MINISTRY OF INDUSTRY AND TRADE OF RUSSIA

GMP VIII ALL-RUSSIA GMP CONFERENCE

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《药品共线生产质量风险管理指南》介绍

Introduction of the Guidelines for Quality Risk Management of different medicinal products in shared facilities

目录 CONTENTS

目录 CONTENTS

- 《指南》起草的背景 Background of the "Guideline“

本《指南》希望为有效降低药品生产过程中混淆、交叉污染风险提供指导性意见；
This "Guideline" hope to provide guiding for effectively reducing the risk of confusion and cross contamination in drug production processes；

本《指南》希望进一步指导和规范药品上市许可持有人、药品生产企业和药品监管部门对药品共线生产的科学管理、监管；
This "Guideline" " hope to further guidance and standardization for the scientific management and supervision of drug multi production by drug marketing license holders, drug production enterprises, and drug regulatory authorities;

本《指南》不是GMP检查指南；
This "Guideline" is not a GMP inspection guideline;

本《指南》是给药品生产企业提供共线生产提供指导的工具；
This "Guideline" is a tool for providing guidance for drug production enterprises of different medicinal products in shared facilities;

- 《指南》起草的思路The ideas for drafting the "Guideline“

研究国内外关于药品共线生产质量管理的法规、指南及文献，提取可借鉴的经验；
Study the regulations, guidelines, and literature on quality management of different medicinal products in shared facilities, and extract valuable experiences for reference;

通过调查用户需求，确立指南适用范围；
Investigate user needs and establish the scope of application of the guidelines;

调研了国内企业共线生产现状，梳理共性和个性问题；
Investigate the current situation of different medicinal products in shared facilities, and sort out common and individual issues;

研究风险管理方法在共线生产质量管理中的使用原则；
Study the principles of using risk management methods in quality management of different medicinal products in shared facilities;

研究共线生产质量管理的基本原则和个性原则；
Study the basic principles and individual principles of quality management of different medicinal products in shared facilities;

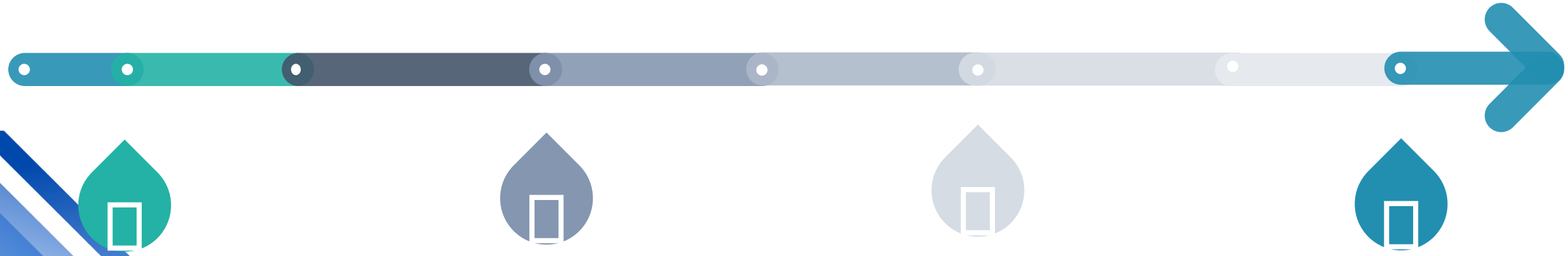
《指南》起草的过程 The process of drafting the "Guideline“

2020.2.18
碰头会

2020.8.31
课题开题会

2020.11-2021.5
形成初稿

2021.12
企业座谈



专家审评会
2020.6.19

实施调研
2020.8-2020.10

公开征求意见
2021.11

指南发布
2023.3

目录 CONTENTS

- 《指南》主要的关注点The main ideas for drafting the "Guideline“

《指南》兼顾前瞻性和适用性，将目前国际上广泛认可的理念和方法纳入指南，同时考虑调研中发现的国内药品生产领域实际的共线情况，力求务实且具指导意义；

The "Guideline" balance foresight and applicability, incorporating widely recognized concepts and methods internationally into the guidelines, while taking into account the actual multi production found in the domestic drug production field during research, striving to be practical and instructive;

《指南》以药品生命周期和风险管理为主线（将清洁验证的生命周期融入其中），以遵守法规及规范要求为准绳，强调药品上市许可持有人主体责任，兼顾风险控制措施与收益整体平衡，以基于健康的暴露限度评价为主要评价指标；

The "Guideline" focus on the drug life cycle and risk management (integrating the life cycle of clean validation), adhere to regulatory and normative requirements, emphasize the main responsibility of drug marketing license holders, balance risk control measures with overall benefits, and use health based exposure limit evaluation as the main evaluation indicator;

《指南》着重阐述了药品研发、技术转移、药品生产和上市后阶段共线策略的考量，讨论了交叉污染途径的影响因素及控制策略，为增加指导性，对某些特殊类型的共线进行了单独论述。

The "Guideline" focus on the consideration of collinearity strategies in drug research and development, technology transfer, drug production, and post market stages, and discuss the influencing factors and control strategies of cross contamination pathways. For added guidance, specific types of different medicinal products in shared facilities are separately discussed.

