Audit Plan 审核计划

Version 版本__1.0__

Order no.项目号: SH20165601

1 Audit Overview 审核概述

Type of Audit 审核类型	☐Stage 1一阶段审核 ☒Stage 2 二阶段审核 ☐Stage 1 + Stage 2 一阶段+二阶段审核 ☐Re-Certification 续证审核 ☐1st Surveillance 第一次监督审核 ☐2nd Surveillance 第二次监督审核 ☐Special Audit Type特殊审核类型: _____
Additional Type of Audit 附加审核类型	☐Scope Expansion QMS (Products / Processes / Facilities) QMS范围扩证（产品/过程/场地） ☐Scope Expansion Regulatory (Products / Processes / Facilities) 法规范围扩证（产品/过程/场地） ☐Upgrade / change QMS Standard 升级/变更QMS标准 ☐Other 其他: _____
Audit criteria 审核准则	☒ (DIN) EN ISO 13485:2016 ☒ ISO 13485:2016 ☒ Defined processes and documentation of the auditee's Quality Management System 受审核方质量管理体系所规定的过程及文件
Audit period (on site) 审核时间（现场）	2020-08-20 - 2020-08-21
Auditee (s) / Location(s) 受审核方 / 地址	Zhejiang Anji Saianfu Biotech Co., Ltd., 2nd Floor,No. 3 Factory, No. 489 WenYun Road,TangPu Industrial Park,Dipu Town, Anji county, HuZhou City, Zhejiang Province, People's Republic of China (108123)
Audit Responsible 审核联系人	Mr. Qing Wang 王倾先生
Lead Auditor / Auditor 审核组长 / 审核员	Mr. WenZhe Xue(ALA)薛文哲先生(X) / Mr. He Yan(L.A)晏鹤先生(Y)
Expert / Trainee 专家 / 实习审核员	N.A / Mr.XiaoJian Fan范小建先生(F)
Auditor Reg. No. (Mainland China only) 审核员注册号 （中国大陆适用）	晏鹤先生 2019-N1QMS-1240575 薛文哲先生 2020-N1QMS-1250113 CCAA auditor specialty code:19.11.00 CCAA审核员专业代码:19.11.0
Translator / Observer and their organization 翻译 / 观察员及其组织	N.A/N.A

Audit Plan 审核计划

Version 版本__1.0__

Order no.项目号: SH20165601

QM Manual: Revision / Date 质量手册包括版本及发布日	
Audit Language 审核语言	Chinese
First release of Audit Plan / Date 审核计划初版发布/日期	1.0/2020.8.1

1.1 Audit Objectives 审核目标

The objectives of this Audit are:
- Determine conformance of the Management System with the Audit Criteria (see above)
- Evaluate the effectiveness of the Management System in meeting its specified quality objectives
- Evaluate the capability of the Management System to ensure compliance with relevant statutory, regulatory and contractual requirements (as applicable)
- Evaluate the effectiveness of the Management System to ensure that agreed requirements for products and/or services are met
- Identify areas for potential improvement of the Management System

此次审核的目标是:

- 确认质量管理体系与审核准则的符合性(见上面的审核准则)
- 评估质量管理体系在满足既定的质量目标方面的有效性
- 评估质量管理体系在保证满足符合相关法律、法规与合同要求(适用时)的能力
- 评估质量管理体系在保证产品 / 服务满足既定的要求方面的有效性
- 识别质量管理体系潜在提高的地方

2 Audit Program(s) 审核程序

The completion of the audit program(s) and the fulfilment of code requirements shall be in accordance with MED_W_09.16, including the limitations for use of QMS auditors. If the audit is related to MED_W_09.46, then the clause coverage related to the combination of the Part A and Part B audit should be entered into the audit being replaced by the MED_W_09.46 approach.

