Notice of the National Medical Products Administration on Issuing the Inspection Guidelines for Good Manufacturing Practice for Medical Devices[1]

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To the drug regulatory authorities of all provinces, autonomous regions and municipalities directly under the Central Government, and of the Xinjiang Production and Construction Corps:

The revised Good Manufacturing Practice for Medical Devices (hereinafter referred to as the "GMP") shall enter into force on 1 November 2026. To better guide drug regulatory authorities at all levels in conducting inspections of medical device manufacturing, the National Medical Products Administration has organised the revision of the Guidelines for On-site Inspections of Good Manufacturing Practice for Medical Devices (Shi Yao Jian Xie Jian [2015] No. 218), resulting in the Inspection Guidelines for Good Manufacturing Practice for Medical Devices (hereinafter referred to as the "Inspection Guidelines"), which are hereby issued. The following matters are notified:

1. From 1 November 2026, drug regulatory authorities shall conduct medical device manufacturing licence inspections and post-market regulatory inspections in strict accordance with the revised GMP, and shall determine inspection outcomes and take action in accordance with the Inspection Guidelines.

2. Before 1 November 2026, drug regulatory authorities shall conduct medical device manufacturing licence inspections in accordance with the currently applicable GMP and, concurrently, assess enterprises' implementation of the revised GMP by reference to the Inspection Guidelines and propose rectification recommendations. Where applications for a manufacturing licence, licence amendment or licence renewal have been accepted before 1 November 2026 but the on-site inspection has not yet been conducted, or where an on-site inspection has been conducted but no administrative licensing decision has been made because the enterprise has not completed rectification, inspections conducted from 1 November 2026 shall follow the revised GMP.

3. Within three months after an enterprise files its Class I medical device manufacturing activities, the drug regulatory authority shall conduct an on-site inspection of the materials submitted and its implementation of the GMP. Where manufacturing activities have been filed before 1 November 2026 but no on-site inspection has been conducted, inspections conducted from 1 November 2026 shall follow the revised GMP.

[1] Translated by Health Law Asia – Pharmaceutical, Medical Device, and Cosmetics Law

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4. Provincial drug regulatory authorities shall, in accordance with the arrangements for implementing the revised GMP, formulate post-market regulatory inspection plans based on the risk levels of products and enterprises, complete inspections covering all enterprises in stages against the revised GMP, and take effective measures to require enterprises to meet the requirements on schedule, ensuring continuing compliance of medical device quality management systems.

5. From 1 November 2026, manufacturing quality management for sterile medical devices, implantable medical devices, in vitro diagnostic reagents, custom-made dentures and standalone software medical devices shall comply with both the revised GMP and the corresponding currently applicable GMP appendices. The corresponding inspection guidelines shall be revised and issued separately.

These Inspection Guidelines shall enter into force on 1 November 2026. The Guidelines for On-site Inspections of Good Manufacturing Practice for Medical Devices (Shi Yao Jian Xie Jian [2015] No. 218), issued by the former China Food and Drug Administration, shall be repealed simultaneously.

National Medical Products Administration

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Inspection Guidelines for Good Manufacturing Practice for Medical Devices

These Guidelines are formulated pursuant to the Good Manufacturing Practice for Medical Devices (hereinafter referred to as the "GMP") to strengthen supervision and administration of medical device manufacturing and guide drug regulatory authorities in inspecting the manufacturing activities of medical device registrants, filing entities and contract manufacturers (hereinafter collectively referred to as "enterprises").

I. Scope of Application

These Guidelines apply to medical device manufacturing licence inspections, including inspections for amendments and renewals, and all types of post-market regulatory inspections of enterprises.

II. Inspection Items and Classification

Based on the importance of each GMP provision within the quality management system and the degree of quality and safety risk resulting from non-compliance, the provisions are classified into three levels: critical items (***), major items (**) and general items (*). There are 200 inspection items in total: 39 critical, 88 major and 73 general items.

Critical items are those having a significant impact on the operation of the product quality management system, non-compliance with which will result in product quality and safety risks.

Major items are those having a substantial impact on the operation of the product quality management system, the combined effect of multiple instances of non-compliance with which will result in product quality and safety risks.

General items are those having some impact on the operation of the product quality management system, non-compliance with which may result in product quality and safety risks.

III. Types of Inspection and Determination of Outcomes

1. Manufacturing licence inspections

A manufacturing licence inspection is an inspection conducted by a drug regulatory authority, in the course of examining an application for a medical device manufacturing licence, including amendment or renewal, to establish whether the applicant meets the conditions for engaging in medical device manufacturing. There are three possible outcomes: "passed", "failed" and "reinspection following rectification".

The criteria for determining manufacturing licence inspection outcomes are as follows:

(1) Where no critical or major nonconformities are found and there are fewer than five general nonconformities, the outcome shall be "passed".

The enterprise shall itself rectify any nonconformities found and explain them in its annual self-inspection report.

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(2) The outcome shall be “failed” where any of the following circumstances is found:

(a) falsification or deception;

(b) three or more critical nonconformities;

(c) ten or more critical and major nonconformities in total; or

(d) twenty or more nonconformities in total.

(3) Where neither the “passed” nor the “failed” criteria are met, the outcome shall be “reinspection following rectification”.

Where the enterprise completes rectification within the prescribed period and a follow-up inspection confirms compliance, the final outcome shall be “passed”. Where the enterprise fails to submit rectification materials within the prescribed period, or a follow-up inspection finds that nonconformities have not been adequately rectified, the final outcome shall be “failed”.

2. Post-market regulatory inspections

Post-market regulatory inspections are divided, according to their coverage, into full-scope and partial-scope inspections. There are four possible outcomes: “no nonconformities found”, “self-rectification”, “suspension of production for rectification” and “rectification within a prescribed period”.

2.1 Full-scope inspections

A full-scope inspection is an inspection by a drug regulatory authority covering all GMP items applicable to an enterprise.

The criteria for determining full-scope inspection outcomes are as follows:

(1) Where no nonconformities are found, the outcome shall be “no nonconformities found”.

(2) Where no critical or major nonconformities are found but there are fewer than five general nonconformities, the outcome shall be “self-rectification”.

The enterprise shall itself rectify the nonconformities found and explain them in its annual self-inspection report.

(3) The outcome shall be “suspension of production for rectification” where any of the following circumstances is found:

(a) falsification or deception;

(b) three or more critical nonconformities;

(c) ten or more critical and major nonconformities in total; or

(d) twenty or more nonconformities in total.

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Where the outcome is “suspension of production for rectification”, the drug regulatory authority shall require the inspected enterprise to suspend production. Production may resume only after all nonconformities have been rectified and a follow-up inspection by the drug regulatory authority confirms compliance.

