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Mazdoor Kisan Shakti Sangathan  
“The Right to Information, The Right to Live”

“पुराने को छोड़ नये के तरफ”  
Jawaharlal Nehru  
“Step Out From the Old to the New”

GOOD MANUFACTURING PRACTICES FOR ORTHOPAEDIC IMPLANTS — GUIDE

UDC 615.477
FOREWORD

This Indian Standard was adopted by the Bureau of Indian Standards, after the draft finalized by the Orthopaedic Instruments, Implants and Accessories Sectional Committee had been approved by the Medical Equipment and Hospital Planning Division Council.

This guide prescribes requirements for a system for the assurance of quality in design and manufacture of orthopaedic implants.

It may be used:

a) as a basis for evaluating the capability of a supplier's quality management system in order to provide assurance to interested parties. This may be done prior to the establishment of a contract;

b) to specify the quality assurance requirements appropriate to the particular orthopaedic implant, where invoked in a contract;

c) in other documents such as product standards where reference to a quality management system is appropriate.

This guide has been prepared at the instance of Ministry of Health and Family Welfare, Government of India. It is intended that this guide would help monitor quality and also provide guidance to the manufacturer in the implementation of good manufacturing practices. The use of this guide is however recommended in conjunction with the basic standards for quality system, that is, IS 14000 series.

In the preparation of this guide, considerable assistance has been derived from the Guide to Good Manufacturing Practices for Orthopaedic Implants, prepared by the Department of Health and Social Security (U.K.) and United Kingdom Trade Association.
Indian Standard

GOOD MANUFACTURING PRACTICES FOR ORTHOPAEDIC IMPLANTS — GUIDE

1 SCOPE

1.1 This guide specifies minimum quality system requirements for application to orthopaedic implants, the technical requirements of which are specified principally in terms of the performance required.

NOTE — The requirements of this guide are common to all kinds of orthopaedic implants. Additional requirements, if any, may be indicated for particular/category of orthopaedic implants.

2 TERMINOLOGY

2.1 Control Number

A distinctive combination of numbers and/or letters which uniquely identifies an individual device or a batch of devices and permits its history to be traced.

2.2 Critical Component

A component of a critical device, the failure of which might reasonably be expected to cause failure of a critical device or to affect its safety or effectiveness.

2.3 Critical Device

A device that is intended for surgical implant into the body or to support or sustain life, the failure of which might reasonably be expected to result in significant injury to the patient or the user.

2.4 Critical Operation

Any operation in the manufacture of a critical device which, if improperly performed, may be reasonably expected to cause the failure of a critical device or affect its safety or effectiveness.

2.5 Device History File

A compilation of records containing or referencing the complete production history of a finished device.

2.6 Device Master File

A file containing or referencing all necessary information about the design, formulation, specification, manufacturing procedures quality assurance requirements and labelling of a finished device.

2.7 Orthopaedic Implant

An object which is surgically implanted in the body to aid in the repair of bone and/or related tissues and to replace these tissues either temporarily or permanently.

2.8 Label

A display of written, printed or graphic matter on the device or on the immediate container of a device.

2.9 Labelling

All labels and other written, printed or graphic matter:

a) on any device or any of its containers or wrappers, or
b) accompanying such a device.

2.10 Material

All components, materials or other supplies which are to be incorporated in the finished device or otherwise used in the manufacturing process.

2.11 Medical Device

An instrument, apparatus, implement, appliance, implant or other similar or related article, which is intended for use in contraception, diagnosis or treatment of humans. A device achieving its principal intended purpose through chemical action within or on the body is excluded from this guide.

2.12 Specified Requirements

The specified requirements shall be either:

a) Requirements prescribed by the purchaser in a contract, or
b) Requirements prescribed by the supplier that are not subject to direct specification by the purchaser.
2.13 Sub-Contract
Any goods or service purchased to the supplier's own specification.

2.14 Supplier
For the purposes of this guide, the finished device manufacturer.

3 DOCUMENTATION AND PLANNING

3.1 Quality System
The supplier shall establish, document and maintain an effective and economical quality system to ensure and demonstrate that the material or services conform to the specified requirements. The documented quality system shall include quality management objectives, policies, organization and procedures to demonstrate compliance with the requirements of this guide.