审核程序的完成和代码要求的完成应符合MED_W_09.16，包括使用QMS审核员的限制。如果审核与MED_W_09.46相关，那么条款中覆盖与A和B部分结合审核相关的应该被MED_W_09.46方法所取代。

2.1 (DIN EN) ISO 13485:2016 / EC-Directives 指令/ EU Regulation 法规

Planning according to (DIN EN) ISO 13485:2016 / EC-Directives / EU Regulation per Location: (if multi site)

依据 DIN EN ISO 13485:2016/EC 指令/EU 法规对每个场地进行策划： （如果多场地）

Clauses 条款	4	5	6					7																							
			1	2	3	4		1	2			3										4			5						
						1	2		1	2	3	1	2	3	4	5	6	7	8	9	10	1	2	3	1	2	3	4	5	6	7	8
Cert / Recert 发证/续证	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	NA	X	NA	X	NA	X
Every S 每次年审	X	X		X				X		X	X									X		X			X							
S1 第一次年审	X	X	X	X	X	X	X	X	X	X	X	/	/	/	/	/	/	/	/	X	/	X	X	X	X	/	NA	/	NA	/	NA	/
S2 第二次年审	X	X	X	X	/	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	/	/	/	X	NA	X	NA	X	NA	X
Recert 续证	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	NA	X	NA	X	NA	X

Clauses 条款	7				8														
	5			6	1	2					3				4	5			
	9	10	11			1	2	3	4	5	6	1	2	3	4		1	2	3
Cert / Recert 发证/续证	NA	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Every S 每次年审	NA					X	X	X	X	X	X			X		X	X	X	X
S1 第一次年审	NA	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
S2 第二次年审	NA	/	X	/	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X
Recert 续证	NA	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X	X

Cycle 周期	EA Code(s) EA 代码	MD/ IVD Code(s) MD/ IVD 代码	MDS Code(s) MDS 代码
Cert / Recert 发证/续证	12.2	IVD000R	N.A
S1 第一次年审	12.2	IVD000R	N.A
S2 第二次年审	12.2	IVD000R	N.A
Recert 续证	12.2	IVD000R	N.A
If multiple site, note site specific differences for codes or process: 如多场地，注意针对代码或过程的不同场地区别：			

Cycle 周期	MDT/IVT Code(s) MDT/IVT 代码	MDS/IVS Code(s) MDS/IVS 代码	MDA/MDN/IVR Code(s) MDA/MDN/IVR 代码	IVP/IVD Code(s) IVP/IVD 代码
Cert / Recert 发证/续证	/	/	/	/
S1 第一次年审	/	/	/	/
S2	/	/	/	/

第二次年审				
Recert 续证	/	/	/	/
If multiple site, note site specific differences for codes or process: 如多场地，注意针对代码或过程的不同场地区别：				

2.2 ISO 9001:2015(N.A)

2.3 MDSAP(N.A)

Audit Plan 审核计划

Version 版本__1.0__

Order no.项目号: SH20165601

3 Audit Plan 审核计划

Date / Time 日期 / 时间 Auditor, Expert, Trainee 审核员，专家，实习审核员	Function / Unit / Location 功能/ 单位/ 地址	Audit Scope (Process) 审核范围 (过程)	Participants Auditees 受审核方参加人员
2020.8.20 10:30-11:00 X,Y,F	TUVSUD & Client 南德与安吉赛安芙	Opening meeting 首次会议	All 所有人员
11:00-11:30 X,F	Management 管理层	Responsibility and Authority, QMS Process Planning, Quality Policy, Quality Objectives, Management review Data analysis,report to regulatory authories (4.1, 4.2.1, 4.2.2, 5.1, 5.2, 5.3, 5.4, 5.5, 5.6, 6.1, 8.1,8.2.3,,8.4) 职责和权限，质量管理体系过程的策划，质量方针，质量目标，管理评审，数据分析，向监管机构报告	Top Management 管理层
11:30-12:30 X,F	CAPA 纠防措施	CAPA (8.5) 纠正预防措施	Related Participants 相关人员
11:00-11:30 Y	Complaint 投诉	Customer related process, Customer feedback, Compliant handling 顾客反馈，投诉处理(8.2.1,8.2.2)	Related Participants 相关人员
11:30-12:30 Y	Sales 销售	Contract review 合同评审（7.2）	Related Participants 相关人员
12:30-13:00 Lunch break 午餐时间			
13:00-15:00 X,F	On-site view 现场	Production process control, work environment control, process inspection, warehouse, products inspection etc. (6.4, 7.1,7.5.1, 7.5.8,7.5.9,7.5.10,7.5.11, 8.2.3, 8.2.5,8.2.6,8.3) 生产过程控制，工作环境控制，过程检验，仓库,不合格品，设备维护保养，产品检验等	Related personnel 相关人员
15:00-17:00 X,F	Traceability DMR 追溯性 主文档	DHR, Traceability control (7.5.9) Device Master File (4.2.3) 批记录，追溯性控制(7.5.9)，产品主文档（4.2.3）	Related personnel 相关人员
13:00-17:00 Y	R&D reagent 试剂研发	Design and development control 研发控制(7.1, 7.3)	R&D 研发部
End of 1st day第一天你审核结束			
2020.8.21 8:30-10:00 X,F	Purhase control 采购控制	Purchasing process, Supplier Control 采购,供应商控制 (7.4)	Related-personnal 相关人员