(4) Where none of the criteria for “no nonconformities found”, “self-rectification” or “suspension of production for rectification” is met, the outcome shall be “rectification within a prescribed period”.

Where the outcome is “rectification within a prescribed period” and critical or major nonconformities exist, the drug regulatory authority shall thoroughly assess product quality risks and, where necessary, issue a risk warning letter to the enterprise, requiring and guiding it to prevent and control potential quality and safety risks effectively.

Where the enterprise fails to submit rectification materials within the prescribed period, or a follow-up inspection finds that nonconformities have not been adequately rectified, the final outcome shall be “suspension of production for rectification”. The drug regulatory authority shall require the enterprise to suspend production, which may resume only after all nonconformities have been rectified and a follow-up inspection by the authority confirms compliance.

2.2 Partial-scope inspections

A partial-scope inspection is an inspection by a drug regulatory authority covering selected GMP chapters in accordance with an inspection plan or work programme.

For registrants and filing entities manufacturing their own products, partial-scope inspections shall cover, at a minimum, the chapters on quality assurance, purchasing and raw material management, production management, quality control and product release, and analysis and improvement. For registrants and filing entities outsourcing manufacturing, they shall cover, at a minimum, quality assurance, organisation and personnel, quality control and product release, contract manufacturing and outsourced processing, and analysis and improvement. For contract manufacturers, they shall cover, at a minimum, quality assurance, purchasing and raw material management, production management, quality control and product release, and analysis and improvement.

When conducting partial-scope inspections, drug regulatory authorities may also inspect other relevant chapters according to the reason for the inspection, its type, the characteristics of the products inspected and other factors. Outcomes shall be determined according to the criteria for full-scope inspections.

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3. Table for determining inspection outcomes

Total	Critical	Major	General	Licence inspection	Post-market inspection
0	0	0	0	Passed	No nonconformities found
<5	0	0	<5	Passed	Self-rectification
<20	2	<8	—	Reinspection following rectification	Rectification within a prescribed period
<20	1	<9	—	Reinspection following rectification	Rectification within a prescribed period
<20	0	<10	—	Reinspection following rectification	Rectification within a prescribed period
—	≥3	—	—	Failed	Suspension of production for rectification
—	Critical + major ≥10		—	Failed	Suspension of production for rectification
≥20	—	—	—	Failed	Suspension of production for rectification

IV. Other Requirements

1. Drug regulatory authorities shall make an overall assessment based on the seriousness of nonconformities and product risks. Where several interconnected nonconformities may give rise to systemic risks within the quality management system, they shall be treated as a critical nonconformity under the Quality Assurance chapter. For nonconformities recurring in the two preceding inspections, the risk classification may be raised by one level according to the circumstances.

2. Where the inspection outcome is “suspension of production for rectification”, the medical device registrant or filing entity shall comprehensively assess product quality and safety risks and, where necessary, recall the products concerned.

3. Matters involving violations of the Regulations on the Supervision and Administration of Medical Devices, the Measures for the Supervision and Administration of Medical Device Manufacturing, or other applicable laws, regulations and rules shall be dealt with in accordance with the law and relevant provisions.

Annex: GMP Inspection Items

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Annex — GMP Inspection Items

Chapter I — General Provisions

No. / clause	Requirement	Risk	GMP article
1 1.1.1	The enterprise shall, in accordance with this GMP and taking account of product characteristics, establish and maintain a sound quality management system appropriate to the medical devices it manufactures and ensure its effective operation. The quality management system shall cover outsourced research and development, contract manufacturing, outsourced processing and outsourced testing, among other activities.	***	3
2 1.2.1	The enterprise shall integrate risk management throughout the operation of its quality management system. The control measures adopted shall be commensurate with the risks associated with the products.	**	4

Chapter II — Quality Assurance

No. / clause	Requirement	Risk	GMP article
3 2.1.1	The enterprise shall fulfil its primary responsibility for medical device quality and safety, establish quality objectives meeting medical device quality management requirements, and systematically implement all requirements relating to medical device safety, effectiveness and controllability of quality throughout the operation of its quality management system, ensuring that the quality objectives are fully understood and effectively achieved.	***	7
4 2.2.1	The enterprise shall provide sufficient resources meeting applicable requirements, including personnel, premises, facilities and equipment, to achieve its quality objectives.	***	8
5 2.2.2	Personnel at all levels of the enterprise shall participate jointly in activities directed towards achieving the quality objectives and assume their respective responsibilities.	**	8

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No. / clause	Requirement	Risk	GMP article
6 2.3.1	The enterprise shall establish a quality assurance system and maintain complete quality management system documentation to ensure the effective operation of the quality management system. The quality assurance system shall ensure that: (1) medical device design and development, production management and quality control activities comply with this GMP; (2) management responsibilities are clearly defined; (3) the raw materials purchased and used are correct; (4) intermediate products are effectively controlled; (5) verification, qualification and validation activities meet applicable requirements; (6) production and testing are performed in strict accordance with procedures; (7) each batch or unit of product is released following review and approval; (8) measures are in place to ensure product quality during storage, transport, installation and other stages; and (9) outsourced research and development, contract manufacturing, outsourced processing, outsourced testing and other such activities remain under control.	***	9
7 2.4.1	The enterprise shall establish a change control procedure, determine the category of change management on the basis of the risk that a change poses to medical device safety, effectiveness and controllability of quality and applicable regulatory requirements, review changes and obtain the appropriate approval before implementation. Where necessary, changes shall be verified, qualified or validated to ensure that they do not adversely affect product safety, effectiveness or controllability of quality.	***	10
8 2.5.1	The enterprise shall continuously improve its quality management system, processes and product quality through quality data monitoring, change management, adverse event monitoring, quality risk management reviews, corrective and preventive action, internal audits and management reviews, among other means.	**	11
9 2.6.1	The enterprise shall establish a quality risk management system, assess quality risks throughout product realisation on the basis of laws, regulations, rules, standards, scientific knowledge and experience, and verify and implement quality risk control measures to ensure effective control of product quality risks.	**	12
10 2.7.1	The enterprise shall collect quality risk information throughout the product life cycle and periodically review quality risk management to ensure the continuing effectiveness of quality risk management measures.	*	13

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Chapter III — Organisation and Personnel

