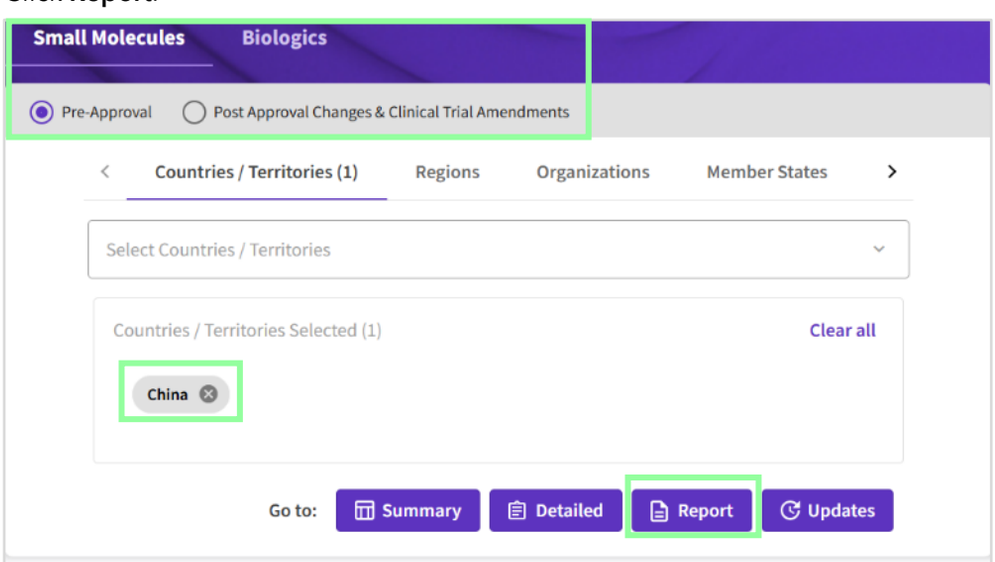
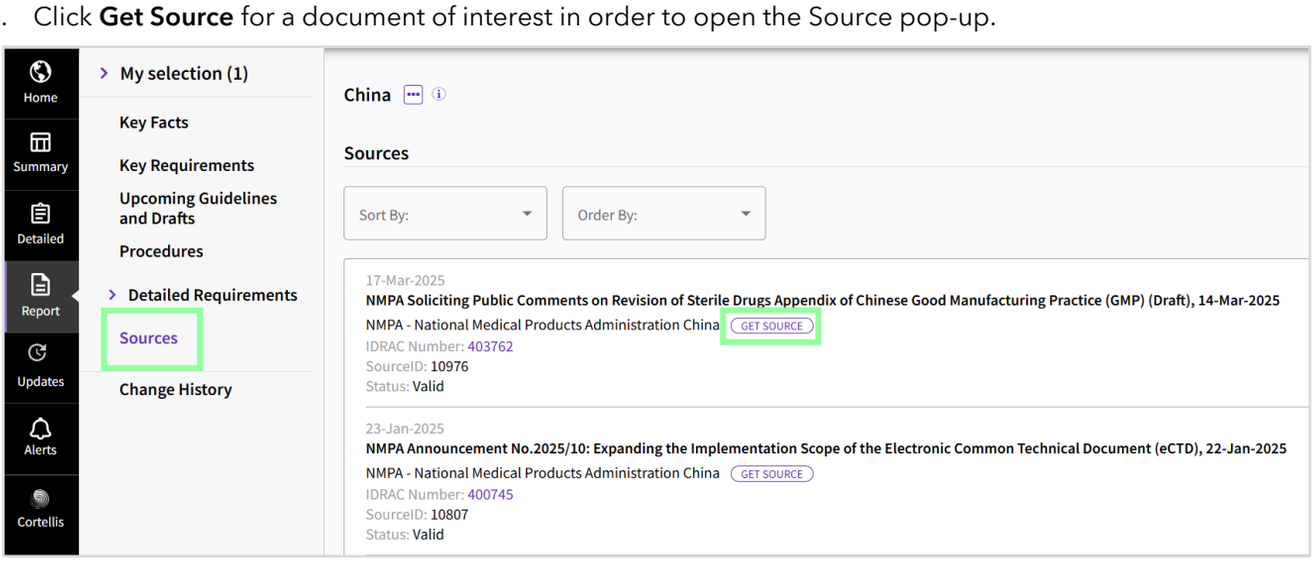
Source documents and English translations

