Draft ICH Q12 Guidance on Lifecycle Management open for public consultation

The International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) has opened their Q12 draft guidance for public consultation (step 2b of the ICH process). In Europe the deadline for comments is December the 18th 2018.

This new guidance draft aims to "provide guidance on a framework to facilitate the management of post-approval Chemistry, Manufacturing and Controls (CMC) changes in a more predictable and efficient manner across the product lifecycle". It adds to the existing quality guidances on product and process understanding (ICH Q8, Q11), the application of risk management principles (ICH Q9), and an effective Pharmaceutical Quality System PQS (ICH Q10).

The draft demonstrates how increased product and process knowledge can reduce the number of regulatory submissions. It is intended for new and marketed pharmaceutical products and supports making continuing improvements under the Pharmaceutical Quality System while reducing the need for extensive regulatory oversight prior to implementation.

The draft covers a wide range of topics like product lifecycle management (PLM), a categorization of post-approval CMC changes, established conditions, post-approval change-management protocols and more. Find all related documents and information here:

Q12 Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management Core Guideline + Annex
http://www.ich.org/products/guidelines/quality/article/quality-guidelines.html#12