No. / clause	Requirement	Risk	GMP article
11 3.1.1	The enterprise shall establish an organisational structure appropriate to medical device manufacturing, define the responsibilities and authority of each department, and clearly define quality management functions.	**	14
12 3.1.2	The heads of the production management department and the quality management department shall not concurrently hold each other's positions.	***	14
13 3.2.1	The enterprise shall establish a quality management department appropriate to the products it manufactures.	***	15
14 3.2.2	The quality management department shall participate in all activities relating to product quality and shall be responsible for reviewing documents relating to this GMP.	**	15
15 3.2.3	The quality management department shall independently perform its quality assurance and quality control duties and shall have veto authority on matters concerning product quality.	***	15
16 3.3.1	The enterprise shall have sufficient professional and technical personnel, management personnel, production operators and dedicated testing personnel with appropriate qualifications, including education, training and practical experience.	**	16
17 3.3.2	The enterprise shall clearly specify the responsibilities of every position. No responsibilities shall be omitted, and overlapping responsibilities shall be clearly defined.	*	16
18 3.4.1	The enterprise shall appoint personnel to key positions appropriate to the products it manufactures. These shall include, at a minimum, the enterprise's legal representative, principal person in charge, management representative, head of production management, head of quality management and product release reviewer. The principal person in charge, management representative, head of production management, head of quality management and product release reviewer shall be full-time personnel of the enterprise.	**	17

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No. / clause	Requirement	Risk	GMP article
19 3.4.2	Personnel in key positions shall be familiar with laws and regulations relating to medical devices, have practical experience in quality management, and be capable of correctly assessing and addressing practical issues in production and quality management.	**	17
20 3.5.1	The enterprise's legal representative and principal person in charge shall be responsible for organising the formulation of its quality policy and quality objectives and ensuring the availability of the human resources, infrastructure, working environment and other conditions necessary for effective operation of the quality management system.	**	18
21 3.5.2	The enterprise's legal representative and principal person in charge shall be responsible for organising management reviews, periodically assessing the operation of the quality management system and ensuring its continuous improvement.	**	18
22 3.5.3	The enterprise's legal representative and principal person in charge shall ensure that the management representative, head of quality management and product release reviewer perform their duties independently, without interference from factors within the enterprise.	***	18
23 3.5.4	The enterprise's legal representative and principal person in charge shall bear overall responsibility for medical device manufacturing and shall organise production in accordance with applicable laws, regulations, rules, mandatory standards and the registered or filed product technical requirements.	***	18
24 3.6.1	The enterprise shall appoint a management representative from among its senior management personnel.	***	19
25 3.6.2	The management representative of an enterprise manufacturing Class II or Class III medical devices shall hold at least a bachelor's degree in a medical device-related discipline or an intermediate or higher technical professional title. The management representative of an enterprise manufacturing Class I medical devices shall hold at least a junior college diploma in a medical device-related discipline. In principle, the management representative shall have at least three years' experience in medical device quality management, production management or technical management, be familiar with product manufacturing and quality management, and be capable of properly performing the duties of the position.	**	19

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No. / clause	Requirement	Risk	GMP article
26 3.6.3	The management representative shall perform, at a minimum, the following duties: (1) implement applicable laws, regulations, rules, mandatory standards and registered or filed product technical requirements; (2) establish and maintain a sound quality management system appropriate to the products manufactured and ensure its effective operation; (3) ensure that products meet release requirements and organise the collection of post-market product quality information; (4) organise quality management system self-inspections, adverse event monitoring, recalls and related work, and periodically report to the enterprise's legal representative and principal person in charge on the operation of the quality management system and the need for improvement; and (5) cooperate with drug regulatory authorities in regulatory inspections and organise the relevant departments to rectify identified problems promptly as required.	**	19
27 3.7.1	The head of quality management at an enterprise manufacturing Class II or Class III medical devices shall hold at least a bachelor's degree in a medical device-related discipline or an intermediate or higher professional technical title. At an enterprise manufacturing Class I medical devices, that person shall hold at least a junior college diploma in a medical device-related discipline. The head of quality management shall have at least three years' experience in medical device manufacturing or quality management.	**	20
28 3.7.2	The head of quality management shall perform the following duties: (1) ensure that the production and testing of raw materials and products comply with applicable laws, regulations, rules, mandatory standards and registered or filed product technical requirements; (2) organise product release reviews; (3) ensure that all major deviations and nonconformities arising during production are investigated and addressed promptly and effectively; (4) organise post-market product quality management activities and ensure that all returns, complaints and adverse events relating to product quality are investigated and addressed promptly and effectively; (5) ensure completion of the annual product quality review and analysis; (6) ensure that departmental personnel receive relevant training and acquire knowledge of applicable regulations, theoretical knowledge and practical operational skills; and (7) take responsibility for other activities relating to product quality.	**	20

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No. / clause	Requirement	Risk	GMP article
29 3.8.1	The head of production management shall hold at least a junior college diploma in a medical device-related discipline and have at least three years' experience in medical device manufacturing or quality management.	**	21
30 3.8.2	The head of production management shall perform the following duties: (1) ensure that production is organised in accordance with manufacturing process procedures, work instructions and other applicable documents; (2) ensure that production records are authentic, accurate, complete, contemporaneous and traceable; (3) organise the maintenance and servicing of premises, facilities and equipment to keep them in good operating condition; (4) ensure that departmental personnel are trained and possess the knowledge and practical operational skills appropriate to their positions; and (5) take responsibility for other activities relating to product manufacturing.	**	21
31 3.9.1	The release reviewer shall be a member of the quality management department or other quality management personnel at a higher level, shall receive training relating to product release, possess the competence to review product release, and be capable of independently assuming product release review responsibilities.	**	22
32 3.10.1	All personnel performing work affecting product quality shall receive training in regulations, job responsibilities and practical operational skills appropriate to their positions, ensuring that they clearly understand their responsibilities, are familiar with the requirements relating to those responsibilities, and possess relevant theoretical knowledge and practical operational skills.	**	23
33 3.10.2	The enterprise shall designate a department or specific personnel responsible for training management, establish a training system, formulate training plans, retain training records and assess the actual effectiveness of training.	*	23
34 3.11.1	The enterprise shall manage the health of personnel performing work affecting product quality according to the characteristics of the products manufactured and establish health records for such personnel.	*	24

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Chapter IV — Premises and Facilities

No. / clause	Requirement	Risk	GMP article
35 4.1.1	The location, design, layout, construction, alteration and maintenance of premises shall meet medical device manufacturing requirements, minimise contamination, cross-contamination, mix-ups and errors, and facilitate cleaning, operation and maintenance.	**	25
36 4.2.1	The enterprise shall appropriately design, arrange and use its premises and facilities according to the characteristics of the products manufactured, the process flow and the applicable cleanliness classification requirements.	**	26
37 4.2.2	The enterprise shall maintain a clean and orderly production environment, with appropriate controls over lighting, temperature, humidity and ventilation, meeting product quality requirements and relevant technical standards.	*	26
38 4.3.1	Premises and facilities shall be designed and installed to prevent the entry of insects or other animals effectively. Necessary protective measures shall be taken according to product characteristics.	*	27
39 4.3.2	Maintenance and repair of premises and facilities shall not adversely affect product quality.	*	27
40 4.4.1	Production areas shall provide sufficient space appropriate to the products manufactured and the scale of production.	*	28
41 4.4.2	Where several production lines are located in the same area, the enterprise shall take effective measures to prevent mix-ups and errors.	**	28
42 4.5.1	Storage areas shall meet the storage condition requirements for raw materials, intermediate products, finished products and other items. Items shall be appropriately stored according to their status, such as awaiting testing, accepted, rejected, returned or recalled, to prevent mix-ups and errors and facilitate inspection and monitoring.	*	29
43 4.5.2	Acceptance, storage, management and other handling of toxic, flammable, explosive and other hazardous goods shall comply with relevant national provisions.	**	29
44 4.6.1	The enterprise shall provide testing premises and facilities appropriate to its production scale, product types and testing requirements.	**	30

