Global Harmonization Working Party

GHWP Towards Medical Device Harmonization

# PROPOSED FINAL DOCUMENT

**Title:** **Guidance Document for Medical Device Organizations- Product Localisation for Manufacturing and Importation**

**Authoring Group:** Working Group 7 – Quality Management System: Operation and Implementation

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## Preface

The document herein was produced by the Global Harmonization Working Party (GHWP). The document has been subject to consultation throughout its development.

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## Introduction

Many medical device companies, large and small, constantly face challenges when navigating various regulatory requirements in order to achieve market entry. For ISO 13485:2016, many clauses mention "applicable regulatory requirements" to emphasize the importance of regulatory compliance as the ISO13485 standard in its intent, was established for regulatory purposes. Regardless of shifting regulatory requirements as well as the increasing regulatory oversight by countries previously unregulated, implementation of product localisation for both importation and manufacturing, has the same fundamental aspects to consider in the organisation's quality management system. GHWP Technical Committee Working Group 7 – Quality Management System: Operation and Implementation (2018-2020), as part of the Working Group Work Plan, aims to provide specific guidance on product localisation.

## Purpose

This document is to provide the general principles of quality management system considerations with regards to the tasks and deliverables necessary to achieve regulatory compliance in various countries and markets, with respect to product localisation for imported medical devices, and manufacturing sites that have transferred to another country with a regulatory framework

## Scope

This document applies to applicable medical devices and IVD medical devices intended to be imported into regulated countries or manufactured in regulated countries.

This document only considers from quality and regulatory perspectives, not from the business or operation during manufacturing and importation.

## References

ISO13485 Standard

# 1. Definitions

## 1.1 Authorized Representative

Natural or legal person established within a country or jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under that country or jurisdiction's legislation

*Note 1 to entry: Need to consider if the authorized representative can have all distribution information to execute the obligations when required by local regulation.*

*[SOURCE: GHTF/SG1/N055:2009, 5.2]*

## 1.2 Distributor

Natural or legal person in the supply chain who, on his own behalf, furthers the availability of a medical device to the end user

*Note 1 to entry: More than one distributor may be involved in the supply chain.*

*Note 2 to entry: Persons in the supply chain involved in activities such as storage and transport on behalf of the manufacturer, importer or distributor, are not distributors under this definition.*

*[SOURCE: GHTF/SG1/N055:2009, 5.3]*

## 1.3 Importer

Importer is a natural or legal person in the supply chain who is the first in a supply chain to make a medical device, manufactured in another country or jurisdiction, available in the country or jurisdiction where it is to be marketed.

*Note 1 to entry: Authorized representative, distributors, importer can be the either same or different natural or legal person.*

*[SOURCE: GHTF/SG1/N055:2009, 5.4]*

## 1.4 Instructions for use (IFU)

Instructions for Use refers to general and technical information provided by the manufacturer to inform the device user of the medical device or IVD medical device's intended purpose and proper use and of any contraindications, warnings, or precautions to be taken. It is provided by the manufacturer to support and assist the device users in its safe and appropriate use. (GHTF/SG1/N70:2011)

Note: Electronic Instructions for Use (eIFU) refers to instructions displayed in electronic form (need to check local regulations if eIFU is allowed):

- by the device ("help" system, or graphical user interface (GUI)-based dialogues),
- contained in portable electronic storage media supplied by the manufacturer together with the device, or
- online, through the manufacturer's website. (TGA # D18-10786654)

## 1.5 Label

Label is written, printed, or graphic information either appearing on the medical device itself, or on the packaging of each unit, or on the packaging of multiple devices. (GHTF/SG1/N70:2011)

*Note Electronic Label is the electronic version of labels.*

## 1.6 Labelling

Labelling includes the label, instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the medical device, but excluding shipping documents (ISO 13485:2016 and GHTF/SG1/N70:2011).