3.1.1 The documented quality system shall include procedures which ensure that the following functions are performed:

a) Periodic review of production records;

b) Acceptance or rejection of all components, manufacturing materials, in-process materials, packaging materials, labelling and finished devices; and acceptance or rejection of devices manufactured, processed, packaged or held under contract by another company;

c) Identification, recommendation and providing of solutions for quality assurance problems and verification of the implementation of such solutions;

d) Ensuring that all quality assurance activities are appropriate and adequate for their purpose and are correctly performed.

3.2 Organization

3.2.1 Personnel Responsible for Functions Affecting Quality
The supplier shall delegate, to all personnel responsible for functions affecting quality both defined responsibility and the authority to identify and evaluate quality problems and to initiate, recommend and provide effective solutions.

3.2.2 Management Representative
The supplier shall appoint a management representative, preferably independent of other functions, who shall have the necessary authority and the responsibility for ensuring that the requirements of this document are implemented and maintained.

3.2.3 Purchaser's Representative
The purchaser may appoint a representative, hereinafter referred to as the 'Purchaser's Representative', to obtain assurance on his behalf that the system established in compliance with this document is effective. The supplier shall provide reasonable access for this purpose.

3.3 Review of the Quality System
The quality system established in accordance with the requirements of this guide shall be periodically and systematically reviewed by the supplier to ensure its continued effectiveness. Records of the review shall be maintained and shall be available to the purchaser's representative.

NOTE — All parts of the quality system shall be subject to planned and documented quality audits. These shall be performed by trained personnel not having direct responsibilities in the functions being audited. Smaller manufacturers might use an outside quality assurance conductor. As quality audits may be personal and confidential, records sufficient only to demonstrate that the requirements of this guide are carried out need be made available.

3.4 Planning
The supplier shall establish a procedure for conducting a sufficiently extensive and timely review of the specified requirements to ensure the following:

a) Adequate and documented control of design, development, manufacturing and installation activities;

b) Identification and acquisition of any controls, processes, inspection equipment, tooling, manpower resources and skills that may be needed to achieve the required quality;

c) Updating of quality control, inspection and testing techniques as necessary, including the development of new instrumentation;

d) Identification of any measurement involving measurement capability that exceeds the known state of the art or any new measurement capability needed to inspect the product in adequate time for such capability to be developed;

e) Clarification of standards of acceptability for all features and requirements
including those which contain a subjective element;

f) Compatibility of design, manufacturing process, installation, inspection, procedures and the applicable documentation before the production is started; and

g) Preparation of documented quality plans when included in the specified requirements.

NOTE — The supplier shall be capable of demonstrating that the above requirements were reviewed before the starting of the production.

3.5 Work Instructions

The supplier shall develop and maintain clear and complete documented instructions that prescribe the communication of specified requirements and the performance of work in design, development, manufacture and installation, which would be adversely affected by the lack of such instructions.

3.6 Records

The supplier shall develop and maintain records that demonstrate achievement of the required quality and the effective operation of the quality system. These records shall be retained and made available for evaluation by the purchaser’s representative for an agreed period. Pertinent sub-contractor records shall be an element of this data. Records shall include, as appropriate, explicit identification of the material, part, sub-assembly, assembly, equipment, sub-system or system, the nature and number of observations made, the number and type of deficiencies found, the quantities approved or rejected and the nature of rectification and corrective action taken.

3.6.1 Device History File

The records of references shall be maintained in a device history file for a period of time equivalent to the design and expected life of the device, but not less than two years from the date of release for commercial distribution by the supplier. Photostatic or other reproduction of records may be used. Records shall include or refer to the following:

a) Specific label, labelling and control number used for each production batch;

b) Documentation of each critical component used in the manufacture of a device including:

i) the control number designating each critical component or batch of critical components used in the manufacture of a device; and

2) the acceptance record of the critical component including acceptance date and signature of the recipient;

c) Record of, or reference to, each critical operation identifying the date performed, the designated individual (s) performing the operation and, when appropriate, the major equipment used; and

d) Inspection checks performed, the methods and equipment used, results, the date, and the signature of the inspection individual.

