康利华咨询
A Tigermed Company

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药政法规更新摘要

目錄

法规要闻

CDE 发布《儿童用药沟通交流中 I 类会议申请及管理工作细则（试行）》

4 月 18 日，国家药监局药审中心发布《儿童用药沟通交流中 I 类会议申请及管理工作细则（试行）》，自发布之日起施行。

国家药监局 公安部 卫健委发布关于调整麻醉药品和精神药品目录的公告

4 月 18 日，国家药监局、公安部、国家卫生健康委发布了关于调整麻醉药品和精神药品目录的公告（2023 年第 43 号），自 2023 年 7 月 1 日起施行。内容如下：

一、 将奥赛利定列入麻醉药品目录。

二、 将苏沃雷生、吡仑帕奈、依他佐辛、曲马多复方制剂列入第二类精神药品目录。

三、 将每剂量单位含氢可酮碱大于 5 毫克，且不含其它麻醉药品、精神药品或药品类易制毒化学品的复方口服固体制剂列入第一类精神药品目录。

四、 将每剂量单位含氢可酮碱不超过 5 毫克，且不含其它麻醉药品、精神药品或药品类易制毒化学品的复方口服固体制剂列入第二类精神药品目录。

CFDI 发布《药物非临床研究质量管理规范认证申请资料要求》

4 月 24 日，国家药监局核查中心发布《药物非临床研究质量管理规范认证申请资料要求》，自 2023 年 7 月 1 日起施行。

EC 公布药品立法改革提案

4 月 26 日，欧盟委员会（European Commission）在官网公布了最新的药品改革立法提案，提出了一项 Directive 和一项 Regulation 的更新：

- COM(2023) 192 ：Proposal for a DIRECTIVE OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on the Union code relating to medicinal products for human use, and repealing Directive 2001/83/EC and Directive 2009/35/EC：将废止并取代 Directive 2001/83/EC 和 Directive 2009/35/EC，整合 Regulation (EC) No 1901/2006 的有关部分。
- COM(2023) 193 ：REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL laying down Union procedures for the authorisation and supervision of medicinal products for human use and establishing rules governing the European Medicines Agency, amending Regulation (EC) No 1394/2007 and Regulation (EU) No 536/2014 and repealing Regulation (EC) No 726/2004, Regulation (EC) No 141/2000 and Regulation (EC) No 1901/2006：修正 Regulation (EC) No 1394/2007 和 Regulation (EU) No 536/2014，废止并取代 Regulation (EC) No 726/2004, Regulation (EC) No 141/2000，废止并整合 Regulation (EC) No 1901/2006 的有关部分。

注：

- *Directive 2001/83/EC and Regulation (EC) No 726/2004 (the general pharmaceutical legislation)*

- *Directive 2009/35/EC on the colouring matters which may be added to medicinal products*
- *Regulation (EC) No 141/2000 on medicines for rare diseases (the Orphan Regulation)*
- *Regulation (EC) No 1901/2006 on medicines for children (the Paediatric Regulation)*
- *Regulation (EC) No 1394/2007, the ATMP Regulation*
- *Regulation (EU) No 536/2014, the Clinical Trials Regulation*

CDE 发布多个技术指导原则

4 月 7 日，国家药监局药审中心发布《抗肿瘤抗体偶联药物临床研发技术指导原则》（2023 年第 25 号）、《基于动物法则的药物研究技术指导原则（试行）》（2023 年第 26 号），自发布之日起施行。

4 月 12 日，国家药监局药审中心发布《成人用药数据外推至儿科人群的定量方法学指导原则（试行）》（2023 年第 27 号）、《呼吸道合胞病毒感染药物临床试验技术指导原则》（2023 年第 28 号），自发布之日起施行。

4 月 14 日，国家药监局药审中心发布《基因治疗血友病临床试验设计技术指导原则》（2023 年第 29 号）、《与恶性肿瘤治疗相关中药新药复方制剂临床研发技术指导原则（试行）》（2023 年第 30 号），自发布之日起施行。