*Note Electronic Labelling refers to any form of labelling content provided in an electronically accessible form supplied by the manufacturer related to a medical device or IVD medical device.*

*[SOURCE: IMDRF/GRRP WG/N52 FINAL:2019].*

## 1.7 Localisation

The localisation in this document not only includes that the Medical Device Organization establish a manufacturing site and transfer the design or manufacture from an existing manufacturing site to produce a medical device in one country, but also import a medical device in one country to go to market.

Manufacturer is a natural or legal person with responsibility for design and/or manufacture of a medical device with the intention of making the medical device available for use, under his name; whether or not such a medical device is designed and/or manufactured by that person himself or on his behalf by another person(s)

*Note 1 to entry: This "natural or legal person" has ultimate legal responsibility for ensuring compliance with all applicable regulatory requirements for the medical devices in the countries or jurisdictions where it is intended to be made available or sold, unless this responsibility is specifically imposed on another person by the Regulatory Authority (RA) within that jurisdiction.*

*Note 2 to entry: The manufacturer's responsibilities are described in other GHTF guidance documents. These responsibilities include meeting both pre-market requirements and post-market requirements, such as adverse event reporting and notification of corrective actions.*

*Note 3 to entry: "Design and/or manufacture", as referred to in the above definition, may include specification development, production, fabrication, assembly, processing, packaging, repackaging, labelling, relabelling, sterilization, installation, or remanufacturing of a medical device; or putting a collection of devices, and possibly other products, together for a medical purpose.*

*Note 4 to entry: Any person who assembles or adapts a medical device that has already been supplied by another person for an individual patient, in accordance with the instructions for use, is not the manufacturer, provided the assembly or adaptation does not change the intended use of the medical device.*

*Note 5 to entry: Any person who changes the intended use of, or modifies, a medical device without acting on behalf of the original manufacturer and who makes it available for use under his own name, should be considered the manufacturer of the modified medical device.*

*Note 6 to entry: An authorized representative, distributor or importer who only adds its own address, contact details and local registration information to the medical device or the packaging, without covering or changing the essential content of existing labelling(e.g.: Identification, LOT, EXP, Barcode, etc. , is not considered a manufacturer.*

*Note 7 to entry: To the extent that an accessory is subject to the regulatory requirements of a medical device, the person responsible for the design and/or manufacture of that accessory is considered to be a manufacturer.*

*Note 8 to entry: here manufacturer stands for legal manufacturer. Need to distinguish the different obligations between legal manufacturer and entrusted manufacturer based on local regulations.*

*[SOURCE: GHTF/SG1/N055:2009, 5.1]*

## 1.8 Medical Device

Instrument, apparatus, implement, machine, appliance, implant, reagent for *in vitro* use, software, material or other similar or related article, intended by the manufacturer to be used, alone or in combination, for human beings, for one or more of the specific medical purpose(s) of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease;
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury;
- investigation, replacement, modification, or support of the anatomy or of a physiological process;
- supporting or sustaining life;
- control of conception;
- disinfection of medical devices;
- providing information by means of *in vitro* examination of specimens derived from the human body;

and does not achieve its primary intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its intended function by such means

Note 1 to entry: Products which may be considered to be medical devices in some jurisdictions but not in others include: — disinfection substances; — aids for persons with disabilities; — devices incorporating animal and/or human tissues; — devices for *in vitro* fertilization or assisted reproduction technologies.

*[SOURCE: GHTF/SG1/N071:2012, 5.1]*

## 1.9 Regulatory Authority

A government body or other entity that exercises a legal right to control the manufacturing, use or sale of medical devices within its jurisdiction, and that may take enforcement action to ensure that medical products marketed within its jurisdiction comply with legal requirements.

*[SOURCE: GHTF/SG1/N78:2012]*

## 1.10 Technical Documentation

The documented evidence, normally an output of the quality management system that demonstrates compliance of a device to the *Essential Principles of Safety and Performance of Medical Devices*.

