

# What's new in Cortellis Regulatory Intelligence

Claudia Haas & Beth Wise | February 2024

# Quick quiz

- What types of English translations does Cortellis Regulatory Intelligence provide?
  - Machine translations
  - Cortellis translations
  - Authority translations
- TRUE or FALSE: You can search across all source documents including the pdf full text using local language.
- Does Cortellis provide structured Summaries that help you bring Advanced Therapy Products (ATMPs) into more markets?



# Quick quiz - answers

- What types of English translations does Cortellis Regulatory Intelligence provide?
  - Machine translations
  - Cortellis translations
  - Authority translations
  - All of the above
- TRUE or FALSE: You can search across all source documents including the pdf full text using local language.
  - TRUE: The upgraded Source Document Search enables you to search the pdf full text using keywords in English or foreign language.
- Does Cortellis provide structured Summaries that help you bring Advanced Therapy Products (ATMPs) into more markets?
  - Yes. "How to market ATMPs" Regulatory Summary expanded to 72 territories with new question structure providing more insights.

# Agenda

- Cortellis Regulatory Intelligence enhancements
- Live demo
- 2024 Outlook
- Feedback, Wrap-up and Q&A

# What is Cortellis Regulatory Intelligence?

Global regulatory information, across all functions and responsibilities



**290K+ official documents**



**9.5K Value-add regulatory reports, analyses and global comparisons**



**Exclusive English translations**



**81 countries and regions  
Drugs & Biologic and  
75 Medical Devices & IVDs**



**Updated daily**



**Regulatory experts & local consultants**



# What's New

# NEW: English Machine translations

Easily access, search and download documents machine translated by Google\*

**Document**

None Swedish

1 of 4 Automatic Zoom

**Om tjänsten Sök restanmälda läkemedel**

I tjänsten Sök restanmälda läkemedel publiceras information om läkemedel som läkemedel har restanmält till Läkemedelsverket. I söktjänsten kan du söka efter alla kommande, pågående och avslutade anmälda restsitu

**Machine Translated by Google**

**About the service Search for backlogged medicines**

In the service Sök residue-notified medicines, information is published about medicines that the pharmaceutical companies have notified as residue to the Swedish Medicines Agency.

In the search service, you can search for all upcoming, ongoing and completed reported residual situations. You can filter the content to find what you are looking for. All residual situations that have been reported since 2018 are published.

Search for which medicines have been reported to the Swedish Medicines Agency.

**To the search service**

**Content and responsibility**

The search service contains information on all pharmaceutical packaging that has been reported to the Swedish Medicines Agency.

**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.

# NEW: Intuitive Search for Regulatory Summaries and Intelligence Reports

Get better results with autosuggestions and easily compare across countries

The image displays the Clarivate Regulatory Intelligence platform interface. On the left, a navigation bar includes 'Regulatory', 'CMC Intelligence', 'All', 'Comparison Tables', 'Intelligence Reports', 'Regulatory Summaries' (marked with a 'New' badge), and 'Source Documents' (marked with an 'Updated' badge). Below this, a 'Search' bar is highlighted with a purple box. A purple arrow points from the search bar to a dropdown menu of autosuggestions. The suggestions include: 'How is the application reviewed and according to which timelines?', 'Which PAC category does a safety-related change belong to? Are there specific requirements concerning procedural ...', 'Are there official timelines for Competent Authority/-ies to respond to CTA/IND Applications?', 'Are there official timelines for the IEC/IRB to respond to applications?', 'What are the timelines for approval/clearance/certification of a product?', and 'How is the application reviewed and according to which timelines? When does the clock start?'. The right side of the image shows a search results page for the query 'How is the application reviewed and according to which timelines? When does the clock start?'. It displays 71 results found. The results are filtered by 'Topic' and 'Last Updated Date'. The first three results are for 'Marketing Authorization Procedures: Review, Communication and Approval' for Argentina, Jordan, and Iraq, respectively. Each result includes a description, country/region, IDRAC number, and last updated date. A yellow highlight is present on the search query in the results list.

Regulatory CMC Intelligence

All Comparison Tables Intelligence Reports Regulatory Summaries New Source Documents Updated

Browse Search

Smarter search outcomes and suggestions with our new intuitive search!

timeline

How is the application reviewed and according to which timelines?

Which PAC category does a safety-related change belong to? Are there specific requirements concerning procedural ...

Are there official timelines for Competent Authority/-ies to respond to CTA/IND Applications?

Are there official timelines for the IEC/IRB to respond to applications?

What are the timelines for approval/clearance/certification of a product?

How is the application reviewed and according to which timelines? When does the clock start?

71 results found for

'How is the application reviewed and according to which timelines? When does the clock start?'

Filters

Topic Last Updated Date

Expand All Collapse All

2023 V

EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides detailed, practical information and flow charts about the national authority review process, for the products (see Definitions in Decree 150/92), - Biological and biosimilar products.

Country/Region: Argentina

IDRAC Number: 26800

Last Updated Date: 01-Jun-2023

How is the application reviewed and according to which timelines? When does the clock start? ✓

Submission clock starts once the application is done. A) Approval process for the registration of a New Product Article 3 F

2023 V

EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides the principal marketing authorization application stages through the national procedure in Jordan

Country/Region: Jordan

IDRAC Number: 215584

Last Updated Date: 23-Mar-2023

How is the application reviewed and according to which timelines? When does the clock start? ✓

The MA includes three main steps: File submission; File evaluation; Final decision. File Evaluation Once the file is received t

2023 V

IQ EN RS

Marketing Authorization Procedures: Review, Communication and Approval

This document provides the principal marketing authorization application stages through the national procedure in Iraq.

Country/Region: Iraq

IDRAC Number: 216318

Last Updated Date: 25-Oct-2023

How is the application reviewed and according to which timelines? When does the clock start? ✓

Iraq The MAA process for imported and locally manufactured drugs includes the following phases; some of these are done



# UPGRADED: Source Document Search

Search all source documents including the pdf full text using English or local language keywords

27 results for 'qualifikation and inspektor\*'

Switch to Comparison Tables

Drugs & Biologics Medical Devices & IVDs

Refine Search

qualifikation and inspektor\* Search

Filter

Document Type Country/Region Topic Date Translation Status Medical Devices Specialty All other filters Reset Filters

Showing 1-10 of 27 results

Customize Columns Sorted by Relevance

	Summary	Title	Abstract	Last Updated Date	Reason for Update	Country/Region	Language(s)
<input checked="" type="checkbox"/>	07-Dec-2022 V DE DE RD	ZLG: Training, Assignment and Continuing Education of GCP Inspectors (VAW 04110804), 07-Dec-2022	The present document, issued by the Central Authority of the Länder for Health Protection with regard to Medicinal	15-Jan-2024	This document has been revised to add a file of English text generated by machine translation tool (retagging).	Germany	German
<input checked="" type="checkbox"/>	07-Dec-2022 V DE DE RD	ZLG Form: Template of a Training Plan for GCP Inspectors (Form 041108_F02_01), 07-Dec-2022	The present document, issued by the Central Authority of the Länder for Health	13-Jan-2024	This document has been revised to add a file of English text generated by machine	Germany	German
<input checked="" type="checkbox"/>	07-Dec-2022 V DE DE RD						

Original file

Training, Beauftragung und Fortbildung von GCP-Inspektorinnen und

qualifikation

Highlight all Match case Whole words 1 of 9 matches

Inspektor, die fortlaufende Fortbildung und die Überprüfung einschließlich der Bewertung sowie den Erhalt und die regelmäßige, dokumentierte Bewertung der Qualifikation von GCP-Inspektorinnen und GCP-Inspektoren bei den Behörden, die für die Durchführung von GCP-Überwachungsaufgaben nach § 64 AMG in Betrieben, Einrichtungen und bei Personen zuständig sind.

as Verfahren der Beauftragung als GCP-Inspektorin/GCP-

# EXPANDED: How to market Advanced Therapy Medicinal Products (ATMPs)\*

Regulatory Summaries for 72 territories with new Q&A structure providing more insights

