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	起草 Prepared By: 李春霞	发布 Issued: 03/01/2020
	评审 Reviewed By: 裴一君	更改 Revised: 7/12/2023
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1.0 目的 Purpose

本程序规定了投诉或申诉如何进行调查并采取适当措施的处理流程。

This procedure outlines the process for handling potential complaints or appeals requiring investigation and appropriate action.

2.0 范围 Scope

本程序适用于 AKA 认证项目所涉及的投诉或申诉的处理。

This procedure applies to AKA's accredited certification programs

3.0 定义 Definitions

3.1 投诉——任何书面、电子或口头的沟通，声称与身份、质量、耐用性、可靠性、安全性、有效性或服务性能有关的缺陷。

Complaint – any written, electronic, or verbal communication that alleges deficiencies related to identity, quality, durability, reliability, safety, effectiveness or performance of services rendered.


3.1.1 投诉包括但不限于下列情况:不符合，反馈，以及 AKA 的雇员/承包商，客户，AKA 认证客户的客户，涉及 AKA 的管理体系。潜在的事件可能存在不符合。

Complaints include but are not limited to the following: Nonconformities, feedback, and opportunities for improvement identified by AKA employees/contractors, clients, customers of AKA certified clients, concerning AKA's management system.

For a potential incident, it may be a nonconformity.

3.1.2 投诉也包括认证监管机构发出的问题通知，如：CNCA (<http://www.cnca.gov.cn/>)、CCAA (<http://www.ccaa.org.cn/>)、国家市场监督管理总局 (<http://www.samr.gov.cn/>)等发网站出的问题通知

Complaints also include notification of problems from certification regulators, such as CNCA (<http://www.cnca.gov.cn/>)、CCAA (<http://www.ccaa.org.cn/>)、State Administration for Market Regulation (<http://www.samr.gov.cn/>), etc.

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3.2 申诉 - 要求重新考虑有关不符合、审核建议或与认证有关的决定，包括执法行动。

Appeal – A request for reconsideration of a decision relating to nonconformities, auditor recommendations, or decisions related to certification including enforcement actions.

3.3 投诉者/申诉人——任何向 AKA 提供信息的人，需要对提供的服务进行评估，并采取纠正措施。

Complainant / Appellant – any individual(s) who provides information to AKA- ISR that would necessitate evaluation of services rendered and potential for corrective action.

4.0 职责 Responsibilities

4.1 技术质量部负责投诉和申诉的管理，督促并控制活动实施的进度，保持申诉、投诉的相关记录。申诉/投诉热线电话:0512-68839099

Technical & Quality Department is responsible for the management of complaint and Appeal process, Supervise and control the implementation progress of the activities and keep the relevant records of complaints and complaints. Complaint & appeal hotline: 0512- 68839099,

4.2 技术委员会负责对客户申诉的事件的技术认定。

Technical Committee is responsible for the technical identification of the Client's appealed incident.

4.3 综合部负责收集政府在网站上公布的与 AKA 相关信息。

The Administration Department is responsible for collecting AKA related information published by the government on the website.

4.4 客服部/营销中心负责对来自于网站的投诉信息进行识别和确认。


The Customer Service Department / Marketing Center is responsible for identifying and confirming the complaint information from the website.

4.5 审核部负责验证客户的纠正措施，并决定是否启动特殊审核流程。

The audit department is responsible for verifying the customer's corrective actions and deciding whether to initiate a special audit process

4.6 事件涉及部门的负责人负责协助技术质量部取得调查资料；实施相关措施并报告措施结果。

The department manager involved in the case is responsible for assisting Technical & Quality Department to obtain the investigation data, implementing relevant actions and reporting the results

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4.7 投诉/申诉代理人负责联系客户、取得资料并将处理结果通知投诉人/申诉人。

The Complaint / Appeal agent is responsible for contacting customers, obtaining information and Notifying the results to Complainant / Appeal.

5.0 客户申诉处理流程 Client's Appeal Handling Flow

5.1 申诉登记与确认 Appeal registration and validation.

5.1.1 对于反馈到公司其它部门的申诉，由相关部门对该申诉核实后发技术质量部。

For the Appeal feed back to other departments, the relevant department shall confirm and pass it to the Technical & Quality Department.