*[SOURCE: GHTF/SG1/N78:2012 and IMDRF/GRRP WG/N47 FINAL: 2018]*

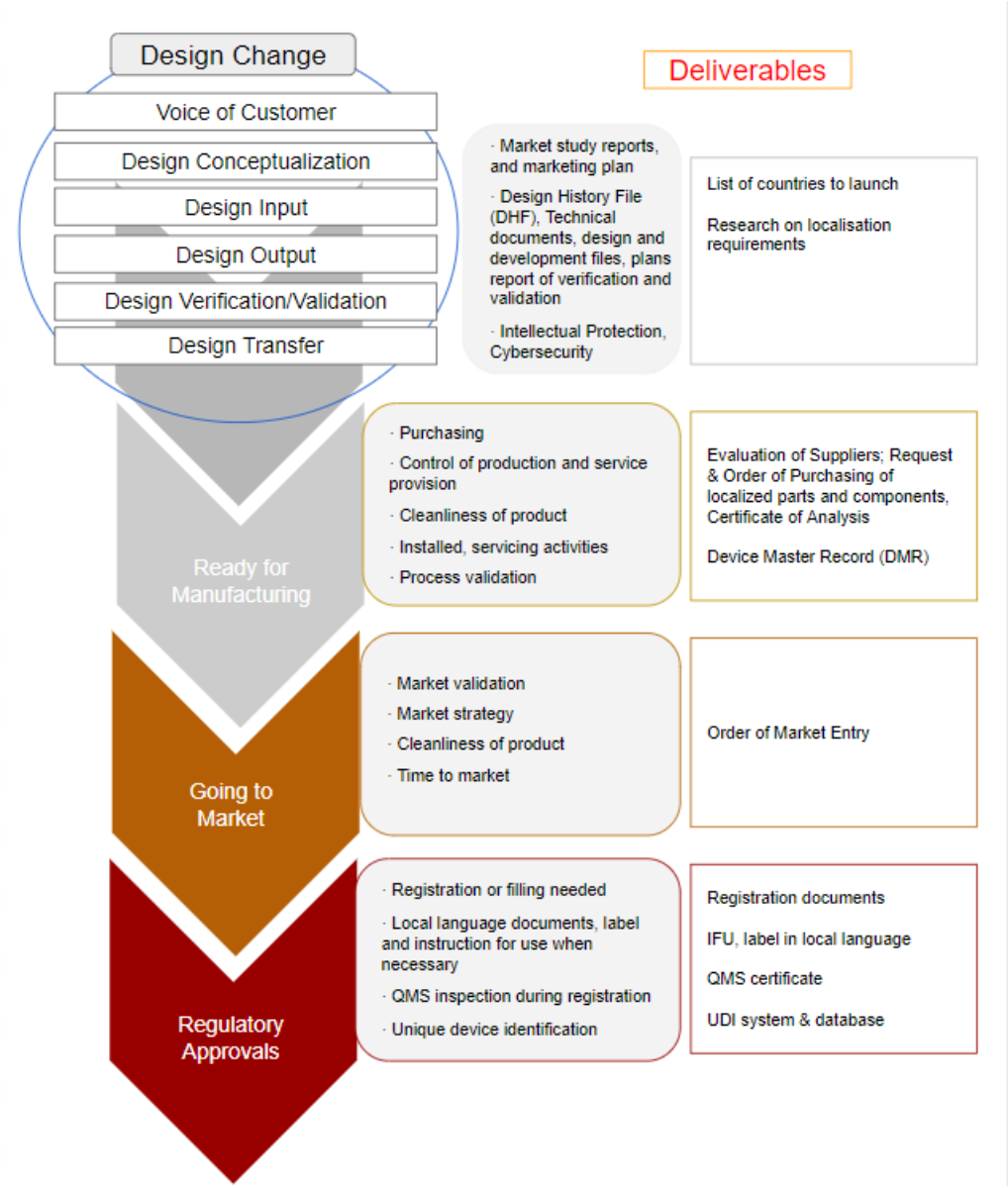
# 2. Process Steps

## 2.1 Localisation Strategy

Medical Device Organisation need to collect local regulations of the target country or region, evaluate and decide the localisation strategy via local manufacturing or importation based on business needs and local regulations.