4 月 26 日，国家药监局药审中心发布《肿瘤主动免疫治疗产品临床试验技术指导原则（试行）》（2023 年第 32 号）、，自发布之日起施行。

4 月 27 日，国家药监局药审中心发布《慢性乙型肝炎病毒感染治疗药物临床试验技术指导原则》（2023 年第 31 号）、《人源干细胞产品药学研究与评价技术指导原则（试行）》（2023 年第 33 号），自发布之日起施行。

4 月 28 日，国家药监局药审中心发布《抗肿瘤光动力治疗药物临床研发技术指导原则（试行）》（2023 年第 34 号）、，自发布之日起施行。

征求意见稿-

4 月 11 日，国家药监局信息中心发布《药品监管信息化标准体系（征求意见稿）》，征求意见时限至 2023 年 5 月 4 日。

4 月 21 日，国家药品监督管理局特殊药品检查中心发布《麻醉药品、精神药品和药品类易制毒化学品生产质量管理指导原则》（征求意见稿）》，征求意见时限至 2023 年 5 月 9 日。此次为第三次征求意见，前两次分别为 2017.10.17（总局办公厅）、2018.06.07（国家药监局办公室）以 GMP 附录命名征求意见。

4 月 26 日，国家药监局核查中心发布《药物非临床研究质量管理规范认证检查要点和判定原则（征求意见稿）》。

技术总结

ANDA 递交的 QBR 中与无菌产品相关部分摘要（续）

注：根据递交指南，灭菌和除热原的信息分成了两个部分，分别在 2.3.P.3.3 Description of the Manufacturing Process and Process Controls 和 2.3.P.3.5 Process Validation and/or Evaluation 进行总结。

几个文件中的术语和缩写（具体含义请自行脑补）：

- *Heat Distribution (HD)*
- *Heat Penetration (HP)*
- *Thermocouple (TC)*
- *Resistance Temperature Detector (RTD)*
- *Endotoxin Indicator (EI)*
- *Biological Indicator (BI)*
- *Programmable Logic Controller (PLC)*
- *Exhibit Batches refer to any batch submitted in support of an NDA or ANDA. This includes bioequivalence, test, and commercial production batches of a drug product.*

2.3.P.3 Manufacture

2.3.P.3.3 Description of the Manufacturing Process and Process Controls

How will the drug product manufacturing process be designed for commercial production? 药品工艺将如何设计用于商业生产？
Q: What information should be presented in this section? 需要提供什么信息？
A: Provide a general summary of the manufacturing process and in-process controls from the end of compounding through terminal sterilization. Describe any steps performed to minimize bioburden prior to terminal sterilization (i.e. use of filtration and/or aseptic processing prior to terminal sterilization, component/ equipment sterilization, or use of pre-sterilized components). Indicate hold time specifications and hold conditions. (Note: Extended hold times or hold times for products that support microbial growth may necessitate additional studies to assess the microbiological quality of the bulk solution). Describe any routine procedures that are in place to test bioburden and/or container/closure integrity during commercial production, as applicable. • 提供从配制结束到终端灭菌的生产工艺和过程控制的总体摘要。 • 描述在终端灭菌之前为最大程度降低生物负荷而执行的任何步骤（即在终端灭菌、组件/设备灭菌或使用预灭菌组件之前使用过滤和/或无菌操作）。 • 标明保留时间标准和保留条件。 （注：延长保留时间或支持微生物生长的产品的保留时间可能需要额外的研究来评估产品溶液的微生物质量）。 • 描述在商业生产过程中测试生物负荷和/或容器/密封系统完整性的任何常规程序（如适用）。

