CTD

Module 1: Administrative and Prescribing Information (Region-Specific)

Section 1.0 Cover Letter

- **Completeness**:
    - "Does the cover letter include the product name?"
    - "Is the product strength mentioned in the cover letter?"
    - "Is the dosage form specified in the cover letter?"
    - "Are the applicant's contact details fully listed (phone number, email, address)?"
    - "Does the cover letter include a statement of purpose for submission?"
- **Compliance**:
    - "Is the cover letter structured according to the specific regional format (e.g., FDA, EMA, or TGA requirements)?"
    - "Does the cover letter reference the correct regulatory submission type, such as NDA, ANDA, or BLA?"
    - "Does the cover letter align with any specific formatting requirements, such as font size, layout, and language as required by the region?"
- **Content Accuracy**:
    - "Is the product name consistent with the product name mentioned in other sections of the CTD?"
    - "Are the applicant's contact details the same across all documents in the CTD?"
    - "Is the product strength and dosage form information accurate and consistent with details in Modules 2 and 3?"

Section 1.1 Table of Contents

- **Completeness**:
    - "Does the Table of Contents (TOC) include all major Modules 1 to 5?"
    - "Is each sub-section within Modules 1 to 5 listed in the TOC?"
    - "Are additional, region-specific sections included in the TOC if applicable?"
- **Compliance**:
    - "Is the TOC organized according to the CTD regional structure (e.g., FDA or EMA)?"
    - "Does the TOC reflect the specific ordering and structure outlined in CTD guidelines?"
- **Content Accuracy**:
    - "Is the pagination accurate for each module listed in the TOC?"
    - "Are section titles correctly represented in the TOC, matching section headers throughout the document?"

Section 1.2 Administrative Forms

- **Completeness**:
  - "Are all necessary administrative forms included (e.g., FDA Form 356h or regional equivalents)?"
  - "Do the forms contain all required fields for the submission process?"
- **Compliance**:
  - "Are the forms formatted and structured according to the specific requirements of each region?"
  - "Is the regulatory submission type (e.g., NDA, BLA) indicated on the forms in compliance with regional standards?"
- **Content Accuracy**:
  - "Are the product name, strength, and applicant details correctly entered in all administrative forms?"
  - "Is the regulatory body's contact information correctly listed where required?"

Section 1.3 Prescribing Information and Labeling

- **Completeness**:
  - "Is there a draft of the product label included?"
  - "Does the prescribing information include inserts for healthcare professionals?"
  - "Are patient leaflets included as required?"
- **Compliance**:
  - "Does the label comply with regional requirements for formatting, language, and required sections (e.g., FDA or EMA standards)?"
  - "Does the prescribing information include appropriate warnings, precautions, and dosing instructions according to regulatory guidelines?"
- **Content Accuracy**:
  - "Is the dosage information on the label consistent with Modules 2 and 5?"
  - "Are indications, contraindications, and precautions accurately stated as per clinical data?"
  - "Are safety warnings and usage instructions aligned with study findings in Module 5?"

Section 1.4 Information on Experts

- **Completeness**:
  - "Are CVs and qualifications provided for all experts involved in the submission?"
  - "Does each CV include necessary details such as education, professional experience, and relevant certifications?"
- **Compliance**:

    - "Are the listed qualifications in line with the standards required by the CTD guidelines for each expert's role?"
    - "Do the experts' credentials meet guideline standards for the specific module sections they oversee?"
- **Content Accuracy**:
    - "Are the expert credentials (degrees, licenses) accurately stated in all documentation?"
    - "Do contact details for each expert match across all CTD modules and forms?"

Section 1.5 Risk Management Plan (RMP)

- **Completeness**:
    - "Does the RMP include a detailed summary of identified risks associated with the product?"
    - "Are safety measures and risk mitigation strategies outlined in the RMP?"
- **Compliance**:
    - "Is the RMP structured according to ICH E2E guidelines and regional standards?"
    - "Are post-market surveillance plans included, if required by the region?"
- **Content Accuracy**:
    - "Are the identified risks consistent with clinical data in Module 5?"
    - "Do safety measures address all relevant findings from the nonclinical and clinical studies?"

Section 1.6 Environmental Risk Assessment

- **Completeness**:
    - "Is there an environmental risk assessment report included in the CTD?"
    - "Does the report justify any categorical exclusions (where applicable)?"
- **Compliance**:
    - "Is the environmental risk assessment prepared according to specific regional guidelines (e.g., FDA environmental requirements)?"
- **Content Accuracy**:
    - "Are environmental impact details consistent with production and waste management descriptions in other sections?"