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No. / clause	Requirement	Risk	GMP article
45 4.7.1	The enterprise shall provide appropriate facilities according to product characteristics, manufacturing processes and the external environment, such as air-conditioning and purification systems, process water systems, process gas systems and antistatic facilities.	***	31
46 4.7.2	The enterprise shall qualify relevant facilities and carry out routine monitoring and maintenance to ensure that they meet their intended use.	**	31
47 4.8.1	Where the production environment is subject to cleanliness classification requirements, the static pressure differential between clean and non-clean areas shall exceed 10 pascals, and that between clean areas of different classifications shall exceed 5 pascals. Where necessary, an appropriate pressure gradient shall also be maintained between areas or operating rooms with different functions but the same cleanliness classification.	*	32
48 4.8.2	Operating areas generating substantial quantities of dust, fumes, toxic or harmful substances during production shall be maintained at relative negative pressure. Exhaust discharged outdoors shall be purified and meet applicable requirements.	**	32
49 4.9.1	Where computerised systems are used in production, testing, storage or other processes, the enterprise shall provide hardware facilities and a software operating environment meeting the intended use and take appropriate measures to prevent external interference.	*	33
50 4.10.1	Production, testing and storage areas shall not serve as direct passageways for personnel not working in those areas. The enterprise shall take appropriate measures to prevent unauthorised entry.	*	34
51 4.11.1	The enterprise shall retain documentation relating to premises and facilities, including, without limitation, overall site plans, production area layout plans, instructions for use and maintenance provisions.	*	35

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Chapter V — Equipment and Instruments

No. / clause	Requirement	Risk	GMP article
52 5.1.1	The enterprise shall provide production equipment, testing instruments and equipment, tooling and fixtures appropriate to the products manufactured and the production scale, and ensure their effective operation.	***	36
53 5.1.2	The design, selection, installation, maintenance and repair of equipment and instruments shall meet their intended use and facilitate operation, cleaning and maintenance.	*	36
54 5.2.1	The enterprise shall establish equipment and instrument files, including, without limitation, documents and records relating to procurement, installation and qualification.	*	37
55 5.3.1	The enterprise shall establish operating procedures for the use, maintenance and repair of major equipment and instruments and retain relevant records to ensure traceability of these activities.	*	38
56 5.4.1	The enterprise shall mark major equipment, instruments, tooling and fixtures with their identification numbers and names. Where abnormal conditions arise, an appropriate status label shall be provided to prevent unintended use.	*	39
57 5.5.1	The enterprise shall periodically calibrate or carry out metrological verification of major equipment and instruments in accordance with operating procedures and calibration or verification plans. The calibrated measurement range shall cover the range actually used.	*	40
58 5.5.2	The enterprise shall provide appropriate measuring instruments whose measurement range and accuracy meet use requirements, and indicate the validity period of calibration or metrological verification.	*	40
59 5.5.3	The enterprise shall retain calibration or metrological verification records.	*	40
60 5.6.1	The enterprise shall requalify equipment and instruments following modification or major repair. They may be used only after compliance with requirements has been established.	**	41

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Chapter VI — Document Management

No. / clause	Requirement	Risk	GMP article
61 6.1.1	The enterprise shall establish and maintain complete quality management system documentation, including the quality policy and quality objectives, quality manual, procedures, technical documents and records, and other documents required by regulations.	**	42
62 6.1.2	The quality manual shall specify the quality management system. Procedures shall be developed according to the actual needs of product design and development, production, quality management and other activities and shall include all procedures prescribed by this GMP.	*	42
63 6.1.3	Technical documents shall include product technical requirements and relevant standards, manufacturing process procedures, work instructions, inspection and test procedures, installation and servicing procedures, and other relevant documents.	**	42
64 6.2.1	The enterprise shall establish a document control procedure for the systematic design, preparation, review, approval, distribution and retention of quality management system documents, meeting the following requirements: (1) drafting, revision, review, approval, replacement or withdrawal, copying, safekeeping and destruction shall be managed under the document control procedure, with corresponding records of distribution, replacement or withdrawal, and destruction; appropriate control methods shall be specified according to document purpose and type; (2) revisions or updates shall be reviewed and approved, and the revision or update status shall be identifiable; (3) documents distributed and used shall be appropriate versions, and withdrawn or obsolete documents shall be identified to prevent unintended use; and (4) retention periods after obsolescence shall be specified for necessary quality management system documents, such as technical documents, to meet needs including product repair and traceability of responsibility for product quality.	*	43
65 6.3.1	The enterprise shall designate departments or personnel to identify changes to external documents relating to medical devices, including laws, regulations, specifications and standards, and promptly update quality management system documents.	*	44

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No. / clause	Requirement	Risk	GMP article
66 6.4.1	The enterprise shall establish a record control procedure covering record identification, safekeeping, retrieval, retention periods and disposition, and meeting the following requirements: (1) records shall ensure traceability of product design and development, production, quality control, product release and other activities; (2) records shall be authentic, accurate, complete, contemporaneous, clear, readily identifiable and retrievable, and protected against damage and loss;	***	45
67 6.4.2	(3) Records shall not be arbitrarily altered or destroyed. Where an amendment is necessary, its reason, the person making it and the date shall be recorded, and the original information shall remain clearly legible; (4) record retention periods shall be at least equal to the medical device lifetime specified by the enterprise or comply with applicable regulatory requirements, and shall in no event be less than two years from product release.	*	45
68 6.5.1	Where computerised management is used, the enterprise shall ensure that electronic records or data are authentic, accurate, complete, contemporaneous and traceable, and shall meet the following requirements: (1) establish user access management to ensure effective control of permissions that may affect the authenticity and accuracy of electronic records or data; (2) changes to or deletion of electronic records or data shall be performed by authorised personnel, and records of changes and deletions shall be retained; (3) electronic records or data shall be backed up and retained for no less than the record retention periods specified in this Chapter, and shall remain readily accessible throughout retention; and (4) electronic signatures, where used, shall comply with applicable laws and regulations.	***	46

