LFB Biotechnologies Comments regarding

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

Part I

Chapter 6: Quality Control

LFB Biotechnologies welcomes the opportunity given by the European Commission to comment the draft GMP Part I Chapter 6: Quality Control through a public consultation.

We would like to ask for clarifications. They are submitted within the following table:

Sections	Proposed text	Comments
Sampling 6.12	Samples should be representative of the batch of materials or products from which they are taken. Other samples may also be taken to monitor the most stressed part of a process (e.g. beginning or end of a process). The sampling plan used should be appropriately justified.	We would like some clarifications. What is expected as justification?
Testing 6.20	Reference standards should be certified, qualified and verified as suitable for its intended use.	We would like some clarifications. What is expected as certification and qualification?