认证组织体系标准和法规要求文件对照表

Comparison Table of Certification Organization System Standards and Regulatory Requirements

填写说明 Filling Instructions:

1.申请认证组织应按照 GB/T42061 idt ISO13485 标准对过程或程序形成文件的 32 处要求，对照《医疗器械经营质量管理规范》相关文件要求，识别组织的体系文件的对应关系，将对应的文件名称填写在“组织对应文件”栏目。

The applying certification organization should identify the correspondence of the organization's system documents with the relevant requirements of the '*Good Sales Practice for Medical Devices '* by comparing the 32 requirements for process or procedure documentation as per the GB/T42061 idt ISO13485 standards, and fill in the corresponding document names in the 'Corresponding Organization Documents' column.

2. 组织的体系文件与标准、规范的文件内容和名称可能不是一一对应关系，在“备注”栏目中简单说明。（如：一份组织的文件内容可能对应多个标准、规范的文件内容，或一个标准、规范的文件要求由多份组织文件体现，这些均在“备注”中说明）

The content and names of the organization's system documents may not correspond one-to-one with the standards and GSP; a brief explanation should be provided in the 'Remarks' column. (For example: the content of one organizational document may correspond to multiple standard or GSP documents, or a requirement from a standard or GSP may be reflected in multiple organizational documents; all of these should be explained in the 'Remarks.')

3.填写本表不仅是文件名称的对应，更重要的是文件内容的符合性、完整性。

Filling out this form is not only about the correspondence of document names but, more importantly, about the compliance and completeness of the document content.

序号 Serial No.	**GB/T42061** GB/T42061 idt ISO13485 **GB/T 42061** GB/T42061 idt	**《规范》文件要求 Requirements of the GSP**	**组织对应文件名称 Corresponding Document Name of the Organization**	**备注 Remarks**

	ISO13485 **文件要求** **Document Requirements**			
		第八条（二）质量管理的规定 Article 8 (2) Regulations on Quality Management		
1	4.1.6 用于质量管理体系计算机软件应用的确认程序形成文件 4.1.6 Document the validation Procedure of Computer Software Applications Used in Quality Management Systems	第三十条 经营第三类医疗器械的企业，应当具有符合医疗器械经营质量管理要求的计算机信息管理系统，保证经营的产品可追溯。 Article 30 Enterprises engaged in the operation of Class III medical devices shall have a computer information management system that meets the quality management requirements for medical device operations, ensuring the traceability of the products operated.		
2	4.2.4 文件控制 形成文件的程序 4.2.4 Document Control Documented procedures			

3	4.2.5 记录控制 建立程序并形成文件 4.2.5 Record Control Establish procedures and document them			
4	5.6 管理评审程序形成文件 5.6 Documented Management Review Procedures			
5	6.2 将确立能力、提供所需的培训和确保人员的意识等一个或多个过程形成文件 6.2 Establishing competence, providing necessary training, and ensuring personnel awareness etc. one or more processes, and documented them.	第八条（一）质量管理机构或者质量管理人员的职责 Article 8 (1) Responsibilities of the quality management organization or quality management personnel （十三）质量管理培训及考核的规定（包括培训记录等） （13）Regulations on quality management training and assessment (including training records, etc.)		ETC
	6.3	第八条（十一）设施设备维护及验证和校准的规定（包括设施设备相关记录和档案等） Article 8 (11)		

		Regulations on the maintenance, verification, and calibration of facilities and equipment (including related records and archives, etc.)		
6	6.4.1 将工作环境要求以及监视和控制工作环境的程序形成文件。 6.4.1 Document the requirements for the working environment and the procedures for monitoring and controlling the working environment.			
7	7.1 将风险管理的一个或多个过程形成文件 7.1 Document one or more processes of risk management			
	7.2	第八条（六）销售和售后服务的规定（包括销售人员授权书、购货者档案、销售记录等） Article 8 (6) Regulations on sales and after-sales service (including sales personnel authorization,		

		purchaser files, sales records, etc.)		
8	7.3.1 总则 组织应将设计和开发程序形成文件 7.3.1 General Principles The organization shall document the design and development procedures			
9	7.3.8 设计和开发转换 组织应将设计和开发输出向制造转换的程序形成文件 7.3.8 Design and Development Transition The organization shall document the procedures for converting design and development outputs to manufacturing			
10	7.3.9 设计和开发更改的控制 组织应将控制设计和开发更改的程序形成文件 7.3.9 Control of Design and Development Changes The organization shall document the procedures for controlling design and development changes			
11	7.4.1 采购过程 组	第八条（三）采购、		

	织应将确保采购的产品符合规定的采购信息的程序形成文件 7.4.1 Purchasing Process The organization shall document the procedures to ensure that purchased products meet specified purchasing information	收货、验收的规定（包括采购记录、验收记录、随货同行单等）； Article 8 (3) Regulations on procurement, receipt, and acceptance (including procurement records, acceptance records, accompanying documents, etc.); （四）供货者资格审核的规定（包括供货者及产品合法性审核的相关证明文件等） (4) Regulations on the qualification review of suppliers (including relevant certification documents for the legality of suppliers and products, etc.)		
12	7.5.4 服务活动 组织应将服务程序、所涉及的材料和所涉及的测量形成文件 7.5.4 Service Activities The organization shall document the service procedures, the materials	第六十四条 Article 64 建立健全售后服务制度 Establish and improve the after-sales service system.		

	involved, and the measurements involved.			
13	7.5.6 生产和服务提供过程的确认 组织应将过程确认程序形成文件 7.5.6 Confirmation of the production and service provision process The organization shall document the process confirmation procedures.			
14	7.5.6 生产和服务提供过程的确认 将用于生产和服务提供的计算机软件应用的确认程序形成文件 7.5.6 Validation of production and service delivery processes The validation procedures for computer software applications used in production and service provision shall be documented.			
15	7.5.7 灭菌过程和无菌屏障系统确认的专用要求 组织应将灭菌过程和无菌屏障系统的确认程序形成文件 7.5.7 Specific Requirements for the			

	Confirmation of Sterilization Processes and Aseptic Barrier Systems: The organization shall document the validation procedures for sterilization processes and aseptic barrier systems.			
16	7.5.8 产品标识 组织应将产品标识程序形成文件 7.5.8 Product Identification: The organization shall document the product identification procedures.			
17	7.5.8 产品标识 组织应建立程序并形成文件以确保返回组织的医疗器械能被识别且能与合格的产品区分开。 7.5.8 Product Identification: The organization shall establish procedures and document them to ensure that medical devices returned to the organization can be identified and distinguished from			

	qualified products.			
18	7.5.9 可追溯性 组织应将可追溯性程序形成文件 7.5.9 Traceability: The organization shall document the traceability procedures.	第八条 购货者资格审核、医疗器械追踪溯源。 Article 8 Buyer Qualification Review, Medical Device Traceability.		
19	7.5.11 产品防护 组织应将为产品符合要求提供防护的程序形成文件 7.5.11 Product Protection The organization shall document the procedures for providing protection to ensure product compliance.	第八条（五）库房贮存、出入库管理的规定（包括温度记录、入库记录、定期检查记录、出库记录等） Article 8 (5) Regulations on the storage and management of warehouses (including temperature records, storage records, regular inspection records, and outbound records, etc.)		
20	7.6 监视和测量设备的控制 组织应建立程序并形成文件，以确保监视和测量活动可行并以与监视和测量要求相一致的方式实施 7.6 Control of Monitoring and Measurement	第五十六条建立质量控制程序 ，规定产品检验部门、人员、操作等要求，并规定检验仪器和设备的使用、校准等要求，以及产品放行的程序 Article 56 Establish		

	Equipment The organization shall establish procedures and document them to ensure that monitoring and measurement activities are feasible and implemented in a manner consistent with monitoring and measurement requirements.	quality control procedures, stipulating the requirements for product inspection departments, personnel, operations, etc., as well as the requirements for the use and calibration of inspection instruments and equipment, and the procedures for product release.		
21	7.6 监视和测量设备的控制 组织应将用于监视和测量要求的计算机软件应用的确认程序形成文件 7.6 Control of Monitoring and Measurement Equipment: The organization shall document the validation procedures for computer software applications used to monitor and measure requirements.			
22	8.2.1 反馈 组织应将反馈过程程序形成文件 8.2.1 Feedback:	第八条（十四）医疗器械质量投诉、事故调查和处理报告的规定（包括质量投		

	The organization shall document the feedback process procedures.	诉、事故调查和处理报告相应的记录及档案等） Article 8 (14) Regulations on Quality Complaints, Incident Investigation, and Handling Reports for Medical Devices (including corresponding records and archives of quality complaints, incident investigations, and handling reports, etc.)		
23	8.2.2 投诉处理 组织应按照适用的法规要求将及时处理投诉的程序形成文件 8.2.2 Complaint Handling The organization shall document the procedures for timely handling of complaints in accordance with applicable regulatory requirements.	第八条（十四）医疗器械质量投诉、事故调查和处理报告的规定（包括质量投诉、事故调查和处理报告相应的记录及档案等） Article 8 (14) Regulations on Quality Complaints, Incident Investigation, and Handling Reports for Medical Devices (including corresponding records and archives		

		of quality complaints, incident investigations, and handling reports, etc.)		
24	8.2.3 向监管机构报告组织应将向有关的监管机构报告的程序形成文件 8.2.3 Reporting to Regulatory Authorities The organization shall document the procedures for reporting to the relevant regulatory authorities.	第八条（九）医疗器械不良事件监测和报告规定（包括停止经营和通知记录等） Article 8 (9) Regulations on Monitoring and Reporting Adverse Events of Medical Devices (including cessation of operations and notification records, etc.)		
25	8.2.4 内部审核 组织应建立程序并形成文件以说明策划和实施审核以及记录和报告审核结果的职责和要求 8.2.4 Internal Audit The organization shall establish procedures and document the responsibilities and requirements for planning and conducting audits, as well as recording and reporting audit results.	第八条 质量管理制度执行情况考核的规定。 Article 8 Regulations on the Assessment of the Implementation of the Quality Management System. 第三类医疗器械经营企业应当建立质量管理自查制度，于每年年底前向所在地设区的市级食品药品监督管理部门		

		提交年度自查报告 Class III medical device operating enterprises shall establish a quality management self-inspection system and submit an annual self-inspection report to the local municipal food and drug supervision and administration department by the end of each year.		
26	8.2.6 产品的监视和测量 监视和测量应依据形成文件的程序 8.2.6 Product Monitoring and Measurement Monitoring and measurement shall be based on documented procedures.	第五十一条 医疗器械出库应当复核并建立记录，复核内容包括购货者、医疗器械的名称、规格（型号）、注册证号或者备案凭证编号、生产批号或者序列号、生产日期和有效期（或者失效期）、生产企业、数量、出库日期等内容。 Article 51: The delivery of medical devices shall be reviewed and records shall be established, includes the purchaser, the name		

		of the medical device, specifications (model), registration certificate number or filing voucher number, production lot number or serial number, production date and expiration date (or expiration period), manufacturing enterprise, quantity, and outbound date.		
27	8.3.1 不合格品控制 组织应建立程序并形成文件以规定不合格品控制以及不合格品识别、记录、隔离、评价和处置的有关职责和权限 8.3.1 Control of Nonconforming Products The organization shall establish procedures and document them to specify the responsibilities and authorities related to the control, identification, recording, isolation, evaluation, and disposal of nonconforming products.	第八条（七）不合格医疗器械管理的规定（包括销毁记录等） Article 8 (7) Regulations on the management of non-conforming medical devices (including destruction records, etc.)		

28	8.3.3 交付后发现不合格品的响应措施 组织应按照适用的法规要求将忠告性通知的发布程序形成文件 8.3.3 Response measures for non-conforming products discovered after delivery. The organization shall document the procedure for issuing advisory notifications in accordance with applicable regulatory requirements.	第八条（七）不合格医疗器械管理的规定（包括销毁记录等）（八）医疗器械退、换货的规定 Article 8 (7) Regulations on the management of non-conforming medical devices (including destruction records, etc.) (8) Regulations on the return and exchange of medical devices （十）医疗器械召回规定（包括医疗器械召回记录等） (10) Regulations on the recall of medical devices (including medical device recall records, etc.)		
29	8.3.4 返工 组织应按照考虑了返工对产品的潜在不良影响所形成文件的程序进行返工 8.3.4 Rework. The organization shall carry out rework according to documented procedures that consider the potential adverse effects	第八条（七）不合格医疗器械管理的规定（包括销毁记录等）（八）医疗器械退、换货的规定 Article 8 (7) Regulations on the management of non-conforming medical devices (including destruction		

	of rework on the product.	records, etc.) (8) Regulations on the return and exchange of medical devices		
30	8.4 数据分析 组织应将确定、收集和分析适当数据的程序形成文件 8.4 Data Analysis The organization should document the procedures for determining, collecting, and analyzing appropriate data			
31	8.5.2 纠正措施 规定要求的程序形成文件 8.5.2 Corrective Actions Document the procedures required by the regulations			
32	8.5.3 预防措施 说明要求的程序形成文件 8.5.3 Preventive Measures Documentation Requirements for Procedures			