**设计和开发转移评审报告（M6）**

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| 项目名称 | |  | | | | | | |
| 评审申请人 | |  | | | 评审时间 |  | | |
| 评审内容 | | | | | | | | |
| 1. 项目目标及范围是否发生变化？如果是，项目计划是否已相应更新并被批准？ | | | | | | | | |
|  | | | | | | | | |
| 1. 设计转移活动是否完成？ | | | | | | | | |
|  | | | | | | | | |
| 1. 设计转移过程是否存在遗留问题？ | | | | | | | | |
|  | | | | | | | | |
| 1. 产品注册相关活动是否完成？是否获得市场准入许可？ | | | | | | | | |
|  | | | | | | | | |
| 1. 风险分析是否持续更新？是否已添加确认报告作为相关风险控制措施的有效性证据？ | | | | | | | | |
|  | | | | | | | | |
| 1. 是否编制IOVV矩阵并保持持续更新？ | | | | | | | | |
|  | | | | | | | | |
| 1. 是否开始策划上市后评价与监督？ | | | | | | | | |
|  | | | | | | | | |
| 1. 所需DHF和DMR文件是否完整？ | | | | | | | | |
|  | | | | | | | | |
| 评审意见及结果 | | | | | | | | |
| 评审意见 | | | 1. 缺陷识别 2. 总体评价及建议 | | | | | |
| 评审结论 | | | 评审通过  评审不通过  评审有条件通过，纠正措施如下 | | | | | |
| 纠正措施及验证 | | | | | | | | |
| 序号 | 整改项 | | | 纠正措施 | | | 结果 | 实施人/日期 |
|  |  | | |  | | |  |  |
|  |  | | |  | | |  |  |
|  |  | | |  | | |  |  |
|  |  | | |  | | |  |  |
|  |  | | |  | | |  |  |
|  |  | | |  | | |  |  |

**评审人员会签**

|  |  |  |  |
| --- | --- | --- | --- |
| 评审人员 | 角色 | 签名 | 日期 |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |
|  |  |  |  |