Public Consultation on Detailed Commission guidelines on GMP for IMPs

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1. INTRODUCTION

Per 28 August 2015, EMA on its public intranet site has asked stakeholders for comments on Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

The period of consultation was stated to be from 28 August 2015 to 24 November 2015.

With this document, Baxalta provides a consolidated response that has been checked across all relevant departments involved in manufacturing, controlling, distribution and application of investigational medicinal products.

2. BAXALTA RESPONSES AND COMMENTS

2.1 General Comment

Baxalta would like to request that the term “third country” used throughout the document “Detailed Commission guidelines on good manufacturing practice for investigational medicinal products for human use, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014” be specified in section 2.13, Glossary of terms. We noticed that for readers less familiar with language used by EMA, the term “third country” is prone to misunderstandings.

2.1.1 Line 179 in GL on GMP for IMP

Baxalta kindly proposes to change the wording regarding requirements for process validation in order to provide utmost clarity for IMP manufacturing throughout product development. See text below with track changes:

Premises and equipment are expected to be ~~validated~~ qualified in accordance with EudraLex, Volume 4, Annex 15 in so far as appropriate, taking into account the stage of product development.

The full text proposed without track changes will read:

Premises and equipment are expected to be qualified in accordance with EudraLex, Volume 4, Annex 15 in so far as appropriate, taking into account the stage of product development.