1 of 10

- Q1 Definitions and Legal Basis
  - Q1.1 What are Advanced Therapy Products in the country/region?
  - Q1.2 What is the regulatory framework for Advanced Therapy Products in the country/region?
  - Q1.3 Are there any new or impending changes to the current Advanced Therapy Products regulations?
- Q2 Advanced Therapy Product Classification
  - Q2.1 How are Advanced Therapy Products classified?
  - Q2.2 What is the procedure for obtaining advice on Advanced Therapy Product classification?
- Q3 Advanced Therapy Product Clinical Investigations
  - Q3.1 Which laws and regulations govern clinical investigations for Advanced Therapy Products?
  - Q3.2 Is there specific information regarding clinical investigations for Advanced Therapy Products?
- Q4 Approval of Advanced Therapy Products
  - Q4.1 Which regulatory bodies oversee Advanced Therapy Products? Is there a specific committee charged with Advanced Therapy Product evaluation?
  - Q4.2 Is there a procedure for authority consultation/scientific advice regarding the requirements for Advanced Therapy Products?
  - Q4.3 What are the requirements for registration, format and content of applications?
  - Q4.4 What are the labelling requirements for Advanced Therapy Products?
- Q5 Post-authorization of Advanced Therapy Products
  - Q5.1 Are there any advanced therapy-specific guidelines regarding pharmacovigilance?
- Q6 Are there any other specific requirements applicable to Advanced Therapy Products in the country/region?
- Q7 Annex

## Regulatory Summary

Continuously monitored and updated



### How to Market Advanced Therapy Products (Taiwan)

Reason for update	Date	Reason for update description
Content Update	2024-02-02	This update added the procedure of Cell Therapy Technology Fee-based Consultation in section Q4.2.
New	2024-01-19	

#### Q1 Definitions and Legal Basis

##### Q1.1 What are Advanced Therapy Products in the country

In Taiwan, "Advanced therapy products" are regulated as "Regenerative

According to the draft version of [Provisions on Regenerative Medicine](#) 377018), "Regenerative medicines" use cells, genes, and derivatives body structures or functions, or for treatment or prevention of human "Regenerative medical technique" and "Regenerative medical prepar

"Regenerative medical technique", is regulated by the [Medical Care / Governing the Application of Specific Medical Technique and Medical](#) the following:

- Specific medical technique (Cell therapy technique, Specific op
- Other specific medical technique)
- Specific examination, laboratory testing, and medical devices



##### (B) Regenerative medical preparations

For "Regenerative medical preparations", the clinical investigations shall follow the requirements of [Pharmaceutical Affairs Act \(PAA\)](#) (IDRAC 253489) and [Regulations for Good Clinical Practice \(GCP\), 28-Aug-2020](#) (IDRAC 317460).

##### For Cell Therapy Medicinal Product

According to [MOHW Announcement No. 1051413931: Revising Clinical Trials Plan Application Procedures for Human Cell Therapy Products, 17-Jan-2017](#) (IDRAC 239002), the Ministry of Health and Welfare established a provisional dual track system for the clinical trial protocol application for human cells therapy products. An applicant for a clinical trial protocol for a human cell therapy product may either choose the option of a consultation procedure prior to document submission or may choose to forego said consultation procedure and proceed directly to submission of the application for a clinical trial protocol for a human cell therapy product to the Food and Drug Administration under the Ministry of Health and Welfare. The document submissions for applications for clinical trial protocols for human cell therapy products are required to comply with requirements of [MOHW Announcement No.1091401592 & MOHW Letter No.1091401633: Clinical Trials Guidelines for Human Cell Therapy Products \(Revised Version\), 01-May-2020](#) (IDRAC 311518) and [MOHW Announcement No.1091401041: Checklist of Technical Documents for Human Cell Therapy Clinical Trials Applications, 12-Feb-2020](#) (IDRAC 306315).

# 2024 Cortellis Regulatory Intelligence outlook

	2023 highlights	H1 2024	H2 2024	Future
 <p><b>Connected Data &amp; Insights</b></p>	<p><b>Enhanced Search</b></p> <ul style="list-style-type: none"> <li>Intuitively surface deeper insights from complex data</li> </ul> <p><b>Content Expansion</b></p> <ul style="list-style-type: none"> <li>New European Public Assessment Reports (EPARs) data expansion streamlines your research process and make more informed decisions</li> </ul>	<p><b>Machine Translations</b></p> <ul style="list-style-type: none"> <li>Top requested feature, expediting translations of non-English language content</li> </ul> <p><b>New Weekly Updates</b></p> <ul style="list-style-type: none"> <li>New version with more user-friendly layout</li> </ul> <p><b>Content Expansion</b></p> <ul style="list-style-type: none"> <li>Expand <i>RS: How to market Advanced Therapy Medicinal Products</i> to all available countries</li> </ul>	<p><b>Cortellis Redesign</b></p> <ul style="list-style-type: none"> <li>Updating core components to improve performance, UeX and expedite future enhancements to the Cortellis platform</li> </ul>	<p><b>Contextualized intelligence</b></p> <p>Continued investment in customer centric feature (such as highlighting changes), and content &amp; country expansion</p>
 <p><b>Advanced Analytics &amp; GenAI</b></p>	<p><b>FDA Analytics tools</b></p> <ul style="list-style-type: none"> <li>New data visualization to facilitate your preparation for FDA inspections or committee meetings for drugs &amp; biologics</li> </ul>	<p><b>FDA Analytics Tools *</b></p> <ul style="list-style-type: none"> <li>Content enhancements and new workflow to enable faster updates</li> </ul>	<p><b>Gen AI Enhanced Search</b></p> <ul style="list-style-type: none"> <li><b>Integrated</b> Drug Discovery, Regulatory and Drug Class Safety data</li> </ul>	<p><b>Unlock value with more data Visualization &amp; GenAI solutions</b></p> <ul style="list-style-type: none"> <li>More in-depth analysis charts</li> <li>Transform structured raw data to user friendly format</li> <li>Continued investment in GenAI</li> </ul>

