Health Canada Santé Canada

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Health Canada's Participation at ICH[1] & Considering ICH-Q12 Implementation[2]

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CASSS WCBP2019
Opening Plenary Session

YOUR HEALTH AND SAFETY... OUR PRIORITY.

History of Health Canada's Participation

- Observer of ICH since its inception in 1990
- Active participation throughout the years even as an observer, and have made the commitment to implement all ICH guidelines
- Became a Standing Member in October, 2015
- Recognized as a Standing Member in the Articles of Association
- Have similar rights as the Founding Members
- As a Standing Member, automatically participate on the ICH Management Committee
- Have the obligation to implement all ICH guidelines

Current Participation at ICH

- Representation on the ICH Assembly and Management Committee
- Have experts participating on about 80% of the working groups
- ICH has grown significantly, cannot participate on every working group
- Collaborating on ICH guidelines with ACSS partners to share information

Specific Guidelines Under Development

- Q12 – Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management (participating)
- Q13 – Continuous Manufacturing of Drugs Substances and Drug Products (participating)
- Q2(R2) / Q14 – Analytical Procedure Development and Revision of Q2(R1) Analytical Validation (not participating)

Some Challenges With Development & Implementation

- ICH aims for *harmonization in every region*
- Need for regulatory changes (e.g., Q7 – Good Manufacturing Practice Guide for Active Pharmaceutical Ingredients)
- Compatibility with policy and operations
- Need for training (e.g., M7 – Assessment and Control of DNA Reactive (Mutagenic) Impurities in Pharmaceuticals to Limit Potential Carcinogenic Risk)
- Harmonized interpretation post implementation

Considering ICH-Q12 Implementation

Challenges ……..

Opportunities ……..

And what will it require?

“How do you get there from here”?

ICH-Q12:
Technical and Regulatory Considerations for Pharmaceutical Product Lifecycle Management

- Key Sections
  - Categorization of Changes
  - Established Conditions
  - Post-approval Change Management Protocol
  - Product Lifecycle Management
  - Pharmaceutical Quality System and Change management
  - Relationship Between Regulatory Assessment and Inspection
  - Post-Approval Changes for Marketed Products
  - Annex

Alignment / Implementation / Challenges
Categorization of Changes

Convergence toward risk-based categorization of post-approval changes is encouraged as an important step toward achieving the objectives of Q12. (Some changes do not need to be reported).

- Health Canada is aligned
- Multiple risk-based communication/reporting categories available
  - Prior approval submission (two categories)
  - Notification and/or Annual Report
- Allows for flexibility to move between categories (an enabler)
  - If certain conditions for change are met (captured in our PNOCC guidance)
  - When linked to a Post Approval Change Management Protocol
  - To accommodate negotiated explicit Established Conditions

- Tweaking needed
  - Clearer delineation of “Immediate Notification” and “Annual Report”
  - Perhaps need an improved “Submission Documentation Form”

Alignment / Implementation / Challenges
Established Conditions

ECs are legally binding information judged necessary to assure product quality and can be “explicit” (proposed & justified) or “implicit” (derived from regulation & guidance); any change necessitates a formal regulatory submission. The number of ECs & how narrowly defined depends on product & process understanding, characterization, development approach & potential risk to product quality. Bonus Alert – concept includes non-ECs!

- Health Canada is essentially aligned
- Fully endorse regulatory flexibility deriving from
  - Fewer ECs and/or better focused ECs;
  - Rationalized lower reporting categories
  - Mixed formats: parameter-based, enhanced approach, performance-based

- Tweaking needed or challenges faced
  - Will benefit from greater experience with explicit ECs
  - How to manage regulatory affairs complexity introduced by explicit ECs
  - Consistent decisions & “level playing field”

Alignment / Implementation / Challenges
Post Approval Change Management Protocols

PACMP provides predictability and transparency in the requirements and studies needed to implement a change; may address one or more changes for a single product, or may address one or more changes to be applied to multiple products; within original Marketing Application or as a stand-alone submission

- Health Canada not yet aligned
- Concept is well understood
- Multiple communication/reporting categories available as enablers
- May consider introducing a pilot program

- Challenges
  - Change to regulatory policy needed (not regulation)
  - Need modified/improved “Submission Documentation Form”
  - Greater scrutiny for “Notifications” as Step 2 of process
  - Adapt to less revenue from supplements!

Alignment / Implementation / Challenges Product Lifecycle Management

A central repository for ECs, reporting category for making changes to approved ECs, PACMPs, and any post-approval CMC commitments. Provides a high level summary of product control strategy to clarify and highlight which elements of the control strategy should be considered ECs. Facilitates and encourages a more strategic approach to lifecycle management.

- Health Canada is partially aligned (and, perhaps, more so than others)
- Concept is well understood – we have our CPID (Certified Product Information Document)

- Challenges
  - What to do with our CPID. Keep as streamlined document separate from submission or merge with PLCM document?

Concluding comments

Current timeframe for ICH-Q12

- Last comment period closed in December, 2018
- Interim meeting in Tokyo 11-15 February, 2019
- June 2019: Finalize Step-4 document

Main implementation issues for Health Canada

- Introduce PACMPs
- Adapt our CPID (Certified Product Information Document)
- More clarity/guidance re current categories & update PNOCC guidance
- Manage potential shift in workload / resource allocation / revenue issues
- Adapt to “negotiated” (explicit) ECs (& precedence over existing guidance)
  - How to maintain consistency between agencies, between divisions, between review teams in the absence of a harmonized “rating guide”?
  - How can we address screening/verification challenges and sponsor errors regarding reporting category used to communicate a change?