3.7 Corrective Action

The supplier shall establish and maintain documented procedures to provide for:

a) a continuing analysis of concessions granted and of material scrapped, reworked, modified or otherwise repaired to determine the cause and the corrective action needed;

b) a continuing monitoring of processes and work operations and analysis of records to detect and eliminate potential causes of non-conforming material;

c) the initiation of appropriate action on receipt of non-conforming supplies; and

d) an assurance that the corrective actions are effective.

4 DESIGN

4.1 Design Control

The supplier shall establish and maintain control of design functions wherever performed. Such functions shall include the following:

a) Provision, where necessary, of a design and development programme;

b) Provision of a code of design practice and procedures;

c) Investigation of new techniques;

d) Identification and control of design interfaces;

e) Preparation and maintenance of drawings specifications, procedures and instruction;

f) Control of physical and functional tolerances to avoid the use of irrational limits;

g) Consideration of statutory requirements including those for health and safety;
h) Evaluation of new material under appropriate environmental conditions;

j) Control of reliability and value engineering task;

k) Establishment of design review procedures to ensure progress towards the achievement of design and development programme objectives through timely identification of problem areas; and

m) Use of defect data feedback from previous designs, where appropriate.

As a result of the requirements given in 4.1 (a) to (m), the engineering data developed for purchasing, manufacturing, inspection, installation purpose, etc, shall reflect the specified requirements.

4.2 Documentation and Change Control

The supplier shall establish and maintain control of all documentation that relates to the requirements of this guide. To this end, the supplier shall ensure that:

a) the pertinent issues of appropriate documents are available at all locations where operations essential to the effective functioning of the quality system are performed;

b) all changes to documentation are in writing and are processed in a manner that will ensure prompt action at the specified and effective point;

c) records are maintained of changes as they are made;

d) documents are reissued after a practicable number of changes have been issued; and

e) provision is made for the prompt removal of obsolete documents from all points of issue or use.

4.2.1 Device Master File

The supplier shall establish and maintain a master file for each device. The device master file shall be prepared, dated and signed by a designated individual (s). Any changes in the device master file shall be authorized in writing by the signature of a designated individual (s). The device master file for each type of device shall include, or refer to the location of the following information:

a) Specifications including appropriate drawings, compositions, formulation and component specifications;

b) Quality assurance procedures and specifications including quality assurance checks used and the quality assurance apparatus used;

c) Full information concerning critical components and critical component suppliers including the complete specifications of all critical components, the sources where they may be obtained, and the written copies of any agreements made with the sub-contractors; and

d) Complete labelling procedures for the device and copies of all approved labels and other labelling.

NOTE — The records or reference shall be maintained in a device master file for a period of time equivalent to the design and expected life of the device but not less than two years from the date of release for commercial distribution by the supplier. Photostatic or other reproduction of records may be used.

5 CONTROL OF INPUTS

5.1 Control of Inspection, Measuring and Test Equipment

The supplier shall provide, control, calibrate and maintain inspection, measuring and test equipment suitable to demonstrate the conformity of material to the specified requirements. Equipment shall be used in a manner which ensures that measurement uncertainty is known and is consistent with the required measurement capability.

Where jigs, fixtures, templates, patterns or other such devices are used as suitable forms of inspection, they shall be proven to be capable of verifying the acceptability of material prior to release for use during manufacture, and shall be re-proven at established periods. The supplier shall establish the extent and frequency of such proving and shall maintain records as evidence of control. Design data pertaining to tools and gauges shall be made available, when required by the purchaser's representative, for verification of functional adequacy of the devices.

5.2 Control of Purchased Material and Services

5.2.1 Purchasing

The supplier shall be responsible for ensuring that all purchased material and services conform to the specified requirements.

The selection of sources and the type and extent of control exercised by the supplier shall be dependent upon the type of material and the sub-contractor's demonstrated capability.
The supplier shall ensure that controls are effective including, if necessary, by monitoring at the sub-contractor's plant.

NOTE - The control exercised by the supplier on the purchase of critical components shall ensure that the supplier is informed in advance of any change in a critical component so that the acceptability of such a change can be determined.