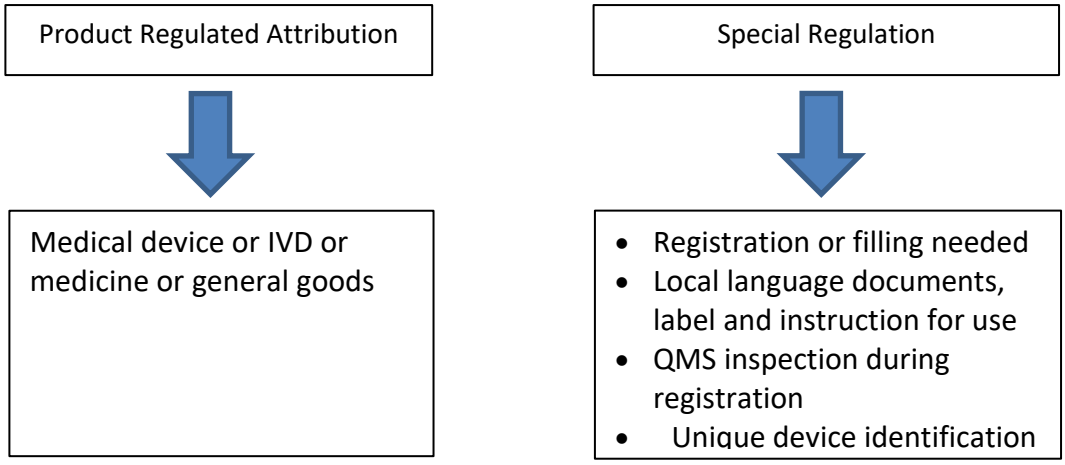
## 2.2 Pre-market

### 2.2.1 Considerations for Organisation about product localization via manufacturing

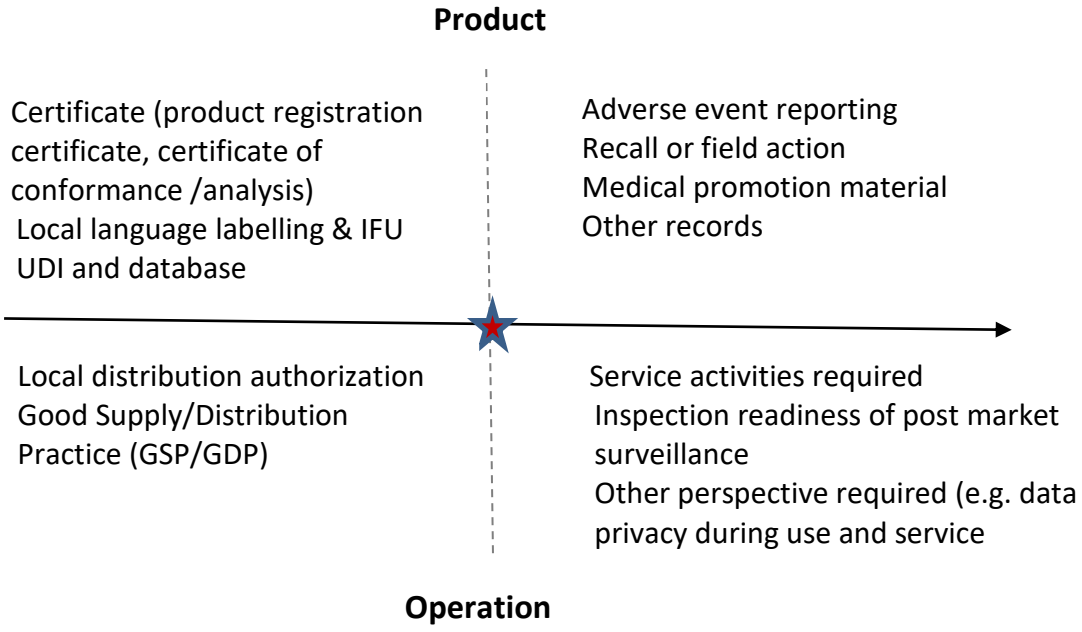


**2.2.2 Considerations for Organisation about product localization via importation**

Select Authorized Representative, Distributor or Importer.




