

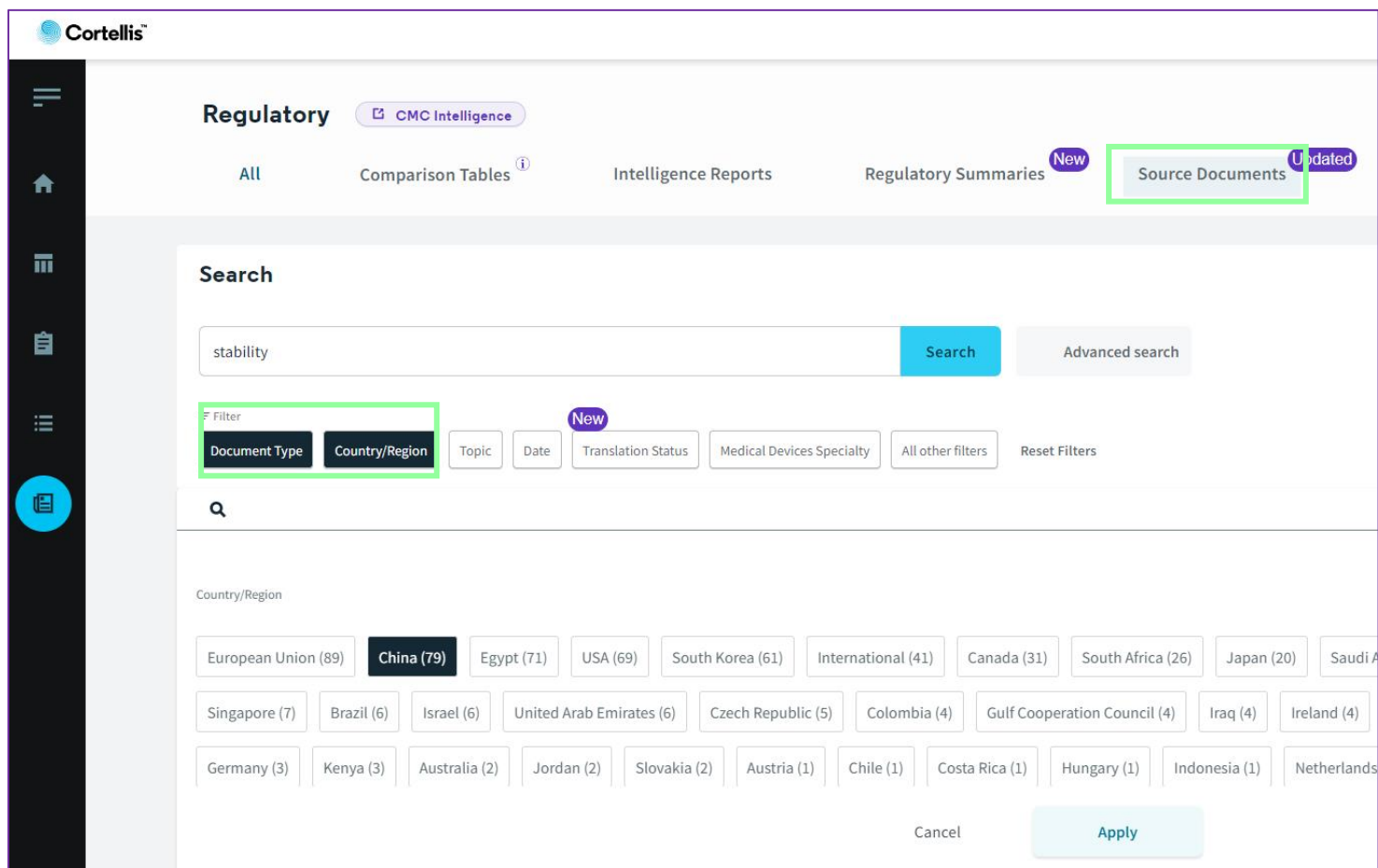
Finding English translations in Cortellis

All valid Source Documents in local language have searchable English translations in Cortellis Regulatory Intelligence. These translations are:

- **Machine Translations:** Automated English translations powered by Google. Available for all Source Documents that do not have a human translation.
- **Authority Official:** Translations published in the Official Journal, or translations from Medicines Agencies which are identified as official.
- **Authority Unofficial:** Translations from Medicines Agencies which are identified as unofficial, or translations provided by non-authority sources (eg. association or research institute).
- **Cortellis Translations:** Human translations curated by certified experts (Clarivate contract translator, consultant, or internal content specialist).
- **Cortellis in Progress:** The local language version is already available and once the Cortellis translation is finished it will be added to the same document.

Example 1: Find Chinese guidelines that mention stability anywhere in the document.

1. Click the **Source Documents** tab.
2. Type the keyword *stability* into the **search field**.
3. Add filters: Open **Document Type** filter and select **Guideline** from the list and click **Apply**. Open **Country/Region** filter and select **China**. Click **Apply**.
4. Click **Search**.



The screenshot shows the Cortellis Regulatory Intelligence interface. The top navigation bar includes tabs for 'Regulatory', 'CMC Intelligence', 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries', and 'Source Documents' (highlighted with a green box and labeled 'Updated'). The 'Search' section has a search bar with the keyword 'stability' and a 'Search' button. Below the search bar, there are filter buttons: 'Document Type' (highlighted with a green box), 'Country/Region' (highlighted with a green box), 'Topic', 'Date', 'Translation Status', 'Medical Devices Specialty', 'All other filters', and 'Reset Filters'. The 'Country/Region' filter is expanded, showing a list of countries and regions with their respective document counts. 'China' is selected and highlighted with a black background. Other countries include European Union (89), Egypt (71), USA (69), South Korea (61), International (41), Canada (31), South Africa (26), Japan (20), Saudi Arabia (20), Singapore (7), Brazil (6), Israel (6), United Arab Emirates (6), Czech Republic (5), Colombia (4), Gulf Cooperation Council (4), Iraq (4), Ireland (4), Germany (3), Kenya (3), Australia (2), Jordan (2), Slovakia (2), Austria (1), Chile (1), Costa Rica (1), Hungary (1), Indonesia (1), and Netherlands (1). At the bottom right of the filter list are 'Cancel' and 'Apply' buttons.

From the results page you can quickly identify which types of translations are available for each document: if English is listed under **Language**, a human translation is available; if not, a machine translation is available. Click the hyperlinked Titles to open the documents.

Showing 1-10 of 430 results							
Customize Columns ? Sorted by Relevance							
<input checked="" type="checkbox"/>	Summary	Title	Abstract	Last Updated Date	Reason for Update	Country/Region	Language(s)
<input checked="" type="checkbox"/>	05-Feb-2015 V CN EN,ZH RD	CFDA Announcement No. 2015/03: Issuance of Two Guidelines - Technical Guidelines for Dissolution Testing of Solid Oral Products and Technical Guideli	This announcement provides two guidelines: Annex 1: Technical Guidelines for Dissolution Testing of Solid Oral	18-Sep-2015	This document replaces the draft of CDE Announcement: Announcement on Soliciting Public Comment on Technical	China	English Chinese
<input checked="" type="checkbox"/>	15-Apr-2015 V CN EN,ZH RD	CFDA Announcement No. 2015/10: Technical Guidelines on Stability Studies of Biological Products (Trial), 15-Apr-2015 (English and Chinese Versions)	This announcement provides the final trial version of Technical Guidelines on Stability Studies of Biological Products. It contains	23-Apr-2015	This version replaces the draft of CDE Announcement: Soliciting Public Comment on Technical Guidelines on Stability Studies	China	English Chinese
<input checked="" type="checkbox"/>	07-Oct-2023 V CN ZH RD	CDE Notification: Soliciting Public Comment on Technical Guidelines for Pharmaceutical Research on the Compatibility and Stability of Chemical Inject	In order to clarify the pharmaceutical research technical requirements for the compatibility stability of chemical	27-Feb-2024	This document has been revised to edit tags which do not affect the content of the document (retagging).	China	Chinese

After opening a Source Document machine translations are accessible from the **translation icon** as shown below, either in **Preview** or **Download (PDF)**. Please note that machine translations are powered by Google and provided in an ‘as is’ format as explained in the Disclaimer.

