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
the Community code relating to medicinal products for human use 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.

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, 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It is therefore necessary that Directive 2003/94/EC is repealed and replaced by a Delegated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:

<table>
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<tr>
<th>Sector</th>
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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.