5.1.2 接到申诉后（受理），技术质量部对投申诉信息进行初确认，以确保其是一个有效申诉；

技术质量部应控制受理、确认和调查申诉的过程不造成针对申诉人的任何歧视行为。确认包括以下信息：


While receiving Appeal information, The Technical & Quality Department shall confirm the Appeal information to insure it is an effective Appeal. The Technical & Quality Department shall control the process of accepting, confirming and investigating Appeal, so as not to cause any discrimination against the Appellant. The information to be confirmed includes the following:

- a) 申诉陈述； Appeal statement;
- b) 申诉人的单位、职务、联系方式； Unit, position and contact information of the Appellant;
- c) 审核组成员 Audit Team Members;
- d) 代理人的姓名和联系方式（视情况而定）。
Name and contact information of agent (as appropriate).

5.1.3 对于确认其属于申诉范围的事件，技术质量部应登记《投诉/申诉清单》，并使用邮件通知相关部门主管及相关人员；

For the incidents confirmed to be within the scope of Appeal, the Technical & Quality Department shall register Complaint / Appeal List and notify the relevant department head and relevant responsible person by email;

5.1.4 技术质量部应通知(包括以邮件、QQ、微信的方式)申诉人申诉的受理情况，并告知其了解申诉处理进展的沟通渠道。技术质量部负责控制整个处理过程中没有审核组成员参与

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事件处理。

The Technology & Quality Department shall inform the Appellant of the acceptance of Appeal in written form (Including by Email, QQ, WeChat), and inform them of the channels for understanding the progress of Appeal handling. The technical control team was not involved in the whole process of handling the incident.

5.2 事件初步调查 Preliminary investigation of the incident.

5.2.1 相关部门负责人在收到技术质量部信件后，应向技术质量部提供相关责任人联系方法并通知到相关责任人配合调查。

While receiving the Email from the Technical & Quality Department, the relevant department manager shall provide contact method of relevant responsible person to technical department and inform relevant responsible person to cooperate with investigation.

5.2.2 技术质量部完成对事件的调查，调查包括：

The Technical Technology & Quality Department shall complete the investigation of the incident, including:

- a) 听取双方对事件的陈述或说明；
Listen to the statements or explanations of both parties on the incident;
- b) 确定问题焦点并提出相关证据和档案的要求；
Determine the problem focus and put forward evidence requirements;
- c) 审查双方提供的证据资料。
Review the evidence provided by both parties.


注：对于不积极回应或不能及时提供充分证据的，将视为放弃；

note: Those who do not respond positively or fail to provide sufficient evidence in time will be regarded as waivers;

5.2.3 技术质量部对申诉事件的案卷进行整理，编写申诉报告，并对所述事件的引证资料进行整理编号。

The Technical Technology & Quality Department shall sort out the files of the Appellant incidents, Prepare the Appellant Report, sort out and number the files of the incidents.

5.3 申诉的初步认定 Preliminary determination of Appeal

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5.3.1 技术质量部负责申诉的初步认定，并将其记录于申诉报告，报技术委员会主任审批。

The Technology & Quality Department is responsible for the preliminary determination of the appeal, and record it in <Appeal Report> and submitted it to the Director of Technical Committee for approval.

5.3.2 对于初步认定申诉不成立的案子，技术质量部书面通知（包括邮件）相关部门和申诉人

（或代理人，若存在）认定结果；

For the case that the Appeal is not established initially, The Technology & Quality Department shall inform the relevant department and Appellant (or Agent, if exist) of the determination result .

5.3.3 对于初步认定申诉成立的案子，技术质量部将认定意见和拟采取的措施写入报告，报技

术委员会主任批准；

For the case that the Appeal is initially confirmed, the Technology & Quality Department will write the confirmation opinion into the report and send it to Director of Technical Committee for approval..

5.3.4 技术质量部制作回复文件书面回复申诉人或代理人（适当时）。如果客户提出异议并提

出新的证据，技术质量部可根据具体情况决定是否开启新的调查。

The technicalTechnology & Quality Department shall prepare a reply document and reply to the complainants or agents in writing (when appropriate). If the customer raises an objection and puts forward new evidence, the technicalTechnology & Quality Department can decide whether to open a new investigation according to the specific situation.

注：以上工作由技术质量部把握进度，尽量在 22 个工作日内完成。

Note: Technology & Quality Department shall grasp the above work progress and try to complete it within 22 working days.


