Implementation of ICH Q12: Successes and Challenges

WCBP 2023 Workshop

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CASSS
SHARING SCIENCE SOLUTIONS

Leveraging an effective PQS for Q12 submissions

- What do you consider the main indicators for PQS to be suitable for implementing Q12 approaches? How can Q10 concepts be leveraged for Q12 submissions?
- What are the challenges in leveraging Q12 for LCM when working with a CMO that operates under their own PQS?
- How should PQS effectiveness be demonstrated for consideration of ECs and reporting categories? What level of detail is appropriate in submissions?

Defining and justifying established conditions

- Is it possible to define clear criteria for established conditions? How are current risk assessment tools that define critical and non-critical parameters leveraged for EC classification?
- What are justifications for including/excluding parameters as established conditions?
- How are prior knowledge and platform approaches leveraged in justification of ECs?
- When should ECs be re-evaluated and how is re-evaluation managed?
- What are the benefits/challenges of ECs for raw materials?
- What are considerations for analytical method ECs?
- How are changes to approved ECs managed within submission?

Successes and challenges in implementation of ICH Q12 concepts within industry and FDA

- Did you try to implement Q12 approaches? What were the biggest challenges?
- Do regulators and industry make use of the harmonized Q12 training published on the ICH website?
- How are you managing Established Conditions in multiple markets?

Establishing a PLCM document

- Can you submit ECs without a PLCM?
- What should be included in a PLCM document? What level of detail is appropriate?

Use of PACMPs

- What the most appropriate use cases for PACMP?
- If you used Comparability Protocols before, did PACMP, as described in Q12 changed how you use it?