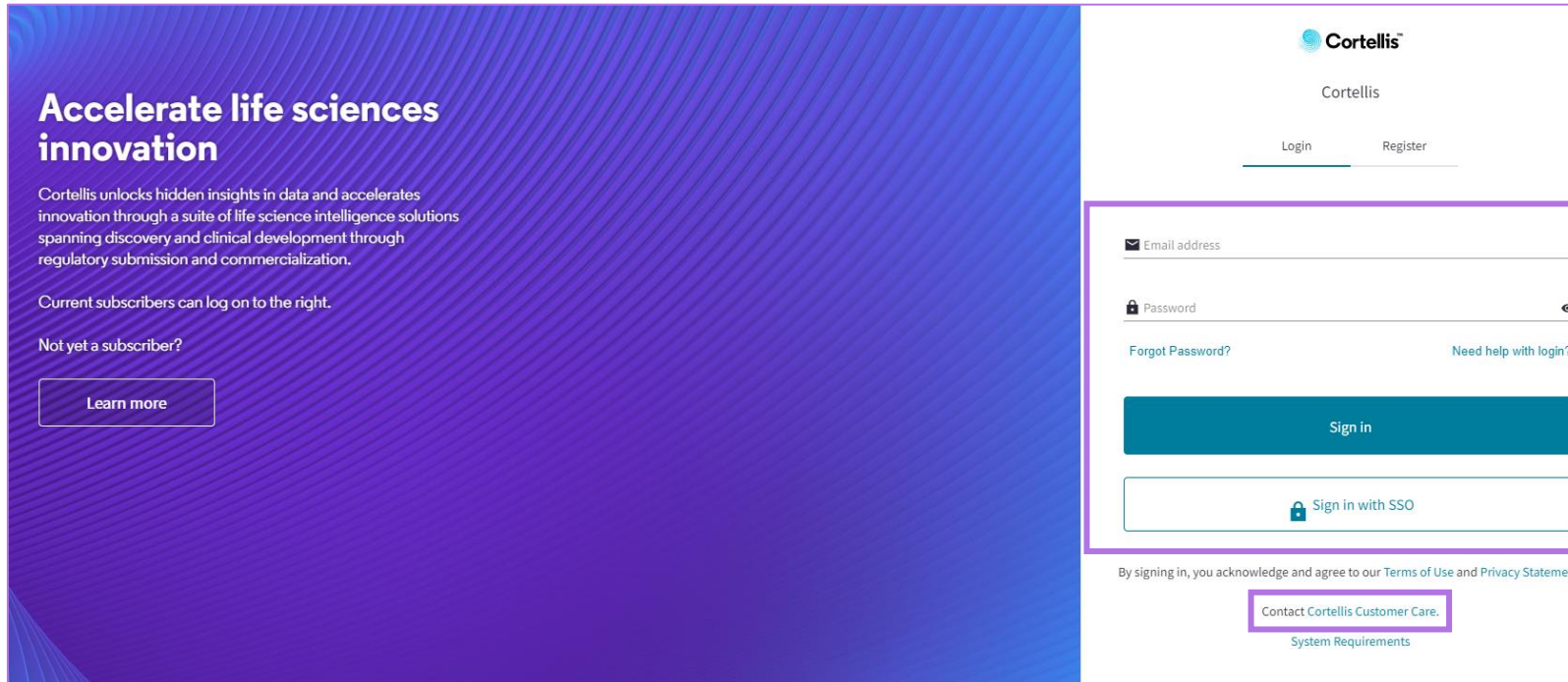


# Handout

- Slides 13-14: How to access Cortellis Regulatory Intelligence
- Slides 15-19: Cortellis English machine translations
- Slides 20-21: Advanced Therapy Products content
- Slides 22-26: Intuitive Search for Regulatory Summaries & Intelligence Reports
- Slides 27-30: Source Documents Search
- Slides 31-32: Get assistance with Cortellis



# How do I access Cortellis?



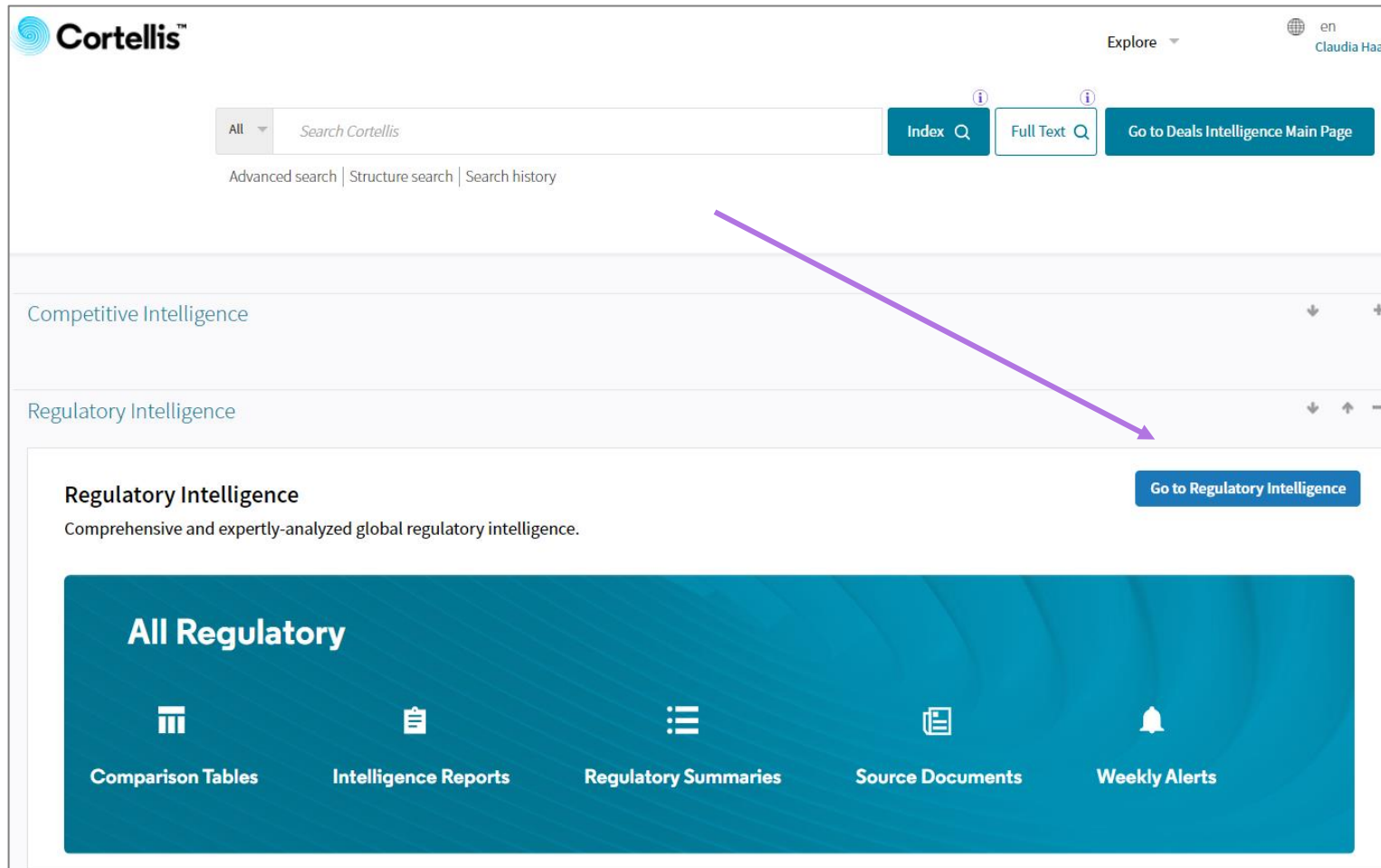
Go to this URL

Cortellis.com

- Username/password access:  
Enter your email address
- If you can't find the Clarivate email with your password, click Forgot Password to reset
- If you are a Single Sign On user, click the Sign in with SSO button and enter your company name
- Contact Customer Care from this link if you need help

# Cortellis Landing Page

If you subscribe to other Cortellis content, click the **"Go to..."** button to access Cortellis Regulatory Intelligence



# Cortellis Regulatory Homepage: Quick Search

Easily find new English machine translations in Cortellis

**Regulatory** **Analytics Tools** **CMC Intelligence**

**All** Comparison Tables <sup>i</sup> Intelligence Reports Regulatory Summaries <sup>New</sup> Source Documents <sup>Updated</sup>

### Quick Search

Quick search English keywords **Search** Advanced search

Filter

Country/Region Topic Document Type Document Category Date **Translation Status** All other filters Reset Filters

Machine Translation (37315) Authority Official (7129) Authority Unofficial (4819) Cortellis Translation (3757) Cortellis in Progress (1)