Chapter VII — Design and Development

No. / clause	Requirement	Risk	GMP article
69 7.1.1	The enterprise shall establish a design and development control procedure, define the stages of design and development, and specify requirements for planning, inputs, outputs, verification, validation, transfer, changes, reviews and related document control, so as to plan and control the entire medical device design and development process.	**	47

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No. / clause	Requirement	Risk	GMP article
70 7.2.1	The enterprise shall integrate risk management throughout design and development and product realisation, establish and document relevant requirements, use risk management methods and tools to carry out risk management activities, and retain relevant records.	**	48
71 7.3.1	The enterprise shall plan design and development according to product characteristics and specify the activities to be performed at stages including inputs, outputs, transfer, verification and validation.	*	49
72 7.3.2	The enterprise shall formulate a design and development plan specifying the verification, validation, transfer, change and review activities applicable at each stage and the output requirements; determine each department's activities and interfaces at different stages; and clearly allocate responsibilities and tasks. The plan shall be reviewed and approved and periodically reviewed during implementation.	**	49
73 7.4.1	Design and development inputs shall include, at a minimum, functional, performance and safety requirements determined according to user needs and intended use, together with requirements relating to regulations, standards and risk control measures.	**	50
74 7.4.2	Design and development input requirements shall be clear and complete and shall be reviewed and approved.	*	50
75 7.5.1	Design and development outputs shall meet the input requirements at each stage.	**	51
76 7.5.2	Design and development outputs shall include, at a minimum, information required for procurement, production, testing, use and servicing, as well as product technical requirements. Outputs shall be verified and approved.	***	51
77 7.6.1	The enterprise shall carry out design and development transfer to production according to product characteristics, ensuring that procedures concerning the production environment, raw material control, manufacturing processes and quality control specified in design and development outputs are verified and suitable for commercial production. Particular attention shall be paid to identifying critical operations and special processes and to verification, qualification and validation.	***	52

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No. / clause	Requirement	Risk	GMP article
78 7.7.1	The enterprise shall conduct reviews at appropriate stages of design and development, continuously evaluate whether outputs can meet input requirements, identify problems and propose necessary improvements.	*	53
79 7.8.1	The enterprise shall verify design and development to ensure that outputs meet input requirements.	**	54
80 7.8.2	The enterprise shall retain verification documentation, including, at a minimum, verification protocols, reports, results and conclusions, and records of the verification process.	**	54
81 7.9.1	The enterprise shall validate design and development to ensure that the product meets specified use requirements or its intended use.	**	55
82 7.9.2	Design and development validation may be performed through clinical or non-clinical evaluation. Where clinical trials are conducted, applicable medical device clinical trial requirements shall be met.	*	55
83 7.10.1	The enterprise shall identify design and development changes and assess their impact. Where necessary, changes shall be verified and validated and shall be approved before implementation.	***	56
84 7.11.1	The enterprise shall establish product design and development files, including records created or referenced during design and development, to ensure traceability of each successive design and development output process and related activities.	**	57
85 7.12.1	Where medical device design and development are outsourced, the commissioning party shall assess the contractor's research and development capabilities and ability to provide continuing technical support.	*	58
86 7.12.2	The enterprise shall enter into an agreement with the contractor specifying the scope of outsourced design and development activities, responsibilities and requirements for transferring design and development documentation.	**	58
87 7.12.3	The enterprise shall manage the process and results of outsourced design and development and assume the corresponding responsibilities, ensuring that the process meets legal, regulatory and contractual requirements.	**	58

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Chapter VIII — Purchasing and Raw Material Management

No. / clause	Requirement	Risk	GMP article
88 8.1.1	The enterprise shall establish a purchasing control procedure to ensure that purchased raw materials or services meet specified requirements, which shall be no less stringent than applicable laws, regulations, rules and mandatory standards.	***	59
89 8.2.1	The enterprise shall apply differentiated management to purchased raw materials or services and suppliers according to their degree of impact on products.	*	60
90 8.2.2	Supplier management shall take account of factors including the raw materials or services purchased, manufacturing process complexity, the degree of impact on product quality and safety, and whether supply is initial or ongoing.	**	60
91 8.3.1	The enterprise shall establish a supplier audit system, define criteria and methods for supplier selection, evaluation and re-evaluation, and establish an approved supplier list based on audit and evaluation results.	*	61
92 8.3.2	The enterprise shall determine whether to conduct on-site supplier audits according to product quality risks, raw material usage quantities and the degree of impact on product quality.	**	61
93 8.4.1	The enterprise shall periodically carry out comprehensive supplier evaluations, reviewing and analysing the quality, technical level and delivery capability of the raw materials or services supplied, among other matters.	*	62
94 8.4.2	Where an assessment identifies major deficiencies in a supplier, the enterprise shall suspend purchasing, promptly analyse the resulting product risks and, where necessary, take appropriate measures.	***	62
95 8.5.1	The enterprise shall enter into quality agreements with critical suppliers specifying technical requirements and acceptance standards for purchased raw materials or services and each party's quality responsibilities.	**	63

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No. / clause	Requirement	Risk	GMP article
96 8.5.2	The enterprise shall establish quality files for critical suppliers. These shall include, at a minimum: supplier qualification documents; audit reports; purchasing contracts or quality agreements; lists of purchased items; product technical requirements or quality standards; acceptance criteria; results of supplier capability or performance monitoring, periodic audits, evaluation and re-evaluation; and records of associated measures arising from these activities.	*	63
97 8.6.1	The enterprise shall specify purchasing information and requirements, including the category of raw materials or services, acceptance criteria, specifications and models, procedures and drawings.	*	64
98 8.6.2	The enterprise shall retain purchasing records, including purchasing contracts, purchase lists and test reports. Purchasing records shall be authentic, accurate, complete and traceable.	**	64
99 8.7.1	The enterprise shall establish an incoming acceptance system for raw materials, examining, testing or verifying purchased raw materials to ensure that they meet requirements before admission to storage.	***	65
100 8.7.2	Sampling for acceptance shall follow sampling rules and be performed under appropriate environmental conditions.	*	65
101 8.8.1	The enterprise shall establish a warehouse management system to ensure correct storage, issue, use and transport of raw materials, intermediate products, finished products and other items, and prevent contamination, cross-contamination, mix-ups and errors. Records of relevant activities shall be retained.	*	66
102 8.9.1	Raw materials shall generally be issued and used on a first-in, first-out basis.	*	67
103 8.9.2	Raw materials exceeding their storage period shall be retested and may be used only after assessment confirms compliance with requirements. Expired raw materials shall be treated as nonconforming products.	***	67
104 8.10.1	The enterprise shall require suppliers to give advance notice of changes to production conditions, specifications and models, drawings, manufacturing processes, quality standards, testing methods and other matters relating to critical raw materials.	*	68

