SUMMARY OF RESPONSES TO THE PUBLIC CONSULTATION ON COMMISSION IMPLEMENTING ACT ON PRINCIPLES AND GUIDELINES ON GOOD MANUFACTURING PRACTICE FOR MEDICINAL PRODUCTS FOR HUMAN USE, PURSUANT TO THE FIRST PARAGRAPH OF ARTICLE 47 OF DIRECTIVE 2001/83/EC

1. GENERAL REMARKS

Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use[1] provides in the 1st paragraph of Article 47 an obligation for the Commission to adopt principles and guidelines of good manufacturing practice for medicinal products for human use in the form of a Directive.

This delegation is the legal basis for Commission Directive 2003/94/EC of 8 October 2003 laying down the principles and guidelines of good manufacturing practice in respect of medicinal products for human use and investigational medicinal products for human use[2].

However, Regulation (EU) No 536/2014 of the European Parliament and of the Council on clinical trials on medicinal products for human use, repealing Directive 2001/20/EC[3], requires that the Commission adopts delegated acts to specify the principles and guidelines of good manufacturing practice and the detailed arrangements for inspection for ensuring the quality of investigational medicinal products.

It is therefore necessary that Directive 2003/94/EC is repealed and replaced by a Delegated Act on principles and guidelines of good manufacturing practice for investigational medicinal products with its legal basis as Article 63(1) of Regulation (EU) No 536/2014 and a new Implementing Directive on principles and guidelines of good manufacturing practice for medicinal products for human use with the 1st paragraph of Article 47 of Directive 2001/83/EC as its legal basis.

This document presents a factual summary of the responses to the public consultation. It does not present the views of the European Commission.

2. CONTRIBUTORS TO THE PUBLIC CONSULTATION

Four contributions were received. The contributors can be classified into the following 2 categories:

Sector	Contributors included
Public authorities	2
Industry stakeholders	2

[1] OJ L 311, 28.11.2001, p. 67.
[2] OJ L 262, 14.10.2003, p. 22.
[3] OJ L 158, 27.5.2014, p. 1.

3. OUTCOME OF THE PUBLIC CONSULTATION

The main comments and remarks were made on the following topics:

- Request for clear definition of "manufacturing".
- Concerns regarding potential duplication of already existing GMP requirements.
- Missing explanation on types of variations should be included.
- Add a definition for the "pharmaceutical quality system" and replace the term "quality assurance system" the term "pharmaceutical quality system";
- Long-term retention of documentation is currently not addressed;
- Deletion of the specific mention of a need for validation in case of electronic data storage;
- Alignment of terminology and content with EudraLex Volume 4;
- Introduction of full CAPA system for self-inspections;
- Relevance of provision on advanced therapy medicinal products questioned;
- Introduction of the concept of "quality risk management" instead of "risk-based approach" for advanced therapy medicinal products.