**NAME: ISPE**

1. **Comments on the guideline text Variations guidelines: Proposed amendments to the European Commission guidelines on variations categories and procedures | European Medicines Agency (europa.eu)**

 ***B.I.e) Additional regulatory tools***

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|  | Please insert reference to relevantscope or section *(e.g. B.I.a.1.a,**Conditions, Documentation)* | Stakeholder name*(to be repeated in all rows)* | Comment and rationale | Proposed guidance text |
| 1 | B.I.e.6 | ISPE  | It is very encouraging to see mention made of the “product lifecycle management document”, one of the pivotal tools in the ICH Q12 guideline, in the updated regulation.  However, the purpose of this addition requires clarification since, for example, no explicit mention is made of established conditions (ECs) or of reporting categories for making changes to ECs as described in ICH Q12. ISPE recommends that the purpose of this additional document, as given in ICH Q12, and how this additional document will be implemented are described.  | This recommendation could be achieved by the inclusion of an additional sub-point in Section 2 of this Guideline or by the inclusion of some appropriate text in the Annex. |

***B.II.g) Additional regulatory tools***

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