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No. / clause	Requirement	Risk	GMP article
105 8.10.2	The enterprise shall assess the scope and degree of the impact of changes on product quality and, where necessary, take measures and conduct on-site supplier audits.	**	68

Chapter IX — Verification, Qualification and Validation

No. / clause	Requirement	Risk	GMP article
106 9.1.1	The enterprise shall determine the scope and extent of verification, qualification or validation on the basis of risk assessment, to demonstrate effective control of relevant facilities, equipment, operations and critical elements of product realisation.	**	69
107 9.2.1	Premises, facilities and major equipment shall be qualified. The enterprise shall use verified or validated manufacturing processes, operating procedures and testing methods for production and testing, ensuring that relevant activities are conducted under verified, qualified or validated conditions.	***	70
108 9.3.1	The enterprise shall prepare qualification documents and records demonstrating that the design, installation and operation of premises, facilities and equipment meet the intended use, design standards and this GMP, and that their performance consistently meets requirements under normal operating methods and process conditions.	**	71
109 9.4.1	Process verification or validation shall demonstrate that the production process, operated within specified process parameters, can consistently produce products meeting mandatory standards, product technical requirements and intended use.	**	72
110 9.4.2	Special processes shall be validated, and critical operations shall be verified.	***	72
111 9.5.1	The enterprise shall verify cleaning methods according to product characteristics, process characteristics and the use of equipment and facilities, demonstrating cleaning effectiveness and effectively preventing contamination and cross-contamination.	**	73

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No. / clause	Requirement	Risk	GMP article
112 9.6.1	Where changes occur in major factors affecting product quality, including critical raw materials, the production environment, manufacturing processes, major production and testing equipment and testing methods, the enterprise shall conduct verification, qualification or validation. Where a registration amendment, filing amendment or report of changes to manufacturing particulars is required, the enterprise shall complete the relevant procedures as required.	***	74
113 9.7.1	Following initial verification, qualification or validation, the enterprise shall reverify, requalify or revalidate manufacturing processes, equipment, facilities and other relevant elements in light of product quality reviews and analyses, to ensure that they achieve the intended results.	**	75
114 9.7.2	Where historical data are used for retrospective verification, qualification or validation, the enterprise shall ensure that the data used are appropriate and sufficient.	**	75
115 9.8.1	The enterprise shall formulate verification, qualification or validation plans and prepare protocols appropriate to the subject matter. Protocols shall be reviewed and approved and shall include, at a minimum, the subject matter, departmental and personnel responsibilities, implementation environment, methods, sampling requirements and acceptance criteria.	*	76
116 9.8.2	The enterprise shall perform verification, qualification or validation in accordance with the protocol, prepare a report and retain relevant records.	*	76
117 9.9.1	Where computer software used in design and development, production, testing, warehousing or other processes affects product quality, the enterprise shall validate it and retain records and conclusions. Software validation shall include, at a minimum, validation before initial use and any necessary revalidation following changes. Validation or revalidation methods and activities shall be commensurate with the risks associated with software use.	**	77

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Chapter X — Production Management

No. / clause	Requirement	Risk	GMP article
118 10.1.1	The enterprise shall establish a production process control procedure specifying requirements for operators, production equipment, raw materials and intermediate products, manufacturing processes and operating procedures, the production environment, in-process testing or monitoring, and other relevant matters, and shall organise production accordingly.	***	78
119 10.2.1	The enterprise shall effectively manage and control raw materials, intermediate products and other items during production. Where cleaning is necessary, cleaning methods and requirements shall be specified and cleaning effectiveness verified.	**	79
120 10.3.1	The enterprise shall monitor and control the environment according to product and manufacturing process characteristics and retain records.	*	80
121 10.4.1	Each batch or unit of product shall have production records meeting traceability requirements.	***	81
122 10.4.2	Production records shall include, at a minimum, the product name, specifications and model, production batch number or product number (unique device identifier), production date, quantity, identification number/batch number/serial number of critical raw materials, intermediate product batch number, major equipment, process parameters and operators, and shall reflect material balance or record the use of critical raw materials.	*	81
123 10.5.1	The enterprise shall check the material balance between actual output and actual consumption of critical raw materials according to product characteristics, ensuring compliance with established limits. Where a deviation occurs, the enterprise shall investigate its cause; the products may be treated as normal products only after the absence of potential quality risks has been confirmed.	**	82
124 10.6.1	The enterprise shall establish a product identification control procedure and use appropriate methods to identify products, preventing mix-ups, errors and the passage of nonconforming intermediate products to the next operation.	*	83

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No. / clause	Requirement	Risk	GMP article
125 10.7.1	Product instructions for use and labels shall comply with applicable laws, regulations, rules and standards and shall be effectively controlled.	**	84
126 10.8.1	The enterprise shall establish a product preservation procedure specifying protective requirements for products and their components, including protection against contamination, electrostatic discharge, dust, corrosion, transport damage and cybersecurity threats. Protective measures include, without limitation, packaging, identification, protective covers and special handling and storage requirements.	*	85
127 10.9.1	The enterprise shall establish a line clearance management system according to product characteristics and actual production conditions to prevent contamination and mix-ups involving raw materials, intermediate products and finished products, and erroneous use of relevant documents.	*	86
128 10.9.2	Before production begins, the enterprise shall confirm completion of the preceding line clearance. Line clearance records and confirmation shall form part of the batch production record.	*	86
129 10.10.1	The enterprise shall establish a deviation handling procedure according to manufacturing process characteristics, specifying deviation identification, reporting, recording, assessment and investigation, disposition, and corrective and preventive action, and shall retain corresponding records. Deviation handling shall cover the entire medical device production and testing process.	**	87
130 10.11.1	The enterprise shall establish a nonconforming product control procedure to ensure prompt and effective identification, recording, segregation and review of nonconforming raw materials, intermediate products, finished products and other items arising during production.	**	88
131 10.11.2	Rework and use following downgrading shall comply with applicable regulatory provisions and customer requirements.	**	88
132 10.12.1	Where nonconforming products are reworked, the enterprise shall establish a rework control procedure, including work instructions and requirements for retesting and reverification. Risks arising from rework shall be assessed.	**	89