TERMINAL MOIST HEAT STERILIZATION

• Autoclave process and performance specifications

What is the design space of the terminal sterilization process for commercial production and what are the critical parameters of the production terminal sterilization cycle? 商业化生产的终端灭菌工艺设计空间是什么，终端灭菌周期的关键参数是什么？
Q: What information should be presented in this section? 需要提供什么信息？
A: Provide a description of the terminal sterilizer(s) to be used for commercial production including make, model/equipment number, and process type (saturated steam, water spray, etc.). Indicate if the process is designed as an overkill, bioburden-based, or combined bioburden/biological indicator-based process. Indicate process control parameters to be used for commercial production including time, temperature, F_0, and pressure set points and acceptance criteria (including limits and ranges), as applicable. • 提供用于商业生产的终端灭菌器的描述，包括品牌、型号/设备编号和工艺类型（饱和蒸汽、水喷淋等）。 • 说明该工艺是设计为过度杀灭、基于生物负荷，还是基于生物负荷/生物指示剂的组合。 • 说明用于商业生产的过程控制参数，包括时间、温度、F_0 和压力设定点以及可接受标准（包括限度和范围）（如适用）
Q: What additional information should be provided if parametric release of the drug product is being requested? 如果要求对药品进行参数放行，应提供哪些额外信息？
A: Indicate the critical parameters and acceptance criteria that must be met for commercial batch release. 说明商业批放行必须满足的关键参数和可接受标准。

• Autoclave loading patterns

What loading patterns are included in the sterilization process design space for the commercial terminal sterilization of the finished drug product? 商业化生产的终端灭菌的灭菌工艺设计空间中包括哪些装载模式？
Q: What information should be presented in this section? 需要提供什么信息？
A: Describe autoclave loading patterns for commercial production, including the following: ♦ Indication if the load sizes will range within defined minimum and maximum load sizes or if a fixed load size will be used ♦ Number of drug product units per minimum, maximum, or fixed load ♦ Arrangement of the drug product units within the load 描述用于商业化生产的高压灭菌器的装载模式，包括以下内容： ♦ 说明装载是否在定义的最小和最大装载范围内，或者是否将使用固定装载 ♦ 每个最小、最大或固定装载的药品数量 ♦ 在装载内药品的布置情况

• Methods and controls to monitor production cycles

How will the critical parameters of the terminal sterilization cycle/process be monitored and controlled during commercial production? 在商业生产过程中，如何监测和控制终端灭菌周期/过程的关键参数？
Q: What information should be presented in this section? 需要提供什么信息？
A: Indicate the types of monitors used and the location of each within the chamber for monitoring the critical parameters during commercial production. Indicate how the critical parameters are controlled (i.e. by a PLC or otherwise). • 说明所使用的监测器类型以及每种监测器在腔室中的位置，以便在商业生产过程中监测关键参数。 • 说明如何控制关键参数（即通过 PLC 或其他方式）。
Q: What additional information should be provided if parametric release of the drug product is being requested? 如果要求药品参数放行，需要提供哪些附加信息
A: The following information should be provided if parametric release is being requested for the drug product: ♦ Description of the load monitors ♦ Performance characteristics of the load monitors and a description of how these performance characteristics were evaluated ♦ Numbers and locations of the load monitors during commercial production ♦ Acceptance criteria for load monitors exposed to the terminal sterilization process ♦ Evaluation method to determine acceptable sterilization results for exposed load monitors 如果药品要求参数放行，应提供以下信息: ♦ 负载监控器的描述 ♦ 负载监控器的性能特征以及如何评估这些性能特征的描述 ♦ 商业生产期间负载监控器的数量和位置 ♦ 暴露于终端灭菌过程的负载监控器的验收标准 ♦ 确定外露负荷监控器可接受灭菌结果的评估方法
If a description of the evaluation method and performance characteristics of the load monitors has previously been submitted and approved, the NDA/ANDA number and supplement number (if applicable), submission date, and approval date for the submission that contained the relevant information may be cited. 如果负载监控器的评估方法和性能特征的描述已经提交并批准，则可以引用包含相关信息的提交的 NDA/ANDA 编号和补充编号(如适用)、提交日期和批准日期

