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

Regulatory guidance for validation and approval of standardized apheresis connectors

IMDRF Open Stakeholder meeting, Nice 20 March 2013

Gilles Folléa
Executive Director, European Blood Alliance

On behalf of the 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.
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
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.
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» **Proposed work plan**: working group to draft guidance; final guidance approved by June 2014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)
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)
Thank you for your attention and your questions / suggestions, to help move forward the NWIP, for the primary benefit of donors and patients.
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