Example: ***Find Source documents and English translations for China.***

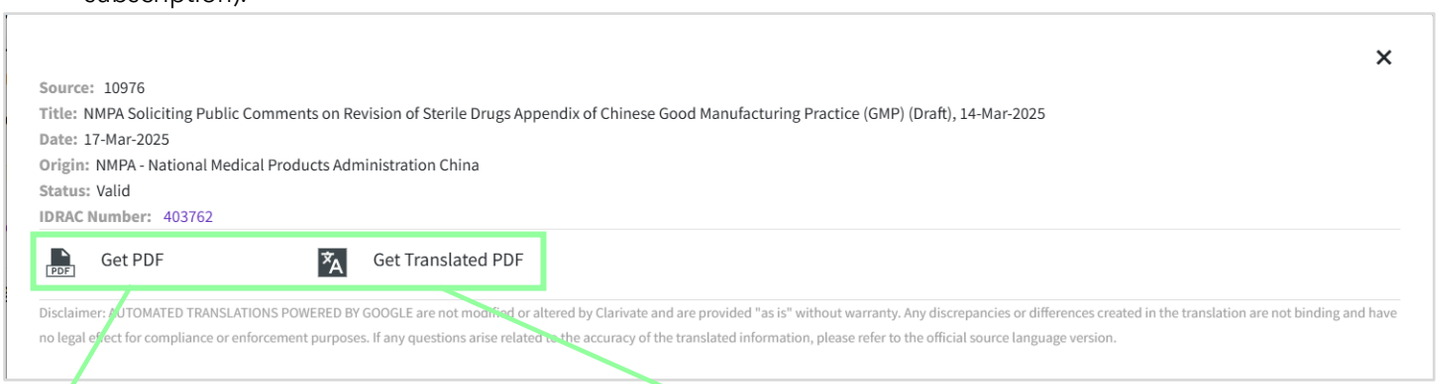
1. From the home page, **select your content**: either Small Molecules or Biologics and either Pre-Approval or Post Approval Changes & Clinical Trial Amendments. For this example, Small Molecules and Pre-Approval are selected, however, regardless of the content selected – or available to you via your subscription – the procedure for finding Sources is the same.
2. Open **Select Countries/Territories** and click **China** and **Apply**.
3. Click **Report**.

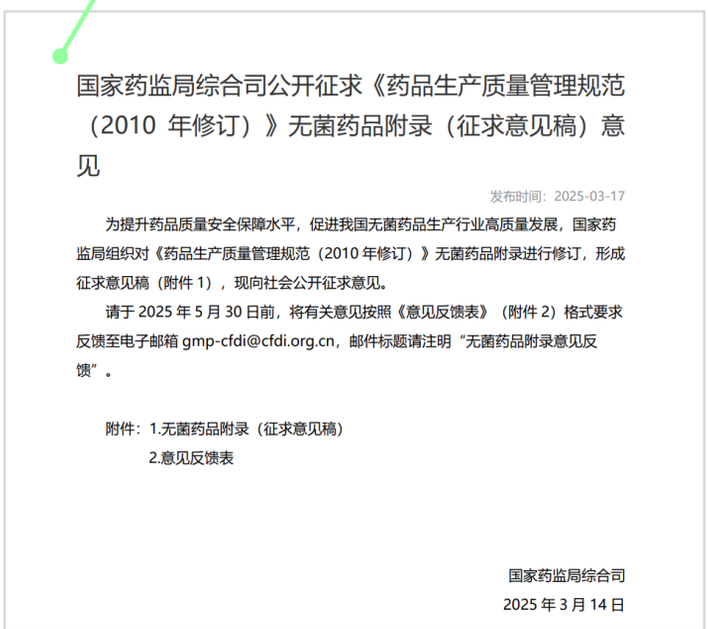


4. Select **Sources** in the report menu. This provides the list of Sources used to create the structured report content for China.
5. Click **Get Source** for a document of interest in order to open the Source pop-up.



