I'm not a bot



The use of the Common Technical Document (CTD) format has become widespread since its last revision. Most manufacturers have created a CTD dossier that they've used to register their products in various countries, and many countries require submission of a CTD format dossier for registration purposes. As of January 1, 2021, the CTD format will be mandatory for vaccine prequalification dossiers. This adoption is expected to reduce regulatory burdens on companies as they'll no longer need to maintain multiple-format dossiers. The CTD Module 1 contains essential information required for prequalification assessment purposes. Modules 2-5 share a common format and content, structured under major headings such as Quality, Nonclinical Study Reports, and Clinical Study Reports, aligning with ICH guidelines. The entire CTD must be written in English and provided in electronic, searchable versions. Manufacturers are required to engage with national regulatory authorities (NRAs) from the beginning of the prequalification application process. This includes informing the NRA of their application, requesting participation in the process, providing necessary authorization for discussions with WHO representatives, and obtaining a marketing authorization from the responsible NRA before submitting a product summary file. Submission deadlines have been established by WHO, with three rounds per year: 31 January, 31 May, and 30 September. Applications must arrive no later than the submission date to be considered in the subsequent review round. For submission, include mutually-agreed meeting minutes between WHO and the applicant, a consistent site master file in line with WHO Guidance document:WHO Technical Report Series, No. 961, Annex 14, 2011. Provide vaccine composition, presentations, and scheduling information, including descriptions of diluents (if applicable), combination products, forms, dose sizes, container types, and vaccine vial monitor (VVM) types and locations. Additionally, offer temperature stability profiles beyond those in Module 3.2.P.8, especially for VVM type assignment or on-label claims for elevated temperature storage. Describe immunization/administration devices to be delivered with the vaccine and recommend schedules and routes of administration. Offer artworks or mockups of labels for primary containers and secondary packaging, as well as samples of package inserts in English. After finalizing the review of the English version, translate packaging inserts into French, Portuguese, Russian, and Spanish as required by UN procurement agencies. Provide a template of lot summary protocol compliant with WHO-recommended format and perform self-assessment against programmatic suitability for prequalification criteria. Include supplemental preclinical and clinical information not covered in national regulatory authority submissions or Modules 2-5, such as lists of preclinical studies, clinical trials, cross references to ERC and NRA approvals, and statements of final conclusions on safety and immunogenicity (and/or efficacy). The submission to the current WHO prequalification application should include essential details such as the study plan and expected result date, clinical trials conducted for different use indications and age groups, and a list of other studies with applicant product not sponsored by the applicant. The applicant is required to compile this list through an extensive literature search and, in cases of co-licensure agreements, from licensed companies holding similar rights. Additionally, a comprehensive clinical summary supporting the product's worldwide use by UN agencies should be provided. This summary must interpret safety and efficacy data obtained from pre-licensure studies and post-licensure period trials that support current prescribing information, paying particular attention to data relevant to WHO recommended schedules. The consistency of manufacturing for vaccine lots used in clinical trials should be demonstrated and well-documented. Ideally, at least three lots with the same formulation intended for marketing are used in late-stage clinical development. However, a formal lot-to-lot consistency clinical study may be considered on a case-by-case basis, particularly when assessing vaccine formulations with inherent variability. Manufacturers must consider significant factors before performing a lot-to-lot consistency clinical study to meet NRA vaccine licensure requirements. These studies should have pre-defined criteria and parameters, be designed as equivalence trials, and demonstrate comparability between clinical lots and the actual product used for marketing. For both initial licensure and any subsequent variations to the licence for changes relevant to clinical data, detailed information is required. The submission should include an independent clinical expert report on clinical studies, highlighting the expert's experience and independence. If extrapolating existing data, the report must discuss compliance with WHO GCP recommendations and current guidance for preclinical and clinical trials. Post-marketing safety documentation is mandatory, including both initial application submissions and reassessment purposes. This includes outlining a pharmacovigilance plan, listing adverse events following immunization (AEFIs) over the past five years, and detailing procedures for collection, notification, and assessment of AEFIs. Additionally, information on regulatory actions taken, such as refusals, withdrawals, suspensions, lot rejection, restrictions on distribution and recalls, clinical trial suspensions, dosage or schedule changes, target population changes, and quantity of finished product distributed in the domestic market over the last three years is required. The packaging procedures for international shipments were established by the National Rifle Association's laboratory and recording system for distribution purposes, as stated in Section 1.8.4. This section also outlines the validation process according to current WHO guidelines, ensuring compliance with International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use standards. Module 2, Common Technical Document (CTD) Summaries, is based on ICH guidelines M4Q, M4S, and M4E. It consists of a table of contents, introduction, quality overall summary, nonclinical overview, clinical overview, and written summaries of pharmacology, pharmacokinetics, toxicology, biopharmaceutic studies, associated analytical methods, clinical efficacy, safety literature references, and synopses of individual studies. Module 3, Quality, adheres to ICH guideline M4Q. It includes a table of contents, body of data, and literature references. Module 4, Nonclinical Study Reports, follows ICH M4S guidelines. This module covers table of contents, study reports, and literature references. Module 5, Clinical Study Reports, aligns with ICH guideline M4E. It comprises table of contents, tabular listings, clinical study reports, and literature references.

Common technical document definition. Common technical document example. Modules of common technical document. Module 2 common technical document summaries. Common technical dokument. Common technical document. Common technical document (module 3).