Audit Plan 审核计划

Version 版本__1.0__

Order no.项目号: SH20165601

Date / Time **日期 / 时间** **Auditor, Expert, Trainee** **审核员，专家，实习审核员**	**Function / Unit / Location** **功能/ 单位/ 地址**	**Audit Scope (Process)** **审核范围 （过程）**	**Participants Auditees** **受审核方参加人员**
10:00-11:00 X,F	Human resoures 人力资源	Training (6.2) 培训（6.2）	HR
11:00-12:30 X,F	Calibration 校准	Calibration 校准（7.6）	Related-personnal 相关人员
9:30-11:00 Y	validation 确认	Special Process validation control 特殊过程确认控制(7.5.6)	Related-personnal 相关人员
11:00-12:30 Y	Document control 文件控制	Documents and Record control, Device Master File 文件和记录控制(4.2.4, 4.2.5) 产品主文档(4.2.3)	Related-personnal 相关人员
12:30-13:00 Lunch break 午餐时间			
13:00-14:30 X	Infrastructure 基础设施	equipment maintenanc 设备维护(6.3)	Related-personnal 相关人员
13:00-14:30 Y,F	Internal Audit 内审	Internal audit, CAPA 内审，纠正预防措施（8.2.4, 8.5.2,8.5.3）	Related-personnal 相关人员
14:30-14:45 X,Y,F	Audit group internal discussion 审核组内部讨论		
14:45-15:15 X,Y,F:	TUVSUD & Client 南德与安吉赛安芙	Close Meeting 末次会议	All personal 所有相关人员

A room for the Audit Team should be provided to ensure undisturbed communication as well as safe keeping of documents. The Auditors are accompanied by the Audit responsible during the Audit. The Audit Plan can be adjusted during the Audit. Opening and closing meeting are fixed.

请为审核组提供一个房间以确保不受干扰的交流以及文件的安全放置。审核中请安排陪同人员。审核计划可以根据情况相应调整。首末次会议的时间是固定的。

Please note: The company and the Lead Auditor should discuss any personal protective equipment needed for the Audit well in advance before the start of the Audit. Protective equipment (helmet, safety shoes, safety goggles, cleanroom clothes) must be provided by the audited company.

请注意：公司与审核组长应该在开始审核之前讨论审核中必要的个人防护用品。个人防护用品（安全帽、安全鞋、护目镜、洁净室衣物等）应由受审核公司准备。

4 Signatures 签名

The parties agree that the contract shall be concluded in text form. To comply with this requirement any transmission using telecommunication means (e.g. via letter, fax, e-mail) and a simple signature (e.g. by electronic signature with Adobe Sign) is sufficient.
双方同意以文本形式订立本合同。为符合此要求，任何使用电信手段的传输(例如通过信件、传真、电子邮件)和简单的签名(例如通过带有Adobe签名的电子签名)都是充分的。

The complete audit plan record may consist of two documents: (1) The audit plan signed by the audit team and client prior to the audit, Sections 4.1 and 4.2; (2) The audit plan signed by the lead auditor after the audit, Section 4.3.
完整的审核计划记录可能包括两个文件:(1)审核小组和客户在审核前签字的审核计划，第4.1和4.2条;(2)审核后由审核组长签字的审核计划，第4.3条。

