New Work Item Proposal (NWIP) initiated by Alliance of Blood Operators:

Regulatory guidance for validation and approval of standardized apheresis connectors

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EBA European Blood Alliance

On behalf of the Alliance of Blood Operators

Alliance of Blood Operators

Purpose

- Aligned with the IMDRF objective to accelerate international medical device regulatory convergence
- Develop regulatory guidance for validation and approval of standardized aphaeresis connectors
- Make this guidance available to all interested stakeholders:
  - Competent Authorities (CAs) for medical devices (MDs), blood, blood components and cells
  - Manufacturers
  - Users of aphaeresis MDs.

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Rationale

- Death of a donor in France in 2009 due to misconnection (use-error) of anticoagulant instead of saline during aphaeresis. Under-declaration internationally of close serious reactions / events.

- Two draft ISO standards recently adopted:
  - Solution connections assignments (ISO TC 76 / ISO 3826-4).
  - Reservoir connector for citrate anticoagulant solutions (ISO TC 210JWG 4).
- Regulatory guidance on the criteria for validation and approval of aphaeresis connectors would enable solution implementation by 2014 -15

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Scope

- **Issues to be addressed**
  - Determine criteria for validation and approval of ISO standardized connectors included in aphaeresis MDs

- **Opportunities for regulatory convergence**
  - Set a precedent for managed regulatory convergence and contribute to streamlining safety innovations from conception to use. Donors and patients would benefit most from this initiative.
  - Provide a framework for future initiatives on international regulatory convergence for other MDs related to blood donor safety and blood product manufacturing.

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Proposed workplan - input and leadership

- **Proposed work plan**: working group to draft guidance; final guidance approved by June 2014

- **Project leader**: one IMDRF regulator

- **Sources of expertise**:
  - IMDRF Regulators
  - Experts from MDs Industry
  - Users' experts (Blood Establishments)

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With thanks to the following participants in the ABO initiative on Aphaeresis Connector Standardisation

Alliance of Blood Operators:

- Jennifer Williams (Chair, Australia)
- Graham Sher (CBS, Canada)
- Jeroen de Wit, Gilles Folléa (EBA)
- Lynda Hamlyn (NHSBT, UK)
- Chris Hrouda (ARC, USA)
- David Green, Jim MacPherson (ABC, USA)

EBA experts:

- Alex Aquilina (Malta)
- Christian Coffe (France)
- Hans Vrielink (NL)
- Janet Sampson, Catherine Howell, Jane Pearson (UK)

Regulators / CAs:

- Jean-Claude Ghislain, Marie-Lise Miguéres (ANSM, France)
- Isabelle Demade, Peter Bischoff-Everding (SANCO, EU)
- Jay Epstein, Ginette Michaud (FDA, USA)

Suppliers:

- Ruth Foster, Thecla Sterk (Eucomed)
- Mark Holmes and Khatereh Calleja (AdvaMed)
- Roger Wilson, Don Sherratt and Sarah White (Terumo)
- Jean-Marc Payrat and Johan Aerts (Fenwal)
- Isabelle Bartier (Haemonetics)

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Thank you for your attention and your questions / suggestions, to help move forward the NWIP, for the primary benefit of donors and patients.

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Alliance of Blood Operators (ABO)

- **A network of not for profit blood service providers with voluntary non-remunerated blood donor bases formed by:**
  - America's Blood Centers (68 independent blood operators in US & CA)
  - American Red Cross
  - Australian Red Cross Blood Service
  - Canadian Blood Services
  - European Blood Alliance (blood operators from 25 Eur. countries)
  - National Health Service Blood and Transplant (England & North WA)
- **ABO's goals**
  - to develop well-researched positions on prioritized global issues
  - to facilitate horizontal learning across its membership to identify and promote good practice, and improve performance

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