<Date of submission>

# Submission of comments on '<EU GMP Part I Chapter 3

## Comments from:

| Name of organisation or individual |
| --- |
| LEEM |

*Please note that these comments and the identity of the sender will be published unless a specific justified objection is received.*

*When completed, this form should be sent to the European Medicines Agency electronically, in Word format (not PDF).*

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## 1. General comments

| Stakeholder number<br>*(To be completed by the Agency)* | General comment (if any) | Outcome (if applicable)<br>*(To be completed by the Agency)* |
|---|---|---|
| | We appreciate the opportunity to comment upon this draft guidance.<br>The text itself appears satisfactory and is at an appropriate level of detail for the chapter update.<br>The question remains about the use of the toxicological tool and the risk assessment, and whether the intention is that industries perform this for new products introduced into their facilities or whether there will be an expectation of a retrospective review of all old products within a facility.<br>The latter option may be very difficult to practically implement in a short time period. | |

## 2. Specific comments on text

| Line number(s) of the relevant text<br>*(e.g. Lines 20-23)* | Stakeholder number<br>*(To be completed by the Agency)* | Comment and rationale; proposed changes<br>*(If changes to the wording are suggested, they should be highlighted using 'track changes')* | Outcome<br>*(To be completed by the Agency)* |
|---|---|---|---|
| **Chapter 3**<br>**Premises and Equipment**<br>**Production Area**<br>**§ 3.6** | | Comment :<br>Should a classification of already known risk products be established, with the recommended types of premises (dedicate/separate) to use? or, should we have to test each product whatever his category.<br>Should a rule be established to define the type of premises to use (dedicated/separate)?<br><br>Proposed change (if any): | |
| **§ 3.39** | | Comment:<br>Should we have to apply a risk analysis about compatibility between materials of manufacturing/ packaging equipments and active substances or excipients?<br><br>Proposed change (if any): | |
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