GMP IN BLOOD ESTABLISHMENTS: A BASIC ELEMENT FOR PLASMA QUALITY

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PLASMA QUALITY: WHAT IS THE AIM (I)?

- Improving the quality and safety of
  - plasma for fractionation as starting material
  - blood components for transfusion

- Optimising the use of a blood donation
  - Less discarded units
  - Increase availability of plasma
  - Contract fractionation programs
PLASMA QUALITY: WHAT IS THE AIM (II)?

- Strengthen the NRA’s technical expertise in regulating blood products
- Establishment of regional network between professionals (blood establishments, fractionator)
- Harmonisation in the regulation of blood and blood products
- Facilitate international cooperation between NRA’s
NEEDS

- Agreed quality and safety requirements, specifications and standards for blood/plasma collection, preparation, testing and distribution activities

- A harmonised and systematic approach to ensure compliance at all steps involved

- Implementation of standards in the blood establishments

- Enforcement by competent regulatory authority

- Building up the necessary technical expertise in NRA
EXPERIENCE FROM PREVIOUS ACTIVITIES

WHO Workshops on GMP for Blood Establishments (e.g. WHO/AMRO PAHO, Buenos Aires (ARG) in 2004)

- Existing GMP standards used as working documents for training
- **GMP as a common language** between blood establishments and fractionator
- In blood establishments, the understanding for need of implementing quality assurance exists
- Development of **GMP standards** for blood establishments needed
- **Harmonisation** and collaboration on a regional level (at least) is important
IMPLEMENTATION OF GMP IN BLOOD ESTABLISHMENTS IS IMPORTANT FOR PLASMA QUALITY
IMPACT OF GMP IN BLOOD ESTABLISHMENTS (I)

✓ In blood establishments, GMP introduces the application of quality assurance principles in all steps involved in the collection, preparation, testing and distribution activities

✓ Benefits for quality and safety of blood components for transfusion and of plasma for fractionation

Good Manufacturing Practice (GMP):
GMP is that part of Quality Assurance which ensures that products are consistently produced and controlled to the quality standards appropriate to their intended use and as required by the marketing authorization or product specification. GMP is concerned with both production and quality control. (PIC/S GMP Guide PE 009-7, Ch. 1.3)
IMPACT OF GMP IN BLOOD ESTABLISHMENTS (II)

- GMP supports systematic application of donor selection criteria for each donation
- GMP ensures appropriate testing methods and testing kits, and use of suitable reagents
- GMP requires the use of suitable facilities, equipment and materials
- GMP reduces errors and technical problems in collection, preparation, testing, and distribution
GMP ensures the existence of validated and robust processes, e.g.
- Disinfection of puncture site before collection
- Separation process
- Testing methods
- Freezing of plasma
- Transport (-> cold chain)

GMP guarantees the release of products which comply with the safety and quality requirements
IMPACT OF GMP IN BLOOD ESTABLISHMENTS (IV)

✓ GMP ensures adequate documentation and full traceability for each collection and product, from donor to recipient

✓ GMP strengthens the competence of the personnel

✓ GMP enables continuous improvement in collection, preparation and testing of starting material
GMP IN BLOOD ESTABLISHMENTS: IMPACT ON AVAILABILITY

✓ Improvement of quality of plasma

✓ Plasma is a precious starting material and could be used for fractionation if quality is assured.

✓ More plasma would be available and less plasma would be discarded, finally resulting also in an increase of the availability of blood products.
SOME ECONOMIC ASPECTS

✓ Achieving plasma of high quality and safety is very demanding
  ✓ commitment of all involved parties
  ✓ human resources
  ✓ financial expenditure
  -> approach with maximal benefit

✓ Less errors and technical problems, better quality of plasma
  -> less waste of products
  -> better use of precious donation

✓ Facilitation of Plasma Contract Fractionation Programs
  -> availability of blood products
GMP IN BLOOD ESTABLISHMENTS: IMPACT ON COOPERATION

- Building up a common language and confidence for regional or international cooperation between NRA in the regulation of blood and blood products

- Building up a common understanding between NRA, blood establishments and fractionation
  - Establishment of regional professional network
What GMP standards?

Existing specific GMP Guide for Blood Establishments, e.g. PIC/S

WHO Recommendations for the production, control and regulation of plasma for fractionation


Draft WHO Guideline for GMP in Blood Establishment (scheduled for consultation in 2009)
Responding to an ICDRA recommendation:
   -> development of a WHO GMP Guideline for Blood Establishments

Jan-April 08: Draft document prepared by drafting group
   (C. Schärer [Switzerland], L. van Loosbroek [The Netherlands],
   W. Atkins [US])

Revision and finalisation of draft
   - after discussions with some experts
   - use as working document in training workshop Nov 08

Open consultation of document in 2009

Presentation for adoption at the ECBS in October 2009
CONCLUSIONS

✓ GMP in blood establishments will be a beneficial tool to help countries in improving plasma quality.
✓ The use of harmonised GMP standards will facilitate regional collaboration between NRA’s, and will serve as a common language between the plasma supplier and the fractionator.
✓ The WHO Guideline will help countries in the implementation of GMP in blood establishments.
✓ GMP in blood establishments will increase availability of plasma and is one of the key issues for a successful plasma contract fractionation program.