Cancel **Apply**

1. Click the Translation Status filter
2. Select Machine Translation
3. Click Apply
4. Click the blue Search button

# Cortellis results page

Easily find new English machine translations in Cortellis

Customize Columns

Sorted by Authority Acceptance Date

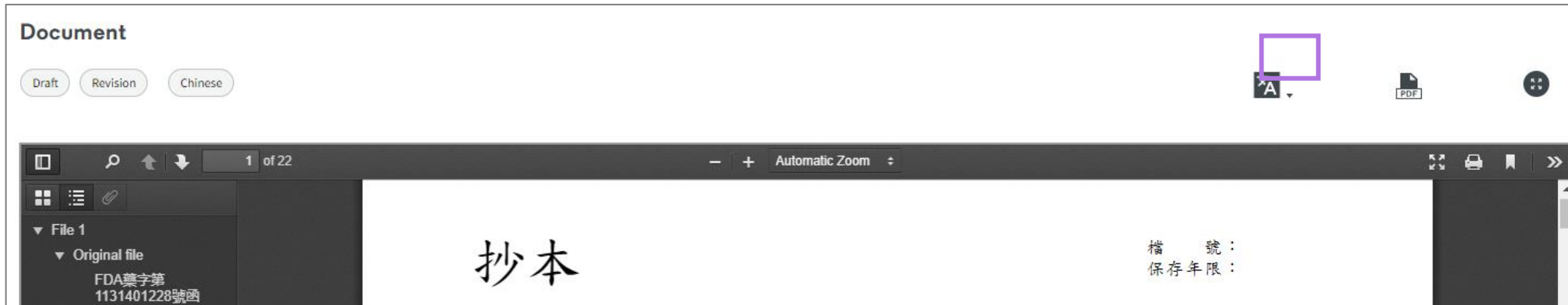
Summary	Relevance	Document Category	Topic	Medical Device Specialty	Document Type	Regulatory Version
<div><div><div>22-Nov-2024</div><div>TRRD</div></div></div>	<div>Title</div> <div>A to Z</div>	<div>Report Draft, 22-</div> <div>Reference Document</div>	<div>Dossier Format and Submis...</div> <div>GMP</div>	<div>N/A</div>	<div>Form</div>	<div>Revision</div>
<div><div><div>31-Mar-2024</div><div>ARRD</div></div></div>	<div>Authority Acceptance Date</div> <div>Most Recent</div> <div>IDRAC Number</div> <div>Highest to Lowest</div>	<div>Reference Document</div>	<div>Packaging and Labelling</div>	<div>N/A</div>	<div>Circular</div>	<div>None</div>
<div><div><div>22-Feb-2024</div><div>ZH</div><div>RD</div></div><div>V</div><div>CN</div></div>	<div>CDE Notification: Soliciting Public Comment on Technical Guidelines for Clinical Trials of Drugs for the Treatment of Gastroesophageal Reflux Disease</div>	<div>Reference Document</div>	<div>Clinical Research</div> <div>Pediatrics</div>	<div>N/A</div>	<div>Guideline</div>	<div>Draft</div>
<div><div><div>21-Feb-2024</div><div>ZH</div><div>RD</div></div><div>V</div><div>TW</div></div>	<div>TFDA Letter No.1131401228: Soliciting Public Comment on International Council for Harmonisation of Technical Requirements for Pharmaceuticals for</div>	<div>Reference Document</div>	<div>Authorities and Organizati...</div>	<div>N/A</div>	<div>Checklist</div>	<div>Draft</div> <div>Revision</div>
<div><div><div>21-Feb-2024</div><div>ZH</div><div>RD</div></div><div>V</div><div>CN</div></div>	<div>CDE Notification: Soliciting Public Comment on List of Reference Products for Generics (79th Batch) (Draft), 21-Feb-2024</div>	<div>Reference Document</div>	<div>Generics and Biosimilars</div> <div>Packaging and Labelling</div>	<div>N/A</div>	<div>Product Miscellaneous</div>	<div>Draft</div>

5. On the results page sort by acceptance date most recent  
- this brings the newest added documents to the top
6. Click the title to open a document of interest (e. g. a draft)



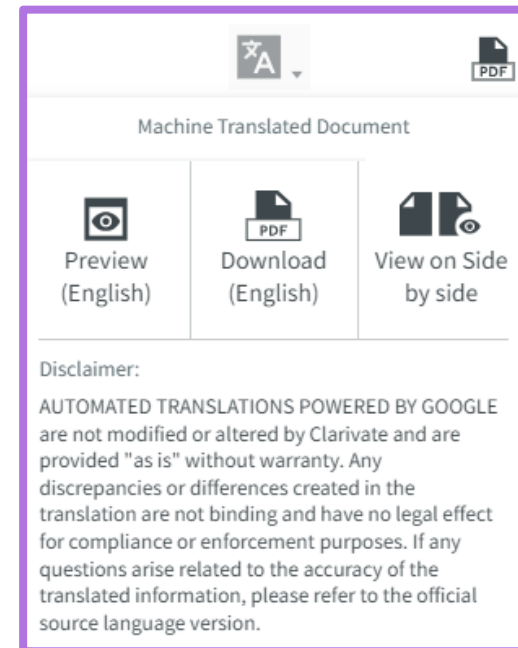
# Cortellis document page

Easily find new English machine translations in Cortellis



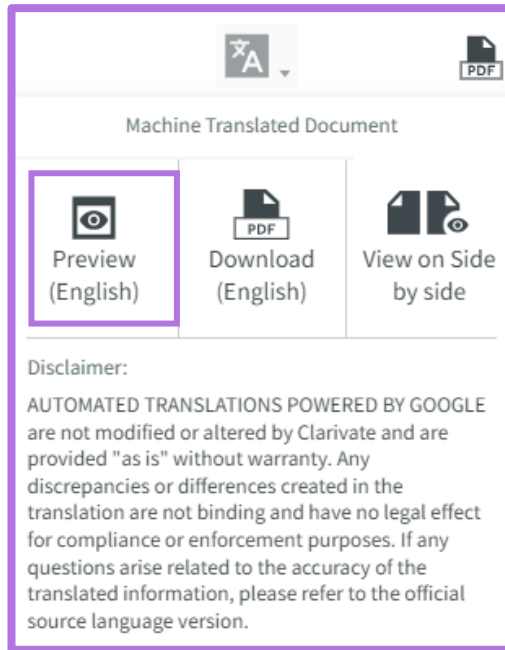
7. Click the new Machine Translation button

A pop-up appears giving you the options to view or download the machine translation or open it in the Side-by-Side viewer



# Cortellis document page

Easily find new English machine translations in Cortellis

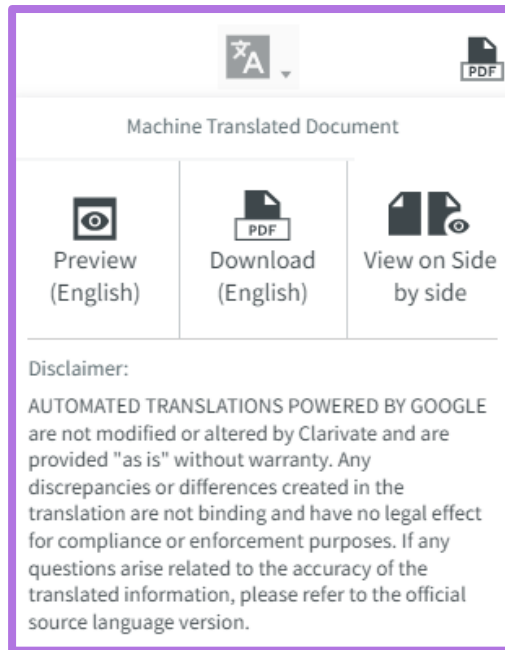


8. Click Preview to open the machine translation in its own pdf window



# Cortellis document page

Easily find new English machine translations in Cortellis



9. Click View on Side by Side to open and compare the local version and the machine translation side by side



# Cortellis Regulatory Summaries

Explore the new content for Advanced Therapy Products

**Regulatory** CMC Intelligence

All Comparison Tables<sup>i</sup> Intelligence Reports Regulatory Summaries<sup>New</sup> Source Documents<sup>Updated</sup>

**Browse** Search

Filter by Country / Region Advanced

Drugs and Biologics Medical Devices and IVDs

► How to Market...

