeij, Brazil, for Cerus)
- Methylene blue/light (Stefan Reichenberg, Germany, for Macopharma)
- Cryoprecipitate from PR-plasma (Salwa Hindawi, Saudi Arabia)
- Mini-pool solvent/detergent of plasma, cryoprecipitate & caprylic acid fractionation of immunoglobulins (VIPS) (Magdy El-Ekiaby, Egypt, for Shabrawishi Hospital)

15:20-15:40 Viral safety of plasma derived components (Johannes Bluemel, Germany, for PEI)

15:40-16:00 Discussion/Q&A

### Day 3. Thursday September 23, 2021 (13:00 – 16:00 CEST)

#### Scale-up for domestic processing of plasma: technology options.

Moderators: Micha Nuebling (Germany, for WHO/PEI) and Thierry Burnouf (Taiwan, ISBT WP GBS)

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13:00-14:40 Technical solutions from the suppliers of single-use equipment for local processing and virus reduction of plasma, cryoprecipitate, cryoprecipitate-poor plasma and immunoglobulins

- Potential contribution of single-use technologies for processing domestic plasma components. (Prity Bengani-lutz, USA, for Sartorius)
- Domestic scalable plasma processing: technological approaches and solutions for LMIC. (Josephine Cheng, Taiwan, for Merck Millipore)
- Potential contribution of nanofiltration to the virus safety of domestic plasma components. (Tomoko Hongo-Hirasaki, Japan, for Asahi Kasei Medical)
- SARS-CoV-2 immunoglobulins in India as an example for domestic production of immunoglobulins: Safety, efficacy and quality attributes. (Suma Ray, India, for Intas Pharmaceuticals)

14.00-14.20 Plasma fractionation of animal-derived immunoglobulins in LMIC: lessons to be learned for human plasma IgG production ( Mariángela Vargas, Costa Rica, for Instituto Clodomiro Picado)

14:20-14:40 Regulatory considerations for authorization of plasma processing devices: example of an EU CE marking (Mohamed Ghonim, Switzerland, for QSE Consulting)

14:40-15:00 Discussion/Q&A

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#### The Way Forward

Moderators: Martin Smid (The Netherlands, ISBT WP GBS) and Jay Epstein (USA, ISBT WP GBS)

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15:00-15:20 Models for technology transfer and technical assistance (Leni von Bonsdorff, Finland, for IPFA)

15:20-16:00 Panel discussion: Lessons learned and next steps

(Yuyun Maryuningsih, WHO; Giuliano Grazzini, FIODS; Cesar Garrido and Salou Diop, WFH; Johan Prevot, IPOPI; Johannes Bluemel, PEI; Leni von Bonsdorff, IPFA; Jan Bult, PPTA)

#### Closure of the Workshop

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