**2.3 Post Market**




Commercial release or distribution

## 3. Clause by Clause Analysis

Organisation should consider below elements besides ISO 13485 requirements when they plan to import their medical device to a specific region. The guidance text is based on Clause 4 to Clause 8 of the ISO13485 Standard.

“Additional Considerations for Requirements” – refer to guidance text for Organisation if they plan to launch medical device in one specific region.

| ISO 13485: 2016 (Clause / Sub-Clause) | Additional Considerations |
|---|---|
| **4 Quality management system** | |
| **4.1 General requirements** | |
| 4.1.1<br>4.1.2<br>4.1.3<br>4.1.4<br>4.1.5<br>4.1.6 | Regulations and standards, applicable to the location of the manufacturing site(s) should be identified, evaluated for impact on the product's design and development processes, production processes, distribution processes, post market surveillance and the organisation's quality management system.<br><br>Regulations and standards, applicable to the market authorization to be gained by the product, should be identified, evaluated for impact on the product's design and development processes, production processes, distribution processes, post market surveillance and the organisation's quality management system.<br><br>Such regulations may include Good Manufacturing Practices/Good Supply Practices/ Good Distribution Practices as defined by the in-country regulations.<br><br>Any gaps identified against the applicable regulations and standards should be documented, its impact is documented, and appropriate actions are implemented in the quality management system.<br><br>The organization should ensure if there are any special requirements for software used in the quality system, such as language localization, server location and information security pertaining to the data residency of the markets for which the products are shipped to.<br><br>Note 1: This may include both regulations and standards for pre-market and post market<br><br>Note 2: All related regulations, their appendix and guideline documents should be considered according to product and the organization's role |
| **4.2 Documentation requirements** | |
| 4.2.1 General | |
| 4.2.2 Quality manual | NA |

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| 4.2.3 Medical device file | NA |
| 4.2.4 Control of documents | Some regions have special procedural requirements and local language requirements. Organization should develop these procedures. |
| 4.2.5 Control of records | Organization should know of any special record retention requirements in target region, such as warehouse temperature record frequency, cold chain record. |
| **5 Management responsibility** | |
| **5.1 Management commitment** | No additional guidance |
| **5.2 Customer focus** | NA |
| **5.3 Quality policy** | No additional guidance |
| **5.4 Planning** | No additional guidance |
| 5.4.1 Quality objective | No additional guidance |
| 5.4.2 Quality management system planning | No additional guidance. See Clause 6.1 Provision of Resources |
| **5.5 Responsibility, authority and communication** | |
| 5.5.1 Responsibility and authority | The formal authorization letter or organization chart are required in some regions.<br>Organization should document this information and keep it completed and updated. |
| 5.5.2 Management representative | No additional guidance |
| 5.5.3 Internal communication | No additional guidance |
| **5.6 Management review** | |
| 5.6.1 General | No additional guidance |
| 5.6.2 Review input | Review inputs should include related region-specific data, for complaints, adverse event reporting, and update of regulatory requirements. |
| 5.6.3 Review output | No additional guidance |
| **6 Resource management** | |
| **6.1 Provision of resources** | Organization should consider allocation of appropriate resources for special local regulations, such as<br>*Market authorisation, for example, product registration |

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| | * Adverse event reporting, product recall<br>* Specific product release management;<br>* Product inspections in-local<br>* Specific environmental control requirements<br>* Special storage and shipment requirements<br>* Local language labels and IFU creation<br>* Unique device identification for labelling and entry to country-specific database<br>*Purchasing requirements for specific components required by local markets (for example, power cords)<br>* Specific Product Promotion requirements<br>* Distributor's qualification should be confirmed if necessary, such as distribution license, product scope in distribution license.* Local authority inspections (for the Organisation who is the manufacturer or distributor）<br>* product post launch change management (if need to get approval based on local regulation requirement)<br>Note: If organization outsource these activities, Clause 7.6 Purchasing requirements apply |
| **6.2 Human resources** | * Some regions may have unique requirements for personnel related to special processes, such as personnel health record, personnel qualification.<br>Organisation should document the rationale if they could not comply with these specific requirements and describe current practice as acceptable which ensures no impact on the product quality.<br>* Responsible people should be trained about related local regulations and standards, and the training record should be maintained.<br>* Some regions may require requirements on personnel background e.g. major, degree of education for specific positions |
| **6.3 Infrastructure** | No additional guidance |
| **6.4 Work environment and contamination control:** | |