▼ Advanced Therapy Medicinal Products

Algeria, Argentina, Australia, Austria, Belgium, Brazil, Bulgaria, Canada, Chile, China, Colombia, Costa Rica, Croatia, Czech Republic, Denmark, EAEU, Egypt, Estonia, European Union, Finland, France, Germany, Greece, Guatemala, Hong Kong, Hungary, India, Indonesia, Iraq, Ireland, Israel, Italy, Japan, Jordan, Kenya, Latvia, Lebanon, Lithuania, Malaysia, Mexico, Morocco, Netherlands, New Zealand, Nigeria, Norway, Panama, Peru, Philippines, Poland, Portugal, Romania, Russian Federation, Saudi Arabia, Serbia, Singapore, Slovakia, Slovenia, South Korea, Spain, Sweden, Switzerland, Taiwan, Thailand, Tunisia, Turkey, USA, Ukraine, United Arab Emirates, United Kingdom, Vietnam

► Combination Products

► Drugs for Pediatric Use

1. Click Regulatory Summaries
2. Click the magnifying glass and enter Advanced in the filtering search field near the top to quickly identify Summaries by title
3. In the How to Market section click Advanced Therapy Medicinal Products to see all available countries & regions
4. Click the country of interest to open the Summary



# Cortellis Regulatory Summaries

Explore the new content for Advanced Therapy Products

1 of 10

- Q1 Definitions and Legal Basis
  - Q1.1 What are Advanced Therapy Products in the country/region?
  - Q1.2 What is the regulatory framework for Advanced Therapy Products in the country/region?
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- Q5 Post-authorization of Advanced Therapy Products
  - Q5.1 Are there any advanced therapy-specific guidelines regarding pharmacovigilance?
- Q6 Are there any other specific requirements applicable to Advanced Therapy Products in the country/region?
- Q7 Annex

## Regulatory Summary

Continuously monitored and updated



### How to Market Advanced Therapy Products (Spain)

Reason for update	Date	Reason for update description
Formatting Change	2024-02-19	This document has been revised to update the following links: <ul style="list-style-type: none"><li>• <a href="#">EMA/149995/2008 rev.1</a> (IDRAC 268785): Draft Guideline on Safety and Efficacy Follow-Up and Risk Management of Advanced Therapy Medicinal Products, 25-Jan 2018;</li><li>• <a href="#">Regulation (EU) No 536/2014</a> (IDRAC 346051) of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/85/EC of 16-Apr-2014 (as Last Amended by Regulation (EU) 2022/2231 of the Council Directive (EU) 2022/2231 of the European Parliament and of the Council of 14-Nov-2022);</li><li>• <a href="#">NTA Volume 2C Rev 14.6</a> (IDRAC 346051) of the European Parliament and of the Council on Clinical Trials on Medicinal Products for Human Use, and Repealing Directive 2001/85/EC of 16-Apr-2014 (as Last Amended by Regulation (EU) 2022/2231 of the Council Directive (EU) 2022/2231 of the European Parliament and of the Council of 14-Nov-2022);</li><li>• <a href="#">EMA/CAT/852602/2018</a> (IDRAC 268785): Guideline on the Quality, Non-Clinical and Clinical Data Requirements for Investigational Advanced Therapy Medicinal Products, 31-Jan-2019.</li></ul>
New	2024-01-19	New

#### Q6 Are there any other specific requirements applicable to Advanced Therapy Products in the country/region?

##### Fees

According to [Royal Legislative Decree 1/2015](#) (IDRAC 292665) : Services and activities related to advanced therapy products not intended for marketing and being carried out by public entities integrated into the National Health System, will be exempt from payment of the corresponding rate, as well as scientific advisory services and clinical studies that are not going to be used to carry out for profit activities.

##### Hospitals

The AEMPS has developed a service on its website in order to bring the regulatory world closer to hospital entities for applications related to non-industrial manufacturing medicinal products (MFNI) to the Agency for evaluation. More information can be found at [AEMPS Information Note MUH\\_21/2023](#) (IDRAC 373941) .

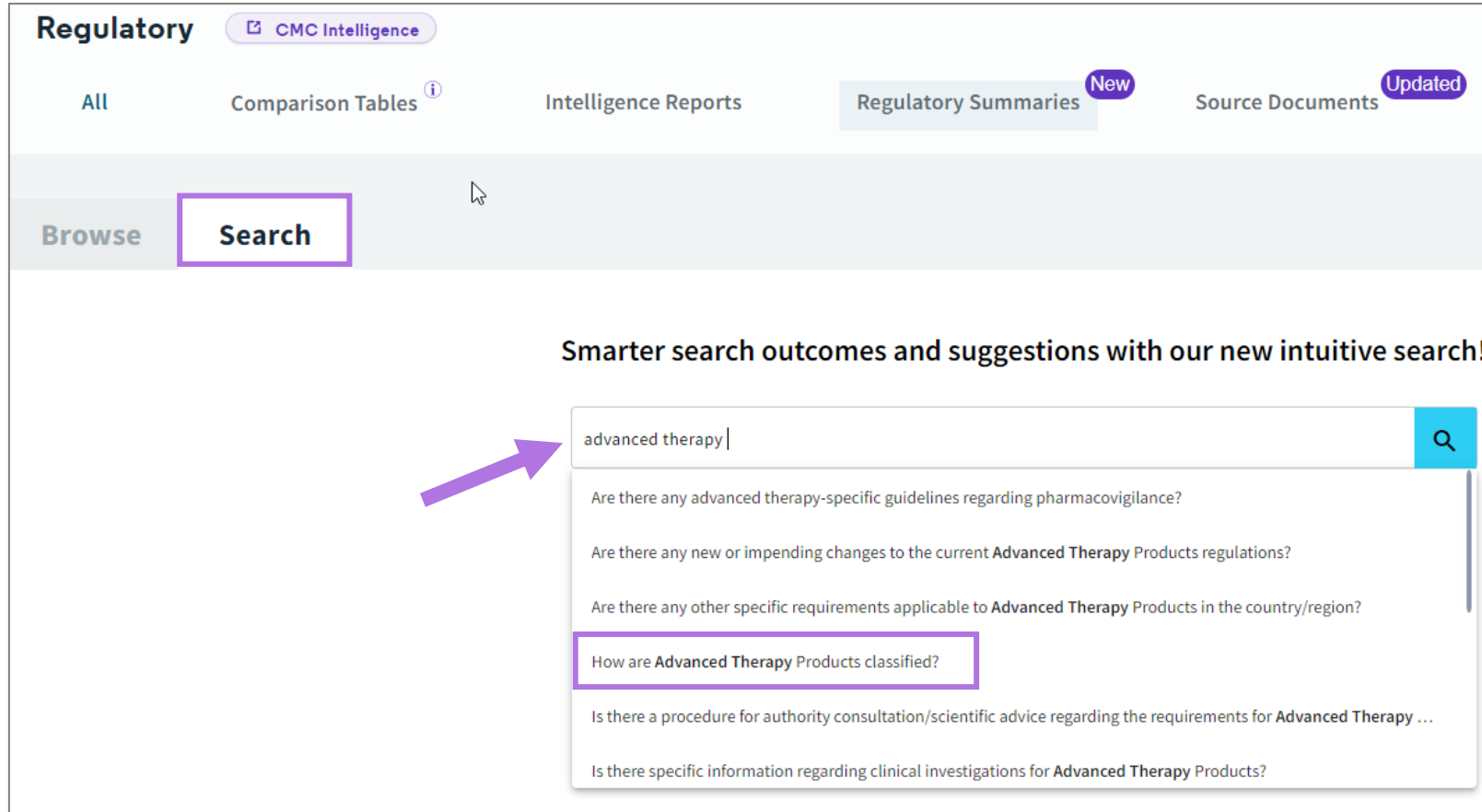
##### Compassionate Use

The authorization procedures for conducting clinical trials and compassionate use are the same for all advanced therapy medicinal products and are not affected by these exclusions. Where it is considered that an Advanced Therapy Medicinal Product may qualify for any of these exclusions, a consultation should be made to the AEMPS's Innovation and knowledge of medicinal products/ Innovation Office ([innov\\_spain@aemps.es](mailto:innov_spain@aemps.es)).

5. Use the bookmarks to jump to the sections and questions for interest
6. Click the hyperlinks to consult associated documents to learn more

# New Intuitive Search for Regulatory Summaries

Get better results with autosuggestions and easily compare answers country by country



1. On the Regulatory Summaries page click Search
2. Enter keywords or a question in English
3. Select a question from the list of suggestions

# New Intuitive Search for Regulatory Summaries

Get better results with autosuggestions and easily compare answers country by country

75 results found for

'How are Advanced Therapy Products classified?'

Filters

Country/Region Topic Last Updated Date

Sorted by Relevance Expand All Collapse All

Summary

1 09-Feb-2024 V  
MX EN RS  
**How to Market Advanced Therapy Products**  
This document includes specific information on advanced therapy medicinal products (gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products) including definitions, the legal framework, registration requirements, clinical research and bioethics, labeling, post-marketing requirements, pricing and reimbursement, and advertising.  
Country/Region: Mexico  
IDRAC Number: 378688  
Last Updated Date: 09-Feb-2024  
**How are Advanced Therapy Products classified?**  
The WHO and OPS have defined ATPMs as medical products of human origin as all biological products.