Document

None Chinese

1 of 40

Automatic Zoom

File 1

Original file

国家药监局器审中心关于发布牙科粘接剂产品等2项医疗器械产品注册审查指导原则的通告（2023年第3号）

附件1牙科粘接剂产品注册审查指导原则

一、适用范围

二、注册审查要点

三、参考文献

附件2人工肩关节假体注册审查指导原则

国家药监局器审中心关于发布牙科粘接剂产品等2项医疗器械产品注册审查指导原则的通告（2023年第3号）

发布时间：2023-03-09

为进一步规范医疗器械的管理，国家药监局器审中心组织制定了《牙科粘接剂产

Machine Translated Document

Preview (English)

Download (English)

View on Side by side

Disclaimer:

AUTOMATED TRANSLATIONS POWERED BY GOOGLE are not modified or altered by Clarivate and are provided "as is" without warranty. Any discrepancies or differences created in the translation are not binding and have no legal effect for compliance or enforcement purposes. If any questions arise related to the accuracy of the translated information, please refer to the official source language version.

Clicking **View on Side by side** displays the local language version and machine translation in the Cortellis Side by Side Viewer.

Side by Side viewer

1 of 40

Automatic Zoom

File 1

Original file

国家药监局器审中心关于发布牙科粘接剂产品等2项医疗器械产品注册审查指导原则的通告（2023年第3号）

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为进一步规范医疗器械的管理，国家药监局器审中心组织制定了《牙科粘接剂产

特此通告。

附件：1. 牙科粘接剂产品注册审查指导原则

2. 人工肩关节假体注册审查指导原则

国家药品监督管理局
医疗器械技术审评中心
2023年3月7日

Machine Translated by Google

Notice from the Device Review Center of the State Food and Drug Administration on the release of the guiding principles for the registration review of two medical device products including dental adhesive products (No. 3, 2023)

Release time: 2023-03-09

In order to further standardize the management of medical devices, the Device Review Center of the State Food and Drug Administration organized and formulated the "Guiding Principles for the Registration Review of Two Medical Device Products" (see attached).