5.4 申诉的后续工作

5.4.1 如果该事件被认为是一个系统问题，技术质量部应将问题反馈给相关部门；

If the incident is considered to be a system problem, the technicalTechnology & Quality Department shall feed back the problem to the relevant departments;

5.4.2 责任部门制定一个措施计划表填入《申诉报告》发技术质量部，包括：

Responsible department shell schedule a action plan, fill it in <Appeal Report> and send it to TQ Department;

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5.4.3 责任部门实施相关措施并记录于《申诉报告》，完成措施后，将发报告连同证据资料技术质量部；

The responsible department shall implement the relevant actions and record them in <Appeal Report>. After completing the actions, send the report together with evidence to TQ Department;

Responsible department shall schedule a action plan, fill it in <Appeal Report> and send it to TQ Department;

5.4.4 技术质量部确认后将最终报告发送管理者代表、总经理；电子资料保存电子档由技术质量部保管。

The Technical & Quality Department shall send the final report to Director of Technical Committee and General Manager; the electronic data shall be kept by the Technical & Quality Department.

6.0 投诉处理流程 Client's Complaint Handling Flow

6.1 投诉登记与确认 Complaint registration and validation.

6.1.1 对于反馈到公司其它部门的申诉，由相关部门应对该投诉核实后发技术质量部。


For the Complaint feed back to other departments, the relevant department shall confirm and pass it to the Technical & Quality Department

6.1.2 接到投诉后，技术质量部对投诉信息进行确认，以确保其是一个有效投诉。技术质量部

应控制受理、确认和调查申诉的过程不造成针对申诉人的任何歧视行为。包括以下信息：

While receiving Complaint information, The Technical & Quality Department shall confirm the complaint information to insure it is an effective complaint. The Technical & Quality Department shall control the process of accepting, confirming and investigating complaint, so as not to cause any discrimination against the Complainant. The information to be confirmed includes the following:

- a) 投诉陈述； Complaint l statement;
- b) 投诉的单位、职务、联系方式； Unit, position and contact information of the Complaint
- c) 被投诉者部门，姓名和联系方式； 投诉/申诉事件；
The name, contact information and the Department of the party complained;
- d) 代理人的姓名和联系方式（视情况而定）。
Name and contact information of agent (as appropriate).

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6.1.3 对于确认其属于投诉范围的事件，技术质量部应登记《投诉/申诉清单》，并使用邮件通知相关部门主管及相关责任人。如果该事件涉及到获证体系的有效性，技术质量部应通知相关部门按程序对证书进行处理。

For the incidents confirmed to be within the scope of Complaint, the Technical & Quality Department shall register Complaint List and notify the relevant department head and relevant responsible person by email. If the incident involves the effectiveness of the certificate system, the Technical & Quality Department shall inform the relevant departments to handle the certificate according to the procedures.

6.1.4 技术质量部应通知（包括以邮件、QQ、微信的方式）投诉人申诉的受理情况，沟通公开事件与否及公开程度，告知其了解投诉处理进展的渠道。技术质量部负责控制整个处理过程中没有与投诉事件有关的人员参与对事件处理。

The Technology & Quality Department shall inform (Including by Email, QQ, WeChat) the complainant of the acceptance of complaint, communicate on whether the incident is open and how open it is, inform them of the channels for understanding the progress of complaint handling. The Technical & Quality Department is responsible for controlling that no personnel related to the complaint participate in the handling of the incident

6.2 事件初步调查 Preliminary investigation of the incident.


6.2.1 相关部门负责人在收到技术质量部信件后，应向技术质量部提供相关责任人联系方式并通知到相关责任人配合调查。

While receiving the Email from the Technical & Quality Department, the relevant department manager shall provide contact method of relevant responsible person to technical department and inform relevant responsible person to cooperate with investigation.

6.2.2 技术质量部完成对事件的调查，调查包括：

The Technical & Quality Department shall complete the investigation of the incident, including:

- d) 听取双方对事件的陈述或说明；
Listen to the statements or explanations of both parties on the event;
- e) 确定问题焦点并提出相关证据和档案的要求；
Determine the problem focus and put forward evidence requirements;
- f) 审查双方提供的证据资料。
Review the evidence provided by both parties.