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No. / clause	Requirement	Risk	GMP article
133 10.13.1	The enterprise shall establish a product traceability procedure specifying the scope, extent, identification methods and necessary records for traceability, including management of raw material identification numbers, batch numbers or serial numbers and unique device identifiers.	*	90
134 10.14.1	The enterprise shall assign unique device identifiers, upload data, and maintain and update them in accordance with national requirements for implementation of unique device identification, ensuring that information is authentic, accurate, complete and traceable.	**	91
135 10.15.1	Where manufacturing workshops, production lines or production equipment are shared, the enterprise shall establish corresponding management systems based on product quality risk management principles to prevent potential risks including mix-ups of raw materials, intermediate products or finished products, cross-contamination and incorrect use of process parameters.	**	92
136 10.16.1	Where continuous production is carried out, the enterprise shall specify the maximum number of batches or maximum production duration and verify the impact of continuous production on the environment, equipment and other relevant factors.	**	93
137 10.16.2	After the maximum number of batches or maximum production duration is reached, the enterprise shall carry out appropriate cleaning and maintenance.	*	93
138 10.17.1	Where production resumes after a shutdown, the enterprise shall establish corresponding procedures specifying assessment requirements for the production environment, production equipment, suppliers, process water, process gases, air-conditioning and purification systems, and other relevant elements, and conduct verification, qualification or validation where necessary.	**	94

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Chapter XI — Quality Control and Product Release

No. / clause	Requirement	Risk	GMP article
139 11.1.1	The enterprise shall establish a quality control procedure specifying the product quality management organisational structure, testing personnel, testing procedures, and requirements for sampling, testing equipment, product release and retained samples, ensuring that necessary testing is completed before raw materials or finished products are released and that quality meets requirements.	***	95
140 11.2.1	The educational background, technical competence and number of testing personnel shall be appropriate to product inspection and testing activities. Such personnel shall receive practical training relevant to the inspection and testing operations performed and pass an assessment before taking up their duties.	**	96
141 11.3.1	The enterprise shall develop incoming inspection, in-process inspection and finished product inspection procedures and other documents in accordance with laws, regulations, rules, mandatory standards and registered or filed product technical requirements, based on risk management principles, product quality assurance capability and other relevant factors.	***	97
142 11.3.2	Inspection procedures shall cover the performance indicators specified in the product technical requirements. Where an indicator cannot be covered, an explanation shall be provided and, where necessary, a validated alternative solution shall be specified.	**	97
143 11.4.1	Testing methods shall be appropriate to the product's performance indicators.	***	98
144 11.4.2	The enterprise shall develop management documents for reference standards or reference materials, microbial strains, culture media and other auxiliary materials required for testing, according to their control characteristics, to ensure that testing requirements are met.	*	98
145 11.5.1	The enterprise shall establish test sample management procedures specifying sampling methods, sample quantities, identification, storage conditions and other requirements, ensuring control of sampling, distribution, receipt, storage, return and disposal.	*	99
146 11.6.1	The enterprise shall carry out inspection and testing activities in accordance with inspection and testing procedures.	***	100

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No. / clause	Requirement	Risk	GMP article
147 11.6.2	Each batch or unit of product shall have testing records meeting traceability requirements.	***	100
148 11.6.3	Testing records shall include incoming, in-process and finished product inspection records, reports or certificates, containing at least product or raw material information, test items, testing equipment, test results, test dates, testing personnel and reviewers.	*	100
149 11.7.1	Testing equipment management shall include, at a minimum: (1) calibration or metrological verification of testing equipment and confirmation of the results; (2) specified requirements for handling, storage, maintenance and repair of testing equipment; and (3) immediate discontinuation of equipment use where requirements are not met, together with evaluation of previous test results and, where necessary, appropriate measures and retention of records.	*	101
150 11.8.1	The enterprise shall specify, monitor and control the testing environment according to product testing requirements and retain records.	*	102
151 11.8.2	Environmental and facility conditions in laboratories conducting specialised testing shall meet the requirements of the relevant speciality.	*	102
152 11.9.1	The enterprise shall establish procedures for investigating and handling failing test results according to product characteristics.	*	103
153 11.9.2	Every failing test result shall be investigated and addressed, and records shall be retained.	**	103
154 11.9.3	Retesting may be performed where a failure was caused by a deviation in the testing process.	*	103

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No. / clause	Requirement	Risk	GMP article
155 11.10.1	The enterprise shall establish a product release procedure specifying release conditions and review and approval requirements. Authorised release personnel shall issue a product release form as prescribed only after confirming that the product meets at least the following conditions: (1) all prescribed process steps have been completed; (2) batch production records are complete; (3) quality control records are complete, results meet specified requirements, and records have been duly issued; (4) special situations arising during production, including nonconformities, rework, repair, use following downgrading and emergency release, have been fully addressed as prescribed; and (5) instructions for use, labels and their versions, and unique device identifier assignment meet specified requirements.	***	104
156 11.10.2	Released products shall be accompanied by documentation demonstrating conformity, which may take the form of a product test report, release form, conformity mark or certificate of conformity.	*	104
157 11.10.3	Where manufacturing is contracted out, product release shall comprise manufacturing release and market release. The medical device registrant or filing entity shall be responsible for market release, and the contract manufacturer shall be responsible for manufacturing release.	***	104
158 11.11.1	The enterprise shall establish retained sample management procedures according to product and process characteristics, retain samples as prescribed and maintain records of observations of retained samples.	*	105
159 11.12.1	Incoming, in-process and finished product inspection items requiring routine control shall generally not be outsourced.	*	106
160 11.12.2	Where testing items involve demanding testing conditions and equipment requirements and outsourcing is genuinely necessary, testing may be entrusted to a qualified institution.	*	106
161 11.12.3	Where testing is outsourced, the enterprise shall enter into a quality agreement with the contract testing institution clearly specifying each party's responsibilities and the requirements for outsourced testing.	*	106
162 11.12.4	The commissioning party shall evaluate the testing capabilities of the contract testing institution and confirm the results of outsourced testing.	**	106

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Chapter XII — Contract Manufacturing and Outsourced Processing

No. / clause	Requirement	Risk	GMP article
163 12.1.1	Where medical device manufacturing is contracted out, the commissioning party's quality management system shall cover the entire medical device life cycle. The contract manufacturer's quality management system shall include matters relevant to the contracted manufacturing activities.	***	107
164 12.1.2	Both parties shall establish an effective communication mechanism to ensure effective coordination and operation of their quality management systems.	**	107
165 12.2.1	The commissioning party and the contractor shall enter into a quality agreement specifying their respective rights, obligations and responsibilities throughout product manufacturing. The commissioning party shall not transfer by agreement obligations or responsibilities that it is legally required to fulfil.	***	108
166 12.3.1	Before outsourcing manufacturing, the commissioning party shall assess on site the contractor's production, quality assurance and risk management capabilities, confirming that it is capable of performing the contracted manufacturing and of continuously complying with this GMP. During contract manufacturing, the commissioning party shall periodically audit and assess the contractor's quality management system on site.	**	109
167 12.3.2	The contractor shall accept audits and supervision by the commissioning party and promptly implement corrective and preventive action to fulfil its rectification requirements.	*	109
168 12.4.1	The commissioning party shall establish an appropriate quality management organisation and provide sufficient, competent, dedicated quality management personnel and technical personnel familiar with the products and possessing appropriate professional knowledge, to monitor and control contracted manufacturing activities effectively.	**	110
169 12.4.2	The contractor's personnel in key positions, including the management representative, head of production management, head of quality management and release reviewer, shall be familiar with production and quality management for the products manufactured under contract.	**	110