• Requalification of production autoclaves

What is the sterilization process requalification/revalidation program? 灭菌工艺再确认/再验证程序是什么?
Q: What information should be presented in this section? 需要提供什么信息？
A: Describe the routine requalification program for the terminal sterilizer(s) including the frequency of requalification, types of studies performed (i.e. empty chamber HD and or

loaded chamber HP/BI challenge, etc.), and number of runs performed for each study type. Describe the loads to be used during requalification, if applicable.
描述灭菌器的常规再确认程序，包括再确认的频率，进行的研究类型(即空载 HD 和/或负载 HP/BI 试验等)，以及每种研究类型的运行次数。如适用，请描述在重新确认期间使用的负载。

• Reprocessing

Will the drug product be re-processed or re-sterilized and how has the impact of any reprocessing/ re-sterilization procedure been assessed? 是否对药品进行再加工或再灭菌?如何评估再加工/再灭菌程序的影响？
Q: What information should be presented in this section? 需要提供什么信息？
A: Indicate if reprocessing or re-sterilization of the drug product is to be performed for commercial batches of the drug product. If so, then describe studies performed to assess the impact of reprocessing/ re-sterilization procedures on microbiological aspects of the drug product including container/closure integrity, hold times, and endotoxin content. 说明是否对该药品的商业批次进行再加工或再灭菌。如果是，请描述为评估再加工/再灭菌程序对药品微生物方面的影响而进行的研究，包括容器/密封系统的完整性、保存时间和内毒素含量

• Environmental monitoring including product bioburden

What are the in-process microbiological controls in place for monitoring the manufacturing environment and product prior to sterilization? 在灭菌前对生产环境和产品进行监控的过程中有哪些微生物控制措施？
Q: What information should be presented in this section? 需要提供什么信息？
A: Provide a description of the bioburden monitoring and control program as follows: (Note that in-depth descriptions of air, surfaces, and personnel monitoring normally submitted for aseptically processed drug products are not necessary for terminally sterilized drug products.) • 对生物负荷监测和控制程序的描述如下:(注意，通常为无菌工艺药品提交的空气、表面和人员监测的深入描述对于最终灭菌的药品来说是不必要的。) • 如果是非最终灭菌产品，需要提供更加详细的信息。
♦ Provide a description of bulk solution bioburden monitoring including at what production stage(s) the bulk is sampled for bioburden. Describe monitoring of filled units and container/closure components, as applicable. 提供溶液生物负荷监测的描述，包括在哪个生产阶段对溶液生物负荷进行取样。描述灌装单元和容器/密封组件的监测，如适用。 ♦ Indicate the alert and action levels for bioburden of the bulk solution and filled containers, if applicable. 如果适用，标明溶液和完成灌装容器的生物负荷的警戒限和行动限。 ♦ Indicate the alert and action levels and test frequencies for bioburden and endotoxin testing of WFI used for compounding. 说明用于配制的 WFI 的生物负荷和内毒素测试的警戒限和行动限以及测试频率。 ♦ If the sterilization process uses process water that directly contacts the drug product in its container/closure system (e.g. cooling water for water overspray processes), then provide microbiological acceptance criteria for the process water.

如果灭菌过程使用直接接触容器/密封系统中药品的工艺用水（例如用于水喷淋工艺的冷却水），则提供工艺用水的微生物可接受标准。

- Describe the action plans taken and risk assessment performed in the event that any alert and/or action levels are exceeded.
  描述在超过任何警戒限/或行动限时所采取的行动计划和执行的风险评估。
- Depending on the design of the manufacturing and sterilization processes, additional information such as the heat resistance of bioburden organisms associated with the product solution, the container and closure components, and/or the facility to date, as well as a description of methods for the detection of spores and heat resistance testing of bioburden may be necessary. For example, more information may be needed for bioburden-based or low thermal input autoclave processes than for overkill processes.
  根据生产和灭菌工艺的设计，可能需要提供附加信息，如与产品溶液、容器和密封组件相关的微生物的耐热性，和/或迄今为止的设施，以及对孢子检测方法的描述和生物负载的耐热性测试。例如，基于生物负荷或低热的高压湿热灭菌工艺可能比过度杀菌工艺需要更多的信息。

COMPONENT DEPYROGENATION

Q: Is component depyrogenation necessary for all terminally sterilized drug products?
成分去热原对所有最终灭菌的药品都是必要的吗？

