E2. EUROPEAN GUIDELINES ON GOOD PRACTICE TO SUPPORT IMPLEMENTATION OF QUALITY SYSTEMS IN BLOOD ESTABLISHMENTS

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Introduction: Directive 2005/62/EC promotes Community standards and specifications for the elaboration and implementation of a quality system for blood establishments and hospital blood banks.

Given the diversity in the organization of various transfusion systems in the EU, the movement of citizens within it, as well as import / export of blood, art. 2.2 of the Directive foresees a best practice guide for the interpretation of these standards and specifications, so as to achieve an equivalent level of quality and safety in Member States and non-EU countries involved in export activities to the EU.

Objective: The presentation introduces the first version of the Guide on good practice.

Methods: In 2010 a EC-CoE joint project has been launched, whose goal was to develop European Guidelines on good practice for the implementation of quality management systems in BEs. A working group was appointed consisting of professionals with expertise in transfusion specific activity, quality systems and GMP-EU.The activities have started in 2011.

The work plan included individual work at home activities coordinated by the project manager, as well as six workshops. According to the objectives approved, the Guide integrates into a consolidated text the Annex of Directive 2005/62/EC, the principles of GMP-EU (according to art. 47 of Directive 2001/83/EC) and Chapter 1 Standards of the Guide for the preparation, use and quality assurance of blood components (16th ed).

Results: The first version of Guidelines on good practice was published in 2013 in the 17th edition of the Guide for the preparation, use and quality assurance of blood components, in Chapter 1 Standards. An updated version will be published after the 2013 public consultation in the 18 th edition of the CoE Guide.

Conclusions: The occurrence of the first version of the Guidelines on good practice to support implementation of quality system in BEs and HBBs provides practitioners and responsible persons an opportunity to review and update the quality system as a measure either to ensure compliance with legal requirements, and to improve the quality and safety in transfusion activity.