6. **Get Translated PDF** opens the Google Translated English version of the document.
7. **Get PDF** opens the native language version of the document.
8. Clicking the **IDRAC Number** opens the document in Cortellis Regulatory Intelligence (requires additional subscription).





国家药监局综合司公开征求《药品生产质量管理规范（2010 年修订）》无菌药品附录（征求意见稿）意见

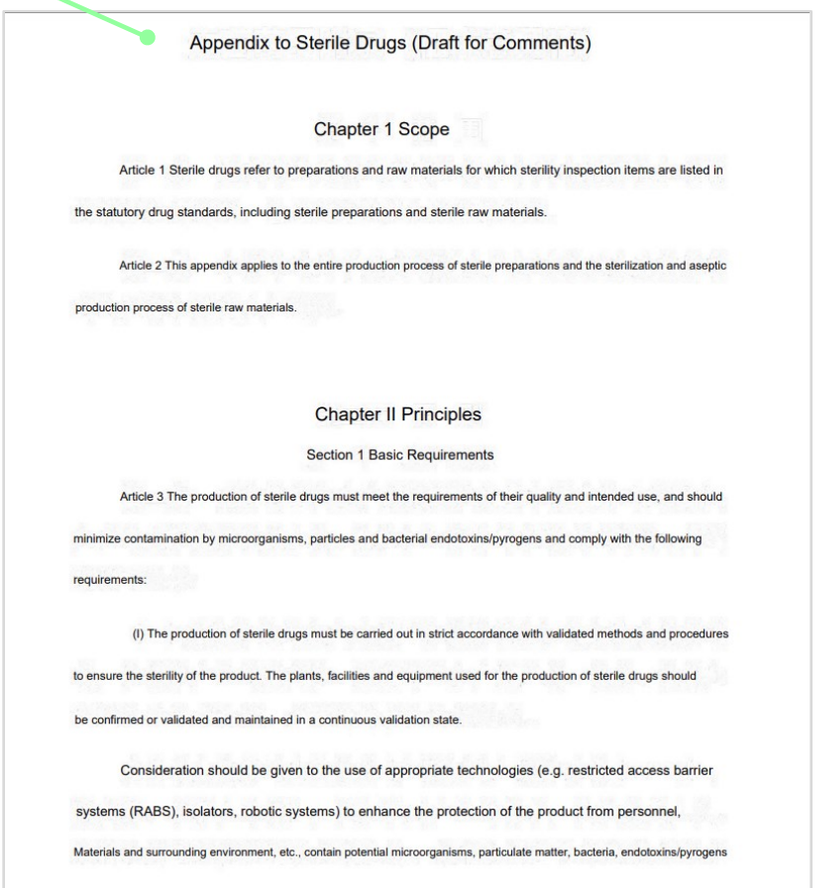
发布时间：2025-03-17

为提升药品质量安全保障水平，促进我国无菌药品生产行业高质量发展，国家药监局组织对《药品生产质量管理规范（2010 年修订）》无菌药品附录进行修订，形成征求意见稿（附件 1），现向社会公开征求意见。

请于 2025 年 5 月 30 日前，将有关意见按照《意见反馈表》（附件 2）格式要求反馈至电子邮箱 gmp-cfdi@cfdi.org.cn，邮件标题请注明“无菌药品附录意见反馈”。

附件：1.无菌药品附录（征求意见稿）
2.意见反馈表

国家药监局综合司
2025 年 3 月 14 日



Appendix to Sterile Drugs (Draft for Comments)

Chapter 1 Scope

Article 1 Sterile drugs refer to preparations and raw materials for which sterility inspection items are listed in the statutory drug standards, including sterile preparations and sterile raw materials.

