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Guidance on the organisation of the information to be presented in registration applications for new pharmaceuticals (including biotechnology This is a technical document that provides instructions on how to implement the Electronic Common Technical Document (eCTD) v specification. The content is provided in a QOSは、申請に係る医薬 品の重要な事項を明確にするとともに、例えば、データや資料を作成する際、既存の ガイドラインによらないときは、その妥当性を説明するものでな 医薬品の承認申請のための 国際共通化資料 コモン・テクニカル・ドキュメント（ CTD ）の構成. guideline. (CTD) for the registration of pharmaceuticals for human useorganisation of CTDScientific. A common format for the technical documentation will significantly The eCTD is the standard format for submitting applications, amendments, supplements, and reports to FDA's Center for Drug Evaluation and Research (CDER) and Center for Biologics Evaluation and This document is intended to provide guidance on the format of a registration application for drug substances and their corresponding drug products as defined in the scope of the ICH Guidelines QA ("NCE") and ICH Guideline QB ("Biotech") This guideline presents the agreed upon common format for the preparation of a well-structured Common Technical Document (CTD) for applications that will be submitted to regulatory authorities Common technical document. ガイドラインの目的 本ガイドラインは、承認申請のために規制当局に提出され SCOPE OF THE GUIDELINE. This guideline presents the agreed upon common format for the preparation of a well-structured Common Technical Document (CTD) for applications that will be submitted Human Scientific guidelines. Guidance on the organisation of the information to be presented in registration applications for new pharmaceuticals (including biotechnology -derived products) This guideline presents the agreed upon common format for the preparation of a well-structured Common Technical Document for applications that will be submitted to regulatory authorities.

Difficulté **Facile** | Durée **752 minute(s)**

Catégories **Alimentation & Agriculture, Sport & Extérieur, Robotique** | Coût **376 EUR (€)**

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