5.2.2 Purchasing data

Each purchasing document shall contain a clear description of material and the services ordered including as applicable:

a) the type, class style, grade or other precise identification; and
b) the title or other positive identification and applicable issue of specifications, drawings, process requirements, instructions and other relevant technical data.

5.2.3 Receiving inspection

The supplier shall ensure that no incoming material is used or processed until it has been inspected or otherwise verified as conforming to the specified requirements.

NOTES

1 Material may be released for urgent production purpose, provided that it is identified in a positive manner that will permit immediate recall and replacement in the event of non-conformance. In determining the amount and nature of receiving inspection, consideration shall be given to the control exercised at a source and documented evidence of quality conformance provided.

2 A sufficient sample of any material released for urgent production purpose shall be retained and subjected to the normal receiving inspection.

3 For critical components the supplier shall establish and maintain procedures for accepting, sampling, testing and inspecting of all batches to ensure that critical components conform to the specifications.

5.2.4 Verification of purchased material

The purchaser's representative shall be afforded the right to verify at source or after receipt of the purchased material that it conforms to the specified requirements. Verification by the purchaser's representative shall not relieve the supplier of the responsibility to provide acceptable material nor shall it preclude subsequent rejection.

When the purchaser's representative elects to perform verification at the sub-contractor's plant, such verification shall not be used by the supplier as evidence of effective control of quality by the sub-contractors.

6 MANUFACTURING CONTROL

6.1 General

The supplier shall ensure that manufacturing operations are carried out under controlled conditions shall include documented work instructions defining the manner of manufacturing equipment and any special working environment.

Criteria for workmanship shall be prescribed to the greatest practicable extent by written standards, photographs or representative sample. Where appropriate, the criteria for workmanship shall be agreed by the supplier and the purchaser's representative.

The supplier shall provide for inspection, as required, after each work operation that affects quality. Alternatively, control by monitoring process methods, equipment and personnel shall be provided.

When essential, both inspection and monitoring shall be done. Inspection methods or controls shall be corrected whenever their unsuitability is demonstrated.

6.2 Personnel Health and Cleanliness

The supplier shall ensure that where personnel are in contact with the material or its environment they shall be suitably attired, clean and in good health where these factors could affect the material. Personnel who appear to violate health and cleanliness conditions which could affect the material shall be excluded from manufacturing operations until the condition is corrected. The supplier shall instruct all personnel to report such conditions to their supervisors.

6.3 Buildings

The supplier shall ensure that buildings in which manufacture, assembly, packaging storage, inspection and test, and labelling are carried out are of suitable design and contain sufficient space to facilitate cleaning, maintenance, and other necessary operations. The premises shall be laid out in such a way and with sufficient allocation of space to facilitate orderly handling of the following items and to prevent mixing between them: incoming material, material scrapped, re-worked, modified or repaired, any other non-conforming material; finished devices; manufacturing equipment, jigs, fixtures, template, patterns and other inspection aids; documents and drawings.
6.4 Environmental Control

The supplier shall ensure that where environmental conditions at the manufacturing site could have an adverse effect on the fitness of material for use, these environmental conditions are controlled to prevent contamination of the material and to provide proper conditions for all the operations performed during production and storage of material. Any environmental control system shall be periodically inspected to verify that the system is functioning properly. Such inspections shall be documented.

6.5 Cleanliness

The supplier shall establish and maintain documented procedures to provide for adequate cleanliness during all stages of manufacture. The following shall be observed:

a) Changing rooms and toilets shall be provided as necessary. They shall be regularly cleaned.

b) The supplier shall establish and maintain documented procedures for the protection of material and finished products against contamination by any substance used for cleaning or for protection against vermin and pests.

c) In cases where the fitness of a product for use could be affected by eating, drinking and smoking by personnel, the supplier shall restrict such practices to designated areas.

d) The supplier shall ensure that waste material of all kinds is disposed off in an appropriate manner at regular and frequent intervals to ensure that the safety and health of personnel and the environment are not at risk.

6.6 Equipment

The manufacturing equipment shall be designed, constructed, correctly installed and sited to facilitate maintenance, cleaning and adjustment.

6.7 Equipment Maintenance

The supplier shall ensure that manufacturing specifications are met by establishing and maintaining documented procedures for maintenance, cleaning and adjustment of equipment. These procedures shall be attached to the equipment or be readily available to maintenance personnel. A written record of maintenance activities shall be maintained.

