
Guidelines on Registration of Medical Device Master Files

(Draft for review)

I. Definition and Purpose

Medical device master files are a form of technical materials relating to medical devices. Such materials, submitted to the technical review body of medical devices by their holders, are used to authorize use by the applicant during submissions for medical device registration, without disclosing the contents to said applicant directly. This *Guidelines* aims to direct master file holders with registration of medical device master files and authorization for use.

II. Regulatory Basis

Regulations on Medical Device Registration

Regulations on Registration of in vitro Diagnostic Reagents

Requirements for Application Dossiers of Medical Devices and Format of Approval Documents

Requirements for Application Dossiers of in vitro Diagnostic Reagents and Form of Approval Documents

III. Scope of Application

This guidance document applies to master files referenced by the applicant during application for approval on registration, change and clinical trials of medical devices (including in vitro diagnostic reagents). Due to the element of technical know-how or to avoid repeated submissions of the same documents, the master files are directly submitted to the technical review bodies of medical devices by the holders.

IV. Basic Principles

During the review and approval of a medical device, the applicant may be required to submit the confidential technical documents of a third-party enterprise (e.g., raw material supplier) to the regulatory authority to support the registration application.

Some third-party enterprises can accept that their technical materials are confidentially reviewed by the competent regulatory authority, but not direct disclosure of their technical materials to the applicant. The master files are created to protect the technical know-how of the master file holders and meanwhile, also to avoid repeated submissions of the same technical documents by different applicants. Submitting the master files for registration is voluntary on their holders. After formal examination following submission, the regulatory authority will have the master files registered.

In the event the master file holder is a foreign enterprise outside China, appointing an agent inside China is recommended to facilitate communication with the regulatory authority on work relating to registration of the master files, update the contents of the master files and authorize reference by the applicant during submission for medical device registration. When registering the master file(s), the master file holder should specify the name, address, contact information and authorizations of the agent. By updating the master file(s), the holder can change the agent information and/or add or delete an agent.

V.Contents of Master File

The contents of master file can pertain to raw materials of medical devices (except for in vitro diagnostic reagents), etc. The master file for the raw material of a medical device can contain the following: description of components in the raw material, performance study data, biological evaluation data/toxicology risk analysis data, etc.

Requirements for the format of master files are detailed in relevant registration criteria. The master files should be electronically submitted in reference to *Guidelines on Electronic Submissions for Medical Device Registration*. If the master files you've submitted are found not to meet the registration criteria in contents after formal examination, they cannot be registered as master file.

The technical sections of master files are recommended to be prepared by referencing the requirements for application dossiers of medical devices/in vitro diagnostic reagents and corresponding contents in relevant guidelines.

VI.Relevant Requirements for Update of Master Files

The master file holder can update the master file(s) through the competent regulatory agency on medical devices, including changes to authorization, changes

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