Module 2: CTD Summaries

Section 2.1 TOC for Modules 2-5

- **Completeness**:
    - "Does the TOC for Modules 2-5 include every section in the summary, quality, nonclinical, and clinical modules?"
- **Compliance**:
    - "Is the TOC formatted according to the CTD layout for Modules 2 through 5?"
- **Content Accuracy**:
    - "Are the page numbers and section titles in the TOC consistent with the content within Modules 2-5?"

Section 2.2 CTD Introduction

- **Completeness**:
    - "Is there a one-page overview included for the CTD introduction?"
- **Compliance**:
    - "Does the introduction adhere to the one-page limit and cover required elements like pharmacology, action mode, and clinical use?"
- **Content Accuracy**:
    - "Is the summary consistent with the clinical and nonclinical data across Modules 3 to 5?"

Section 2.3 Quality Overall Summary (QOS)

- **Completeness**:
    - "Does the QOS include summaries for drug substance and product, covering formulation, stability, and manufacturing?"
- **Compliance**:
    - "Is the QOS structured according to ICH Q8-Q10 requirements?"
- **Content Accuracy**:
    - "Are stability and manufacturing details in the QOS consistent with detailed data in Module 3?"

Section 2.4 Nonclinical Overview

- **Completeness**:
    - "Does the nonclinical overview include a comprehensive summary of pharmacology, pharmacokinetics, and toxicology?"
- **Compliance**:
    - "Is the overview compliant with ICH M3 guidelines?"
- **Content Accuracy**:

- "Are pharmacological and toxicological findings consistent with data in Module 4?"

Section 2.5 Clinical Overview

- **Completeness**:
  - "Does the clinical overview include a summary of efficacy and safety data?"
- **Compliance**:
  - "Is the clinical overview formatted according to ICH E3 guidelines?"
- **Content Accuracy**:
  - "Are risks, benefits, and study findings consistent with data in Module 5?"

Section 2.6 Nonclinical Written and Tabulated Summaries

- **Completeness**:
  - "Does this section include both text and tables summarizing nonclinical pharmacology and toxicology data?"
- **Compliance**:
  - "Are the summaries structured according to ICH S6 requirements?"
- **Content Accuracy**:
  - "Do the summaries reflect accurate data that align with nonclinical studies in Module 4?"

Section 2.7 Clinical Summary

- **Completeness**:
  - "Is the clinical summary comprehensive, covering biopharmaceutics, efficacy, and safety data?"
- **Compliance**:
  - "Is the clinical summary formatted according to ICH E3 standards?"
- **Content Accuracy**:
  - "Are efficacy and safety data consistent with findings detailed in Module 5?"

Module 3: Quality

Section 3.1 TOC for Module 3

- **Completeness**:
  - "Does the TOC for Module 3 include every required sub-section related to drug substance, drug product, appendices, and regional information?"

- **Compliance**:
    - "Is the TOC organized according to the CTD Quality module layout?"
- **Content Accuracy**:
    - "Are the section titles and page numbers accurate in the TOC and consistent with the content throughout Module 3?"

Section 3.2.S Drug Substance

- **Completeness**:
    - "Is the information on the drug substance fully detailed, including chemical name, molecular structure, and physical properties?"
    - "Does the section cover the entire manufacturing process of the drug substance, including sources and quality control?"
    - "Are stability studies for the drug substance provided with sufficient data to support shelf life?"
- **Compliance**:
    - "Are all details in the drug substance section compliant with ICH Q7-Q10 guidelines?"
    - "Does the documentation align with regional quality standards (e.g., FDA, EMA)?"
- **Content Accuracy**:
    - "Is the chemical structure and nomenclature of the drug substance consistent across all sections?"
    - "Are stability data consistent with other stability studies presented within Module 3?"

Section 3.2.P Drug Product

- **Completeness**:
    - "Does the drug product section provide detailed information on formulation, including excipients and manufacturing process?"
    - "Is there a detailed description of the stability testing performed on the drug product, including all test conditions?"
- **Compliance**:
    - "Is the formulation and manufacturing process in line with ICH Q8-Q10 guidelines for quality control?"
    - "Do the stability studies meet regional regulatory guidelines for environmental conditions?"
- **Content Accuracy**:
    - "Are excipient details and concentrations in this section consistent with data from the Quality Overall Summary (QOS)?"

- "Is the product's stability data consistent with the shelf-life claims made elsewhere in the CTD?"