In order to verify that the scheduled maintenance is being performed the supplier shall establish procedures for independent periodic inspection of maintenance records.

6.8 Limits and Tolerances

The supplier shall ensure that where applicable any limits or tolerances on the setting of manufacturing equipment are shown in the maintenance documentation on or near the equipment.

6.9 Manufacturing Materials

The supplier shall ensure that, where necessary, the work instructions cover the adequate removal of cleaning agents, mould release agents, lubricating oils, etc, from the material after manufacture.

6.10 Control of Special Processes

The supplier shall establish and maintain control of all special processes that form part of production or inspection. Equipment, essential processing environment and any necessary personnel qualifications shall be prescribed to the satisfaction of purchaser's representative.

NOTE — Special processes and test procedures are those whose effectiveness or completion cannot normally be verified by subsequent inspection or testing of the product.

7 INSPECTION AND TESTS

7.1 Finished Item Inspection and Test

The supplier shall perform all inspections and tests on the finished product or service necessary to complete the evidence of full conformance to specified requirements.

Procedures for final inspection and test shall ensure that inspections and tests that should have been conducted at earlier stages have, in fact, been performed and that the data are acceptable.

7.1.1 The supplier shall ensure that any device which does not meet inspection and test specifications is investigated. A report shall be written including conclusion and follow-up procedures. Before a device is released for distribution, all test results and acceptance records shall be checked by a designated individual(s). Release shall be authorized by signature of a designated individual(s).
7.2 Sampling Procedures

Sampling procedures used by the supplier shall be in accordance with the specified requirements or shall be subject to agreement by the purchaser's representative.

7.2.1 Sampling procedures shall be regularly reviewed in the light of defective product or quality audit reports.

7.2.2 Where a statistical rationale is the basis of a sampling procedure, the estimates of percentage defective items and percentage of batches rejected shall be recorded and identified with the source.

7.3 Control of Non-Conforming Material

The supplier shall establish and maintain procedures for controlling material that does not conform to the specified requirements. These procedures shall include provision for identification, segregation and disposition, as appropriate.

All non-conforming material shall be clearly identified to prevent unauthorized use, shipment or mixing with the conforming material.

Holding areas or procedures, mutually agreed between the supplier and the purchaser's representative, shall be provided. Repair, rework or concessions on non-conforming material and reinspection shall be in accordance with documented procedures and, when applicable, shall be acceptable to the purchaser's representative. Adequate records, clearly identifying the material, the nature and extent of non-conformance and the disposition, shall be maintained.

7.3.1 The supplier shall establish and maintain documented procedures for the reprocessing of devices or critical components. The procedures shall describe the equipment, method of quality assurance and tests. The effect of reprocessing shall be determined and recorded.

7.3.2 The reprocessed device or component shall meet the original or modified and approved specification in the device master file. Any previous quality assurance checks shall be repeated on the reprocessed device or component if the reprocessing could have altered any performance previously inspected.

7.3.3 There shall be a formal approval procedure for instituting a new or altering an approved reprocessing procedure.

7.4 Indication of Inspection Status

The supplier shall establish and maintain a system for identifying the inspection status of material during all stages of manufacture. The supplier shall ensure the ability to distinguish between inspected and uninspected material by using some suitable form of identification.

8 MARKING AND PACKING

8.1 Protection and Preservation of Finished Product

The supplier shall establish and maintain a system to control packing, preservation and marking, processes (including materials used) to the extent necessary to ensure conformance to specified requirements and to identify, preserve and segregate all material from the time of receipt until the supplier's responsibility ceases.