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注：对于不积极回应或不能及时提供充分证据的，将视为放弃；

note: Those who do not respond positively or fail to provide sufficient evidence in time will be regarded as waivers;

6.2.3 技术质量部对投诉事件的案卷进行整理，编写投诉报告，并对所述事件的引证资料进行整理编号。

The Technical Technology & Quality Department shall sort out the files of the Complainant incidents, Prepare the Complainant Report, sort out and number the files of the incidents.

6.3 投诉的初步认定 Preliminary determination of Complaint / Appeal

6.3.1 技术质量部将调查资料（《投诉报告》及引证资料）及初步认定结论，发管理者代表审核、总经理批准；

The Technical & Quality Department distribute the investigation data (<Complaint Report> and citation files) and preliminary conclusion to the Management Representative for review, General manager for approved.

6.3.2 若投诉不被认可，技术质量部书面通知相关部门和投诉人（或代理人，若存在）认定结果；

If the complaint is admitted, the Technical & Quality Department shall inform the relevant department and Complainant / Appellant (or Agent, if exist) of the determination result in writing.


若投诉被认可，技术质量部将确定投诉/申诉处理小组及小组会议时间。

If the complaint is not admitted, the Technical & Quality Department will determine the member of Complaint handling team and team meeting.

6.3.3 技术质量部在提前通知相关部门相关会议（小组成员一般情况下包括：总经理、分管副总、管理者代表、相关部门负责人和技术质量部负责人，小组成员数为单数且不得与投诉事件有关）。需要小组成员提前准备时，应将报告发小组成员。

Technical department shall inform relevant departments of relevant meetings in advance. (Team members generally include: General Manager, Deputy General Manager in charge, deputy general managers in charge, relevant department manager and Technical & Quality Department manager; The number of team members shall be odd; The members shall not be related to the complaint). If the team members need to prepare in advance, the report shall be sent to the team members.

6.4 小组决议与最终认定 Group meeting and final determination

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6.4.1 技术质量部主持会议投诉小组会议，对投诉事件进行说明；

The Technical & Quality Department shall preside over the meeting of Complaint Team and explain the Complaint / Appeal incident;

6.4.2 小组成员应对事件的原因及处理（包括纠正和纠正措施）发表意见；参见 5.5.3；

The team members shall express their opinions on the causes and handling (including correction and corrective action) of the incident; See 5.5.3;

6.4.3 技术质量部汇总小组意见，做出最终处理决定，编写《投诉报告》，适用时，包括以下方面：

The Technical & Quality Department summarizes the opinions of the Team and makes the final decision, and compile the <Complaint Report>, including the following aspects when applicable:


- a) 事件的最终认定；The final determination of the incident;
- b) 对相关责任人的处置决定（适用时）；
Disposal decision of relevant responsible person (when applicable)
- c) 给投诉人或代理人（如果存在）的正式答复文件；Formal response to the complainants or agents (if any);
- d) 当事件被认为是系统问题时，对问题的原因分析与纠正措施。
When the incident is considered as a system problem, analyze the causes of the problem and take corrective actions.
- e) 相关部门执行纠正及纠正措施的时间表

6.4.4 技术质量部将《投诉报告》报管理者代表审核，总经理批准。

The Technical & Quality Department shall submit the <Complaint Report> to the Management Representative for review and the general manager for approval. The approved report shall be sent to relevant departments。

6.4.5 技术质量部将投诉正式答复文件发送给投诉人或代理人；（可以邮件、QQ、微信的方式）。

The Technical & Quality Department will send the formal reply document to the complainants or agents; (It can be in the form of email, QQ and wechat).

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注：以上工作由技术质量部把握进度，尽量在 22 个工作日内完成。

Note: Technical & Quality Department shall grasp the above work progress and try to complete it within 22 working days.

6.5 纠正和纠正措施的实施 Complaint Handling

6.5.1 责任部门实施相关措施并记录于《投诉报告》，完成措施后，将发报告连同证据资料技术质量部；

The responsible department shall implement the relevant actions and record them in <Complaint Report>. After completing the actions, send the report together with evidence to TQ Department;
Responsible department shall schedule a action plan, fill it in <Complaint Report> and send it to TQ Department;

6.5.2 技术质量部对纠正措施的有效性进行确认，并记录于投诉报告。相关资料由技术质量部保管。

After confirm the action, The Technical & Quality Department shall send the final report to the vice general manager and general manager in charge; the electronic data shall be kept by the Technical & Quality Department.