Article 2 This appendix applies to the entire production process of sterile preparations and the sterilization and aseptic production process of sterile raw materials.

Chapter II Principles

Section 1 Basic Requirements

Article 3 The production of sterile drugs must meet the requirements of their quality and intended use, and should minimize contamination by microorganisms, particles and bacterial endotoxins/pyrogens and comply with the following requirements:

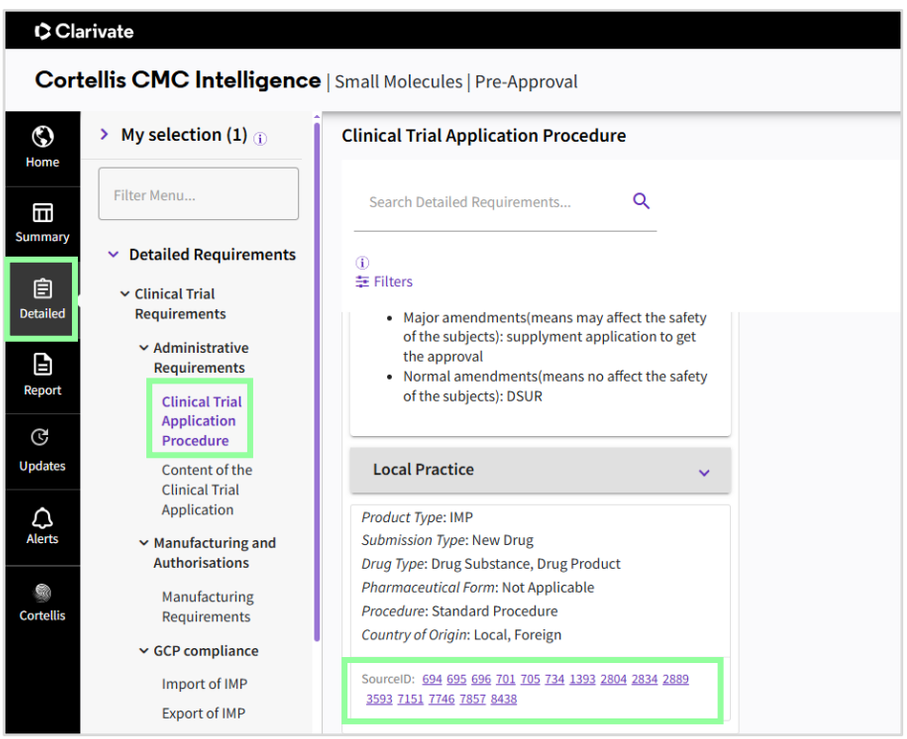
(I) The production of sterile drugs must be carried out in strict accordance with validated methods and procedures to ensure the sterility of the product. The plants, facilities and equipment used for the production of sterile drugs should be confirmed or validated and maintained in a continuous validation state.

Consideration should be given to the use of appropriate technologies (e.g. restricted access barrier systems (RABS), isolators, robotic systems) to enhance the protection of the product from personnel, Materials and surrounding environment, etc., contain potential microorganisms, particulate matter, bacteria, endotoxins/pyrogens

Source documents and English translations are also available in the Detailed Requirements section.

Continue with China as the selected country or go back to the Homepage and select others as desired.

1. Once the desired countries are selected, click **Detailed** in the black navigation bar.
2. Select your content of interest from the menu on the left, for this example let's select **Clinical Trial Application Procedure.**
3. Read and scroll through the Official Regulations and Local Practice content. Underneath you'll find the links to the Source documents.



4. Click the **SourceID** hyperlinks to open the Source pop up and access the native language and English translated documents as explained above.

*Please note that some documents may not have a Google translated English version available.

For any questions, please contact Customer Care at **LSH.support@clarivate.com**