8.1.1 Product Labelling

The supplier shall establish and maintain documented procedures to ensure that:

a) the labels are designed, printed and applied so as to remain legible during normal conditions of processing, storage, handling, distribution and use;

b) the identity of the manufacturer should be engraved on the implant and not labelled with the stickers;

c) no new labels or other labelling are brought into use before inspection for accuracy by a designated individual(s);

d) all labelling or packaging operations are sufficiently segregated to avoid cross-mixing;

e) before the start of any labelling or packaging procedure, the area where the procedure is to take place is inspected by a designated person to ensure that material from previous batch does not remain in the area;

f) the labels and other labelling are sorted and maintained in such a way that they are properly identified and cross mixing is avoided;

g) the labelling materials issued for devices are inspected before use for identity and where applicable, the correct expiry date, control number, storage instructions, handling instruments and additional processing instructions. A record of the inspection, including the date and
IS 13423 : 1992

name of the inspector shall be included in the device history file;

h) the labels contain a control number;
j) the signature of the person responsible for the inspection of labels and the date of the inspection are provided;
k) the access to labels and other labelling is restricted to authorized personnel.

8.2 Handling of Implants

The supplier shall provide methods of handling of implants that prevent abuse, misuse, damage or deterioration.

8.2.1 Storage

The supplier shall provide secure storage areas or stock rooms for isolation and protection of implants, pending use or shipment. Appropriate systems for authorizing receipt and the despatch to and from such areas shall be prescribed. To detect deterioration, the condition of material in stock shall be periodically assessed.

8.2.2 Delivery

The supplier shall arrange for the protection of quality of the product after final inspection including, where appropriate, specified packing and preservation during transit. The supplier shall ensure to the extent practicable, the safe arrival and ready identification of the product at its destination.

8.2.2.1 Distribution records

The supplier shall establish and maintain records of distribution for the devices. The record shall include the following:

a) Name and address of the consignee,
b) Quantity despatched,
c) Date of transfer to consignee, and
d) Control number (s).

9 TRAINING

9.1 The supplier shall establish a system for identifying training needs and certification requirements for all contracting, design, manufacturing, installation and quality assurance functions that would be adversely affected by lack of such training. All personnel performing such functions shall have the appropriate experience or training.

NOTE — Personnel shall be made aware of the intended use of products in order to achieve greater motivation towards quality requirements.

9.1.1 Personnel working in controlled environments shall be given training related to maintaining the integrity of the controlled environment.

9.1.2 All other persons entering a controlled environment shall be given adequate instruction about conduct necessary in such an environment.

10 SYSTEM OF FEEDBACK INFORMATION

10.1 The supplier shall keep close liaison with the hospital/surgeons to whom implants have been supplied and evolve a suitable system to obtain feedback information from them in case of failed implants. The information shall be analysed and steps taken to improve the quality of the device, wherever defects/shortcomings have been observed. If the improvements made are found effective, these shall be properly recorded and related records updated.

10.2 This process shall be continuous and an individual shall be designated for this purpose.

10.3 This system shall provide for an assurance that corrective actions taken are effective.

11 COMPLAINTS

11.1 The supplier shall formally designate a person who shall review all written and oral complaints relating to the identity, quality, durability, reliability, safety, effectiveness or performance of a medical device. This person shall determine whether or not an investigation is necessary. When no investigation is made, the supplier shall maintain a record that includes the reason and the name of the person responsible for the decision not to investigate.

11.2 The supplier shall establish and maintain procedures to ensure that any complaint involving the possible failure of the product to meet any of its performance specifications is reviewed, evaluated and investigated. The procedures shall ensure that any complaint relating to injury, death, or any hazard to safety is immediately reviewed, evaluated and investigated by a designated individual, and the record of the complaint and the investigation is maintained in a separate portion of the complaints file.

11.3 The supplier shall ensure that records of investigations are maintained and that such records include the name of the device, any
control number used, the name of the complaint, the nature of the complaint and the reply to the complainant.

11.4 The supplier shall ensure that where the formally designated person is located at a site separate from the actual manufacturing establishment, a duplicate, copy of the records of investigation of any complaint is transmitted to and maintained at the actual manufacturing establishment in a file designated for product complaints.
The use of the Standard Mark is governed by the provisions of the Bureau of Indian Standards Act, 1986 and the Rules and Regulations made thereunder. The Standard Mark on products covered by an Indian Standard conveys the assurance that they have been produced to comply with the requirements of that standard under a well defined system of inspection, testing and quality control which is devised and supervised by BIS and operated by the producer. Standard marked products are also continuously checked by BIS for conformity to that standard as a further safeguard. Details of conditions under which a licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.
Bureau of Indian Standard

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