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No. / clause	Requirement	Risk	GMP article
170 12.5.1	The commissioning party shall jointly plan and complete production transfer activities with the contractor, ensuring effective transfer of product technical requirements, raw material and manufacturing process requirements, instructions for use, labels and other relevant information.	**	111
171 12.5.2	The contractor shall conduct trial production and corresponding verification, qualification and validation activities. Trial production shall cover all transferred production and quality control processes.	***	111
172 12.6.1	The commissioning party shall promptly notify the contractor of design changes, purchasing changes and other changes and supervise implementation of the change requirements. It shall take effective measures to ensure timely awareness of changes at the contractor that may affect product quality and conduct joint assessments with the contractor.	**	112
173 12.6.2	The contractor shall implement the commissioning party's change requirements and communicate its own change needs to the commissioning party in light of manufacturing quality management conditions.	**	112
174 12.7.1	The commissioning party shall establish a market release procedure specifying release standards and conditions and shall review medical device production records, quality control records and the contractor's manufacturing release documents. Products meeting the standards and conditions may be placed on the market only after signature by authorised release personnel. The commissioning party shall itself perform market release and shall not entrust it to another enterprise.	***	113
175 12.7.2	The contractor shall establish a manufacturing release procedure specifying release standards and conditions and shall review medical device production records and quality control records. Products meeting the standards and conditions may leave the factory only after signature by authorised release personnel.	***	113
176 12.8.1	The contractor shall promptly report to the commissioning party deviations, changes and abnormal circumstances arising during production that may affect product quality, and retain records of their handling.	**	114

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No. / clause	Requirement	Risk	GMP article
177 12.9.1	Where product realisation involves outsourced processing, the enterprise shall establish an outsourced processing control procedure and control the outsourced processes to ensure compliance with applicable laws and regulations.	*	115
178 12.10.1	The enterprise shall, at a minimum, manage outsourced processors as suppliers and assess their processing, quality assurance and risk management capabilities and other relevant capabilities.	**	116
179 12.10.2	Both parties shall enter into an outsourced processing quality agreement specifying the scope of processing, quality standards or technical requirements, acceptance criteria and each party's responsibilities, together with requirements relating to processes, verification, qualification and validation, release conditions, changes and communication mechanisms.	**	116

Chapter XIII — Sales and After-sales Service

No. / clause	Requirement	Risk	GMP article
180 13.1.1	Product sales, after-sales service and other such activities shall comply with laws, regulations, rules and specifications relating to medical devices.	**	117
181 13.1.2	The enterprise shall retain product sales records meeting traceability requirements.	**	117
182 13.1.3	Sales records shall include, at a minimum, the medical device name, specifications, model, quantity, production batch number or product number (serial number), unique device identifier, service life (expected service life) or expiry date, date of sale, and the purchaser's name, address and contact details.	*	117
183 13.2.1	The enterprise shall transport products using verified or validated transport conditions and means and ensure appropriate product protection.	**	118
184 13.2.2	Where special requirements apply, the enterprise shall monitor and control the transport process.	*	118
185 13.3.1	The enterprise shall possess after-sales service capabilities appropriate to the products it manufactures and establish and maintain a sound after-sales service system.	*	119

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No. / clause	Requirement	Risk	GMP article
186 13.3.2	The enterprise shall specify after-sales service requirements and retain after-sales service records meeting traceability requirements.	*	119
187 13.4.1	Where a medical device requires installation by the enterprise, the enterprise shall determine installation requirements and installation verification acceptance criteria and retain installation and acceptance records.	*	120
188 13.4.2	Where installation or repair is performed by the user organisation or another enterprise, the enterprise shall provide installation requirements and standards, repair parts, documentation, passwords and other necessary materials, and provide guidance.	*	120

Chapter XIV — Analysis and Improvement

No. / clause	Requirement	Risk	GMP article
189 14.1.1	The enterprise shall monitor, analyse and improve its products and quality management system to ensure product safety and effectiveness and the continuing effective operation of the quality management system.	**	121
190 14.2.1	The enterprise shall establish procedures for handling product quality complaints and customer feedback, define relevant departmental responsibilities, promptly receive, investigate, evaluate and address complaints and feedback, and retain relevant records.	*	122
191 14.3.1	The enterprise shall establish a medical device adverse event monitoring system, promptly report adverse events, conduct investigations, analyses and evaluations, and take risk control measures where necessary.	**	123
192 14.4.1	The enterprise shall establish a data analysis procedure, determine appropriate data collection methods, control standards, analytical methods and statistical techniques, collect and analyse data concerning product quality, adverse events, customer feedback and quality management system operation, evaluate product safety and effectiveness, prepare quality risk assessment reports as required, and use data analysis results as inputs for improvement.	**	124

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No. / clause	Requirement	Risk	GMP article
193 14.5.1	The enterprise shall establish a corrective action procedure to determine the causes of problems and take effective measures to prevent recurrence. It shall establish a preventive action procedure to determine the causes of potential problems and take effective measures to prevent their occurrence.	**	125
194 14.5.2	Corrective and preventive measures taken by the enterprise shall be commensurate with the impact of the problems and verified as having no adverse effects. Their effectiveness shall be confirmed.	**	125
195 14.6.1	The enterprise shall establish a medical device recall management system, collect information relating to medical device safety, investigate and assess potentially defective products, promptly recall defective products and report to the relevant authorities as prescribed.	**	126
196 14.7.1	The enterprise shall establish a product information notification procedure to promptly notify relevant enterprises, user organisations or consumers of changes concerning product safety.	*	127
197 14.8.1	The enterprise shall establish an internal quality management system audit procedure specifying audit criteria, scope, frequency, participants, methods, record requirements, assessment of the effectiveness of corrective and preventive action, and other relevant matters.	**	128
198 14.8.2	The enterprise shall formulate an internal audit plan, conduct internal audits according to the plan and prepare audit reports. Corrective and preventive action shall be taken in respect of nonconformities identified by audits.	*	128
199 14.9.1	The enterprise shall establish a management review procedure and conduct management reviews periodically. Reviews shall include quality risk reviews, product quality evaluation, the need for changes to the quality management system, regulatory compliance and opportunities for improvement.	**	129
200 14.9.2	The enterprise shall prepare management review reports and adopt corresponding improvement measures to ensure the continuing suitability, adequacy and effectiveness of the quality management system.	*	129

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