LFB Biotechnologies Comments regarding

EC Public Consultation on the Revision of EU Commission guideline on Good Manufacturing Practices for Medicinal Products

Annex 16: Certification by a Qualified Person and Batch Release

LFB Biotechnologies welcomes the opportunity given by the European Commission to comment the draft GMP Annex 16: Certification by a Qualified Person and Batch Release through a public consultation.

Sections	General Comments
Legal basis for publishing the detailed guidelines:	We would suggest to insert the directive 2001/20/EU related to clinical trials among the legal basis.
1. Scope 1.1	*"… The principles of this guidance also apply to investigational medicinal products, subject to any difference in the legal provisions and more specific guidance in Annex 13 to the Guide."* **LFB Biotechnologies Comments:** To make consistency with IMP application in the revised annex 13, each time it is referred to: - marketing authorisation could you add "or clinical trial authorisation" - marketing authorisation holder could you add "or sponsor of clinical trials", when appropriate.