**更改历史**

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| **版本号** | **文件更改号** | **更改概要** | **修改人** | **批准人** |
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| 发放范围 |  | | | |

1. **SCOPE 范围**

This document describes the procedures to be followed when any safety alert and advisory notice is necessary to be handled. 本文件描述的程序是用于处理预警和忠告性通知发布所必须遵守的流程。

1. **PURPOSE 目的**

To handle safety alert and advisory notice in time so as to avoid the re-occurrence of similar affairs.

为及时处理预警、忠告性通知，防止同类事件的再次发生。

1. **ASSOCIATED DOCUMENTS 相关文件**

Advisory Notice 忠告性通知书

Adverse Event Reporting Procedure 不良事件报告控制程序

Corrective & Preventive Actions Control Procedure 纠正和预防行动控制程序

1. **DEFINITIONS AND ACRONYMS 定义和缩写**

Advisory Notice of medical devices: After the delivery of medical devices, the complementary information or advisory actions issued by organization related to the aspects in usage, modification,recall and destruction of devices. 医疗器械忠告性通知：在医疗器械交付后，由组织发布的通知，在器械的使用、改动、召回、销毁方面给出的补充信息或建议采取的措施。

1. **RESPONSIBILITIES 职责**

5.1 Quality dept. is responsible for the analysis, investigation, management of quality informations, and reporting the related situation. 质量部统筹对质量信息的分析、调查、处理工作，并协调通报相关的情况。

5.2 Production dept., Engineering dept., Material dept., Purchasing dept. should take part in the analysis, investigation, and management of the quality information. 生产部门、工程部、物料部、采购部参与对质量信息的分析、调查、处理。

5.3 Related personnel responsibility of early safety alert system refer to attachment one"Safety alert system Function matrix". 早期预警系统的各部门相关人员职责详见附件一 “预警系统职能矩阵表”。

1. **PROCEDURE 程序**
   1. **Early safety alert system早期预警系统**

6.1.1 If ATL recognized the delivered products couldn’t reach the expected purpose and the possibility and potential hurt will done to the patients because of some poor quality, the Engineering dept. and Quality dept. should analyze the causes and effects for the poor quality. 如本厂发现已发运后的产品未能达到预期用途及由于某种质量缺陷怀疑产品可能对病人造成伤害或潜在的伤害，由工程部及质量部对质量缺陷进行原因及影响分析。

6.1.2 Engineering dept. and Quality dept. should take relevant actions according to the severity degree of issues. For example, start the early safety alert system. Releasing the “Advisory Notice” to customer after approved by the management. 工程部及质量部依据问题的严重程度采取应的行动措施，如：启动早期预警系统。交于管理层审批，经批准后向顾客发出“忠告性通知书”。

6.1.3 Carrying on the risk analysis after early safety alert system started, and implementing relevant actions according to “SOP-B12-2011 Corrective & Preventive Actions Control Procedure”. 启动早期预警系统后，要进行风险分析并按“纠正和预防行动控制程序”规定执行相应措施。

Note: Pay attention to the local national laws and regulations during the process of application.

注：应用时要注意当地的国家或法规的要求。

* 1. **Advisory Notice忠告性通知**

6.2.1 When below situations occurred, quality dept and Engineering dept. could hold a meeting for the consideration of releasing “Advisory Notice”. 当发生以下情况时，质量部、工程部召开会议研讨考虑发出“忠告性通知书”。

a) Any supplement information about the usage of medical device 医疗器械在使用时应注意的补充事宜；

b) The modification of medical device 医疗器械的改动

c) Medical device return to company or agent 医疗器械被退回公司或代理商

d) The destroy of medical device 医疗器械的销毁

e) The recall of medical device 医疗器械需要召回

6.2.2 "Advisory Notice" shall include following content: 忠告性通知包括下列内容：

a) The name, Lot No,specification and quantity about the involved product出现问题的产品名称、批号、规格和数量

b) The reason which lead to release Advisory Notice 发布忠告性通知的理由

c) Possible occurred hazard可能产生的危害

d) Follow up actions 随后采取的措施

6.2.3 Engineering dept. and quality dept. are responsible for collecting relevant information, and calling for the concerned departments to have a meeting for discussing, when the comments showed recall is unnecessary and the same effect could be reached through other ways, the detailed "advisory notices" should be prepared and released to customer after approved by management. 工程部、质量部负责相关资料收集，并召集相关部门开会研讨，当分析讨论认为不需要采取召回形式，可通过其它方式处理，也可达到同样的效果时，应编制详细的忠告性通知书，经管理层批准后向顾客发出“忠告性通知书”。

6.2.4 Market shall confirm the distribution address, receiver and contact information of involved product according to the delivery record, inform and release "D-QA035 Advisory Notices" to customer or agent timely, and keep the relative releasing and following record. 市场部依照产品分销记录，确定需发布忠告性通知的该批产品的销往地址、负责收货人姓名和联系电话等，及时告知并发放给相关顾客或代理商“D-QA035忠告性通知书”。并保持忠告性通知发布和跟踪确认的记录。

6.2.5 If the national or local regulation require to report advisory notice to local FDA Bureau, quality dept conduct it after approved by General Manager. 如果国家和地区法规要求本厂将忠告性通知报告给当地药品监管部门，经总经理审核批准后由质量部负责执行。

6.3 If applicable, adverse event report refer to" Adverse Event Reporting Procedure". 适用时，不良事件报告按“不良事件报告程序”执行。

1. **Flow Chart 流程图**

**N/A**

1. **Attachment 附件**

**Attachment One** Safety alert system Function matrix 附件一：预警系统职能矩阵表

|  |  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- | --- |
| **人员 Personnel** | 客户Customer | 总经理 General manager | 管理者代表 Management representative | 项目经理 Project manager | 工程师 Engineer | QA员 QA inspector | QE | 生产负责人 Production responsible person |
| **职责 Responsibility** |
| 收集相关资料 Collection of relevant information |  |  |  |  |  | √ | √ | √ |
| 客户信息沟通（包括忠告性通知及调查表的发出及收回）Information communicated with customer(including the send and reclaim of advisory notice and investigation form) |  |  | √ |  | √ | √ | √ |  |
| 对客户的抱怨进行评审  Review customer complaint | √ | √ | √ | √ | √ | √ | √ | √ |
| 编制忠告性通知 Compile advisory notice |  |  | √ |  |  |  |  |  |
| 编制召回产品报告  Compile product recall report |  |  | √ |  |  |  |  |  |
| 产品检验和试验分析 Product inspection and testing analysis |  |  |  | √ | √ | √ | √ | √ |
| 分析不合格原因及影响 Analyze the cause and effect of the nonconformity |  |  | √ | √ | √ | √ | √ |  |
| 分析结果的审批  Approval of the analysis result |  | √ |  |  |  |  |  |  |
| 顾客和其他相关方对质量管理体系事项进行的沟通 Communication between customer and other related party on quality management system | √ |  |  |  | √ |  | √ |  |
| 对不良事件进行调查  Conduct an investigation for adverse events | √ |  |  |  | √ |  | √ | √ |