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| 6.4.1 Work environment | Organization should be aware if the local regulations have specific requirements for the working environment, such as temperature, protective equipment for pollution, static, dust, corrosion.<br>Such requirements must be incorporated in the organisation and its quality management system |
| 6.4.2 Contamination control | Organization should be aware if the local regulations have specific requirements for contamination control, especially about cleanroom, such as cleanroom classification, operation requests.<br>Such requirements must be incorporated in the organisation and its quality management system |
| **7 Product realization** | |
| **7.1 Planning of product realization** | During the design control process, the Organization considers related regulation and local standards requirements into the design planning phase, according to local standards of the markets the product would be launched in. This may include, but not limited to:<br>* local mandatory standard of the product<br>*Power cords<br>* Local labelling<br>* Power supply requirements and related power, electromagnetic compatibility (EMC) requirements<br>* Sterilization requirements<br>* Local type testing requirements |
| **7.2 Customer-related processes** | |
| 7.2.1 Determination of requirements related to the product | No additional guidance |
| 7.2.2 Review of requirements related to the product | No additional guidance |
| 7.2.3 Communication | Organisation should develop processes in the quality management system that would collect, evaluate, and act upon updated regulatory requirements |
| **7.3 Design and development** | |

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| 7.3.1 General | No additional guidance |
| 7.3.2 Design and development planning | Organization implement related regulation and local standards requirements into the planning phase, involving proper personnel into the whole product realization process including input, review, verification and validation, approval, output, transfer. |
| 7.3.3 Design and development inputs | Design input should include related regulation and local standards besides harmonized international standards |
| 7.3.4 Design and development outputs | No additional guidance |
| 7.3.5 Design and development review | No additional guidance |
| 7.3.6 Design and development verification | No additional guidance |
| 7.3.7 Design and development validation | No additional guidance |
| 7.3.8 Design and development transfer | No additional guidance |
| 7.3.9 Control of design and development changes | Local regulatory resources should be involved in the review of design changes before the change notification is released. |
| 7.3.10 Design and development files | Relevant Technical documentation shall be made available by electronic, or paper means to the local countries where the local regulations require the technical file to be easily accessible<br>Note 1: If electronic solutions are implemented, appropriate software validation, and supplier controls should be considered.<br>Note 2: if paper solutions are implemented, communication processes defined by the quality management system shall ensure that the various local countries have the updated technical file. |
| **7.4 Purchasing** | |
| 7.4.1 Purchasing process | Organization should confirm if any specific quality agreement needs to be signed according to local regulation |
| 7.4.2 Purchasing information | Qualification of suppliers may be required for some regions' requirements. |
| 7.4.3 Verification of purchased product | Organization should ensure suppliers have objective evidence required by the specific regulations of the markets in which the product is shipped to, with regards to the production process. |

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| | This may include and not limited to formal test reports, acceptance criteria |
| **7.5 Production and service provision** | |
| 7.5.1 Control of production and service provision | If local language labels and IFU are required, the procedure and control measurement should be developed to ensure regulatory compliance and accuracy.<br><br>Appropriate equipment and procedure for the product has special storage and shipment requirements. |
| 7.5.2 Cleanliness of product | No additional guidance |
| 7.5.3 Installation activities | Specific installation records may be required by local regulations to be stored locally. Organisation shall ensure document and records control as per Clause 4.2 are applied to the distributors or service providers |
| 7.5.4 Servicing activities | Specific servicing records may be required by local regulations to be stored locally. Organisation shall ensure document and records control as per Clause 4.2 are applied to the distributors or service providers |
| 7.5.5 Particular requirements for sterile medical devices | Specific local regulation may need to be considered. |
| 7.5.6 Validation of processes for production and service provision | Specific local regulation may need to be considered. |
| 7.5.7 Requirements for validation of processes for sterilization and sterile barrier systems | Specific local regulation may need to be considered. |
| **7.5.8 Identification** | Some member economies may have unique device identification regulations, which includes the requirements for label and entry to the database.<br>Organization should ensure the label and database submission comply with local regulations |
| **7.5.9 Traceability** | |
| 7.5.9.1 General | No additional guidance |
| 7.5.9.2 Particular | No additional guidance |
| **7.5.10 Particular requirements for implantable medical devices** | No additional guidance |

