变更控制(Change Control)

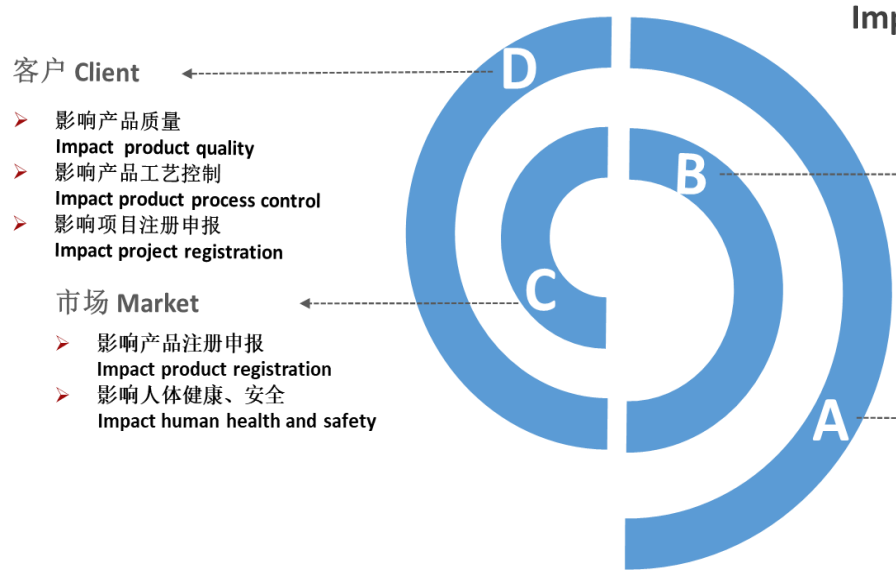
“变更”是药品在研发、生产、质量控制、使用条件等诸多方面提出的涉及来源、方法、控制条件等方面的变化。这些变化可能影响到药品的安全性、有效性和质量可控性以及体系和验证的状态。

研发阶段实施变更流程：
Implement the change control during R&D phase

关键设备的引入
Introduction of critical equipment
关键系统的引入
Introduction of critical system
质量协议/变更声明中要求的变更条款
Change requirements specified in quality agreement and change statement

Changes in sources, methods and control conditions are proposed in drugs' research, production, quality control and use conditions. These changes may affect the safety, effectiveness and quality controllability of drugs, as well as the status of system and validation.

变更会造成的影响
Impact of Change



客户 Client
- 影响产品质量 Impact product quality
- 影响产品工艺控制 Impact product process control
- 影响项目注册申报 Impact project registration

市场 Market
- 影响产品注册申报 Impact product registration
- 影响人体健康、安全 Impact human health and safety

体系 System
- 影响已经建立体系的稳定性 Impact the stability of established system

验证状态 Validation Status
- 对已经确认/验证状态的影响（设备、系统、工艺） Impact on qualification/validation status (equipment, system, process)

客户关注的变更控制点
Items of change that will cause customer's caution

01 生产场地 Production site
02 关键工艺参数 Critical process parameters
03 关键物料 Critical materials
04 产品最终步骤的溶剂、试剂 Solvents and reagents used in final step production
05 产品质量标准 Product specification
06 产品检验方法 Product test method
07 包装材料 Packing materials
08 关键生产设备 Critical production equipment