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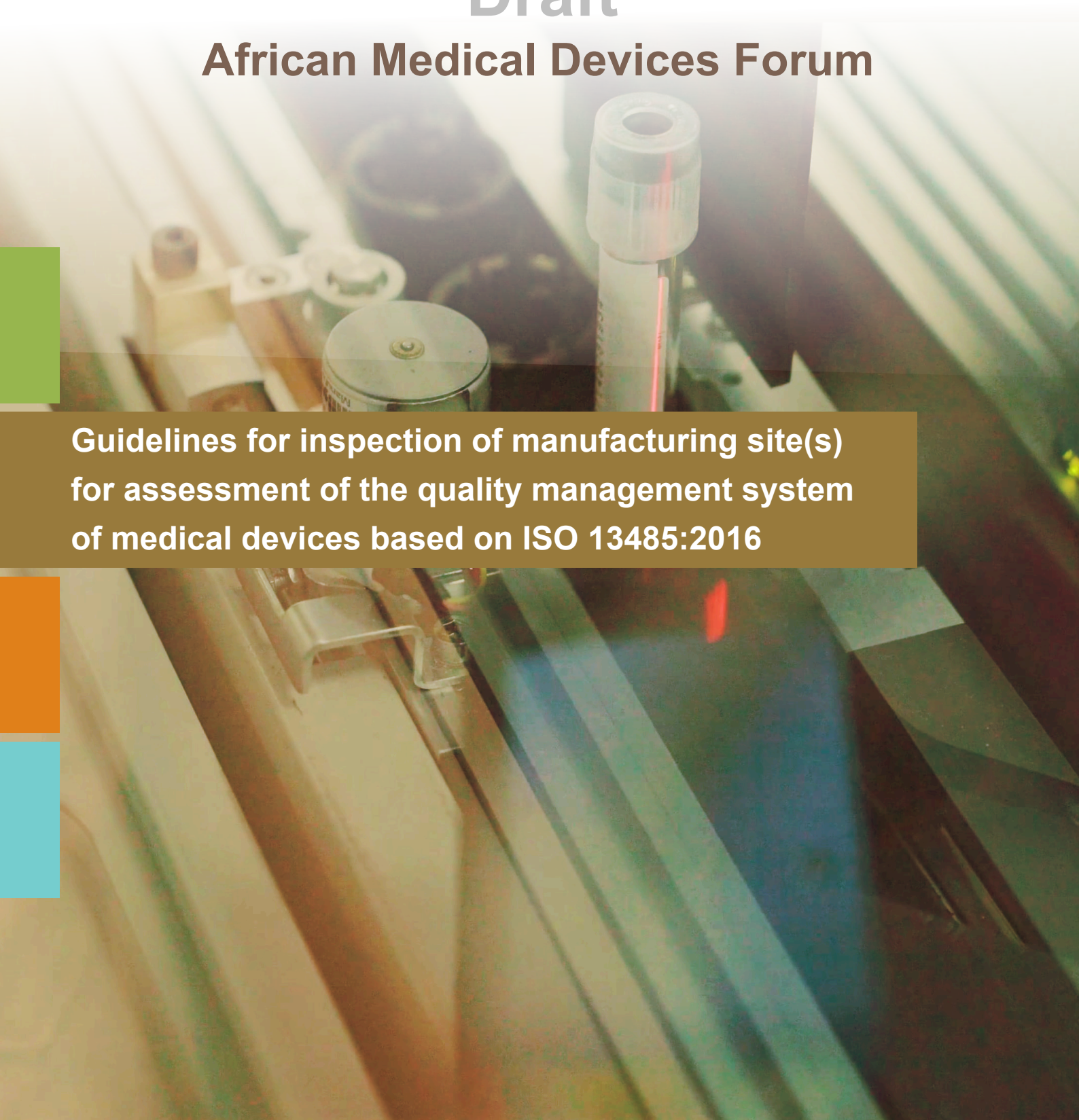

Guidelines for inspection of manufacturing site(s) for assessment of the quality management system of medical devices based on ISO 13485:2016

CONTENTS

ABBREVIATIONS

CAP	corrective action plan
GHTF	Global Harmonization Task Force
IMDRF	International Medical Device Regulators Forum
ISO	International Organization for Standardization
IVD	in vitro diagnostic medical device
MDSAP	Medical Device Single Audit Program
NOC	notice of concern
NRA	national regulatory authority
QMS	quality management system
WHO	World Health Organization

DEFINITIONS

Abridged assessment: Assessment including performance evaluation, clinical studies and abridged inspection of manufacturing site(s) and labelling review.

Audit: Systematic independent and documented process for obtaining audit evidence and evaluating it objectively to determine the extent to which the audit criteria are fulfilled (1, 2).

Audit criteria: Set of policies, procedures or requirements.

Note: Audit criteria are used as a reference against which audit evidence is compared (2, 3).

Audit evidence: Records, statements of fact or other information, which are relevant to the audit criteria and verifiable.

Note: Audit evidence may be qualitative and/or quantitative and is used to substantiate audit observations (3,5).

Audit findings: Results of the evaluation of the collected audit evidence against audit criteria.

