<7th December 2015>

Submission of comments on "Volume 4 EU Guidelines for GMP for Medicinal Products for Human and Veterinary Use – Annex 17: Real time release testing"

Comments from:

Name of organisation or individual
IFAH-Europe

1. General comments

Stakeholder number	General comment (if any)	Outcome (if applicable)
	IFAH-Europe welcomes the opportunity to comment on this document. After finalization of the GMP Annex 17, it is felt that a review of the current guideline EMEA/CVMP/QWP/339588/2005 "GUIDELINE ON PARAMETRIC RELEASE" will be necessary to include the regulatory requirements for introduction of Real Time Release Testing (RTRT). The requirements for variations should be taken in consideration as well.	

2. Specific comments on text

Line number(s) of the relevant text	Stakeholder number	Comment and rationale; proposed changes	Outcome
		Comment: N.A **Proposed change:** N.A	

Please add more rows if needed.