Article Content

Title：	Pharmaceutical Good Manufacturing Practice Regulations CH
Amended Date：	2013-07-30
Category：	Ministry of Health and Welfare（衛生福利部）

Part 1 General Provisions

Article 1 This set of regulations is formulated in accordance with regulations of Paragraph 5, Article 57 of the Pharmaceutical Affairs Act (hereafter referred as the Act).

Article 2 Factory buildings and facilities, equipment, organization and personnel, production, quality control, storage, distribution, handling of customer complaints and other compliance matters, shall conform to these Regulations. Any matters for which these Regulations make no provision shall be governed by other relevant laws and regulations.

Part 2 Good Manufacturing Practices for Pharmaceuticals

Chapter 1 Good Manufacturing Practices for Western Pharmaceuticals

Article 3 The manufacturing, processing, re-packaging, packaging, storage, and distribution of Western medicinal products, including those only for export, shall comply with the good manufacturing practices for Western medicinal products adopted by the competent central health authority with reference to the Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme (PIC/S). Implementation of the aforesaid good manufacturing practices may be phased in; the items to which the phased-in implementation applies and the related schedules shall be announced by the competent central health authority.

Chapter 2 Good Manufacturing Practices for Chinese Herbal Medicines

Section 1 General Provisions

Article 4 Terms used in Chapter 2 are defined as follows:
(1) Raw materials: any materials used in the manufacture of pharmaceuticals, including those that do not remain in the end product.
(2) Semi-finished or intermediate products: any products that are obtained during the manufacturing process, and that, with further processing, can become finished products.

(3) Products: active pharmaceutical ingredients, or preparations that contain active pharmaceutical ingredients and may contain other non-active ingredients, for which all manufacturing processes have been completed.
(4) Labeling: refers to all text and graphics that appear on labels, instruction sheets or packages, or that come with products.
(5) Packaging materials: include product containers, caps, and any materials used in the outer packages of products.
(6) End products: refer to pharmaceutical products that have been packaged, and whose outer packaging clearly indicates the contents therein.
(7) Batch: refers to a specific amount of pharmaceutical or other substance produced under a single set of manufacturing instructions, and that is consistent in character and quality. However, under conditions of continuous production, a batch refers to a specific amount of pharmaceutical or other substance produced within a specific time period, or that, within specific parameters, is consistent in character and quality.
(8) Batch number: refers to any definite combination of letters, numbers or other symbols that can be used to look up comprehensive information on a batch of products or other substances.
(9) Content: the unit quantity of the components of a pharmaceutical.
(10) Validation: written documentation attesting that any procedure, manufacturing process, mechanical device, raw material, action or system is capable of achieving its anticipated effect.
(11) Active pharmaceutical ingredient: an active substance or ingredient that is produced through physical, chemical processes for use in the manufacture of a pharmaceutical product.
(12) Tamper-proof packaging: packaging with an identifying mark or barrier that enables consumers to clearly identify the contained product.
(13) Clinical trial drug: a pharmaceutical or placebo that is undergoing clinical trials, and has not yet obtained approval.

Article 5 Chinese herbal medicine manufacturers shall implement validation procedures; the categories to be implemented, as well as the implementation methods and schedule, shall be announced by the central competent health authority.

Article 6 The manufacturing, processing, re-packaging and packaging of raw materials of Chinese herbal medicine shall be governed by the provisions of Chapter 2; the categories to be implemented, as well as the implementation methods and schedule, shall be announced by the central competent health authority.

Section 2 Environmental Sanitation

Article 7 In treating hazardous waste materials, toxic containers, hazardous gases, dust, wastewater, biological components and other hazardous components or materials, Chinese herbal medicine factories shall act not only in accordance with relevant laws, but also with the following principles:

(1) For hazardous waste materials and toxic containers, storage facilities shall be established, and these materials and containers shall be decomposed in accordance with their properties, and then appropriately incinerated or buried. If toxic containers are to be reused, they shall be washed and rigorously controlled, and may not be used to hold food products.

(2) For hazardous gases and dust, airtight facilities, local exhaust ventilation systems and negative pressure procedures shall be established; these substances shall, in accordance with their properties, be scrubbed, collected, oxidized, reduced, combusted, or otherwise appropriately treated. If exhaust gas contains dust, it shall first be subjected to centrifuging, filtering, scrubbing, or some other form of dust-removal processing; the emission of such gases must comply with air pollutant emission standards.

(3) For the processing of wastewater, impermeable storage pools shall be established, and acidification, alkalization, neutralization, active carbon adsorption, or other effective methods shall be used to break down or remove wastewater toxins; the release of wastewater must comply with water release standards.

Section 3 FactoryBuildings and Facilities

Article 8 Chinese herbal medicine factory buildings shall be well constructed and safe; manufacturing, processing and packaging areas shall be completely separated from offices, reception rooms, laboratories, restaurants and their associated lavatories; the use of asbestos shall be avoided.

The buildings described in the preceding Paragraph shall be designed to prevent the entry of rodents, insects and dust; interior ceilings, walls and floors shall be smooth and free of cracks and crevices, easy to clean, and non-conducive to the collection of dust; where necessary, materials that are easily

cleaned and disinfected, such as epoxy resins shall be used. Interior ducts shall be constructed of materials that do not easily collect dust, and shall be hidden where possible; drainage facilities and drainage exits shall be equipped to prevent wastewater backflow.

Article 9 Areas at Chinese herbal medicine factories used for the storage of raw materials, product containers, caps, and labeling and packaging materials, and for the manufacture, processing, re-packaging, packaging and storage of products, shall be appropriately sized and located. These areas shall be suitably arranged, with operation areas clearly delineated by production type. Moreover, appropriate work space and levels of insulation and cleanliness shall be established as needed.

Levels of cleanliness, as mentioned in the preceding Paragraph, shall be established in accordance with the type of product being manufactured. Operation areas requiring the same level of cleanliness shall be grouped together; buffer zones or entry rooms shall be established between areas with different levels of cleanliness, and different colors or types of work clothes may be used to indicate the cleanliness levels of the various operation areas.

No operation area may be used as a passageway by personnel from other operation areas; passageways for people and for the transport of goods shall be separate, and shall not cross.

Facilities for the storage of raw materials, product containers, caps, labeling and packaging materials, semi-finished or intermediate products, and products shall be given “pre-inspection,” “approved for use” and “not approved for use” designations; if items are present that need to be kept frozen or toxic, appropriate storage facilities shall be established.

Semi-finished or intermediate products shall be stored separately; if they are not stored separately, special care shall be taken to prevent contamination and degradation of quality.

Where Chinese herbal medicine factories manufacture environmental sanitation agents, environmental sanitation agent manufacturing, processing and re-packaging areas, as well as raw material storage facilities, shall be separated from pharmaceutical manufacturing, processing and re-packaging areas by a distance of no less than eight meters.

Where Chinese herbal medicine factories manufacture pharmaceutical feed additives, the pharmaceutical feed additive operation area shall be independent from other operation areas.

Where Chinese herbal medicine factories use their pharmaceutical production facilities to manufacture food products, cosmetics or

general goods, care shall be taken to prevent cross-contamination, and validation procedures shall be carried out.

Article 10 All operation areas in Chinese herbal medicine factories shall be equipped with appropriate illumination and ventilation facilities; where necessary, aforesaid areas shall also be equipped with appropriate facilities for the regulation of temperature and humidity.

Each production and processing area shall, in accordance with its air purity requirements, be equipped with appropriate air filtration systems, including pre-filters and particulate filters.

In areas for the storage of raw materials, products, semi-finished or intermediate products, and areas where products are manufactured, processed, re-packaged or packaged, conditions conducive to the prevention of quality degradation shall be maintained.

Article 11 For Chinese herbal medicine factory production areas involving hazardous or flammable raw materials, solvents, semi-finished or intermediate products, or products, appropriate protective, first-aid and segregation facilities shall be established.

Facilities used in the manufacturing, processing and re-packaging process shall be airtight from start to finish; where facilities are not airtight and dust or hazardous gases are produced, local exhaust ventilation systems and negative pressure procedures shall be established.

Lighting, switches, sockets, motors and other electric devices for operation areas that produce dust, where organic solvents are used, or where hazardous substances are present, shall, as needed, be explosion-proof, airtight, or isolated from operation area.

Boilers, pressure vessels, cranes and other types of dangerous equipments and facilities shall be inspected and approved in accordance with relevant regulations before use.