Section 3.2.A Appendices

- **Completeness**:
  - "Does the section include detailed appendices for facility descriptions, equipment specifications, and excipient sources?"
- **Compliance**:
  - "Do appendices on safety and facility information comply with regional standards for safety and manufacturing (e.g., FDA and EMA)?"
  - "Is there documentation on excipients from animal or synthetic origins, as required?"
- **Content Accuracy**:
  - "Are facility details accurately represented and consistent with site details found in other sections of the CTD?"
  - "Are safety details for excipients verified against the manufacturing data?"

Section 3.2.R Regional Information

- **Completeness**:
  - "Does the regional information section include additional details specific to each region’s regulatory requirements?"
- **Compliance**:
  - "Is the information aligned with region-specific guidelines, such as additional stability requirements or packaging regulations?"
- **Content Accuracy**:
  - "Are region-specific data, such as stability and packaging details, consistent with other areas of the CTD?"

Module 4: Nonclinical Study Reports

Section 4.1 TOC for Module 4

- **Completeness**:
  - "Does the TOC for Module 4 cover all sections, including pharmacology, pharmacokinetics, and toxicology studies?"
- **Compliance**:
  - "Is the TOC structured according to the standard format for nonclinical study reports in the CTD?"

- **Content Accuracy**:
    - "Are the section headings and pagination accurate, reflecting the detailed content in Module 4?"

Section 4.2 Pharmacology

- **Completeness**:
    - "Does the pharmacology section include both primary and secondary pharmacodynamic data?"
    - "Are safety pharmacology studies detailed with methodology and findings?"
- **Compliance**:
    - "Are pharmacology studies in compliance with GLP standards and ICH S7A guidelines?"
- **Content Accuracy**:
    - "Is the description of the drug's mechanism of action consistent with efficacy data from clinical trials in Module 5?"
    - "Are pharmacodynamic effects accurately represented and verified?"

Section 4.3 Pharmacokinetics

- **Completeness**:
    - "Is there a comprehensive presentation of ADME (Absorption, Distribution, Metabolism, Excretion) data?"
    - "Does the section include information on pharmacokinetic studies in various species?"
- **Compliance**:
    - "Are ADME studies performed in accordance with GLP requirements?"
- **Content Accuracy**:
    - "Are pharmacokinetic parameters (e.g., half-life, clearance) accurately recorded and consistent across summaries?"
    - "Is animal-to-human dose translation accurately reported for regulatory consistency?"

Section 4.4 Toxicology

- **Completeness**:
    - "Does the toxicology section include studies on acute, sub-chronic, and chronic toxicity?"
    - "Are studies on genotoxicity, mutagenicity, and carcinogenicity presented?"
- **Compliance**:

    - "Does the toxicology data comply with ICH S6 guidelines and include GLP certifications where applicable?"
- **Content Accuracy**:
    - "Are toxicology results consistent with safety data in the RMP (Risk Management Plan)?"
    - "Are safety margins calculated accurately to ensure human safety?"

Module 5: Clinical Study Reports

Section 5.1 TOC for Module 5

- **Completeness**:
    - "Is the TOC for Module 5 complete, listing all clinical study reports for each phase (Phase I-IV)?"
- **Compliance**:
    - "Is the TOC structured in line with the CTD format for clinical study data?"
- **Content Accuracy**:
    - "Are section numbers and pagination accurate, reflecting the specific clinical studies provided?"

Section 5.2 Tabular Listing of All Clinical Studies

- **Completeness**:
    - "Does the tabular listing include a summary of all clinical studies conducted, including study designs and endpoints?"
- **Compliance**:
    - "Is the table compliant with ICH E3 guidelines for clinical study presentation?"
- **Content Accuracy**:
    - "Are study designs, endpoints, and outcomes accurately listed and consistent with individual study reports?"

Section 5.3 Clinical Study Reports

- **Completeness**:
    - "Does the section contain complete reports for each clinical study phase, from Phase I through Phase IV?"
- **Compliance**:
    - "Do clinical study reports meet the ICH E3 guidelines for efficacy and safety reporting?"

    - "Are reports presented in the required format for each phase of study (e.g., dose-ranging in Phase I, efficacy in Phase III)?"
- **Content Accuracy**:
    - "Are primary and secondary endpoints accurately documented across all study phases?"
    - "Is there consistency in reported outcomes compared to summaries provided in Modules 2 and 5?"

Section 5.4 Literature References

- **Completeness**:
    - "Does the section include a comprehensive list of all relevant literature references supporting clinical data?"
- **Compliance**:
    - "Are references formatted consistently according to ICH requirements for citation and bibliography?"
- **Content Accuracy**:
    - "Is each cited reference correctly attributed and aligned with data presented in the clinical study reports?"