Practical PAC Examples

Published

1. Administrative changes to excipient suppliers (e.g. name change, address change)
2. DS/ DP shelf life extension
3. Analytical instrument upgrade

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


PDA Journal of Pharmaceutical Science and Technology

Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches Industry One-Voice-of-Quality (1VQ) Solutions

Emma Ramnarine, Anders Vinther, Kimberly Bruhin, et al.

PDA Journal of Pharmaceutical Science and Technology 2020.

Authors: Richard Rolke and Emma Ramnarine

Published on IVT Network (www.ivtnetwork.com)

IVT Volume 26, Issue 6 – December 2020

IVT NETWORK INSTITUTE OF VALIDATION TECHNOLOGY

Industry One-Voice-of-Quality (1VQ) Solutions: Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches

PEER REVIEWED

CHANGES TO ANALYTICAL EQUIPMENT/INSTRUMENTATION THAT ARE DEEMED EQUIVALENT

ABSTRACT

Authors: Nasir Egal and Kevin Lombardi

Published on IVT Network (www.ivtnetwork.com)

IVT Volume 26, Issue 6 – December 2020

IVT NETWORK INSTITUTE OF VALIDATION TECHNOLOGY

Industry One-Voice-of-Quality (1VQ) Solutions: Effective Management of Post-Approval Changes in the Pharmaceutical Quality System (PQS) - Through Enhanced Science and Risk-Based Approaches

PEER REVIEWED

SHELF-LIFE EXTENSIONS FOR PHARMACEUTICAL PRODUCTS

ABSTRACT

Post-approval changes (PACs) are inevitable and necessary throughout the lifecycle of pharmaceutical products - to implement new knowledge, maintain a state of control, and drive continual improvement.

In Commenting Phase

1. Replace ID testing of liquid DS with ID visual verification
2. Change in size of thermal shipping solution used for transport of product
3. Addition of a testing lab at an existing testing site

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
3. PACs that bring additional restrictions on product compared to registered conditions

Planned

1. Reference standard changes
2. Compendial excipient change
3. Manufacturing equipment/line change
4. 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