Article 12 Chinese herbal medicine factories shall, as needed, establish employee lounges and shower rooms outside of work areas.

Manufacturing and processing areas shall be installed with appropriate lavatory facilities, and wastewater, garbage and other waste materials produced in aforesaid areas shall be treated in a safe and sanitary manner. Lavatory facilities shall be separated from work areas.

Article 13 Chinese herbal medicine factories shall, as needed, install facilities for the processing of general use and wastewater, and facilities for the production of boiler water or distilled

water. Water supply facilities shall be kept from contaminating products.

Article 14 Container washing facilities shall be installed in Chinese herbal medicine factories.

Section 4 Facilities

Article 15 Facilities at Chinese herbal medicine factories used for the manufacture, processing, re-packaging, packaging and storage of products shall be appropriately designed, sized and located for ease of usage, cleaning and maintenance.
Facilities needed for the production of different dosage forms shall be positioned according to manufacturing process sequence.

Article 16 The surfaces of facilities at Chinese herbal medicine factories that come into direct contact with raw materials, semi-finished products, intermediate products or products shall be made of non-reactive, non-releasing and non-adsorptive materials; where any process requires the use of lubricants, coolants or other similar substance, aforesaid substances may not come into contact with raw materials, product containers, caps, semi-finished products, intermediate products or products.

Article 17 Facilities and appliances at Chinese herbal medicine factories used for the manufacturing, processing, re-packaging, packaging, and storage of the products shall be cleaned and maintained regularly, and written operation procedures shall be established.

Article 18 The production capacities of mechanical facilities used at Chinese herbal medicine factories to produce a single product shall be carefully coordinated to ensure consistency of product quality.
Automated machinery and electronic facilities used in the manufacturing process, as well as software and equipment related to computers or to the manufacture, processing, re-packaging, packaging or storage of pharmaceuticals, shall be regularly recalibrated, inspected, examined and maintained.
Computer systems used to control production and production management records shall be properly maintained, and alterations may not be made to aforesaid systems without permission from the personnel in charge; all data that is input or printed shall be checked for accuracy, and its period of validity shall be determined based on the complexity and reliability of the computer system.
Air used by drying facilities during the manufacturing process shall first be treated with a purification filter.
Facilities used to manufacture pharmaceuticals for internal and

external use shall be kept strictly separate, and may not be used interchangeably.
Pharmaceutical factories shall install weighing facilities that comply with regulations, and shall recalibrate aforesaidfacilities regularly.

Article 19 Chinese herbal medicine factories shall keep facilities and equipment for the production of pharmaceuticals for human and animal use separate, and these two types of production may not be carried out in the same structure unless the two areas are completely separated. However, pharmaceuticals for animal use that comply with the standards governing drugs for human use are not subject to this restriction.

Article 20 Chinese herbal medicine factories shall, in accordance with the requirements of the products being manufactured, install necessary manufacturing, processing, re-packaging and packaging facilities.

Article 21 Chinese herbal medicine factories shall, in accordance with their specification testing requirements for raw materials, semi-finished products, intermediate products and products, establish testing departments and appropriate testing facilities. However, if tests are conducted on a contract basis by an organization approved by the competent authority, in accordance with the Contract Drug Manufacturing and Testing Operating Principles, and clear documentation is provided, establishment of aforesaid facilities may be waived.
Testing departments shall include testing and instrument laboratories. Instrument laboratories shall be separate from testing laboratories, and shall be kept at an appropriate temperature and level of humidity and air purity; testing laboratories shall be installed with sufficient and easy to use test benches, test stands, drug cabinets, fume hoods, water supply and washing facilities, as well as electric heating, thermostatic and drying facilities, and shall also be stocked with utensils and containers, chemical reagents and solutions, standard solutions and other necessary items.
Areas, facilities and equipment necessary for total viable count and other microorganism tests shall be installed as needed; microorganism strains, culture mediums, and animals necessary for conducting bioassays shall be adequately stocked and maintained.
For pyrogen testing, priority shall be given to replacing testing on live animals with alternative techniques.

Section 5 Organization and Personnel

Article 22 Quality control departments and manufacturing departments at Chinese herbal medicine factories shall be established separately.

Article 23 A person shall be placed in charge of each Chinese herbal medicine factory department, and sufficient personnel shall be assigned to carry out and supervise the manufacture, processing, re-packaging, packaging or storage of each product.

Article 24 The person in charge, supervisors and employees of each Chinese herbal medicine factory department shall all possess suitable educational backgrounds, and shall all undergo practical training in implementing the rules prescribed in Part 3 of this set of Standards; Microbiological testing personnel shall receive specialized trainings.

Article 25 Chinese herbal medicine factories shall establish in writing sanitary standards for employees; the standards shall include the following items:
(1) Regular health examinations in accordance with the nature of the employee’s job;
(2) Measures to prevent employees with illnesses or open wounds from having a negative impact on pharmaceutical safety or quality;
(3) Rules requiring employees to wash or disinfect their hands when entering work areas, refrain from wearing jewelry, eating, drinking, smoking, or engaging in any other behavior that may impact sanitation in manufacturing areas;
(4) Standards for the types of work clothes, hoods, face masks, gloves, arm covers, and shoe covers for each job.

Section 6 Management of Raw Materials and Product Containers and Caps

Article 26 Chinese herbal medicine factories shall establish detailed quality specifications for raw materials and product containers and caps, as well as operational procedures for the acceptance, labeling, storage, handling, sampling, testing and inspection of these items.
Containers that hold raw materials, product containers or caps shall be clearly labeled with batch numbers and status, pending-inspection, approved for use, not approved for use, or to be isolated; this information shall be entered into the disposition record of each batch.
Container caps shall, as needed, be fitted with children safety devices to prevent accidental consumption.

Article 27 When Chinese herbal medicine factories receive shipments of raw materials, product containers or caps, they shall collect

representative samples from each batch for testing; a note of this action shall be made on the original container.
Containers holding the samples described in the preceding Paragraph shall be appropriately labeled to facilitate tracking of sample names, batch numbers, sampling basis, original container and name of sampler.

Article 28 The samples referred to in the preceding Article shall be tested in accordance with the following principles:
(1) Every raw material shall be tested to determine whether it is in compliance with documented specifications. However, aside from identification tests, other tests may be waived if the test reports provided by the supplier are evaluated and found to be reliable.
(2) Products containers and caps shall be tested to determine whether they are in compliance with established specifications.
(3) Where raw materials, product containers or caps are susceptible to contamination by filth, insects, foreign objects or microorganisms, thus affecting their intended uses, relevant test items and methods shall be included in the quality specifications for aforesaid items, and each batch shall be inspected for contamination.

Article 29 Where raw materials, product containers or caps are tested and found to be in compliance with documented specifications, Chinese herbal medicine factories may approve them for use; where aforesaid items are not in compliance, they shall not be approved for use.
Raw materials, product containers or caps that are approved for use shall be used in the order of approval. However, where aforesaid items have been stored for long periods, exposed to the air or high temperatures, or subjected to other detrimental conditions, retesting shall be carried out.
Raw materials, product containers or caps that are not approved for use shall be labeled to this effect, and kept isolated prior to their proper disposal.

Section 7 Manufacturing Process Control

Article 30 To insure that each product batch is of consistent quality, Chinese herbal medicine factories shall have designated personnel establish process control standards for every product, and have announced the standards independently reviewed by other personnel.
The process control standards mentioned in the preceding Paragraph shall include the following items:
(1) Product name, content and dosage form;
(2) Name and weight or volume of each active ingredient per

product by unit weight, volume or dosage form, and total weight or volume of unit dosage form;
(3) Names and specifications of all raw materials; if a code name or number is used to represent a raw material, aforesaid code shall be sufficient to determine the nature of the material;
(4) Quantity of each product batch;
(5) Weight or volume required by each raw material for each product batch. However, the quantities of raw materials used to produce a given dosage form may be increased or varied within a reasonable range; aforesaid range shall be explained in the manufacturing process control standards;
(6) Appropriate theoretical weights or volumes for each stage of the manufacturing process;
(7) Theoretical production quantity, including upper and lower production quantity limits expressed as percentage;
(8) Product container, cap and packaging material specifications (along with label signed and dated by inspector and samples or copies of all other labeling);
(9) Complete manufacturing and control manuals, sampling and test procedures, specifications and guidelines.

Article 31 Chinese herbal medicine factories shall establish in writing process control procedures; aforesaid procedures shall be approved by the quality control department. Where actual operations deviate from documented procedures, aforesaid deviation shall be recorded, a determination of how to handle the deviation shall be made, and an explanation shall be given.