A: The combination of the following factors should be used in determining whether or not component depyrogenation is necessary:

- Non-pyrogenic label claim
- Capacity of the container/closure components to withstand depyrogenation processes
- Component manufacturing process, component design, and depyrogenation feasibility (e.g. Blow-Fill-Seal processes)
- Route of administration

在确定是否需要组分去热原时，应综合考虑以下因素:

- 无热原标签声明
- 容器/密封组件承受去热原过程的能力
- 组件制造工艺、组件设计和去热原可行性(例如 BFS 工艺)
- 给药途径

What is the design space of the container/closure depyrogenation process for commercial production and what are the critical parameters for each container/closure depyrogenation process?
用于商业生产的容器/密封系统去除热原工艺的设计空间是什么?每个容器/密封系统去除热原工艺的关键参数是什么?

Q: What information should be provided in this section?
这部分应该提供什么信息？

A: Indicate how container/closure components are depyrogenated. Include the manufacturer and model number of the equipment used to perform the depyrogenation process, and critical process control parameters, and acceptance criteria (including limits and ranges, if applicable) to be used for depyrogenation of components during commercial production.

说明容器/密封组件是如何去除热原的。包括用于执行去除热原工艺的设备的制造商和型号，关键的工艺控制参数，以及在商业生产中用于组件去除热原的可接受标准(包括限度和范围，如果适用)。
How will the critical parameters of each depyrogenation process be monitored and controlled during commercial production? 在商业生产过程中，如何监测和控制每个去除热原过程的关键参数？
Q: What information should be provided in this section? 这部分应该提供什么信息？
A: Indicate how the critical parameters are controlled (i.e. by a PLC or otherwise), and monitored (i.e. TCs, RTDs for dry heat). 说明关键参数是如何控制(即通过 PLC 或其他方式)和监测(即 TC，干热 RTD)。
What loading patterns are included in the design space for each depyrogenation process for container/closure components of the finished drug product used for commercial production? 商业生产成品的容器/密封组件的每个去除热原过程的设计空间中包括哪些装载模式？
Q: What information should be provided in this section? 这部分应该提供什么信息？
A: Describe loading patterns for commercial production, including the following: ♦ Indication if the load sizes will range within defined minimum and maximum load sizes or if a fixed load size will be used ♦ Number of units per minimum, maximum, or fixed load ♦ Arrangement of the container/closure components within the load 描述商业生产的装载模式，包括以下内容: ♦ 负载大小是否在定义的最小和最大负载范围内，或者是否使用固定的负载大小 ♦ 每个最小、最大或固定负载的单元数 ♦ 负载内容器/密封组件的布置
What is the requalification/ revalidation program for each container/ closure component depyrogenation process? 每个容器/密封组件去除热原过程的再确认/再验证程序是什么？
Q: What information should be provided in this section? 这部分应该提供什么信息？
A: Describe the routine requalification program for each depyrogenation process, including the frequency of requalification, types of studies performed (i.e. empty chamber HD and or loaded chamber HP/EI challenge, etc.), and number of runs performed for each study type. Describe the loads to be used during requalification, if applicable. • 描述每个去除热原工艺的常规再确认程序，包括再确认的频率，所进行的研究类型(即空载 HD 和或负载 HP/EI 试验等)，以及每种研究类型的运行次数。 • 如果适用，请描述在重新确认期间使用的负载。

COMPONENT STERILIZATION

Q: Is this section needed for all applications?