4.1 Audit Team (Prior to the Opening Meeting) 审核组（首次会议之前）

- We have read, understood and accepted the “Independence, Impartiality, Conflict of Interest and Confidentiality Requirements” procedure MED_P_09.09.
- 我们已经阅读、理解并接受程序文件MED_P_09.09中“独立性、公正性、利益冲突及保密性的要求”。
- To the best of our knowledge we hereby declare that we are independent, impartial and objective in respect of this project and have no conflict of interest.
- 据我们所知，特此声明，我们对于此项目具有独立性、公正性和客观性并且不存在利益冲突。
- Lead Auditor: I confirm that the Audit Plan is released prior to the Audit.
- 审核组长：我确认审核计划已于审核前发布。

Auditor(s) / Expert(s) / Trainee (signature, date) 审核员/ 专家/ 实习审核员（签名，日期）

4.2 Client (Prior to the Opening Meeting) 客户（首次会议之前）

- We confirm that Quality Management System certification marks are not used in any advertising that implies that they apply to products.
- 我们确认质量管理体系认证标志没有用于任何宣传材料来暗示该证书适用于产品。
- We confirm that this Audit Plan including Audit objectives are accepted.
- 我们确认接受该审核计划，包括审核目标。
- We confirm that the Auditors / Experts / Translator are accepted**.**
- 我们确认接受审核员/专家/翻译人员。
  - Including the fact that the following person(s) is/are employed by the local TÜV SÜD Product Service company: Mr He Yan, Mr WenZhe Xue, Mr XiaoJian Fan;
  - 包括下列TÜV SÜD产品服务有限公司当地公司雇用的审核员：晏鹤先生，薛文哲先生，范小建先生；
- We confirm that we have the necessary infrastructure to support the Information and Communication Technology (ICT) proposed within the audit program and approve the use of ICT.
- 我们确认我们配备必需的基础设施，以支持审核程序中提出的信息和通信技术(ICT)，并批准使用ICT。

Audit Responsible (signature, date) 审核联系人（签字，日期）

4.3 Lead Auditor (Prior to Closing Meeting) 审核组长（末次会议之前）

The audit has been performed as documented within this audit plan.

审核已按本审核计划中的文件规定执行。

Based on the objective evidence, the Audit Team confirms that the Audit objectives have been met. The Audit Team concludes that the company's Quality Management System

基于客观证据，审核小组确认以上审核目标已达成。审核小组的结论是受审核方的质量管理体系

☐ Conforms with the Audit criteria as specified above 满足上述审核准则

☐ Does not fully conform with the Audit criteria as specified above.
The Audit Team did identify nonconformities
Refer to See **Findings List** for more details including follow-up actions

不完全满足上述审核准则，审核小组识别的不符合项详见审核发现清单其中包含后续措施。

☐ Re-Certification Audit:
The Audit results from the last three (3) years were considered for both the Audit planning and the current conclusion for this recertification

续证审核：

审核计划及本次续证结论会参考过去三年的审核结果。

Lead Auditor (signature, date): 审核组长（签字，日期）：

---

cc: Audit responsible; Audit Team members, Certification Body

抄送: 审核联系人; 审核团队成员，发证机构

5 Version History 版本历史

Rev. No. 版 本号	Date 日期 (yyyy-mm-dd)	Name of Reviewer 评审人	Description of Change 变更描述
0			Creation of report
1			

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 108123

Holder of Certificate: **Zhejiang Anji Saianfu Biotech Co., Ltd**
2nd Floor, No. 3 Factory
No. 489 WenYun Road
TangPu Industrial Park, Dipu Subdistrict
Anji county
313303 Huzhou City, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

Facility(ies):
Zhejiang Anji Saianfu Biotech Co., Ltd
2nd Floor, No. 3 Factory, No. 489 WenYun Road, TangPu Industrial Park, Dipu Subdistrict, Anji county, 313303 Huzhou City, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of in vitro Diagnostic Reagents for Rapid Tests for Fertility, Drug of Abuse, Cardiac Diseases, Infectious Diseases, Oncology**

Applied Standard(s):
EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: SH20165601

Valid from: 2020-07-21
Valid until: 2023-07-20

Date, [#ISU_DT#] Christoph Dicks

Head of Certification/Notified Body

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany