

## CMD 认证组织合规管理指南（试行稿）

# **CMD Certified Organizations Compliance Management Guidelines (Draft for Trial)**

### 1、目的 Objective

为规范组织合规管理，有效防范合规风险，确保组织在 QMS 运行中满足适用的法规要求，实现合规目标。

To standardize compliance management within organizations, effectively prevent compliance risks, ensure that organizations meet applicable regulatory requirements during QMS operations, and achieve compliance objectives.

现参照 GB/T42061 标准、YY/T0595 标准和 GB/T35770 标准，制定 CMD 认证组织合规管理指南。

Currently, the CMD Compliance Management Guidelines are formulated with reference to GB/T 42061 standards, YY/T 0595 standards, and GB/T 35770 standards.

### 2、范围 Scope

每个组织都应实施一系列的适用法规要求，这些法规要求相互关联、相互依赖构成组织的合规系统。组织应依据组织的环境、相关方的需求和期望、合规的适用法规要求，确定合规管理范围。

Each organization should implement a series of applicable regulatory requirements, which are interrelated and interdependent, forming the organization's compliance system. Organizations should determine the scope of compliance management based on their environment, the needs and expectations of relevant stakeholders, and applicable regulatory requirements.

本程序文件适用于组织合规系统管理的收集、识别、评定、运行和控制、检查和改进、与监管机构沟通和向监管机构报告等过程。

This procedural document applies to the processes of collecting, identifying, assessing,

operating and controlling, inspecting and improving the organization's compliance system management, communicating with regulatory agencies, and reporting to regulatory agencies.

### 3、职责 Responsibilities

#### 3.1 最高管理者 Top Management

——领导组织的合规管理，制定合规方针，坚守合规承诺，实现合规目标；

Lead the organization's compliance management, establish compliance policies, uphold compliance commitments, and achieve compliance objectives;

——宣贯法规，倡导合规文化，增强员工法规意识，明确员工合规承诺；

Promote regulations, advocate a compliance culture, enhance employees' awareness of regulations, and clarify employees' compliance commitments;

——确定组织职能部门的合规职责权限以及分配、沟通与理解；

Determine the compliance responsibilities and authorities of the organization's functional departments, as well as allocation, communication, and understanding;

——确保配备合规管理所需资源；

Ensure the provision of resources necessary for compliance management;

——指定一名合规代表（见附录）。

Designate a compliance representative (see appendix).

#### 3.2 合规代表

##### Compliance Representative

——在最高管理者的领导下负责合规管理的日常工作，以及合规管理和组织QMS的融合；

Responsible for the daily work of compliance management under the leadership of the top management, as well as the integration of compliance management and organizational QMS;

——组织编制合规管理各过程的作业指导文件，明确职能部门或责任人的合规

职责，并监督落实。文件的详略程度取决于组织的规模、结构、复杂性、产品类别等因素；

Organize the preparation of work instruction documents for each process of compliance management, clarify the compliance responsibilities of functional departments or responsible persons, and supervise the implementation. The level of detail in the documents depends on factors such as the size, structure, complexity, and product categories of the organization;

——组织合规要求的教育和持续培训，确保员工有能力履行合规承诺，特别要及时宣贯新的或变更的适用法规要求，确保组织持续合规；

Education and ongoing training on organizational compliance requirements to ensure that employees are capable of fulfilling compliance commitments, particularly to promptly communicate new or amended applicable regulatory requirements, ensuring the organization remains in compliance;

——负责合规风险的识别和评估，以达到对合规风险的有效应对和管控，实现合规目标；

Responsible for the identification and assessment of compliance risks to achieve effective response and control of compliance risks, thereby realizing compliance objectives;

——组织合规检查和改进，按照监管部门的要求编写合规检查报告，识别和确定合规管理改进，以持续实现合规目标；

Organize compliance inspections and improvements, prepare compliance inspection reports according to the requirements of regulatory departments, identify and determine improvements in compliance management, and continuously achieve compliance objectives;

——负责与监管机构沟通和向监管机构报告；

Responsible for communication with regulatory agencies and reporting to regulatory agencies;

——组织参与国家、省市相关法规和标准的制修订工作和研讨。

Organize participation in the formulation and revision of relevant national and provincial regulations and standards, as well as discussions.

### 3.3 职能部门和员工

#### Functional Departments and Employees

——坚持履行合规职责，坚守合规承诺；

Adhere to compliance responsibilities and uphold compliance commitments;

——按照合规管理要求参与培训教育；

Participate in training and education according to compliance management requirements;

——报告合规问题，坚持改进优化合规管理的过程，确保组织满足法规要求。

Report compliance issues, adhere to the process of improving and optimizing compliance management, and ensure that the organization meets regulatory requirements.

## 4、 合规管理的运行策划和控制

### Planning and Control of Compliance Management Operations

组织应策划合规管理所需的过程，合规管理的过程包括法规的收集——识别——评定——运行和控制——检查和改进——与监管机构沟通和向监管机构报告的过程。各过程应按照 3.1、3.2 的有关要求，明确责任部门或责任人的合规职责，并编制作业指导文件，保留运行和控制的记录，以及防范合规风险的记录。

Organizations should plan the processes required for compliance management, which include the collection of regulations—identification—assessment—operation and control—inspection and improvement—and communication with regulatory agencies and reporting to regulatory agencies. Each process should clarify the compliance responsibilities of the responsible department or person according to the relevant requirements of 3.1 and 3.2, and prepare work instruction documents, retain records of operations and controls, as well as records to prevent compliance risks.

## 4.1 法规的收集和识别

### Collection and Identification of Regulations

4.1.1 确定法规收集的范围，组织应系统的收集和识别适用的法规。法规收集范围应考虑以下内容：

Determine the scope of regulatory collection; organizations should systematically collect and identify applicable regulations. The scope of regulatory collection should consider the following aspects:

——组织的类型、所属行业、在产业链中的角色所涉及的法律、法规、规章及规范性文件等，并包括省市地方的法规；

The type of organization, the industry it belongs to, the laws, regulations, rules, and normative documents involved in its role within the industry chain, including local regulations from provinces and cities;

——医疗器械全生命周期各阶段涉及的法规；

Regulations involved in all stages of the medical device lifecycle;

——利益相关方涉及的法规，如组织的客户、客户的顾客、政府部门（市场监管部门、医疗器械监管部门、卫健委、环保部门、信息安全部门等）、社会组织行业协会、社会及公众等；

Regulations related to stakeholders, such as the organization's customers, the customers' clients, government departments (market regulatory departments, medical device regulatory departments, health commissions, environmental protection departments, information security departments, etc.), social organizations, industry associations, society, and the public;

——相关标准(强制性标准、推荐性标准、国家标准、行业标准等)；

Relevant standards (mandatory standards, recommended standards, national standards, industry standards, etc.);

——出口国法规（适用时）；

Regulations of the exporting country (if applicable);

——法规收集是动态的，要及时收集新的及变更的法规（废止已失效的法规）；

Regulatory collection is dynamic and should timely gather new and amended regulations (repealing those that are obsolete);

#### 4.1.2 法规收集的渠道和方法

##### Channels and Methods for Regulatory Collection

主要通过政府部门的网络，医疗器械审评审批平台，不良事件监测信息平台，标准管理平台等渠道，以及和监管部门沟通等，按照 4.1.1 提出的范围及时收集新出台的法规和已发布法规的变化信息（包括修订、废止等）。

Mainly through government department websites, medical device review and approval platforms, adverse event monitoring information platforms, standard management platforms, etc., as well as communication with regulatory departments, timely collect newly issued regulations and changes to published regulations (including revisions, repeals, etc.) according to the scope proposed in 4.1.1.

#### 4.1.3 识别确定组织应贯彻执行的应用法规

##### Identify Applicable Regulations that the Organization Should Implement

按照组织自身的类型、在产业链中承担的角色及定位，定期的对收集的法规进行识别，确定组织应贯彻执行的应用法规。

Based on the organization's type, role, and positioning within the industry chain, regularly identify the collected regulations to determine the applicable regulations that the organization should implement.

合规代表组织相关人员定期确定组织适用的法规要求并融入组织合规予以管理。

The Compliance Representative shall regularly identify the regulatory requirements applicable to the organization and integrate them into the organization's compliance management.

## 4.2 合规要求的评定

### Assessment of Compliance Requirements

合规要求的评定包括识别的适用合规要求与组织 QMS 运行的关联，并进行风险评估。风险评估是用于不合规发生的可能性及其后果估计的过程。

The assessment of compliance requirements includes identifying applicable compliance requirements and their relationship with the operation of the organization's QMS, as well as conducting a risk assessment. Risk assessment is the process used to estimate the likelihood of non-compliance occurring and its consequences.

#### 4.2.1 合规代表组织相关职能部门及专业人员开展合规要求的评定；

The Compliance Representative organizes relevant functional departments and professionals to carry out the assessment of compliance requirements;

#### 4.2.2 合规要求与 QMS 运行的关联和风险评估；

The relationship between compliance requirements and QMS operation, and risk assessment;

组织要基于风险的思维，系统的评定合规众多法规要求与 QMS 运行的关联、风险评估。

Organizations should systematically assess the relationship between numerous regulatory requirements and QMS operation based on risk thinking and conduct risk assessments.

#### ——合规要求对组织产品、服务和活动的关联及风险评估；

The relationship and risk assessment of compliance requirements concerning the organization's products, services, and activities;

#### ——合规要求对 QMS 过程运行的关联及风险评估；

The relationship and risk assessment of compliance requirements to the operation of the QMS process;

#### ——合规要求对组织工作环境、基础设施、检测设备、人员能力等资源的关

联及风险评估；

The relationship and risk assessment of compliance requirements to the organization's work environment, infrastructure, testing equipment, personnel capabilities, and other resources;

——合规要求对组织其他相关方（供应链合作方等）的关联及风险评估；

The relationship and risk assessment of compliance requirements to other relevant parties of the organization (such as supply chain partners);

通过以上的评定，组织将系统的识别合规要求和组织 QMS 过程、产品、服务和活动的关联性，从而确定合规要求与 QMS 过程、产品、服务和活动融合的具体方法和途径，为合规要求在 QMS 运行中奠定基础。

Through the above assessment, the organization will systematically identify the relevance of compliance requirements to the organization's QMS processes, products, services, and activities, thereby determining specific methods and approaches for integrating compliance requirements with QMS processes, products, services, and activities, laying the foundation for the implementation of compliance requirements in QMS operations.

通过以上的评定，组织将对合规要求和组织 QMS 过程、产品、服务和活动关联中合规风险进行风险评估，识别可能发生的不合规场景，分析评估不合规的原因，即不合规可能造成的人员伤害、环境污染、经济财产损失、组织声誉的损害和相关责任等后果。通过风险评估，策划应对合规风险的措施，提升合规管理的有效性，以防范合规风险。

Through the above assessment, the organization will conduct a risk assessment of compliance risks associated with the relevance of compliance requirements to the organization's QMS processes, products, services, and activities, identifying potential non-compliance scenarios, analyzing and evaluating the causes of non-compliance, and the consequences of non-compliance, such as personnel injury, environmental pollution, economic property loss, damage to the organization's reputation, and related liabilities. Through risk assessment, plan measures to address compliance risks, enhance the



effectiveness of compliance management, and prevent compliance risks.

组织应保留合规要求评定的相关文件化信息。

The organization should retain relevant documented information regarding the assessment of compliance requirements.

#### 4.3 合规要求的运行和控制

##### Operation and Control of Compliance Requirements

##### 4.3.1 策划 Planning

——组织按照 4.2 合规要求的评定结果进行策划；

The organization plans according to the assessment results of compliance requirements in 4.2;

——合规代表组织编制合规要求融入 QMS 通用作业指导文件；

The compliance representative organizes the integration of compliance requirements into the general work instruction documents of the QMS;

主要有以下内容 The main contents are as follows:

- 补充或修订组织的 QMS 相关文件，将合规要求转化为 QMS 过程相关文件的组成部分，实施运行和控制，并确保合规要求的完整性；

Supplement or revise the organization's QMS-related documents, transforming compliance requirements into components of QMS process-related documents, implementing operation and control, and ensuring the integrity of compliance requirements;

- 确定相关职能部门或责任人的合规职责和合规承诺；

Determine the compliance responsibilities and compliance commitments of relevant functional departments or responsible persons;

- 需要时配备适宜的资源；

Provide appropriate resources when necessary;

- 编制合规要求的接收准则，确保 QMS 运行受控，并满足合规要求；

Develop acceptance criteria for compliance requirements to ensure that the QMS

operates under control and meets compliance requirements;

——依据合规要求的复杂程度和强制性标准的有关要求，组织需要编制特定的作业指导文件及接收准则，需要时要实施验证以确保满足合规要求；

Based on the complexity of compliance requirements and the relevant requirements of mandatory standards, the organization needs to develop specific work instruction documents and acceptance criteria, and implement verification when necessary to ensure compliance requirements are met;

——对新的和变化的法规要按 4.2 对以上要求及时进行评定和策划以确保组织持续合规。

New and changing regulations must be assessed and planned in a timely manner according to 4.2 to ensure the organization remains compliant.

#### 4.3.2 合规要求运行和控制

##### Operation and Control of Compliance Requirements

——按 4.3.1 的策划，合规要求融入组织的 QMS 中运行；

According to the planning in 4.3.1, compliance requirements are integrated into the operation of the organization's QMS;

——按 QMS 要求和合规要求的接收准则予以控制，以实现合规目标；

Control is implemented according to the acceptance criteria of QMS requirements and compliance requirements to achieve compliance objectives;

——合规要求在 QMS 运行中的任何变更，需经合规代表的批准。

Any changes to compliance requirements in the operation of the QMS must be approved by the Compliance Representative.

#### 4.4 合规检查和改进

##### Compliance Inspection and Improvement

##### 4.4.1 合规检查和改进

##### Compliance Inspection and Improvement

——合规代表负责组织对合规要求的实施情况进行检查，以确定组织合规的有效规范运行和控制，合规要求得到有效实施和落实；

The Compliance Representative is responsible for inspecting the organization's implementation of compliance requirements to determine the effective and normative operation and control of compliance, ensuring that compliance requirements are effectively implemented and fulfilled;

——合规检查宜包括在组织 QMS 内审中；

Compliance inspections should be included in the internal audits of the organization's QMS;

——合规要求检查中发现不合规事例和问题要及时进行风险评估，采取措施消除不合规原因及负面影响，确保合规系统规范运行和控制以满足合规要求；

Non-compliance cases and issues identified during the compliance requirements inspection must be promptly assessed for risk, and measures should be taken to eliminate the causes of non-compliance and negative impacts, ensuring the compliance system operates and controls in accordance with compliance requirements;

——合规代表应按照监管机构的要求编制合规检查报告；

The compliance representative should prepare the compliance inspection report in accordance with the requirements of the regulatory agency;

——合规检查报告应作为组织管理评审的输入。

The compliance inspection report should serve as input for the organization's management review.

#### 4.4.2 合规运行和控制的改进

##### Improvement of Compliance Operation and Control

——合规代表应考虑以下信息，实施合规运行和控制的改进；

The compliance representative should consider the following information to implement improvements in compliance operation and control;

- 组织自身的合规检查相关信息；

Information related to the organization's own compliance inspections;

- 监管机构日常监管和飞行检查、产品抽验等信息以及发布的监管处罚信息、产品召回信息等；

Information from the regulatory agency's routine supervision and spot checks, product sampling, as well as published regulatory penalties, product recall information, etc.;

- 相关不良事件信息；

Relevant adverse event information;

- 市场、顾客投诉信息；

Market and customer complaint information;

- 重大质量事故；

Significant quality incidents;

- 媒体、社会关注的有关信息；

Information of media and social concern;

- 其他信息；

Other information;

——合规代表依据以上信息，组织职能部门或责任人就提出的合规运行和控制的改进建议，形成改进计划，报最高管理者批准实施并进行验证。

The compliance representative organizes the functional departments or responsible persons to develop improvement plans based on the above information regarding compliance operations and control suggestions, which are then submitted for approval and implementation by the highest management and verified.

## 5、与监管机构沟通和向监管机构报告

### Communication with regulatory agencies and reporting to regulatory agencies

5.1 组织建立向监管机构报告的制度，规定报告的类别（如，质量管理规范自查报告、不良事件报告、产品召回报告、风险管理报告）、内容、方式和要求，并保留报告的记录。

The organization establishes a system for reporting to regulatory agencies, specifying the categories of reports (e.g., quality management standard self-inspection reports, adverse event reports, product recall reports, risk management reports), content, methods, and requirements, and retains records of the reports.

5.2 组织应建立和监管机构沟通的制度，规定沟通内容、沟通频次、沟通渠道、沟通对象、沟通方式、实施沟通的有效性。

The organization shall establish a system for communication with regulatory agencies, specifying the content, frequency, channels, recipients, methods of communication, and the effectiveness of the communication.

### 5.3 参与相关法规与标准的制修订和研讨工作

Participate in the formulation, revision, and discussion of relevant regulations and standards.

——组织应积极参与国家、省市监管机构法规制修订与研讨工作，提出意见和建议，为法规建设做贡献；

The organization shall actively participate in the formulation and revision of regulations by national and provincial regulatory agencies, providing opinions and suggestions to contribute to regulatory development;

——组织应积极参与国家标准、行业标准、团体标准的制修订与研讨工作，为标准建设做出贡献。

The organization shall actively participate in the formulation and revision of national standards, industry standards, and group standards, contributing to standard development.

## 附录 Appendix:

### 合规代表职责要求:

#### Responsibilities and Requirements of the Compliance Representative:

1. 遵纪守法，具有良好职业道德素养且无不良从业记录；

Abide by laws and regulations, possess good professional ethics, and have no negative employment record;

2. 熟悉并能正确执行国家相关法律、法规、规章，经过医疗器械相关法规、标准等方面的培训；

Familiar with and able to correctly implement relevant national laws, regulations, and rules, and trained in medical device-related regulations and standards;

3. 具有 YY/T 0287/ISO 13485 和/或 GB/T42061/ISO 13485 和 GB/T19001 /ISO9001 内审员培训证书，且证书应在有效期内；

Hold a training certificate for internal auditors of YY/T 0287/ISO 13485 and/or GB/T 42061 /ISO 13485 and GB/T 19001/ISO 9001, and the certificate must be valid;

4. 具有良好的语言沟通能力；

Possess good language communication skills;

5. 熟悉医疗器械质量管理体系运行，具备指导、监督本组织各部门按规定实施体系运行的能力；

Familiar with the operation of the medical device quality management system and capable of guiding and supervising various departments of the organization to implement the system operation as required;

6. 医疗器械组织合规代表应当具有大学本科及以上学历，并具有 3 年以上医疗器械企业工作经历。或具有 5 年以上医疗器械质量、生产、技术、经营服务管理工作经历，熟悉本企业管理情况，经实践证明具有良好履职能力的合规代表，可适当放宽相关学历要求；

Compliance representatives of medical device organizations should have a bachelor's degree or higher and at least 3 years of work experience in medical device companies. Alternatively, compliance representatives with more than 5 years of experience in quality, production, technology, or management services in the medical device field, who are familiar with the management situation of the enterprise and have demonstrated good performance capabilities in practice, may have the relevant educational requirements relaxed.

7、合规代表在任职后还应当持续加强知识更新，积极参加各类有利于岗位能力提升的学习和培训活动，及时掌握相关法律、法规，不断提高合规管理水平。

After taking office, compliance representatives should continuously enhance their knowledge, actively participate in various learning and training activities beneficial to improving their job capabilities, keep up to date with relevant laws and regulations, and continuously improve compliance management levels.

---