Advancing Transfusion and Cellular Therapies Worldwide

Regulatory/Legal Issues and Barriers to Progress Regulatory Harmonisation – Desirable Goals

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The Future for Blood and Plasma Donations

M. Allene Carr-Greer, AABB

Overview

- AABB Plasma Task Force
- Inconsistencies
  - manufacturing processes
  - regulations
- Identify areas for harmonization

Why the Need for a Plasma Task Force?

Plasma Collected by US Blood Centers

- Plasma for Transfusion
  - Frozen and liquid products, manual and automated methods
- Plasma for Further Manufacture – Injectables
  - Recovered Plasma using short supply agreements and contracts, manual collections
  - Source Plasma license, primarily infrequent collection schedule, automated collections
- Generally, Blood Center collections occur at fixed, satellite, and mobile sites

AABB Plasma Task Force - Goals

- Seeking pathway to licensure for Recovered Plasma
  - Currently shipped via short supply agreement
- Any product not needed for transfusion
  - Should be available for further manufacturing at any point in the shelf life of the product
- New Licensable Product
  - Labeling provides the conditions of storage/freezing

AABB Plasma Task Force

- Proposals submitted to the FDA
- Clarifications provided to the FDA
- Position statement provided to the FDA's Blood Products Advisory Committee
  http://www.aabb.org/advocacy/statements/Pages/statement042811.aspx

Donor Questionnaire

- Donor Questionnaire – products for transfusion and further manufacture
  http://www.aabb.org/tm/questionnaires/Pages/dhqaabb.aspx

http://www.pptaglobal.org/safety-quality/donor-history-questionnaire

- Additional screening for cornea and xenotransplants are required by some plasma contracts
  - May 2015 Final Rule will require an assessment of all whole blood donors for xenotransplants
- HIV Risk Reduction draft guidance – male donors who report sex with other males assessed in a 12 month category rather than “since 1977”
  - Argentina, Australia, Brazil, Hungary, Japan, Sweden and United Kingdom

Donor Testing

"Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use", 22 May 2015, Final Rule

- Defines testing algorithms for whole blood and source plasma donors
- Framed in context of relevant transfusion-transmitted infections (RTTIs)
- No real change to current testing requirements
- Makes provision for selective testing by amending 21 CFR 640.5

http://www.gpo.gov/fdsys/pkg/FR-2015-05-22/pdf/2015-12228.pdf

Specific Plasma Components

"Circular of Information for the Use of Human Blood and Blood Components"
http://www.aabb.org/tm/coi/Pages/default.aspx

PLASMA FOR TRANSFUSION

- FFP, PF24, PF24RT24
  - FFP → Cryo and Plasma Cryo Reduced
  - FFP and PF24 → Thawed Plasma (4 additional days)
  - Plasma Cryo Reduced → Thawed Plasma Cryo Reduced (4 additional days)
- Psoralen treated whole blood-derived plasma and apheresis plasma
- Liquid Plasma

Specific Plasma Components

PLASMA FOR FURTHER MANUFACTURE

- Current options that are commonly used by US blood centers
  - Recovered Plasma, manual collections shipped under short supply agreements
  - Source Plasma, automated, Infrequent collections shipped under license

Plasma for Further Manufacture

AABB Plasma Task Force - discussions with FDA since early 2000s

- Simplified algorithm
- Any plasma product not needed for transfusion could be labeled for use in further manufacturing
- Licensed product; SSAs would no longer be needed.

AABB and ABC continue to engage with the agency on this issue.

Plasma for Further Manufacture

FDA feedback – April 2011 BPAC, CY2015 Guidance Agenda, May 2015 Final Rule

- Concurrent Plasma (CCP) and Component Plasma (CMP) described at April 2011 BPAC
- Potential use for labeled product "Concurrent Plasma" – FDA working on a guidance.
  - "Component Plasma" – no indication from FDA that they are working on this pathway…
- Final Rule describes infrequent plasma collections

Harmonization (Harmonisation) Requested

- In the US we have a history of labeling plasma for transfusion
  - to indicate storage/freezing conditions
  - that enables the transfusion service/clinician to select the component
  - needed for particular protocols/patient populations.

- The AABB Plasma Task Force asked FDA to provide a similar pathway so that plasma for further manufacture could be labeled
  - to indicate storage/freezing conditions
  - that enables plasma fractionators to select the component
  - needed for particular protocols/manufacturing needs.

Harmonization (Harmonisation) Requested

- Canada, Europe – Source Plasma is placed in the freezer before 24 hours
- US – the requirement for placing in the freezer is described as “immediately”
- US Blood Centers collect at satellite and mobile sites – physically removed from freezers
- US Blood Centers have started a conversation with the FDA to see if a pathway is available to harmonize with European requirements.

Thank you!

acarrgreer@aabb.org