2 18-Jan-2024 V  
FI EN RS  
**How to Market Advanced Therapy Products**  
This document includes specific information on advanced therapy medicinal products (gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products) including definitions, the legal framework, registration requirements, clinical research and bioethics, labeling, post-marketing requirements, pricing and reimbursement, and advertising.  
Country/Region: Finland  
IDRAC Number: 377063  
Last Updated Date: 18-Jan-2024  
**How are Advanced Therapy Products classified?**  
The Regulation (EC) No 1394/2007 on advanced therapy medicinal products classifies the ATPMs as: Gene Therapy Medicinal product means a biological medicinal product which has the following characteristics: (a) It contains an active substance that contains or consists of a recombinant nucleic acid used in or administered to human beings with a view to regulating, repairing, adding or deleting a genetic sequence. (b) Its therapeutic, prophylactic or diagnostic effect relates directly to the recombinant nucleic acid sequence it contains, or to the product of genetic expression of this sequence. Somatic Cell Therapy Medicinal Product is a biological product that has the following characteristics: (a) Contains or consists of cells or tissues that may have been subject to substantial manipulation (annex 1) so that biological, physiological functions or structural properties relevant for the intended clinical use have been altered, or of cells or tissues that are not intended to be used for the same essential function(s) in the recipient and the donor. (b) Is presented as having properties for, is used in or administered to human beings with a view to treating, preventing or diagnosing a disease through the pharmacological, immunological or metabolic action of its cells or tissues. 3. Tissue Engineered Product (a) contains or consists of engineered cells or tissues (b) is presented as having properties for, or is used in or administered to human beings with a view to regenerating, repairing or replacing a human tissue. Cells or tissues shall be considered engineered 1. if they have been subjected to substantial manipulation so that biological characteristics, physiological functions or structural properties relevant for the intended regeneration, repair or replacement are achieved. 2. if they are not intended to be used for the same essential function or functions in the recipient as a donor. ATPMs as defined in Article 28 of Regulation EC No 1394/2007: The Hospital Exemption: ATPMs which are prepared on a non-routine basis according to specific quality standards and used within the same Member State in a hospital under the exclusive professional responsibility of a medical practitioner to comply with an individual prescription for a custom-made product for an individual patient are exempt from the Regulation. These types of ATPMs can be referred to as 'hospital-exempt' ATPMs and are exempt from the formal requirement for marketing authorisation from the European Commission.

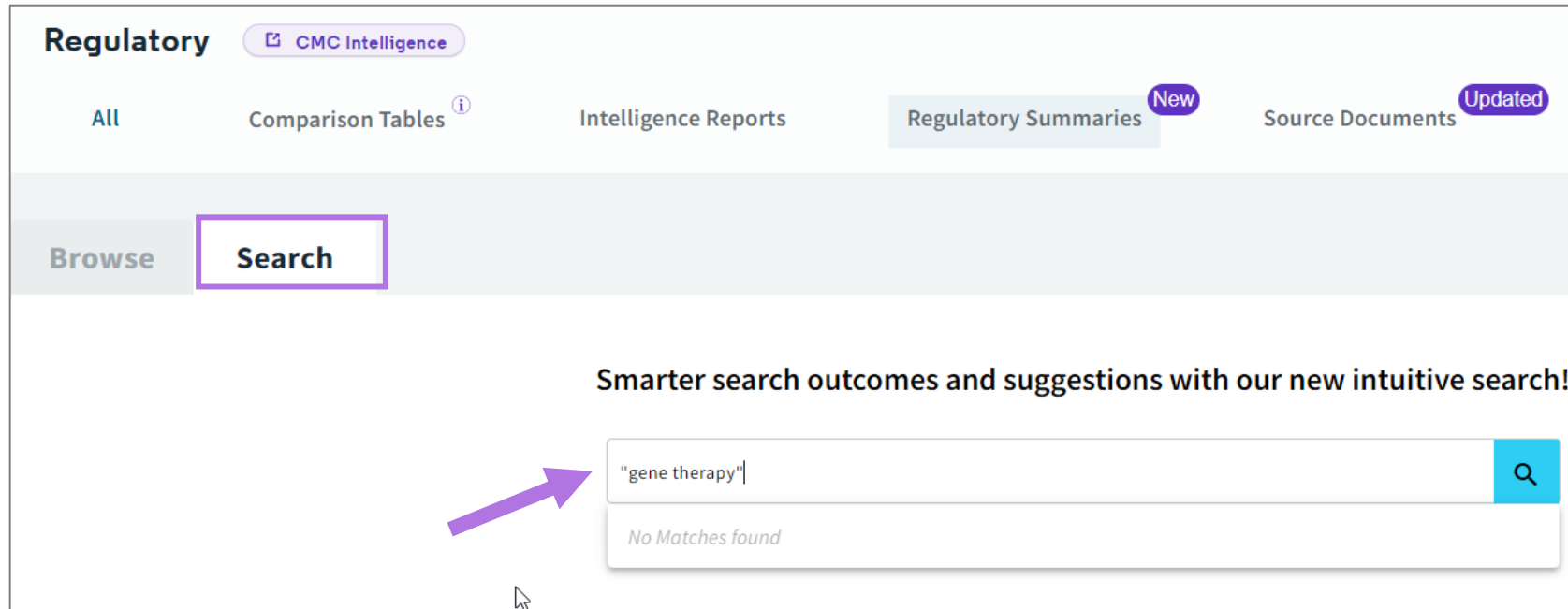
3 19-Jan-2024 V  
PA EN RS  
**How to Market Advanced Therapy Products**  
This document includes specific information on advanced therapy medicinal products (gene therapy medicinal products, somatic cell therapy medicinal products and tissue engineered products) including definitions, the legal framework, registration requirements, clinical research and bioethics, labeling, post-marketing requirements, pricing and reimbursement, and advertising.  
Country/Region: Panama  
IDRAC Number: 377141  
Last Updated Date: 19-Jan-2024  
**How are Advanced Therapy Products classified?**  
There is no classification of ATPM in Panama.

Relevant answers appear on the same page

4. Click Expand All to compare full answers across countries directly on the screen
5. If desired: Click a blue hyperlink to open a Regulatory Summary for more details

# New Intuitive Search for Regulatory Summaries

Quickly find out which Summaries talk about a topic for a country or region



1. On the Regulatory Summaries page click Search
2. Enter keywords or a question in English. For phrases use quotation marks
3. Click the blue Search button even if there were no suggestions



# New Intuitive Search for Regulatory Summaries

Quickly find out which Summaries talk about a topic for a country or region

**Browse Search**

Smarter search outcomes and suggestions with our new intuitive search!

"gene therapy"

150 results found for "gene therapy"

Filters

Country/Region Topic Last Updated Date

Clear Filters

Select all Clear all Sort by Frequency

My Regions

Country/Region

Singapore (11) Germany (8) China (6) Switzerland (6) France (5) Malaysia (5) European Union (4) Hong Kong (4) Italy (4) Japan (4) South Korea (4) Spain (4) Ukraine (4) USA (4)

Australia (3) Belgium (3) Brazil (3) Estonia (3) Israel (3) Norway (3) Serbia (3) United Kingdom (3) Bulgaria (2) Chile (2) Croatia (2) Denmark (2) Eurasian Economic Union (2)

Finland (2) Hungary (2) Indonesia (2) Saudi Arabia (2) Slovenia (2) South Africa (2) Sweden (2) Taiwan (2) Argentina (1) ASEAN (1) Austria (1) Canada (1) Colombia (1)

Cancel **Apply**

4. Click the Country/Region filter
5. Select the country of interest
6. Click Apply
7. Optional: click the Topic filter, select the topic(s) of interest and Click Apply
8. Click the blue Search button to filter your search

# New Intuitive Search for Regulatory Summaries

Quickly find out which Summaries talk about a topic for a country or region

11 results found for  
"gene therapy"