7 政府投诉处理 Handling of government complaints

7.1 信息的获取与登记 Information acquisition and registration

7.1.1 综合部每周三登录 CNCA (<http://www.cnca.gov.cn/>)、CCAA (<http://www.ccaa.org.cn/>)、


市场监督管理总局 (<http://www.samr.gov.cn/>)网站、国家药品监督管理局

(www.nmpa.gov.cn)、FDA (<https://www.fda.gov/>) 查询相关的公告、通告；包括国家监督对产品质量抽查结果的通告、不符合相关法规要求的通告。

The Administration Department logs in CNCA every Wednesday (<http://www.cnca.gov.cn/>), CCAA (<http://www.ccaa.org.cn/>)General Administration of market supervision and Administration (<http://www.samr.gov.cn/>), National Medical products Administration

(www.nmpa.gov.cn)、FDA (<https://www.fda.gov/>)、

https://europa.eu/european-union/index_en Website, query the relevant announcement, notice, including the national supervision of product quality spot check results, and notice of non-compliance with relevant regulatory requirements.

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	评审 Reviewed By: 裴一君	更改 Revised: 7/12/2023
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7.1.2 综合部对获取的信息进行筛选，可通过认证企业查询网站查询企业名称以识别与本公司相关的公告、通知，包括涉及本公司认证客户的相关通报。对于获取的信息不足以确认是否为本公司客户的，应在公司的 ERP 系统中输入关键词进行确认。

The Administration Department shall screen the information obtained, and query the client name through the certification client inquiry website to identify the announcements and notices related to the company, including those related to the company's certified customers. If the information obtained is not enough to confirm whether it is our customer, keywords should be input into the company's ERP system for confirmation.

7.1.3 对已经确认与本公司相关的企业，由综合部登记《政府/监管机构投诉管理看板》，登记内容包括，投诉时间、投诉发出部门、投诉涉及的企业、投诉陈述。

For those company who have been confirmed to be related to our company, the Administration Department shall register <Management Kanban of the Government / Regulatory Agency Complaint>. The registration contents include the complaint time, the Department issuing the complaint, the client involved in the complaint and the complaint statement.

7.1.4 对于登记后的《政府/监管机构投诉管理看板》由综合部传到公司 General 文件夹，并同时发邮件到客服部和技术质量部，通知新增的投诉。（内容以截取《政府/监管机构投诉管理看板》中『投诉时间、投诉发出部门、投诉陈述』四段内容为标准。）任何此类不符合项应立即传达给被审核组织。The registered <Management Kanban of the Government / Regulatory Agency Complaint> will be traAKAerred to the company's General folder by the Administration Department, and an email will be sent to the Customer Service Department and the Technical & Quality Department to inform the new complaints. (the content is based on the four paragraphs of <Management Kanban of the Government / Regulatory Agency Complaint> in the complaint management Kanban of government / regulatory agencies.) Such non-compliances are immediately communicated to the organization being audited.


7.1.5 对于双随机检查发现的问题，参照第 6 章流程处理。

For the problems found in double random inspection, refer to the process in Chapter 6.

7.2 事件确认、调查与处理 Accident confirmation, investigation and handling

7.2.1 客服部主管/营销中心主管负责确定涉及的客户经理/业务经理，并通知客户经理/业务经理投诉事件，沟通相关调查事宜。

The management of Customer Service Department / Marketing Center is responsible for determining the customer Manager / Business Manager involved, notifying the Customer

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Manager / Business Manager of the complaint and communicating the relevant investigation matters.

7.2.2 客户经理/业务经理负责联系客户，调查事件详情，包括：

The Customer Manager / Business Manager is responsible for contacting customers and investigating the details of the accident, including:

- a) 主管部门检查情况说明； Explanation of inspection by competent department;
- b) 涉及的产品/服务范围； Scope of products / services involved;
- c) 涉及的产品/服务目前的交付情况； Current delivery of products / services involved;
- d) 目前的生产/经营状态； Current production / operation status;
- e) 目前的应对措施。 Current measures.