Article 32 To insure the each product batch is of consistent quality and integrity, Chinese herbal medicine factories shall take steps to evaluate and validate the consistency of process control operations, including related equipment and facilities, for each product; documented procedures for the validation of each manufacturing process shall also be established, and shall be complied with and validated on a regular basis.
All original verification records and statistical analysis data related to evaluation and validation procedures shall be compiled and filed for future reference.

Article 33 Chinese herbal medicine factories shall clearly mark the contents and product batch manufacturing stage dates and times of mixing and storage containers, production lines and main manufacturing facilities used in the production and manufacture of each product batch, and enter the information into the batch manufacturing records.

Article 34 In regard to the quantities of raw materials used by Chinese herbal medicine factories in the manufacture of products, the amounts of active ingredients in each product batch may not fall below the nominal quantity.
Weighing, dividing and other procedures carried out on raw materials shall be performed in designated segregation areas, and shall be appropriately supervised and controlled.
Documented operational procedures shall include detailed test and control procedures for representative samples from each batch of semi-finished or intermediate products.
During the manufacturing and production process, the quality control departments of pharmaceutical factories shall carry out tests on semi-finished or intermediate products in accordance with established test procedures, thereby determining whether to approve aforesaid products for use; semi-finished or intermediate products that are not approved for use shall be labeled to this effect and kept isolated.

Article 35 Chinese herbal medicine factories shall include appropriate measures to prevent contamination by harmful microorganisms in written operation procedures.

Section 8 Management of Packaging and Labeling

Article 36 Chinese herbal medicine factories shall establish in writing management procedures for the acceptance, labeling, storage, handling, sampling and testing of packaging and labeling materials.
Where over-the-counter drug products for human use are produced, packaging for aforesaid products shall be tamper-proof, and shall be kept intact during the manufacturing, shipping and retail display process; moreover, aforesaid packaging shall be designed in such a manner that tampering is easily detectable by consumers.
Prior to the acceptance or use of labeling and packaging materials, representative samples shall be taken from each batch for testing; testing results shall be recorded and samples preserved. Where test results comply with established specifications, aforesaid materials may be approved for use; where aforesaid materials are not in compliance, they shall not be approved for use.

Article 37 Chinese herbal medicine factories shall, in accordance with product type, content and dosage form, separately store and appropriately mark labels and other labeling materials; storage areas for aforesaid materials may not be entered without the consent of the personnel in charge.
Packaging or labeling materials that have expired or are not

approved for use shall be returned or destroyed. The amounts of labeling materials received, used and returned shall be kept track of, and no discrepancies shall be allowed.
Unused portions of labeling materials printed with batch numbers shall be destroyed; unused labeling materials that are not printed with batch numbers shall be appropriately identified and stored.

Article 38 Prior to packaging and labeling products, Chinese herbal medicine factories shall first inspect packaging and labeling materials to ensure that they are correct and suitable for use; aforesaid inspection results shall be entered into the batch manufacturing record.
Packaging and labeling facilities shall be inspected prior to use to ensure that all pharmaceuticals from the previous run and packaging and labeling materials not suited to the present run have been completely removed; aforesaid inspection results shall be entered into the batch manufacturing record.
During the final stage of production, products that have already been packaged and labeled shall be inspected to ensure that every container or package is correctly labeled.

Article 39 To ensure that the ingredients, contents, quality and purity of products ready for use are in compliance with established specifications, Chinese herbal medicine factories shall, unless other regulations apply, label aforesaid products with a usage period or expiration date as determined through stability testing; products that must be prepared before use shall be clearly labeled with the method of preparation and usage period following preparation.

Section 9 Storage, Shipping and Sales

Article 40 Chinese herbal medicine factories shall establish in writing product storage procedures; aforesaid procedures shall include the following items:
(1) Segregation measures for products awaiting approval for use;
(2) Appropriate temperature, humidity and light exposure standards to ensure that product ingredients, contents, quality and purity are not adversely affected by storage.

Article 41 Chinese herbal medicine factories shall establish in writing shipping and sales procedures; aforesaid procedures shall include the following items:
(1) Measures to ensure that products are sold in the order of manufacture;
(2) Shipping and sales methods that ensure product ingredients, contents, quality and purity are not adversely affected by

environmental factors;
(3) Systems to ensure prompt recycling.

Section 10 Quality Control

Article 42 Chinese herbal medicine factories shall establish in writing quality department duties and operational procedures; aforesaid duties and procedures shall include the following items:
(1) Examination of approval, non-approval and manufacturing records for all raw materials, product containers, caps, semi-finished or intermediate products, packaging materials, labeling materials and products;
(2) Examination of operational procedures specifications that affect product ingredients, contents, quality and purity;
(3) Inspection of facilities used in the testing of raw materials, product containers, caps, semi-finished or intermediate products, packaging materials, labeling materials and products;
(4) Establishment in writing of operational procedures governing the calibration of instruments, devices, meters and recording apparatuses; aforesaid procedures shall clearly prescribe calibration methods, schedules, accuracy limits, as well as usage restrictions and remedial measures for items that do not comply with accuracy limits;
(5) Establishment in writing of operational procedures governing sample quantities, test intervals and test methods for product stability testing.

Article 43 Specifications, standards, sampling plans, test procedures, and test control measures established for the various departments of a Chinese herbal medicine factory, and any alterations related to aforesaid items, shall be examined and approved by the quality control department of aforesaid factory prior to implementation.
Chinese herbal medicine factories shall faithfully follow the operational guidelines that they have established and keep records of the implementation process; where a deviation from aforesaid guidelines occurs, aforesaid deviation shall be recorded, a determination of how best to handle the deviation shall be made, and an explanation shall be given.
Chinese herbal medicine factories shall select senior specialist personnel from each department to establish a quality assurance team or committee to advice, review and supervise activities related to quality system.

Article 44 Chinese herbal medicine factories shall test every batch of products to ensure that they are in compliance with established specifications; each batch of products that must not contain

harmful microorganisms shall, where necessary, be subjected to appropriate tests.
Representative samples shall be removed from each batch of products or end products, and taken from the raw materials containing active ingredients used in making aforesaid products, and placed in reserve; aforesaid reserve samples shall be stored under indicated conditions, and shall be of at least twice the quantity needed for all required tests.
Reserve samples shall be retained until one year after the expiration date of the product from which it was taken; reserve samples of products that do not require expiration dates shall be kept for at least three years after the date of dispatch of the last batch of aforesaid product.

Section 11 Records and Reports

Article 45 The manufacturing, control, shipping and sales records prescribed in Chapter 2 shall all be stored in suitable locations, made available for inspection, and used at least once a year in the assessment of product quality standards; aforesaid records shall be kept until one year after the expiration date of the batch of products or end products in question. However, records for products that do not require expiration dates shall be kept for three years after the date of dispatch of the batch of products or end products in question.
When relevant competent authorities make inspections, they may photocopy, or copy by other means, the records described in Paragraph 1 or copies of aforesaid records.

Article 46 Chinese herbal medicine factories shall keep batch manufacturing records for each batch of products produced; aforesaid records shall contain comprehensive manufacturing and quality control information on the product batch in question.
Chinese herbal medicine factories shall produce accurate copies of manufacturing management standards, verify the accuracy of aforesaid copies, and sign and date them.
Chinese herbal medicine factories shall make detailed records of the important steps in the manufacture, processing, re-packaging, packaging and storage of each batch of products; aforesaid records shall include the following items:
(1) Date and product batch number;
(2) Identification marks for each batch of raw materials and semi-finished or intermediate products;
(3) Identity of major facilities and production lines;
(4) Quantity and volume of raw materials used in product processing;
(5) Manufacturing process, testing and control results;
(6) Pre- and post-use inspection of labeling and packaging

areas;
(7) Ratio of actual production output to theoretical output at appropriate stages of manufacturing process;
(8) Comprehensive labeling control records, including samples or copies of all labeling;
(9) Product container and cap identification marks and usage quantity;
(10) Sampling record;
(11) Dates and times of each major step in the production process, as well as signatures and dates for operation personnel, direct supervisors or inspectors involved in each step.

Article 47 The test records produced by Chinese herbal medicine factories shall include all test data used in determining compliance with established specifications and standards; aforesaid data shall include the following items:
(1) Sampling location, quantity, batch number or other clear identifying code, sampling date, and date of test completion;
(2) Basis of all test methods;
(3) Weight or volume of all samples tested;
(4) Comprehensive records of all data generated during testing process, including charts, graphs and spectra produced by test instruments, and clearly listing all the raw materials, product containers, caps, semi-finished products, intermediate products or products tested, along with the batch numbers of aforesaid items;
(5) Record of all test-related calculations;
(6) Records of test results and comparison of aforesaid results with established specifications;
(7) Names and dates for all personnel involved in conducting tests;
(8) Signatures of inspectors testifying that the original records inspected are accurate, truthful and in compliance with established specifications.

Article 48 The manufacturing and quality control records (including packaging and labeling control records) for all products manufactured by Chinese herbal medicine factories shall be examined by the quality control departments of aforesaid factories to ensure that all products are in compliance with all established documented operational procedures prior to release, shipment or sale.
Where the theoretical production quantity exceeds the upper or lower production quantity limits prescribed by manufacturing control standards, or if any other similar discrepancy occurs, or if any batch or raw material does not conform to specifications, a thorough investigation shall be conducted even

if aforesaid batch of products has already been shipped or sold; such investigations shall be extended to other batches of the product in which aforesaid discrepancy occurred, and to any other products that may be affected by aforesaid discrepancy.
Written records shall be kept of the investigations described in the preceding Paragraph; aforesaid records shall include investigation conclusions and methods.

Article 49 Chinese herbal medicine factory's shipping and sales records shall include products names, contents, dosage forms, recipient names and addresses, and shipping dates and quantities.

Article 50 Chinese herbal medicine factories shall make written records of product complaints, and keep aforesaid records in product complaint files; aforesaid files shall be stored in a suitable location, or in a facility where they can be easily accessed for inspection.
The written records referred to in the preceding Paragraph shall be kept until the expiration date of the product in question, or for one year after the complaint was received, whichever period is longer. However, for products that do not require expiration dates, aforesaid records shall be kept for at least three years after the date of dispatch of the product in question.

Article 51 Records of returned products kept by Chinese herbal medicine factories shall include product names, contents, batch numbers, reasons for return, quantities, disposition dates, final disposition methods; aforesaid records shall be kept in accordance with the regulations prescribed in Article 81.

Section 12 Handling of Complaints and Returned Products

Article 52 Chinese herbal medicine factories shall establish in writing procedures for the handling of oral and written complaints from consumers; all oral and written complaints shall be investigated and assessed by the quality control departments of aforesaid factories.
Where Chinese herbal medicine factories discover serious and unanticipated product defects, they shall report aforesaid defects to the relevant competent authorities, and handle aforesaid defects in accordance with the stipulations of the Act.
Written records shall be kept of the handling of all complaints; aforesaid records shall be properly collated and filed.

Article 53 Chinese herbal medicine factories shall properly identify and separately store returned products. If there are any doubts regarding a product's safety, ingredients, contents, quality or purity due to storage or shipping conditions, the condition of

the product, container, packaging or labeling, or any other relevant circumstances either before or after the product is returned, unless the product's safety, ingredients, contents, quality and purity are confirmed to be in compliance with established specifications through testing or investigation, aforesaid product shall be destroyed. However, where aforesaid product can be brought into compliance with established specifications through remanufacturing, remanufacturing may be carried out.

Section 13 Pharmaceuticals for Use in Clinical Trials

Article 54 The production and manufacturing of Chinese herbal medicine for use in clinical trials by Chinese herbal medicine factories shall, unless otherwise regulated by regulations of this Chapter, be governed by other relevant regulations prescribed in this Part.

Article 55 Where Chinese herbal medicine factories have not yet established validated manufacturing processes for Chinese herbal medicine for use in clinical trials, or have not yet established comprehensive manufacturing control standards, aforesaid factories shall establish in writing operational procedures and keep detailed and accurate records for each batch of products manufactured and each batch of raw material used. Batch manufacturing records shall be kept until clinical trials are completed, or until at least two years after the product is completed, whichever period is longer.

Article 56 Where Chinese herbal medicine factories produce Chinese herbal medicine for use in clinical trials, aforesaid Chinese herbal medicine, in addition to complying with regulations governing labeling in the Act, must also be labeled "for use in clinical trials only," and marked with the name of the party that commissioned the clinical trial and a trial code sufficient to identify the trial location and research personnel involved. However, where pharmaceuticals for use in clinical trials are tested in closed trials (double-blind trials), drug name, potency and efficacy may be replaced by product codes, serial numbers and packaging batch numbers.

Article 57 Chinese herbal medicine factories shall determine suitable expiration dates for Chinese herbal medicine for use in clinical trials based on the product properties, container characteristics and storage conditions; the expiration dates marked on aforesaid Chinese herbal medicine may not exceed the expiration dates marked on the original product packaging. Where clinical trials do not provide stability testing

information, the usage period of a repackaged product may not exceed 25% of the remaining portion of the usage period of the original bulk product, or the six-month period following repackaging, whichever period is shorter.

Article 58 Where a Chinese herbal medicine factory has a Chinese herbal medicine for use in clinical trials manufactured or tested on a contract basis, aforesaid contract shall clearly state that the product in question is for use in clinical trials only.

Article 59 Where Chinese herbal medicine factories destroy Chinese herbal medicine for use in clinical trials, destruction of aforesaid Chinese herbal medicine may not take place until all clinical trials and the final report are completed; detailed records shall be kept of the destruction process, and aforesaid records shall be preserved by the manufacturer.

Part 3 Good Manufacturing Practices for Medical Devices

Chapter 1 General Provisions

Article 60 In this Part, standards related to the design, development, production, installation, and servicing of medical devices are prescribed in accordance with the contents of medical device quality management system of the International Standard Organization (ISO 13485: Medical devices – Quality management systems – Requirements for regulatory purposes).

Article 61 The terms used in this Part are defined as follows:
(1) Active medical device: means a medical device relying for its functioning on a source of electrical energy or any source of power other than that directly generated by the human body or gravity;
(2) Active implantable medical device: means an active medical device which is intended to be totally or partially introduced, surgically or medically, into the human body or by medical intervention into a natural orifice, and which is intended to remain after the procedure;
(3) Implantable medical device: means a medical device intended to be totally or partially introduced into the human body or a natural orifice, or to replace an epithelial surface or the surface of the eye, by surgical intervention, and which is intended to remain after the procedure for at least 30 days, and which can only be removed by medical or surgical intervention;
(4) Advisory notice: means a notice issued by the manufacturer in accordance to the regulations of central competent health authority, subsequent to delivery of the medical device, to provide supplementary information and/or to advise what action should be taken in the use of a medical device, the modification

of a medical device, the return of the medical device to the organization that supplied it, or the destruction of a medical device;

(5) Customer complaint: means a written, electronic or oral communication that alleges deficiencies related to the identity, quality, durability, reliability, safety or performance of a medical device that has been placed on the market.

Article 62 For Class 2, Class 3, and Class 1 medical devices that are not listed as non-sterile or without a measuring function under Attachment 2 of the Regulations Governing Management of Medical Devices, their manufacturers shall comply with the requirements in Chapter 2 of this Part.

For Class 1 medical devices that are listed as non-sterile or without a measuring function under Attachment 2 of the Regulations Governing Management of Medical Devices, their manufacturers shall comply with the requirements in Chapter 3 of this Part.

Requirements in Chapter 3 of this Part shall be implemented one year after the date of promulgation.

Chapter 2 Standard Mode

Section 1 Quality Management System

Article 63 Manufacturers shall establish, implement and maintain a documented quality management system that conforms to the requirements of these Regulations.

Manufacturers shall adopt the following measures:

(1) Identifying the processes and applications needed for the quality management system;

(2) Determining the sequence and interaction for implementation of the quality management system;

(3) Determining criteria and methods needed for the quality management system to ensure effective operation and control of the processes;

(4) Ensuring the availability of resources and information necessary to support the operation and monitoring of quality management system processes;

(5) Monitoring, measuring and analyzing the processes of quality management system;

(6) Implementing actions necessary to achieve planned results of quality management system processes and maintain the effectiveness of these processes.

Where manufacturers choose to purchase from a supplier part or whole of any process that affects product conformity with quality management system requirements, the manufacturers shall ensure control over such purchased processes.

Control of such purchased processes shall be identified within the quality management system.

Article 64 The quality management system documentation shall include the following:

(1) Documented statements of a quality policy and quality objectives;

(2) A quality manual;

(3) Documented procedures required by these Regulations;

(4) Documents needed by the manufacturer to ensure the effective planning, operation and control of its quality management system processes;

(5) Records required by these Regulations; and

(6) Any other documentation specified by the central competent health authority.

Where these Regulations specify that a requirement, procedure, activity or special arrangement be documented, it shall, in addition, be implemented and maintained by the manufacturers.

For each type or model of medical device, manufacturers shall establish and maintain a file either containing or identifying documents defining product specifications and quality management system requirements. These documents shall define the complete manufacturing process and, if applicable, installation and servicing.

Article 65 Manufacturers shall establish and maintain a quality manual, the contents of which include the following:

(1) The scope of the quality management system;

(2) The documented procedures established for the quality management system; and

(3) A description of the interaction between the processes of the quality management system.

The above quality manual shall outline the structure of the documentation used in the quality management system.

Article 66 Documents required by the quality management system shall be controlled. These include but not limited to any type of documented records, which shall all be controlled according to the requirements of these Regulations.

Manufacturers shall establish a documented procedure that includes the following, to define the controls needed to:

(1) Review and approve documents for adequacy prior to issue;

(2) Review and update as necessary and re-approve documents;

(3) Ensure that changes and the current revision status of documents are identified;

(4) Ensure that applicable documents are available at points of use;

(5) Ensure that documents remain legible and readily

identifiable;
(6) Identify documents of external origin and control their distribution; and
(7) Prevent the unintended use of obsolete documents, and to apply suitable identification to them if they are retained for necessity.
Manufacturers shall ensure that changes to documents are reviewed and approved either by the original approving function or another designated function which has access to pertinent background information upon which to base its decisions.
Manufacturers shall define the period for which at least one copy of obsolete controlled documents shall be retained. This period shall ensure that documents to which medical devices have been manufactured and tested are available for at least the lifetime of the medical device as defined by the manufacturers, but not less than the retention period of any resulting record, or as specified by regulatory requirements.

Article 67 Manufacturers shall establish and maintain records to provide evidence of conformity to requirements and of the effective operation of the quality management system. Records shall remain legible, readily identifiable and retrievable.
Manufacturers shall establish a documented procedure to define the controls needed for the identification, storage, protection, retrieval, retention time and disposition of records.
Manufacturers shall retain the records for a period of time at least equivalent to the lifetime of the medical device as defined by the manufacturers but not less than three years from the date of product release by the manufacturers or as specified by other relevant regulatory requirements.

Section 2 Management Responsibility

Article 68 Top management shall be committed to the development and implementation of the quality management system and maintain its effectiveness by providing the following evidence:
(1) Communicating internally within the manufacturer on the importance of meeting customer as well as statutory and regulatory requirements concerning the safety and performance of the medical device;
(2) Establishing the quality policy;
(3) Establishing the quality objectives;
(4) Conducting management reviews; and
(5) Ensuring the availability of resources.

Article 69 Top management shall ensure that customer requirements are determined and are met.

Article 70 Top management shall ensure that quality policy includes the following:
(1) Purpose that is appropriate for and conforms to the manufacturer;
(2) Commitment to comply with requirements and to maintain the effectiveness of the quality management system;
(3) Framework provided for establishing and reviewing quality objectives;
(4) Communication and understanding achieved within the manufacturer’s organization; and
(5) Review of the suitability of quality policy.

Article 71 Top management shall ensure that quality objectives, including those needed to meet requirements for product, are established at relevant functions and levels within the manufacturer. The quality objectives shall be measurable and consistent with the quality policy.

Article 72 Top management shall ensure the following:
(1) The planning of the quality management system is carried out in order to meet the quality objectives, as well as the requirements of Article 63; and
(2) The integrity of the quality management system is maintained when changes are made to the quality management system.

Article 73 Top management shall establish a documented procedure to ensure that responsibilities and authorities are defined, documented and communicated internally within the manufacturer.
Top management shall establish the interrelation of all personnel who manage, perform and verify work affecting quality, and shall ensure the independence and authority necessary to perform these tasks.
Manufacturers shall nominate responsible persons for activities related to monitoring experience from the post-production stage and reporting adverse events.

Article 74 Top management shall appoint a member of the management who, irrespective of other responsibilities, shall have responsibility and authority that include the following:
(1) Implementing and maintaining processes needed for the quality management system;
(2) Reporting to top management on the performance of the quality management system and any need for improvement;
(3) Promoting manufacturer’s awareness of regulatory and customer requirements; and
(4) Ensuring the safety and effectiveness of manufactured medical devices.
The above responsibility of a management representative can

include liaison with external parties on matters relating to the quality management system.

Article 75 Top management shall establish appropriate processes for communicating the effectiveness of the quality management system.

Article 76 Top management shall review the manufacturer’s quality management system, at planned intervals, to ensure its continuing suitability, adequacy and effectiveness. This review shall include assessing opportunities for improvement and the need for changes to the quality management system, including the quality policy and quality objectives.

Article 77 The input to management review shall include the following information:
(1) Results of audits;
(2) Customer feedback;
(3) Process performance and product conformity;
(4) Status of preventive and corrective actions;
(5) Follow-up actions from previous management reviews;
(6) Changes that could affect the quality management system;
(7) Recommendations for improvement; and
(8) New or revised regulatory requirements.

Article 78 The output from the management review shall include any decisions and actions related to the following:
(1) Improvements to the effectiveness of the quality management system and its processes;
(2) Improvement of product related to customer requirements;
(3) Resource needs.

Section 3 Resource Management

Article 79 Manufacturers shall determine and provide the following resources needed to:
(1) Implement and promote the quality management system and to maintain its effectiveness;
(2) Meet regulatory and customer requirements.

Article 80 Manufacturers shall ensure their personnel performing work affecting product quality are competent on the basis of appropriate education, training, skills and experience.

Article 81 Manufacturers shall establish documented procedures to implement the following:
(1) Determining the necessary competence for personnel performing work affecting product quality;
(2) Providing training or taking other actions to satisfy the

above needs;
(3) Evaluating the effectiveness of the actions taken;
(4) Ensuring that the personnel are aware of the relevance and importance of their activities and how to achieve the quality objectives; and
(5) Maintaining records of personnel education, training, skills and experience.

Article 82 Manufacturers shall determine, provide and maintain the infrastructure needed to achieve conformity to product requirements.
Infrastructure shall include the following:
(1) Buildings, workspace and associated utilities;
(2) Process equipment (both hardware and software); and
(3) Supporting services (such as transport or communication).
Manufacturers shall establish documented requirements for maintenance activities, including their frequency, when such activities or lack thereof can affect product quality.
The above records of maintenance shall be maintained.

Article 83 Manufacturers shall determine and manage the work environment needed to achieve conformity to product requirements, including adopting the following measures:
(1) Manufacturers shall establish documented requirements for health, cleanliness and clothing of personnel if contact between such personnel and the product or work environment could adversely affect the quality of the product.
(2) If work environment conditions can have an adverse effect on product quality, manufacturers shall establish documented requirements for the work environment conditions and documented procedures or work instructions to monitor and control these work environment conditions.
(3) Manufacturers shall ensure that all personnel who are required to work temporarily under special environmental conditions within the work environment are appropriately trained or supervised by a trained person.
(4) If appropriate, manufacturers shall establish documented special arrangements for the control of contaminated or potentially contaminated product in order to prevent contamination of other product, the work environment or personnel.

Section 4 Product Realization

Article 84 Manufacturers shall plan and develop the processes needed for product realization. Planning of product realization shall be consistent with the requirements of the other processes of the quality management system. In planning product realization,

manufacturers shall determine the following:
(1) Quality objectives and requirements for the product;
(2) The need to establish processes, documents, and provide resources specific to the product;
(3) Required verification, validation, monitoring, inspection and test activities specific to the product and the criteria for product acceptance;
(4) Records needed to provide evidence that the realization processes and resulting product meet requirements.
The output of the above planning shall be in a form suitable for the manufacturer’s method of operations.
Manufacturers shall establish documented requirements for risk management throughout product realization.
Records arising from risk management shall be maintained.

Article 85 Manufacturers shall determine the following:
(1) Requirements specified by the customer, including the requirements for delivery and post-delivery activities;
(2) Requirements not stated by the customer but necessary for specified or intended use, where known;
(3) Statutory and regulatory requirements related to the product; and
(4) Any additional requirements determined by the manufacturers.

Article 86 Manufacturers shall establish and maintain documented procedures for contract review and for the coordination of these activities.

Article 87 Manufacturers shall review the requirements related to the product. This review shall be conducted prior to the manufacturers' commitment to supply a product to the customer and shall ensure the following:
(1) Product requirements are defined and documented;
(2) Contract or order requirements differing from those previously expressed are resolved; and
(3) Manufacturers have the ability to meet the defined requirements.
Records of the results of above review and actions arising from the review shall be maintained.
Where the customer provides no documented statement of requirement, the customer requirements shall be confirmed by manufacturers before acceptance.
Where product requirements are changed, manufacturers shall ensure that relevant documents are amended and that relevant personnel are made aware of the changed requirements.

Article 88 Manufacturers shall determine and implement effective arrangements for communicating with customers in relation to the

following:
(1) Product information;
(2) Enquiries, contracts or order handling, including amendments;
(3) Customer feedback, including customer complaints; and
(4) Advisory notices.

Article 89 Manufacturers shall establish documented procedures for design and development, and plan and control the design and development of product.
During the design and development planning, manufacturers shall determine the following:
(1) The design and development stages;
(2) The review, verification, validation and design transfer activities that are appropriate at each design and development stage. Design transfer activities during the design and development process ensure that design and development outputs are verified as suitable for manufacturing before becoming final production specifications; and
(3) The responsibilities and authorities for design and development.
Manufacturers shall manage the interfaces between different groups involved in design and development to ensure effective communication and clear assignment of responsibility.
Manufacturers shall document planning output and update it appropriately as the design and development progress.

Article 90 Manufacturers shall determine and maintain the inputs relating to product requirements, which include the following:
(1) Functional, performance and safety requirements, according to the intended use;
(2) Applicable statutory and regulatory requirements;
(3) Where applicable, information derived from previous similar designs;
(4) Other requirements essential for design and development; and
(5) Output(s) of risk management.
Manufacturers shall review and approve inputs for adequacy. Every requirement shall be complete, unambiguous and not in conflict with each other.

Article 91 Manufacturers shall ensure the outputs of design and development be provided in a form that enables verification against the design and development input and shall be approved prior to release. Design and development outputs shall conform to the following:
(1) Meeting the input requirements for design and development;
(2) Providing appropriate information for purchasing, production and for service provision;

(3) Containing or referencing product acceptance criteria; and
(4) Specifying the characteristics of the product that are essential for its safe and proper use.
Records of the design and development outputs shall be maintained.

Article 92 Manufacturers shall, at suitable stages, perform systematic reviews of design and development in accordance with planned arrangements and comply with the following requirements:
(1) Evaluating the ability of the results of design and development to meet requirements; and
(2) Identifying any problems and propose necessary actions.
Participants in such reviews shall include representatives of functions concerned with the design and development stage(s) being reviewed, as well as other specialist personnel.
Records of the results of the reviews and any necessary actions shall be maintained.

Article 93 Manufacturers shall perform verification in accordance with planned arrangements to ensure that the design and development outputs have met the design and development input requirements.
Records of the results of the verification and any necessary actions shall be maintained.

Article 94 Manufacturers shall perform design and development validation in accordance with planned arrangements, and complete it prior to the delivery or implementation of the product to ensure that the resulting product is capable of meeting the requirements for the specified application or intended use.
Records of the results of validation and any necessary actions shall be maintained.
Manufacturers shall perform clinical evaluation and evaluation of performance of the medical device in accordance with the regulatory requirements of central competent health authority.

Article 95 Manufacturers shall identify design and development changes and maintain their records. The changes shall be reviewed, verified and validated, as appropriate, and approved before implementation. The review of design and development changes shall include evaluation of the effect of the changes on constituent parts and product already delivered.
Records of the results of the review of above changes and any necessary actions shall be maintained.

Article 96 Manufacturers shall establish documented procedures to ensure that purchased product conforms to specified purchase requirements.
The type and extent of control applied to the supplier and the

purchased product shall be dependent upon the effect of the purchased product on subsequent product realization or the final product.
Manufacturers shall evaluate and select suppliers based on their ability to supply product in accordance with the manufacturers' requirements. Criteria for selection, evaluation and re-evaluation shall be established. Records of the results of evaluations and any necessary actions arising from the evaluation shall be maintained.

Article 97 Purchasing information shall describe the product to be purchased, including the following:
(1) Requirements for approval of product, procedures, processes and equipment;
(2) Requirements for qualification of personnel; and
(3) Quality management system requirements.
Manufacturers shall ensure the adequacy of specified purchase requirements prior to their communication to the supplier.
Manufacturers shall maintain relevant purchasing information, i.e., documents and records, according to the scope and extent required for traceability as set forth in these Regulations.

Article 98 Manufacturers shall establish and implement the inspection or other activities necessary for ensuring that purchased product meets specified purchase requirements.
Where manufacturers or their customers intend to perform verification at the suppliers' premises, the manufacturers shall state the intended verification arrangements and method of product release in the purchasing information.
Records of the above verification shall be maintained.

Article 99 Manufacturers shall plan and carry out production and service provision under controlled conditions. Controlled conditions shall include the following, as applicable:
(1) The availability of information that describes the characteristics of the product;
(2) The availability of documented procedures, documented requirements, work instructions, and reference materials and reference measurement procedures as necessary;
(3) The use of suitable equipment;
(4) The availability and use of monitoring and measuring devices;
(5) The implementation of monitoring and measurement;
(6) The implementation of release, delivery and post-delivery activities; and
(7) The implementation of defined operations for labeling and packaging.
Manufacturers shall establish and maintain a record for each

batch of medical devices that provides traceability to the extent specified in these Regulations and identifies the amount manufactured and amount approved for distribution. The batch record shall be verified and approved.

Article 100 Under the following condition, manufacturers shall establish documented requirements for cleanliness of product:
(1) Product is cleaned by the manufacturer prior to sterilization and its use;
(2) Product is supplied non-sterile to be subjected to a cleaning process prior to sterilization and its use;
(3) Product is supplied to be used non-sterile and its cleanliness is of significance in use; or
(4) Process agents are to be removed from product during manufacture.
If product is cleaned in accordance with the preceding Subparagraph 1 or 2, the requirements contained in Subparagraphs 1 and 2 of Article 83 do not apply prior to the cleaning process.

Article 101 Manufacturers shall establish documented requirements which contain acceptance criteria for installing and verifying the installation of the medical device.
If the agreed customer requirements allow installation to be performed other than by manufacturers or their authorized agents, the manufacturers shall provide documented requirements for installation and verification.
Manufacturers shall maintain records of installation and verification performed by manufacturers or their authorized agents.

Article 102 Manufacturers shall establish documented procedures, work instructions, and reference materials and reference measurement procedures, as necessary, for performing servicing activities and verifying that they meet the specified requirements.
Records of servicing activities carried out by the manufacturers shall be maintained.

Article 103 Manufacturers shall maintain records of the process parameters for the sterilization process which was used for each sterilization batch. Sterilization records shall be traceable to each production batch of medical devices.

Article 104 Any processes for production and service provision where the resulting output cannot be verified by subsequent monitoring or measurement, and any processes where deficiencies become apparent only after the product is in use or the service has been delivered, shall be validated by the manufacturers.

The above validation shall demonstrate the ability of these processes to achieve planned results.
Manufacturers shall establish arrangements for these processes, including the following as applicable:
(1) Defined criteria for review and approval of the processes;
(2) Approval of equipment and qualification of personnel;
(3) Use of specific methods and procedures;
(4) Requirements for records; and
(5) Revalidation.
Manufacturers shall establish documented procedures for the validation of the application of computer software, and changes to such software and its application, for production and service provision that affect the ability of the product to conform to specified requirements. Such software applications shall be validated prior to initial use.
Records of the above validation shall be maintained.

Article 105 Manufacturers shall establish documented procedures for the validation of sterilization processes. Sterilization processes shall be validated prior to initial use.
Records of validation of sterilization process shall be maintained.

Article 106 Manufacturers shall identify the product by suitable means throughout product realization, and shall establish documented procedures for such product identification.
Manufacturers shall establish documented procedures to ensure that medical devices returned to the manufacturers are identified and distinguished from conforming product.

Article 107 Manufacturers shall establish documented procedures for traceability. Such procedures shall define the extent of product traceability and the records required.
Where traceability is a requirement, the manufacturers shall control and record the unique identification of the product.

Article 108 In defining the records required for traceability of active implantable medical devices and implantable medical devices, manufacturers shall include records of all components, materials and work environment conditions, if these could cause the medical device not to satisfy its specified requirements.
Manufacturers shall require that their agents or distributors maintain records of the distribution of active implantable medical devices and implantable medical devices to facilitate the need for traceability and inspection.
Manufacturers shall maintain the name and address of the shipping package consignee of active implantable medical devices and implantable medical devices.

Article 109 Manufacturers shall identify the product status with respect to monitoring and measurement requirements.
Manufacturers shall maintain the identification of product status throughout production, storage, installation and servicing of the product to ensure that only product that has passed the required inspections and tests, or released under an authorized concession, is dispatched, used or installed.

Article 110 Manufacturers shall exercise care with customer property while it is under their control or being used by them. Manufacturers shall identify, verify, protect and safeguard customer property provided for use or incorporation into the product. If any customer property is lost, damaged or otherwise found to be unsuitable for use, the manufacturers shall report to the customer and maintain records.

Article 111 Manufacturers shall establish documented procedures or documented work instructions for preserving the conformity of product during internal processing and delivery to the intended destination.
This preservation shall include identification, handling, packaging, storage and protection. Preservation shall also apply to the constituent parts of a product.
Manufacturers shall establish documented procedures or documented work instructions for the control of product with a limited shelf-life or requiring special storage conditions. Such special storage conditions shall be controlled and recorded

Article 112 Manufacturers shall determine the monitoring and measurement to be undertaken and the monitoring and measuring devices needed to provide evidence of conformity of product to determined requirements.
Manufacturers shall establish documented procedures to ensure that monitoring and measurement can be carried out and are carried out in a manner that is consistent with the monitoring and measurement requirements.
Where necessary to ensure valid results, measuring equipment shall conform to the following:
(1) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification shall be recorded;
(2) Be adjusted or re-adjusted as necessary;
(3) Be identified to enable the calibration status to be determined;
(4) Be safeguarded from adjustments that would invalidate the

measurement result;
(5) Be protected from damage and deterioration during handling, maintenance and storage.
In addition, manufacturers shall assess and record the validity of the previous measuring results when the equipment is found not to conform to requirements. Manufacturers shall take appropriate action on the equipment and any product affected. Records of the results of calibration and verification shall be maintained.
When used in the monitoring and measurement of specified requirements, the ability of computer software to satisfy the intended application shall be confirmed. This shall be undertaken prior to initial use and reconfirmed as necessary.

Section 5 Measurement, Analysis and Improvement

Article 113 Manufacturers shall plan and implement the monitoring, measurement, analysis and improvement processes needed to comply with the following:
(1) Demonstrating conformity of the product;
(2) Ensuring conformity of the quality management system;
(3) Maintaining the effectiveness of the quality management system.
The above requirement shall include determination of applicable methods, including statistical techniques, and the extent of their use.
Manufacturers shall establish and maintain documented procedures to implement and control the application of the statistical techniques.

Article 114 As one of the measurements of the performance of the quality management system, manufacturers shall monitor information relating to whether they have met customer requirements. Manufacturers shall determine the methods for obtaining and using this information.
Manufacturers shall establish a documented procedure for a feedback system to provide early warning of quality problems and for input into the corrective and preventive action processes.
Manufacturers shall gain experience from the post-production phase in accordance with the regulations of central competent health authority, and the review of this experience shall form part of the feedback system.

Article 115 Manufacturers shall conduct internal audits at planned intervals to determine whether the quality management system conforms to the following requirements:
(1) Conforms to the planned arrangements, to the requirements of these Regulations and to the quality management system

requirements established by the manufacturers; and
(2) Is effectively implemented and maintained.
Manufacturers shall establish an audit programme, taking into consideration the status and importance of the processes and areas to be audited, as well as the results of previous audits. The audit criteria, scope, frequency and methods shall be defined. Selection of auditors and conduct of audits shall ensure objectivity and impartiality of the audit process. Auditors shall not audit their own work.
Manufacturers shall define in a documented procedure the responsibilities and requirements for planning and conducting audits, and for reporting results and maintaining records.
The management responsible for the area being audited shall ensure that actions are taken without undue delay to eliminate detected nonconformities and their causes.
Follow-up activities shall include the verification of the actions taken and the reporting of verification results.

Article 116 Manufacturers shall apply suitable methods for monitoring and, where applicable, measurement of the quality management system processes.
The above methods shall demonstrate the ability of the processes to achieve planned results. When planned results are not achieved, correction and corrective action shall be taken, as appropriate, to ensure conformity of the product.

Article 117 Manufacturers shall monitor and measure the characteristics of the product to verify that product requirements have been met. The foregoing shall be carried out at appropriate stages of the product realization process in accordance with the planned arrangements and documented procedures.
Manufacturers shall maintain the evidence of conformity with the acceptance criteria. Records shall indicate the person(s) authorizing release of product.
Product release and service delivery shall not proceed until the planned arrangements have been satisfactorily completed.

Article 118 Manufacturers shall record the identity of personnel performing any inspection or testing of active implantable medical devices and implantable medical devices.

Article 119 Manufacturers shall ensure that product which does not conform to product requirements is identified and controlled to prevent its unintended use or delivery. The controls and related responsibilities and authorities for dealing with nonconforming product shall be defined in a documented procedure.
Manufacturers shall deal with nonconforming product by one or more of the following ways:

(1) By taking action to eliminate the detected nonconformity;
(2) By authorizing its use, release or acceptance under concession;
(3) By taking action to preclude its original intended use or application.
Manufacturers shall ensure that nonconforming product is accepted by concession only if regulatory requirements are met.
Records of the identity of the person(s) authorizing the concession shall be maintained.
Records of the nature of nonconformities and any subsequent actions taken, including concessions obtained, shall be maintained.
When nonconforming product is corrected, manufacturers shall re-verify to demonstrate conformity to the requirements.
When nonconforming product is detected after delivery or use has started, manufacturers shall take action appropriate to the effects, or potential effects, of the nonconformity.
If product needs to be reworked one or more times, manufacturers shall document the rework process in a work instruction that has undergone the same authorization and approval procedure as the original work instruction. Prior to authorization and approval of the work instruction, a determination of any adverse effect of the rework upon product shall be made and documented.

Article 120 Manufacturers shall establish documented procedures to determine, collect and analyze appropriate data to demonstrate the suitability and effectiveness of the quality management system and to evaluate if improvement of the effectiveness of the quality management system can be made.
The data analyzed shall include those generated as a result of monitoring and measurement and from other relevant sources.
The analysis of data shall provide information relating to the following:
(1) Feedback;
(2) Conformity to product requirements;
(3) Characteristics and trends of processes and products including opportunities for preventive action; and
(4) Suppliers.
Records of the results of the analysis of data shall be maintained.

Article 121 Manufacturers shall identify and implement any changes necessary to ensure and maintain the continued suitability and effectiveness of the quality management system through the use of the quality policy, quality objectives, audit results, analysis of data, corrective and preventive actions and management review.
Manufacturers shall establish documented procedures for the

issue and implementation of advisory notices. These procedures shall be capable of being implemented at any time.
Manufacturers shall maintain the records of all customer complaint investigations. If investigation determines that the activities outside the manufacturers contributed to the customer complaint, relevant information shall be exchanged between the organizations involved.
If any customer complaint is not followed by corrective and/or preventive action, manufacturers shall authorize and record the reason.
Manufacturers shall establish reporting procedures in accordance with the regulations of central competent health authority for the notification of adverse events or recall actions to the central competent health authority or its designated organization.

Article 122 Manufacturers shall take action to eliminate the cause of nonconformities in order to prevent recurrence. Corrective actions shall be appropriate to the effects of the nonconformities encountered.
Manufacturers shall establish a documented procedure to define each of the following requirements:
(1) Reviewing nonconformities (including customer complaints);
(2) Determining the causes of nonconformities;
(3) Evaluating the need for action to ensure that nonconformities do not recur;
(4) Determining and implementing action needed, including, if appropriate, updating documentation,
(5) Recording of the results of any investigation and of action taken; and
(6) Reviewing the corrective action taken and its effectiveness.

Article 123 Manufacturers shall determine action to eliminate the causes of potential nonconformities in order to prevent their occurrence. Preventive actions shall be appropriate to the effects of the potential problems.
Manufacturers shall establish a documented procedure to define each of the following requirements:
(1) Determining potential nonconformities and their causes;
(2) Evaluating the need for action to prevent occurrence of nonconformities;
(3) Determining and implementing action needed;
(4) Recording of the results of any investigations and of action taken;
(5) Reviewing preventive action taken and its effectiveness.

Chapter 3 Essential Mode

Article 124 Manufacturers shall appoint a member of its own management who, irrespective of other responsibilities, shall have defined authority for the following tasks:
(1) Ensuring that a quality system is established, implemented and maintained in accordance with this Chapter;
(2) Reporting on the performance of the quality system to the management for review and as a basis for improvement of the quality system;
(3) Ensuring the safety and effectiveness of manufactured medical devices.

Article 125 Manufacturers shall establish and maintain a file for manufacturing procedures, installation and servicing, or referring to the location(s) of this information. Their file or information shall contain documents defining the product specifications and quality system requirements (including process and quality assurance) for each type or model of medical device.

Article 126 All design changes and modifications of manufacturers shall be identified, documented, reviewed and approved by authorized personnel before their implementation.

Article 127 Manufacturers shall establish and maintain documented procedures to control all documents and data that relate to the requirements of this Chapter.

Article 128 Manufacturers shall adopt the following measures with respect to subcontractors:
(1) Evaluating and selecting subcontractors on the basis of their ability to meet subcontract requirements including the quality system and any specific quality assurance requirements;
(2) Defining the type and extent of control exercised over subcontractors depending upon the type of product, the impact of subcontracted product on the quality of final product; and, where applicable, also taking into account the quality audit reports or quality records of the previously demonstrated capability and performance of subcontractors; and
(3) Establishing and maintaining quality records of subcontractors.
Verification by the customer shall not be used by manufacturers as evidence for their effective quality control of subcontractors.

Article 129 Manufacturers shall require that their agents or distributors maintain and retain records of the distribution of medical devices and that such records are available for inspection.

Article 130 Manufacturers shall identify and plan the production, installation and servicing processes which directly affect quality and shall ensure that these processes are carried out under controlled conditions.

The above controlled conditions shall include the following:

(1) Documented procedures defining the manner of production, installation and servicing, where the absence of such procedures could adversely affect quality;

(2) Use of suitable production, installation and servicing equipment, and a suitable working environment;

(3) Compliance with all types of reference codes, standards, quality plans or documented procedures;

(4) Monitoring and control of suitable process parameters and product characteristics;

(5) The approval of processes and equipment, as appropriate;

(6) Criteria for workmanship stipulated in the clearest practical manner (e.g., written standards, representative samples or illustrations);

(7) Suitable maintenance of equipment to ensure continuing process capability.

Where the results of processes cannot be fully verified by subsequent inspection and testing of the product (including processing deficiencies that may become apparent only after the product is in use), the processes shall be carried out by qualified operators or shall require continuous monitoring and control of process parameters to ensure that the specified requirements are met.

The requirements for any qualification of process operations, including associated equipment and personnel, shall be specified.

Article 131 Manufacturers shall establish and maintain documented procedures for inspection and testing activities in order to verify that the specified requirements for the product are met.

Article 132 Manufacturers shall carry out final inspection and testing and prepare records in accordance with the quality plan or documented procedures to ensure conformance of the finished product to the specified requirements.

Article 133 Manufacturers shall establish and maintain records which provide evidence that the product has been inspected and/or tested.

The above records shall include the following:

(1) Showing clearly whether the product has passed or failed the inspections or tests according to defined acceptance criteria. Where the product fails to pass any inspection or test, the procedures for control of nonconforming product shall apply;

(2) Identifying the inspection authority responsible for the release of product.

Article 134 Manufacturers shall establish and maintain documented procedures to control, calibrate and maintain inspection, measuring and test equipment (including test software) used by them to demonstrate the conformance of product to the specified requirements.
The above inspection, measuring and test equipment shall be used in a manner which ensures that the measurement uncertainty is known and is consistent with the required measurement capability.

Article 135 Manufacturers shall identify the inspection and test status of product by suitable means, which indicate the conformance or nonconformance of product with regard to inspection and tests performed.

Article 136 Manufacturers shall establish and maintain documented procedures to ensure that product that does not conform to specified requirements is prevented from unintended use or installation.
The above control shall provide for identification, documentation, evaluation, segregating (when practical), disposition of nonconforming product, and for notification to the functions concerned.

Article 137 Manufacturers shall establish and maintain documented procedures for implementing corrective and preventive action.
Any corrective or preventive action taken to eliminate the causes of actual or potential nonconformities shall be to a degree appropriate to the magnitude of problems and commensurate with the risks encountered.
Manufacturers shall implement and record any changes to the documented procedures resulting from corrective and preventive action.
Manufacturers shall establish and maintain a documented feedback system to provide early warning of quality problems and for input into the corrective and preventive action system.
Manufacturers shall gain experience from information feedback in the post-production phase, and the review of this experience shall form part of the feedback system.
Manufacturers shall maintain records of all customer complaint investigations. When the investigation determines that the activities at remote premises contributed to the customer complaint, relevant information shall be communicated between the manufacturer and the remote premises.
If any customer complaint is not followed by corrective and preventive action, the reason shall be recorded.

Manufacturers shall establish reporting procedures to notify the central competent health authority of those incidents in which a harmful event has occurred.
Manufacturers shall establish and maintain documented procedures for the issue of advisory notice for medical devices, and ensure these procedures shall be capable of being implemented at any time.

Article 138 Manufacturers that manage the handling, storage, packaging, preservation and delivery of product shall comply with the following requirements:
(1) Handling: Appropriate methods for handling product that prevent damage or deterioration shall be provided.
(2) Storage: Designated storage areas or stock rooms shall be used to prevent damage or deterioration of product, pending use or delivery. Appropriate methods for authorizing receipt to and dispatch from such areas shall be stipulated. In order to detect deterioration, the condition of product in stock shall be assessed at appropriate intervals.
(3) Packaging: Packing and marking processes (including materials used) shall be controlled to the extent necessary to ensure conformance to specified requirements.
(4) Preservation: Appropriate methods for preservation and segregation of product shall be applied when the product is under the manufacturer’s control.
(5) Delivery: Protection of the quality of product shall be arranged for after final inspection and test. Where contractually specified, this protection shall be extended to include delivery to destination.

Article 139 Manufacturers shall establish and maintain documented procedures for identification, collection, indexing, access, filing, storage, maintenance and disposition of quality records.
Quality records of manufacturers and their control shall conform to the following requirements:
(1) Quality records shall be maintained to demonstrate conformance to specified requirements and the effective operation of the quality system.
(2) Pertinent quality records from the subcontractor shall be part of the records.
(3) Quality records shall be retained for a period of time at least equivalent to the lifetime of the medical device as defined by the manufacturer, but not less than two years from the date of dispatch from the manufacturer.
(4) All quality records shall be legible and shall be stored and retained in such a way that they are readily retrievable in facilities that provide a suitable environment to prevent damage or deterioration and to prevent loss.

(5) Where agreed contractually, quality records shall be made available for evaluation by the customer for an agreed period.

Chapter 4 Medical Devices for Use in Clinical Trials

Article 140 The design, development, manufacture, processing, packaging, storage, installation method and facility of medical devices for use in clinical trials shall, unless otherwise regulated by regulations of this Chapter, be governed by regulations of Chapter 2 in this Part.

Article 141 Where manufacturers have not yet established validated manufacturing processes for medical devices for use in clinical trials, or have not yet established comprehensive manufacturing control standards, aforesaid manufacturers shall establish in writing operational procedures and keep detailed and accurate records for each batch of products manufactured and each batch of raw material used. Batch manufacturing records shall be kept until clinical trials are completed, or until at least two years after the product is completed, whichever period is longer.

Article 142 Where manufacturers provide medical devices for use in clinical trials, aforesaid devices, in addition to conforming to regulations governing labeling in the Act, must also be labeled “for use in clinical trials only”, and marked with the name of the trial sponsor and a trial code sufficient to identify the trial site and research personnel involved.

Article 143 Manufacturers shall determine suitable expiration dates for medical devices for use in clinical trials based on the product properties, container characteristics and storage conditions; the expiration dates marked on aforesaid devices may not exceed the expiration dates marked on the original product packaging.

Article 144 Where manufacturers have medical devices for use in clinical trials manufactured or tested on a contract basis, aforesaid contract shall clearly state that the product in question is for use in clinical trials only.

Article 145 Where manufacturers destroy medical devices for use in clinical trials, destruction of aforesaid devices may not take place until all clinical trials and the final report are completed; detailed records shall be kept of the destruction process, and aforesaid records shall be preserved by the manufacturers.

Part 4 Supplementary Provisions

Article 146 This set of standards shall be implemented on the date of announcement.