Filters

Country/Region Topic Last Updated Date

Sorted by Relevance Expand All Collapse All

Summary

1 16-Feb-2024 V  
SG EN RS  
**Application Format, Content and Submission**  
This document provides information on the format and content of applications with additional data  
Country/Region: Singapore  
IDRAC Number: 33358  
Last Updated Date: 16-Feb-2024

**What is the legal basis for local format in the country/region?** ▼  
It should be submitted via CD-rom or via the agency website in ICH CTD or ACTD format. One could

**Is ICH CTD format required/accepted in the country/region? For which type of application?** ▼  
The modular framework is referable in ICH Topic M4. The checklist of application is avail

**What are the language requirements?** ▼  
According to Guideline: TPB-GN-005-012: Guidance on Therapeutic Product Registration

**What are the Module 1 country/region-specific content requirements?** ▼  
**Gene**ral Information for Applicants A company seeking to market a therapeutic product

2 14-Dec-2023 V  
SG EN RS  
**Quality Assurance: Good Manufacturing Practice and Inspections**  
This document covers aspects of GMP and GMP inspection in Singapore.  
Country/Region: Singapore  
IDRAC Number: 63209  
Last Updated Date: 14-Dec-2023

**Product specific requirements** ▼  
HSA is a member of the Pharmaceutical Inspection Convention and Pharmaceutical Ins

**Introduction** ▼  
Under the Medicines Act of Singapore, Health Products Act (Chapter 122D): Health Pro

**Legal basis and regulatory framework** ▼  
The legal basis for GMP for marketed products is provided in PIC/S: Guide to Good Manu

This gives you the Summaries for the country talking about your topic or keyword(s) (including synonyms).

9. Click Expand All to see the context

10. If desired: Click a blue hyperlink to open a Regulatory Summary for more details

**Quality Assurance: Good Manufacturing Practice and Inspections**  
This document covers aspects of GMP and GMP inspection in Singapore.  
Country/Region: Singapore  
IDRAC Number: 63209  
Last Updated Date: 14-Dec-2023

**Product specific requirements** ▲  
HSA is a member of the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S) and adopt the PIC/S Guide to GMP for Medicinal Products (Part I) and its relevant annexes as our current GMP standards. According to PIC/S guide, there are specific requirements for sterile medicinal products, biological medicinal substances and products for human use, radiopharmaceuticals, veterinary medicinal products, gases, herbal medicinal products, liquids, creams and ointments, metered dose aerosol preparations for inhalation, ionising radiation in the manufacture of medicinal products, investigational medicinal products, medicinal products derived from human blood or plasma. Good Manufacturing Practice for Cell, Tissue and **Gene Therapy** Products The Guideline: Good Manufacturing Practice for Cell, Tissue And **Gene Therapy** Products, 01-Mar-2021 incorporate the requirements of the PIC/S Guide to Good Manufacturing Practice for Medicinal Products and the European Commission Guidelines on Good Manufacturing Practice specific to Advanced **Therapy** Medicinal Products. This Guidelines are applicable to the manufacture of CTGTP which are subjected to processing other than minimal manipulation and intended for medical use in humans.

**Introduction** ▲  
Under the Medicines Act of Singapore, Health Products Act (Chapter 122D): Health Products Act (Amendment of First Schedule) order, 2016 and Health Products Act (Chapter 122D): Health Products (Cells, Tissue and **Gene Therapy** Products) Regulations 2021, manufacturers and assemblers of therapeutic products and Chinese Proprietary Medicines (CPM) and Cells, Tissue and **Gene Therapy** Products (CTGTP) are required to conform to GMP. As a member of PIC/S, HSA's GMP auditors will conduct audits in accordance with PIC/S: Guide to Good Manufacturing Practice for Medicinal Products (PE 009-17), 21-Jun-2023 and its relevant annexes, which encompass all the recommendations of the World Health Organisation (WHO) in relation to GMP. The Good Manufacturing Practice (GMP) certificate issued by the HSA is a certificate relating to the manufacture of a therapeutic product, medicinal product, an active pharmaceutical ingredient or a cosmetic product and CTGTP attesting to its conformity with the relevant GMP Standard as appropriate.

**Legal basis and regulatory framework** ▲  
The legal basis for GMP for marketed products is provided in PIC/S: Guide to Good Manufacturing Practice for Medicinal Products (PE 009-17), 21-Jun-2023, the Medicines Act of Singapore and Health Products Act (Chapter 122D): Health Products Act (Amendment of First Schedule) order, 2016. HSA Guides: Guideline: Guidance on the Licensing, GMP Certification, and Inspection of Therapeutic Products Manufacturers, 03-Jan-2022 Guideline: GUIDE-MQA-020-015: Guidance Notes on GMP Conformity Assessment of an Overseas Manufacturer, Jul-2020 Guideline: GN-MQA-031-001: Secondary Packaging of Therapeutic and Medicinal Products, 07-May-2021 Guideline: GUIDE-MQA-019-008: Guidance Notes on Preparation of a Quality System Dossier (QSD), Dec-2021 Guideline: Good Manufacturing Practice for Cell, Tissue And **Gene Therapy** Products, 01-Mar-2021 Health Products Act (Chapter 122D): Health Products (Cells, Tissue and **Gene Therapy** Products) Regulations 2021 PIC/S Guides: PIC/S: Guide to Good Manufacturing Practice for Medicinal Products (PE 009-17), 21-Jun-2023 PIC/S: Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of a Site Master File, 01-Jan-2011 PIC/S: Recommendations on Sterility Testing, 25-Sep-2007 PIC/S: Recommendations on Validation Master Plan, Installation and Operational Qualification, Non-Sterile Process Validation and Cleaning Validation, 25-Sep-2007 PIC/S Recommendation: Recommendation on the Validation of Aseptic Processes, 01-Jan-2011 PIC/S: Guideline on Setting Health Based Exposure Limits for use in Risk Identification in the Manufacture of Different Medicinal Products in Shared Facilities, 18-Apr-2018 PIC/S: Guidelines on the Formalised Risk Assessment for Ascertaining the Appropriate Good Manufacturing Practice for Excipients of Medicinal Products for Human use, 18-Apr-2018 More GMP-related guidelines are published on the PIC/S website. ICH Guides: ICH Guideline Topic Q7 Q&As: Good Manufacturing Practice for Active Pharmaceutical Ingredients, Questions and Answers, 10-Jun-2015

# Upgraded Source Document Search

Search all source documents including the pdf full text using English or local language keywords

**Regulatory**

☒ Drugs & Biologics ☒ Medical Devices & IVDs

All Comparison Tables Intelligence Reports Regulatory Summaries **Source Documents**

**Search** [View all](#)

stability **Search** Advanced search

Filter

**Document Type** **Country/Region** **Topic** Date Translation Status Medical Devices Specialty All other filters Reset Filters

q ☐ Select all ☒ Clear all Sort by Frequency

Regulatory Procedures (43) **Dossier Format and Submission (40)** Manufacturing and Control (33) Packaging and Labelling (19) Import Export (17) Compliance and Inspection (12) Distribution (10)

Generics and Biosimilars (10) Legislative Framework (10) Active Pharmaceutical Ingredient (6) Pharmacovigilance Technovigilance Risk Management (5) Product Assessment (5) Clinical Research (4)

Authorities and Organizations (3) Fees (2) GXP (2) Pricing Reimbursement HTAs (2) Advertising and Promotion (1) Environment (1) Non Clinical Studies (1) Post authorization Studies (1)

Cancel **Apply**

1. Click Source Documents
2. Enter your English or local language keyword(s) in the search bar
3. Optional: select filters and apply as desired, e.g.
  - Document Type: Guideline
  - Country/Region: Egypt
  - Topic: Dossier Format and Submission
4. Click the blue Search button

# Upgraded Source Document Search

Search all source documents including the pdf full text using English or local language keywords

57 results for 'stability'

[Switch to Comparison Tables](#)

Refine Search Include Outdated

stability Search

Filter

Document Type Country/Region Topic Date Translation Status Medical Devices Specialty All other filters Reset Filters