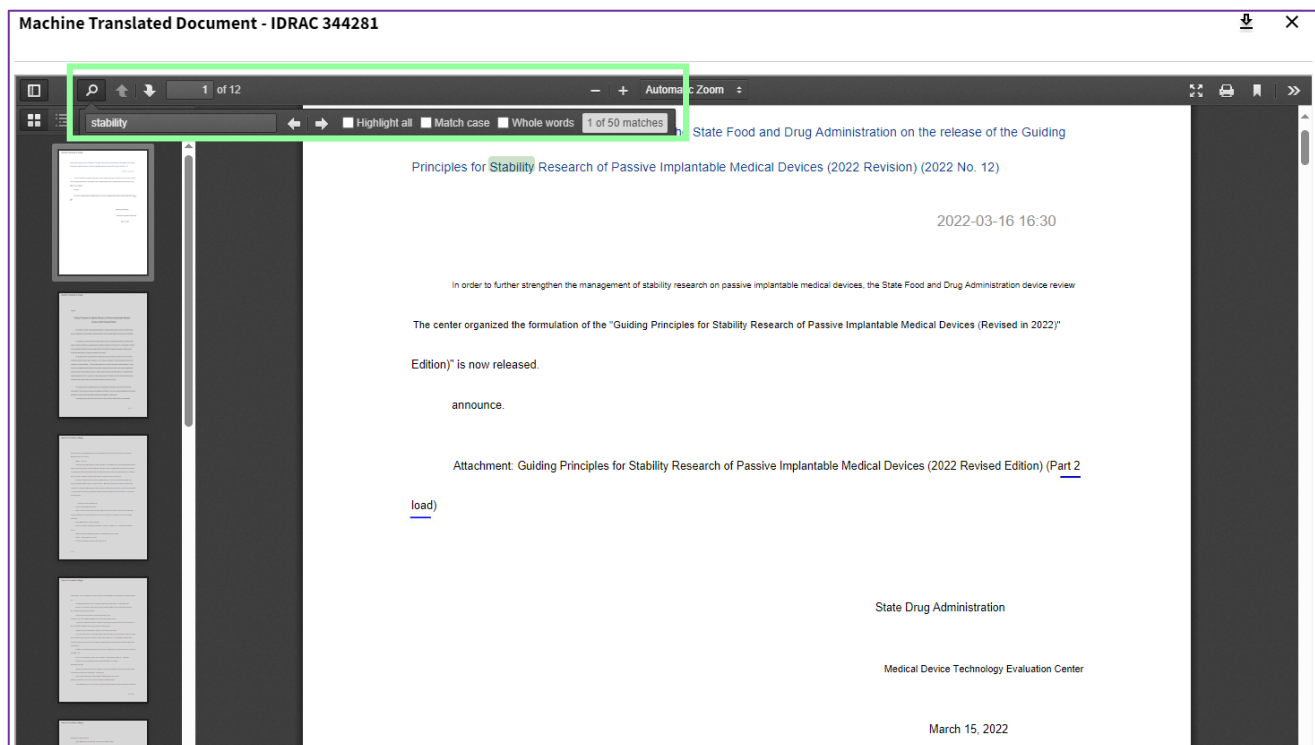
Two guiding principles for medical device product registration review (see attachment), including "Guiding Principles for Product Registration Review" and "Guiding Principles for Product Registration Review".

Attachment: 1. Dental Adhesive Product Registration Review Guidelines

2. Guidelines for Registration Review of Artificial Shoulder Joint Prosthesis

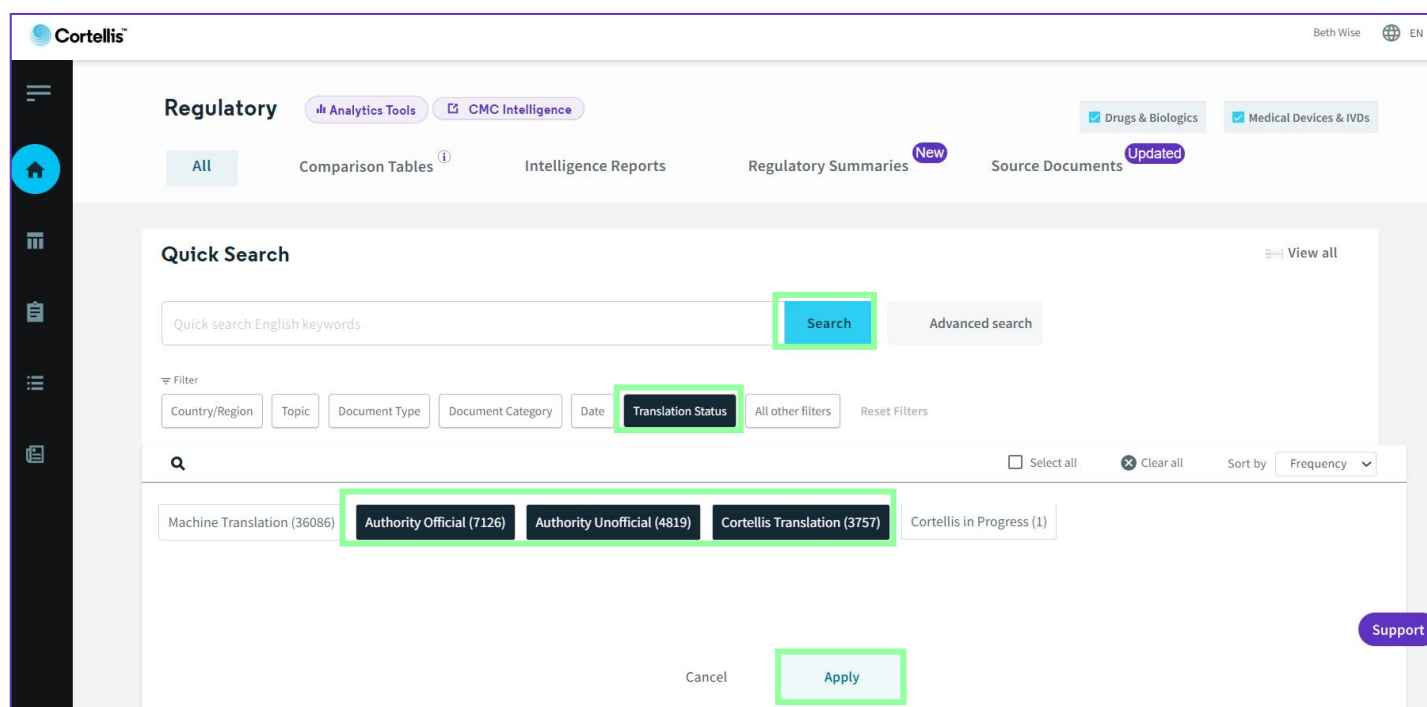
State Drug Administration
Medical Device Technology Evaluation Center
March 7, 2023