7.2.3 客服部主管根据沟通的结果，对事态做出评估后，对事情的严重程度进行简要说明并提出处理意见； ， 处理可包括以下决定：

According to the results of communication, the supervisor of Customer Service Department makes an assessment of the situation, briefly describes the severity of the matter and puts forward handling suggestions; the handling may include the following decisions:


- a) 暂停/撤消证书； Suspension / withdrawal of certificates;
- b) 发出整改/纠正措施要求； Issue rectification / corrective action requirements;

7.2.4 企业将纠正及纠正措施报告提交客服部， 如未提交， 将撤消证书。

The client will submit the corrective and corrective action report to the Customer Service Department. If not, the certificate will be revoked.

7.2.5 客服部将收到的报告交审核部， 审核部确定是否恢复证书， 或安排特殊审核。该决定记录于《政府/监管机构投诉管理看板》并邮件通知客户经理抄送技术质量部。

The Customer Service Department will submit the report received to the audit department, which will determine whether to restore the certificate or arrange special audit. The decision is recorded in <Management Kanban of the Government / Regulatory Agency Complaint> , and the Customer Manager is informed by email and copied to the Technical & Quality Department.

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7.2.6 技术质量部验证处理有效性，并记录于《政府/监管机构投诉管理看板》。


The Technical & Quality Department shall verify the effectiveness of handling and record it in <Management Kanban of the Government / Regulatory Agency Complaint>.

8.记录 Record

《申诉报告 Appeal Report》


《投诉报告 Complaint Report》

《政府/监管机构投诉管理看板 Management Kanban of the Government / Regulatory Agency Complaint》

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《投诉报告 Complaint Report》

投诉信息	
日期 Date:	
投诉人 Complainant:	投诉人的单位、职务、联系方式; Unit, position and contact information of the Complainant
代理人 Agent (if any):	
责任人 responsible:	被投诉人, 单位、职务、联系方式; Unit, position and contact information of the Complainant
投诉陈述 Complaint statement:	
投诉确认 Complaint confirm	
受理与否	
通知顾客时间	
事件调查 Incident investigation	
事件认定 Incident definition	
(处理 Handling)	
(小组会议与处理决定 Team meeting and handling decision)	
小组成员 Team member:	
会议时间 Meeting time:	
事件认定 Incident definition	
相关处理 handle decision:	
措施计划 Action plan (被认定为系统性问题时 when it is identified as a systematic problem)	
原因分析 Cause analysis:	
纠正措施 Corrective action:	
措施计划 action schedule:	
实施情况 Implementation situation:	
验证/备注 verification / Remarks	

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《申诉报告 Appeal Report》

申诉信息 Appeal Information	
日期 Date:	
申诉人 Appellant:	申诉人的单位、职务、联系方式; Unit, position and contact information of the Complaint
代理人 Agent (if any):	
审核组 Audit team	
投诉陈述 Complaint statement:	
投诉确认 Appeal confirm	
受理与否	
通知顾客时间	
申诉陈述 Appeal statement	
事件调查 Incident investigation	
认定 Definition	
处理决定 Handling Decision	
措施计划 Action plan (被认定为系统性问题时 when it is identified as a systematic problem)	
原因分析 Cause analysis:	
纠正措施 Corrective action:	
措施计划 action schedule:	
实施情况 Implementation situation:	
验证/备注 verification / Remarks	

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《政府/监管机构投诉管理看板》

<Management Kanban of the Government / Regulatory Agency Complaint>

1 序号 No.	2 投诉时间 Complaint time:	3 投诉发出部门 Complaint sending Department	4 投诉涉及的企业 Client involved in complaints	5 投诉陈述 Complaint statement	6 客服调查结果 Customer service survey results	7 客服部处理意见 Handling opinions of Customer Service Department	8 审核部验证与决定 Verification and decision of audit department	9 技术质量部验证并确定是否采取纠正措施 The technical department verifies and determines whether corrective measures are taken

日期 Date	变更简述 Description of Change	发起人 Originator
03/01/2020	初始建立 Initial establishment	赵建忠
1/28/2021	3.1.1 updated 更新	赵建忠
5/16/2021	7.1 updated: add National Medical products Administration (www.nmpa.gov.cn)、FDA (https://www.fda.gov/)、CE https://europa.eu/european-union/index_en Website 增加信息的获网站 add information acquisition website	裴一君
7/12/2023	公司简称更新, LOGO 更新, 表单号更新 Company abbreviation update, logo update, form number update	裴一君