所有申请都需要此部分吗？
A: No, this section applies to components such as port tube-closure assemblies for flexible containers that are sterilized separately prior to attachment to the container during manufacture. The moist heat of the terminal sterilization process may not adequately penetrate into septated compartments within the ports, resulting in dry heat conditions. As a result, any microorganism located in these areas might not be killed during the terminal sterilization process. Therefore, ancillary sterilization of port assemblies prior to attachment to the drug product container may be necessary to achieve sufficient lethality at these sites. 不，本节适用于柔性容器的端口管关闭组件，这些组件在制造过程中连接到容器之前必须单独灭菌。终端灭菌过程的湿热可能无法充分渗透到端口内的分隔中，导致干热条件。因此，在最后的灭菌过程中，位于这些区域的任何微生物都可能不会被杀死。 因此，在连接到药品容器之前，可能需要对端口组件进行辅助灭菌，以在这些位置实现足够的致死率。
Separate sterilization processes for stoppers and seals do not need to be described in this section, as these components are adequately sterilized by the terminal sterilization process. 瓶塞和密封件的单独灭菌过程不需要在本节中描述，因为这些部件已通过终端灭菌过程充分灭菌。
If components require individual sterilization prior to assembly and terminal sterilization of the filled drug product, what is the design space of each component sterilization process for commercial production and what are the critical parameters for each component sterilization process? 如果各组分在灌装药品的组装前和最终灭菌前需要单独灭菌，那么商业生产中各组分灭菌工艺的设计空间是什么?各组分灭菌工艺的关键参数是什么？
Q: What information should be supplied in this section? 这部分应该提供什么信息？
A: Indicate the method of sterilization, sterilizer used, and critical parameters and acceptance criteria for sterilization of components to be used for commercial production. Include pre-sterilization bioburden acceptance criteria (including limits and ranges), if applicable. 说明用于商业生产的部件的灭菌方法、使用的灭菌器、关键参数和灭菌可接受标准。如适用，应包括灭菌前生物负荷接受标准(包括限度和范围)。
How will the critical parameters of each component sterilization process be monitored and controlled for commercial production? 如何监控和控制商业生产中每个成分灭菌过程的关键参数？
Q: What information should be provided in this section for radiation sterilization processes? 关于辐射灭菌过程，本节应提供哪些信息？
A: Indicate how the critical parameters are controlled and monitored including numbers and locations of dosimeters and/or BIs, if applicable. 说明如何控制和监测关键参数，包括剂量计和/或 BI(如适用)的数量和位置。
Q: What information should be provided in this section for dry or moist heat sterilization processes? 对于干热或湿热灭菌过程，本节应提供哪些信息?

A: Indicate how the critical parameters are controlled and monitored including numbers and locations of TCs/RTDs. 说明如何控制和监控关键参数，包括 TC /RTD 的数量和位置.
Q: What information should be provided in this section for ethylene oxide sterilization processes? 对于环氧乙烷灭菌过程，本节应该提供哪些信息
A: Indicate how the critical parameters are controlled and monitored, including the types of monitoring devices used and their locations. Describe how residuals are monitored. 说明如何控制和监控关键参数，包括使用的监控设备类型及其位置。 描述如何监控残留.
What loading patterns are included in the design space for each sterilization process for container/closure components of the finished drug product used for commercial production? 商业生产的成品的容器/密封组件的每个灭菌过程的设计空间中包括哪些装载模式？
Q: What information should be provided in this section? 这部分应该提供什么信息？
A: Describe loading patterns for commercial production, including the following: • Indication if the load sizes will range within defined minimum and maximum load sizes or if a fixed load size will be used • Number of units per minimum, maximum, or fixed load • Arrangement of the container/closure components within the load 描述商业生产的装载模式，包括以下内容: • 负载大小是否在定义的最小和最大负载范围内，或者是否使用固定的负载大小 • 每个最小、最大或固定负载的单元数 • 负载内容器/密封组件的安排
What is the requalification/revalidation program for each component sterilization process? 每个组件灭菌过程的再确认/再验证程序是什么?
Q: What information should be provided in this section? 这部分应该提供什么信息
A: Describe the routine requalification program for the component sterilization process including the frequency of requalification, types of studies performed (i.e. empty chamber HD and or loaded chamber HP/BI challenge, etc.), and number of runs performed for each study type. Describe the loads to be used during requalification, if applicable. 描述组分灭菌工艺的常规再确认程序，包括再确认的频率，所进行的研究类型(即空载 HD 和或负载 HP/BI 试验等)，以及每种研究类型的运行次数。如果适用，请描述在重新确认期间使用的负载。

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