Note: Audit findings can indicate either conformity or nonconformity with audit criteria or opportunities for improvement (3, 5).

Auditor: A person with relevant qualifications and competence to perform an audit or specified parts of an audit and who belongs to, or is authorized by, the auditing organization (3).

Dossier review: Review and assessment of documentation (including data, protocols, reports, procedures, etc.) to support the quality, safety and performance of medical devices for the purpose of national regulatory authority (NRA) assessment.

Full assessment: Premarket assessment, including dossier review, performance evaluation, clinical trials, inspection of manufacturing site(s) and labelling review.

Inspection of manufacturing site(s) or inspection: On-site inspection of the manufacturing site(s) of medical devices undergoing assessment.

Inspector: Official who carries out inspections or specified parts of such inspections and who belongs to, or is authorized by, the NRA.

In-vitro diagnostic medical device (IVD): A medical device, whether used alone or in combination, intended by the manufacturer for the in-vitro examination of specimens derived from the human body solely or principally to provide information for diagnostic, monitoring or compatibility purposes.

Note: IVDs include reagents, calibrators, control materials, specimen receptacles, software and related instruments or apparatus or other articles, and are used, for example, for the following test purposes: diagnosis, aid to diagnosis, screening, monitoring, predisposition, prognosis, prediction, determination of physiological status (6).

Manufacturer: Any natural or legal person with responsibility for design and/or manufacture of a diagnostic product with the intention of making the diagnostic product available for use, under his/her name; whether such a diagnostic product is designed and/or manufactured by that person himself/herself or on his/her behalf by another person(s) (7).

Nonconformity or noncompliance or nonconformance: Nonfulfilment of specified requirements within the planned arrangements.

Objective evidence: Verifiable information or records pertaining to the quality of an item or service or to the existence and implementation of a quality system element, which is based on visual observation, measurement or test.

Observation: Statement of fact made during a quality inspection and substantiated by objective evidence (8 , 9).

Performance evaluation: Evaluation including evaluation of operational characteristics of a product for the purpose of the pre-market assessment (10, 11).

Quality management system (QMS): A set of interrelated or interacting elements of an organization to establish quality policies and quality objectives and to establish the processes that are needed to ensure that those policies are followed and those objectives are achieved (3).

Regulatory version: Relates to the information associated with a submission for approval by a regulatory authority. The submitted version is defined by all of the documentation related to development, manufacture and intended use, labelling and post-market surveillance of the product and all the documented evidence supporting the safety and performance claims associated with that submission. If any aspect of this documentation is different in any way between the submissions to different regulatory authorities or assessment bodies (United States Food and Drug Administration, Health Canada, a notified body for Conformité Européene (CE) marking, etc.) it is considered to be a different regulatory version.

Subcontractor: An entity separate from the manufacturer that supplies to the manufacturer: (1) a material, product or subassembly (or a component thereof) to a proprietary specification which is incorporated into or used in the manufacture of the finished medical device; or (2) a service (e.g. testing, sterilization) to enable the medical device to meet defined requirements. If the separate entity is owned by the manufacturer, it may or may not be considered a subcontractor.

1. Introduction

Pre-market authorization by a national regulatory authority (NRA) is a comprehensive quality assessment of individual medical devices through a standardized procedure aimed at determining whether the product meets the Authority's requirements. Generally, pre-market assessment process includes review of a technical or product dossier; assessment of the performance of the medical device including operational characteristics; and inspection of manufacturing site(s). When some of the regulatory assessment information is already available, an abridged pre-market assessment can be performed based on reliance and recognition.

2. Intended audience

This document has been prepared to provide manufacturers with information on the inspection of manufacturing site(s) of product(s) undergoing NRA assessment, including the assessment of their quality management system (QMS). In addition, this document is issued to inspection team members.

3. Scope

This document describes the application of internationally recognized standards and guidelines to the inspection of manufacturing site(s), including assessment of the QMS. This document is guided by standards and technical reports prepared by the International Organization for Standardization (ISO) and guidelines from the International Medical Device Regulators Forum (IMDRF). Publications from these organizations are prepared by recognized experts and are referred to by several mature regulatory agencies throughout the world.

The process for an inspection of a manufacturing site is based on the standards, guidelines and other reference documents listed in the Annex to this document. Although it is not mandatory for manufacturers to use these standards and guidelines, a quality system and manufacturing process that fulfil the requirements laid down in these documents will also comply with NRA requirements. The manufacturer must indicate which standards are used to establish and maintain the QMS and the manufacturing process under which the product to be assessed is manufactured.

The inspection of manufacturing site(s) is based on the principles outlined in the standard ISO 19011:2011, Guidelines for auditing management systems. Additional references relating to good practice for the manufacture of medical devices including in-vitro diagnostic devices (IVDs), including other ISO standards, will be utilized during the NRA assessment.

As a general overview, the criteria for inspection of manufacturing site(s) are product-specific and are based on an assessment of compliance with ISO 13485:2016, Medical devices – Quality management systems – requirements for regulatory purposes.

