ISPE Regulatory Comment Form

Proposed Regulation/Guidance Document: European Commission Eudralex The Rules Governing Medicinal Products in the European Union, Volume 4, EU Guidelines for Good Manufacturing Practice for Medicinal Products for Human and Veterinary Use, Part 1, Chapter 3: Premises and Equipment

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General Comments
The cover sheet to this GMP change details an implementation date of 6 months. The expectation on implementation of the new requirements for existing products/processes/facilities is no, however, clear. Depending on several factors as to when products were developed, available toxicological data, existing validation data and design of equipment and facilities, the consequences of this GMP change could be minor or quite extensive. If the new requirements are expected to be implemented for all existing products and facilities there would be a need for a longer implementation timeframe (after the new regulations have come into operation) in order to allow for new risk assessments to be performed and, if needed, new validations and changes to equipment and facilities.
The timetable for the proposed date for the new draft Annex 15 is December 2013, i.e. potentially after or at a similar date as these changes in Chapters 3 & 5. Given that the main chapters of EU GMP normally apply to manufacture of finished products but that the scope of this proposed change (and that to chapter 5) appear to include both IMPs and active substances clarification is needed now on how the requirements in the new guideline on health based exposure limits should be used in relation to requirements on cleaning validation according to Annex 15 of the EU GMP.
The proposed GMP changes make it clear that introducing new products into a facility will require a toxicological risk assessment. There is no mention either in the cover note or the text if this change is expected to give rise to any associated license changes or not, e.g. will future authorisations for production plants be given per active material handled, would a facility change require documentation submission such as a toxicological study etc.