In Preview, Download PDF or View on Side by Side, use the **find in document icon** to locate your keyword.



Example 2: Find documents with human translations.

1. From Quick Search use the **Translation Status** filter and select **Authority Official** and/or **Authority Unofficial** and/or **Cortellis Translations** and click **Apply**.
2. Click **Search**.



Once in a Cortellis document, you can also check the type of translation under the title.

NMPA Announcement No.2021/119: Implementation of Drug eCTD Submission, 29-Sep-2021

Valid 336355 China Reference Document Announcement Translation: Cortellis Translation

Drugs and Biologics

Dossier Format and Submission Regulatory Procedures

Human translations are added to the Source Document itself, above the local language version.

Document

Final 27-Jul-2023 Chinese English

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File 1

Internal English version

Notification of Centre for Drug Evaluation of the National Medical Products Administration on Issuing the Technical Guidelines for the Design of Patient-Centred Drug Clinical Trials (Trial), the Technical Guidelines for the Conduct of Patient-Centred Drug Clinical Trials (Trial) and the Technical Guidelines for Patient-Centred Drug Benefit-Risk Assessment (Trial) (No. 44 of 2023)

Release Date: 27 July 2023

"Patient-centred" drug development refers to the process of drug development, design, conducting and decision-making based on patient's perspective, aiming at the efficient development of clinically valuable drugs that better meet the needs of patients, and is a field that is currently being actively explored by drug regulatory agencies in various countries. In order to promote the practical application of "patient-centred" concept in drug research and development, the Centre for Drug Evaluation organised the formulation of the Technical Guidelines for the Design of Patient-Centred Drug Clinical Trials (Trial), the Technical Guidelines for the Conduct of Patient-Centred Drug Clinical Trials (Trial) and the Technical Guidelines for Patient-Centred Drug Benefit-Risk Assessment (Trial) (see Annexes 1-3). In accordance with the requirements of the Notification of the Comprehensive Department of National Medical Products Administration on the Issuance of the Procedures for Releasing the Technical Guidelines for Pharmaceutical Products (NMPA Comprehensive Drug Administration [2020] No. 9), the present notification is hereby issued after review and approval of the National Medical Products Administration and is to be implemented since the date of release.

This is hereby announced.

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Supp

Scroll down to the local language version

1. Background

2. Purpose and scope of application

II. General Principles

1. Integrating patient

"以患者为中心"的药物研发是指基于患者角度开展的药物开发、设计、实施和决策的过程，旨在高效研发更符合患者需求的有临床价值的药物，是当前各国药品监管机构积极探索的领域，为推动"以患者为中心"理念在药物研发的实践应用，药审

For more information contact Customer Service at [LS Product Support](#).