Health Canada / Santé Canada

BGTD
CTD-Quality Guidances

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Overview

- **Update on CTD-Quality documents**
- **Changes to BGTD CTD-Q Guidances**
- **Other Comments**
- **CTD-Q Library**
- **Ongoing Developments**

Update on CTD-Q Documents

- **ICH CTD-Q Guidelines**
  - **No updates on ICH M4Q guideline**
  - **ICH CTD-Q Q&A/ Location Issues document reached Step 4 on July 17/03. Now adopted by Health Canada.**

Update on CTD-Q Documents (cont'd)

- **BGTD Notice (May 2004)- WHAT'S NEW?**
  - **Finalization of CPID (Schedule D Drugs) template and 4 guidances (supercede June 25/04 versions) :**
    - **Biotechnological/ Biological (Biotech) Products**
    - **Blood Products**
    - **Conventional Biotherapeutic Products**
    - **Vaccines**

Update on CTD-Q Documents (cont'd)

- **Under Scope of Blood Products guidance, considering the inclusion of: "human or animal blood or blood component products intended for transfusion, which are subjected to manufacturing steps using for example, pathogen reduction technologies or chemical treatments, whereby raw materials are further introduced to the biological source material, possibly resulting in structural, physicochemical, and/or biological changes of the product, e.g. platelet-inactivated blood, SD-treated blood, psoralen-treated blood, blood substitutes."**

Update on CTD-Q Documents (cont'd)

- **BGTD Notice (May 2004)- WHAT'S THE SAME?**
  - **Encourage the use of the CTD format for all Schedule D drugs and all submission types: NDSs, SNDS, NCs, DIN-B, CTAs, CTA-As**
  - **No WP QOS template developed for Schedule D drugs**
  - **CPID (Schedule D Drugs) template unchanged**
  - **Republished June 25, 2003 Appendices to help applicant with migration to CTD format and cross-referencing across different submission formats**

Changes to BGTD CTD-Q Guidances

- **Same minor changes made to all 4 product-specific guidances**
- **Incorporation of changes made to ICH CTD-Q Q&A/Location Issues document (July /03)**
- **Edits made to address comments received to-date on Preparation of the Quality Information for Drug Submissions in the CTD Format (June/03 versions)**

Changes to BGTD CTD-Q Guidances (cont'd)

- **Under 3.2.A.2 Adventitious Agents Safety Evaluation, addition of guidance to address:**
  - **detailed information regarding the routine manufacturing control of adventitious agents (e.g. bacteria, mycoplasma, fungi) using well-established tests (e.g. pharmacopoeial), and/or detailed information on tests, should be provided under 3.2.S and 3.2.P**
  - **detailed information on non-viral adventitious agents (e.g. TSEs, prions), should be placed under 3.2.A.2.**

Changes to BGTD CTD-Q Guidances (cont'd)

- **Under 2 LOCATION, FORMAT & CONTENT of the QUALITY INFORMATION: deletion of note "…where differences exist between ICH and domestic guidances, the ICH guidances would take precedence". No differences between ICH and Health Canada guidances with respect to CTD-Q format. Content is a different matter.**

Changes to BGTD CTD-Q Guidances (cont'd)

- **Under 3.2.S.7.2 Post-approval Stability Protocol and Stability Commitment: deletion of the commitment to place the first 3 production batches of the drug substance manufactured post-approval, on a long-term stability study and using the same stability protocol as in the original submission. Refer to Q1A(R2) and Q5C instead.**

Changes to BGTD CTD-Q Guidances (cont'd)

- **Under 3.2.R.1.1 Executed Batch Records, addition of:**
  - **"During the review process, executed batch records for drug substance may be requested, if necessary."**
  - **"Blank batch records should be submitted only when they are different from executed batch records. In this case, a summary of the discrepancies, and the rationale for the differences, should also be submitted."**

Other Comments

- **Movement of Canadian-specific information to 2.3.R Regional Information, instead of integrating it within the QOS is considered to be inconsistent with Module 3 and it disrupts review flow, consequently affecting review efficiencies.**

Other Comments (cont'd)

- **Under Facilities and Equipment of the CPID (Schedule D Drugs) template: inclusion of developmental or approved products manufactured or manipulated in the same areas as applicant's products in CPID, is new. It is considered important information particularly for a multi-use facility and for an OSE. This information can be transferred from 3.2.A.1 easily.**

Other Comments (cont'd)

- **Under Adventitious Agents Safety Evaluation of the CPID (Schedule D Drugs) template: inclusion of a summary of the reduction factors for viral clearance is not new. This information was found under Process Validation in the CPID-B.**

CTD-Q Library

Preparation of NDSs in the CTD Format

Guidance for Clinical Trial Sponsors CTAs

BGTD Notice: Revised Quality Guidances on the Implementation of the CTD for Biological Products

Preparation of the Quality Information for Drug Submissions in the CTD Format:
- Biotech Products
- Blood Products
- Conventional Biotherapeutics
- Vaccines

Technical Guidances:
- Biotech Products
- Blood Products
- Conventional Biotherapeutics
- Vaccines

ICH CTD Overall Guideline

ICH CTD-Quality (Biotech)

ICH CTD-Q Q&As (Biotech)

ICH Technical Guidelines

- CPID (Schedule D drugs)
- Biotech Products
- Blood Products
- Conventional Biotherapeutics
- Vaccines

Ongoing Developments

- **Initiate discussion and consultation regarding potential changes to scope of Blood Products guidance**
- **Complete draft Preparation of the Quality Information for Drug Submissions in the CTD Format: Radiopharmaceuticals guidance by Q4/04**
- **Development of DIN-B guidance**

Thanks!

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