Practical PAC Examples

Published

1. Administrative changes to excipient suppliers (e.g. name change, address change) –published

In Commenting Phase

1. DS/ DP shelf life extension
2. Analytical instrument upgrade
3. Replace ID testing of liquid DS with ID visual verification
4. Change in size of thermal shipping solution used for transport of product
5. Addition of a testing lab at an existing testing site

Each example follows the published 4-step risk-based assessment; applying ICH Q9 & ICH Q10, Annex 1

Under development

1. DP batch/scale change with no change to equipment MOC or technology
2. Automated colony counter for water, EM testing, product testing

Planned

1. Reference standard changes
2. Compendial excipient change
3. PACs that tighten controls compared to registered conditions
    i. Tightening of acceptance criteria on tests performed on the product or raw materials or excipients
    ii. Addition of a test performed on the product or raw materials or excipients
    iii. Addition or tightening of a validity criterion for an analytical method
    iv. Addition of a Critical Process Parameter in the batch record of the product
4. Manufacturing equipment/line change
5. Replacement of API suppliers

Intended to
a) stimulate dialog with regulatory agencies to consider downgrading PAC reporting category for specified changes;
b) encourage application of ICH Q9 by regulatory agencies