Showing 1-10 of 57 results

Customize Columns Sorted by Relevance

<input checked="" type="checkbox"/>	Summary	<input checked="" type="checkbox"/> Relevance <span>Lowest to Highest</span>	Abstract	Last Updated Date	Reason for Update	Country/Region
<input checked="" type="checkbox"/>	01-Oct-2021 AR, EN <span>RD</span>	Title Country/Region A to Z <span>↓</span> A to Z <span>↓</span>	g Pharmaceutical 2021 This document contains requirements for submitting pharmaceutical product analysis file to the Egyptian Drug Authority (EDA).	17-Dec-2021	Please note that the delay in document addition is due to external technical changes (new website, progressive addition)	Egypt
<input checked="" type="checkbox"/>	07-Feb-2022 EN <span>RD</span>	Authority Acceptance Date IDRAC Number Most Recent <span>↓</span> Highest to Lowest <span>↓</span>	ce for Ownership & on 1, 07-Feb-2022 This guideline was published by the Egyptian Drug Authority (EDA) to provide manufacturers with detailed lists of	28-Apr-2022	Please note that the delay in integration is due to a scope extension that includes a more comprehensive regulatory summary	Egypt
<input checked="" type="checkbox"/>	26-Jul-2023 EN <span>RD</span>	<span>V</span> <span>EG</span> Submission Guidance for Human Pharmaceutical Product Initial Re-registration File According to EDA Chairman Decree 150/2022, 26-Jul-2023	This guidance applies for any human pharmaceutical product submitted for re-registration according to EDA Chairman	19-Dec-2023	N/A	Egypt
<input checked="" type="checkbox"/>	13-Sep-2022 EN <span>RD</span>	<span>V</span> <span>EG</span> Soft File Arrangement Guidance For Initial Re-Registration Products According to EDA Chairman Decree 150/2022 (Code QI:CAPP.013.01), 13-Sep-2022	In this document, the Egyptian Drug Authority (EDA) provides the structure of the renewal files that are submitted as per EDA	09-Feb-2023	Please note that the delay in document addition is due to external technical changes (posted on a new webpage).	Egypt

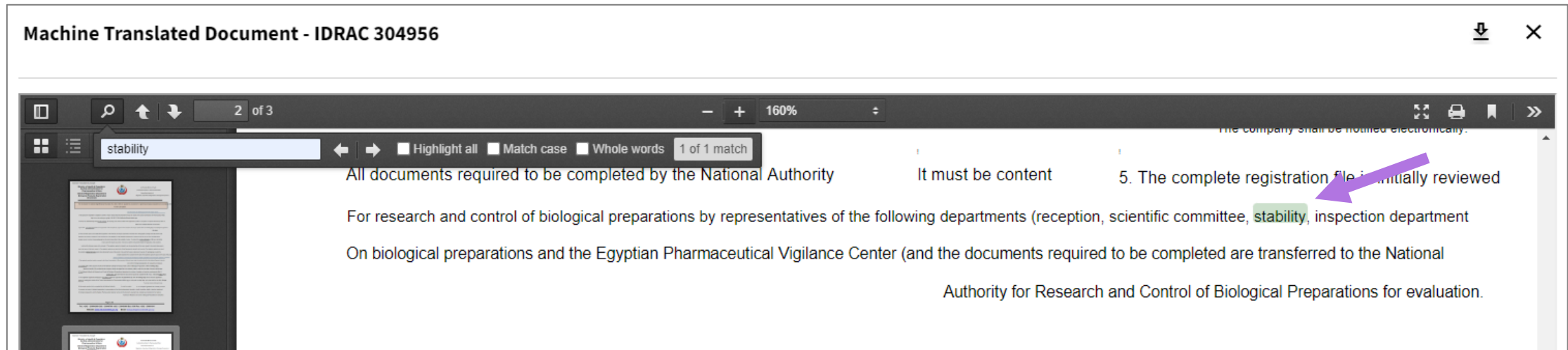
Results retrieved by relevancy highest to lowest as default, will mostly include your English keywords in the title and/or abstract.

- Optional: Change the relevance sorting to lowest to highest, to retrieve documents that may not mention your keyword in title or abstract
- Click the hyperlinked title to open a document of interest

# Upgraded Source Document Search

Search all source documents including the pdf full text using English or local language keywords

7. Use the Find in Document tool to jump to the relevant section(s) talking about your keyword(s).





# Source Document Search and Quick Search Comparison

Different ways of searching depending on your queries and needs

## Source Document Search

- Supports English and local language keywords
- Searches local source/reference documents only
- Searches entire documents including pdf full text („Search in any language anywhere“)
- More comprehensive results: usually retrieves more results than Quick Search
- Stability example showcased (Slides XX) retrieved 57 results as of Feb 22nd, 2024

## Quick Search

- Supports English keywords only
- Searches through all Cortellis regulatory documents (including Regulatory Summaries and Intelligence Reports)
- Searches the title, abstract, reason for update and indexing fields (all provided in English)
- More target results (keywords being always mentioned in title and/or abstract and/or other key fields)
- Stability example run with Quick Search retrieved 19 results as of Feb 22nd, 2024

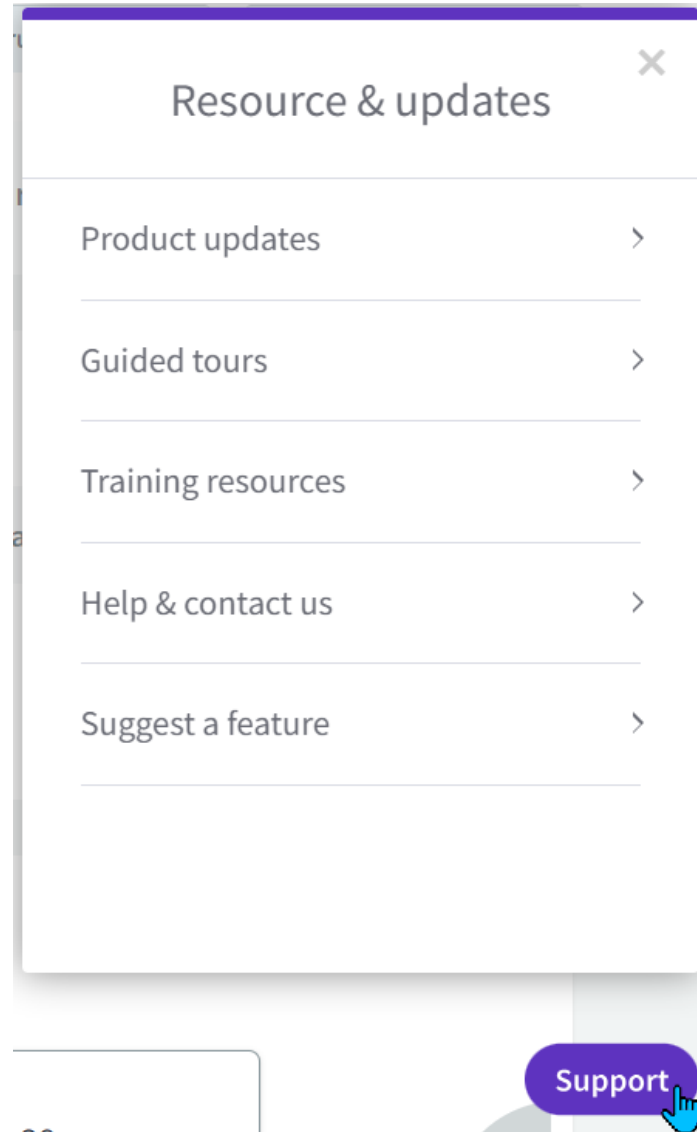
# Get assistance with Cortellis

In-product guidance to assist you with your questions

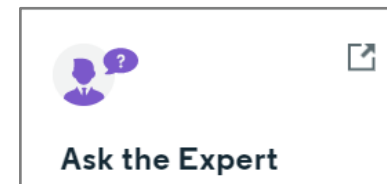
- Click at the Support button at the bottom of the screen

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- Help & contact us - contact Customer Care
- Guided tours - walk through the Cortellis platform
- Training resources - recorded trainings, Quick guides and short videos
- Ask the Expert (on Regulatory homepage)





# Thank you! Questions?

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