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| **7.5.10 Customer property** | See guidance notes in Clause 7.5.3, and 7.5.4 |
| **7.5.11 Preservation of product** | See guidance notes in Clause 7.5.3, and 7.5.4 |
| **7.6 Control of monitoring and measuring devices** | No additional guidance |
| **8 Measurement, analysis and improvement** | |
| **8.1 General** | |
| **8.2 Monitoring and measurement** | |
| 8.2.1 Feedback | Feedback covers all commercial distribution regions.<br>If distributors take this responsibility, this should be included in the quality agreement to clarify the role and responsibility. |
| 8.2.2 Complaint handling | Complaint handling covers all commercial distribution regions.<br>If distributors take this responsibility, this should be included in the quality agreement to clarify the role and responsibility. |
| 8.2.3 Reporting to regulatory authorities | Organization should collate various adverse event and recall reporting criteria and timelines in the countries that the product is launched in. This will be useful to communicate customer requirements and for management review.<br>Note: If the distributor takes the responsibility for post market surveillance in the country, this scope of work must be included in quality agreement to clarify the roles and responsibilities. |
| 8.2.4 Internal audit | Internal audit processes within the Organisation may include the distributors who may be subjected to regulations such as Good Supply Practices/ Good Distribution Practices as defined by the in-country regulations |
| 8.2.5 Monitoring and measurement of processes | No additional guidance |
| 8.2.6 Monitoring and measurement of product | If specific localisation activities can be performed outside of the Organisation quality management system's direct jurisdictions (for example, adding of power cord, adding localised label, adding localised IFU, re-packaging, combining several devices / components in one package, limited re-work), these activities should be treated as an |

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| | extension of manufacturing shall be carefully checked with local regulation to ensure compliance, and be monitored and measured accordingly<br><br>Such requirements should be included in the quality agreements that are issued by the Organisation to these service providers<br><br>If product sample retention is required the Organization shall document the product retention procedure, ensure resource and infrastructure and keep record according to regulation. |
| **8.3 Control of nonconforming product** | |
| 8.3.1 General | No additional guidance |
| 8.3.2 Actions in response to nonconforming product detected before delivery | No additional guidance |
| 8.3.3 Actions in response to nonconforming product detected after delivery | Local Regulatory Authority may mandate specific actions or require specific documentations. Organisation shall ensure sufficient resources and management commitment is obtained to ensure compliance. |
| 8.3.4 Rework | See guidance notes on Clause 8.2.6 |
| **8.4 Analysis of data** | See guidance notes on Clause 5 6 2, and 8.2.6 |
| **8.5 Improvement** | |
| 8.5.1 General | No additional guidance |
| 8.5.2 Corrective action | No additional guidance |
| 8.5.3 Preventive action | No additional guidance |

## 4. Conclusion

The global regulatory frameworks are constantly evolving. The general trends globally include:

- Good Distribution Practices requirements for distributors to be certified
- Databases for unique device identification
- Local labelling in paper or electronic form
- Post market reporting requirements

This document aims to help the Organisation keep pace with these changes by suggesting the general principles in which the Organisation's quality management system can manage these changes.

Organisation should always ensure that these suggestions are incorporated into their quality management system to achieve regulatory compliance in various countries and markets, with respect

to product localisation via imported medical devices, or manufacturing sites that have transferred to another country with a regulatory framework.

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