AFI, the Italian Association of Industrial Pharmacists, is a scientific society representing the scientists and the professional people working in the pharmaceutical fields in Italy. AFI welcomes the opportunity to submit the following contributions in response to the public consultation on “Commission Delegated Act on principles and guidelines on good manufacturing practice for investigational medicinal products and on inspection procedures, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014.

The here under reported table is the output of some meetings held by the working group on “Manufacture of Investigational Medicinal Products” on the proposed guideline.

Milan, 24 November 2015

Alessandro Rigamonti

Prof. Alessandro Rigamonti
President of AFI

Submission of comments on: Detailed Commission guidelines on good manufacturing practice for investigational medicinal products, pursuant to the second subparagraph of Article 63(1) of Regulation (EU) No 536/2014

Comments from:

Name of organisation or individual
AFI – Associazione dei Farmacisti Industriali (Italian Association of the Industrial Pharmacists) Milan (Italy)

1. General comments

Stakeholder number (To be completed by the Agency)	General comment (if any)	Outcome (if applicable)
	The Annex 13 is currently a useful guidance for aspects that are at the interface between GMP and GCP. Some of these (e.g., regulatory release, transfer of the IMPs, relabeling) are very peculiar and critical from a compliance point of view. The proposed guideline is focused only on GMP side, we would like to underline that this gap should be covered to achieve a full compliance during the management of a clinical trial.	
	We would like to highlight that the proposed document should contain provisions regarding the relationship between the Sponsor and the Manufacturer/Imported and the Qualified Person accounted for the final certification of the batch	
	The chapter 2.3 on ”Pharmaceutical Quality System” deals with the management of specification, we wonder if this approach is not enough mandatory to cover also the chapter 2.6.3 on “Product Specification File”	

	The proposed guideline does not explain some important words used in the clinical trial management. For instance, glossary lacks to define the terms like sponsor, blinding.	
	The Regulation No 536/2014 reports both the terms expiry date and re-test date (as applicable) in relation to the period of use, while the proposed guideline specifies only the term “expiry date”. We would like to suggest to address this discrepancy.	
	The template for “Release Certification”, attached to the current Annex 13, is not present in the proposed guideline. A harmonized model for the certification of the IMP batch is very valuable and we would like to suggest reintroducing it in the new guideline.	