目录 CONTENTS

《指南》主要内容的介绍 Introduction to the Main Content of the "Guidelines"

第一章节“总则”部分，阐述了《指南》编写的目的，对药品共线生产的定义给出了说明，同时明确了《指南》适用的范围。
The "General Provisions" section explains the purpose of writing the "Guidelines", explains the definition of different medicinal products in shared facilities, and clarifies the scope of application of the "Guidelines".

第二章节“基本原则”部分，给出了《指南》的五大基本原则，即法律法规优先原则、药品上市许可持有人主责原则、生命周期原则、质量风险管理原则和风险控制措施与收益整体平衡原则，并对这些基本原则进行了详细阐述。
The "Basic Principles" section provides the five basic principles of the "Guidelines", namely the priority principle of laws and regulations, the main responsibility principle of drug marketing license holders, the life cycle principle, the quality risk management principle, and the overall balance principle between risk control measures and benefits, and elaborates on these basic principles in detail.

- 《指南》主要内容的介绍Introduction to the Main Content of the "Guidelines"

第三章节“药品研发阶段的共线生产策略”部分，主要包括药品的毒理学评估和基于健康的暴露限度评价、清洁工艺的设计和开发两方面内容，引入了HBEL和PDE，对研发阶段清洁工艺和残留物检测方法的开发要点进行了阐述。

The section on “Multi production strategy in the Drug Development Phase" mainly includes two aspects: toxicological evaluation of drugs, health based exposure limit evaluation, and design and development of clean processes. HBEL and PDE are introduced to elaborate on the development points of clean processes and residue detection methods in the research and development phase.

第四章节“技术转移阶段的共线生产策略”部分，主要包括特殊品种共线应考虑的因素和设备清洁验证应考虑的因素两方面内容。

The section on “Multi production strategy in the technology transfer stage" mainly includes two aspects: factors to be considered for special types of co production and factors to be considered for equipment cleaning and validation.

《指南》主要内容的介绍Introduction to the Main Content of the “Guidelines”

第五章节“药品生产阶段的共线生产策略”部分，介绍了交叉污染途径的影响因素及控制策略、已有控制措施的执行评估和上市后共线策略发生变化后的考量三个方面的内容。
The section on “Multi production strategies in the Drug Production Phase" introduces three aspects: the influencing factors and control strategies of cross contamination pathways, the evaluation of existing control measures, and considerations after changes in co line strategies occur after marketing.

第六章节“术语” 部分对《指南》中出现的 “危害”、“基于健康的暴露限度”、“每日允许暴露量”、“每日可接受暴露量”、“职业暴露限值”和“一次性使用技术”给出了定义。
The "Terminology" section defines the "hazards", "health based exposure limits", "daily allowable exposure levels", "daily acceptable exposure levels", "occupational exposure limits", and "disposable technologies" that appear in the Guidelines.

- 《指南》主要内容的介绍Introduction to the Main Content of the “Guidelines”

  第七章节“附录：抗肿瘤产品共线生产评估示例”部分以某企业引入新产品为例，从危害等级判定的原则、高毒高活产品生产示例给出案例和参考。
  The "Appendix: Examples of Multi production Evaluation for Antitumor Products" section takes the introduction of a new product by a certain enterprise as an example, and provides a case and reference based on the principles of hazard level determination and production examples of high toxicity and high activity products.

  第八章节“参考法规和指南” 列出了《指南》参考的国内外相关法律法规、规范性文件和指南
  The 'Reference Regulations and Guidelines' lists the relevant domestic and foreign laws, regulations, normative documents, and guidelines referenced in the' Guidelines'

总结 Summarize

药品共线生产中的交叉污染问题是制药行业目前存在的一个共性的难题；
The cross contamination in of different medicinal products in shared facilities is a common problem in the pharmaceutical industry;

《指南》的起草借鉴了国际的一些做法，引入了全生命周期的理念，希望通过指南给监管和业界提供一些指导。
The "Guidelines" draws on some international practices and introduces the concept of a full lifecycle, hoping to provide some guidance to regulators and the industry through the guidelines.

《指南》给出的是通用原则，企业针对自身品种灵活运用，以向监管方证明共线决策的科学和合理性，并不能以此不遵守法规要求。
The "Guidelines" provide a general principle that enterprises can flexibly apply their own varieties to prove the scientific and reasonable of different medicinal products in shared facilities decision-making to regulatory authorities, and cannot fail to comply with regulatory requirements.

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