4. The process of inspection of manufacturing site(s)

4.1. Objectives and scope of the inspection of manufacturing site(s)

4.1.1. Objectives of the inspection of manufacturing site(s)

The overall intent of the manufacturing site inspection is to assess the safety, performance and quality of commercially available medical devices including IVDs. Therefore, the specific objectives of this process are: to assess compliance of the manufacturer's QMS and manufacturing practices with international standards to:

a) determine the effectiveness of the implemented QMS in meeting appropriate quality standards;
b) verify the data supporting the claims presented in the submitted pre-submission form and product dossier; and
c) inspect the QMS according to the manufacturer's own requirements.

4.1.2. Scope of the inspection of manufacturing site(s)

The scope of the manufacturing site inspection is limited to the manufacturing site(s) and product(s) agreed upon with the manufacturer. The inspection of a manufacturing site is product-specific, and more than one product may be assessed in a single inspection. The inspection of a manufacturing site will include all organizational units, activities and processes associated with these products.

The initial manufacturing site inspection will be performed in two stages. In the Stage 1 inspection, usually in the form of a desk audit, the Authority will first assess the documents related to the QMS and establish the readiness for the Stage 2 on-site inspection, and then determine the scope and objectives of the on-site inspection. Such documents may include, inter alia, standard operating procedures and quality records. The manufacturer must submit to the Authority, as requested, all the aforementioned documents prior to the commencement of the inspection of the manufacturing site.

On-site inspections are a sampling process. That is, not all details of the manufacturer's QMS will be examined. However, the expertise of the inspectors will guide them in selecting those processes that are indicative of producing a medical device, including an IVD, of good quality.

The inspection of the manufacturing site will be limited to the time allocated by the inspection team and agreed upon with the manufacturer prior to the inspection.

IMPORTANT NOTE: At the time of the inspection of the manufacturing site, the manufacturing site must be in active production of at least one, or part of one, of the products undergoing NRA assessment in order for the inspection of the manufacturing site to proceed and to enable the inspection team to perform an adequate inspection. In addition, key personnel must be present at the time of the inspection of the manufacturing site, and the inspection team must have access to all areas and documentation relevant to the production of the aforementioned products.

4.2.Principles relating to the inspection of manufacturing site(s)

The following are considered guiding principles governing the inspection of manufacturing site(s):

4.2.1. Independence

The inspectors, including Authority staff members and selected regulatory and technical experts,

shall be impartial and free from influences that could affect their objectivity.

4.2.2. Inspection objectives and scope

The objectives and scope of the inspection of the manufacturing site shall be defined in a general inspection plan supplied to and agreed with the manufacturer prior to the inspection. Modification of the plan may occur to accommodate the manufacturing site processes and to follow audit trails depending on the observations made at the time of the inspection.

4.2.3. Roles and responsibilities

Roles and responsibilities of all personnel involved in the inspection shall be clearly defined so that expectations can be met and accountabilities understood.

4.2.4. Resources

Resources shall be adequate in terms of competent inspectors, the expertise deemed necessary, time allocation and access to external technical and other information. The resources utilized shall be designed to obtain inspection results that are highly reliable.

4.2.5. Competence of the inspection team

The inspection team shall consist of the Authority staff and external experts appointed by the Authority (inspectors) with inspection skills and with the education and experience in regulatory requirements and device technologies appropriate for their tasks during the inspection. Representatives of the national regulatory authorities or procurement agencies may accompany the inspection team to the manufacturing site(s) as observers or for training purposes.

4.2.6. Consistency of procedures

The inspection procedure shall be performed according to defined guidelines and with a lead inspector to enable consistency during the inspection. The Authority staff member responsible for inspections will ensure consistency between inspections of the same type and scope.

4.2.7. Adequacy of inspection documentation

Documentation associated with each inspection, such as inspection reports, shall provide adequate information related to the pre-market assessment of the product and to post-market surveillance for continuity between successive inspections and to provide the manufacturer with opportunities for quality improvement.

4.2.8. Confidentiality and standard of conduct

The inspectors shall maintain confidentiality with regard to information and documentation related to the inspection and shall comply with the applicable Authority standards of conduct and conflict of interest rules. Within these considerations, the inspection process shall be transparent to all participants.

4.2.9. Inspection results and conclusions

The results and conclusions of the inspection shall be consistent and accurate, subject to the normal limitations of an inspection, noting that the objective evidence collected during the inspection is generally no more than a sample. The grading of nonconformities is the responsibility of the Authority, including the final release of all reports.

4.2.10. Quality system

Inspections are conducted in compliance with the QMS prescribed by the Authority.

5. Types of inspection

Generally, inspections of a manufacturing site consist of four types of inspections, which are outlined in this section.

5.1. Initial inspection

The initial inspection will be performed in two stages.

a) The Stage 1 inspection, usually a desk audit, will evaluate the documentation related to the QMS to establish readiness for a Stage 2 inspection. General information about the documented QMS, including the quality manual and manufacturing processes, organigram, workflows, critical suppliers and floor plan, will be reviewed in the Stage 1 inspection to establish the readiness of the quality management system (QMS) and to prepare for an on-site visit. Any issues of concern will be communicated to the manufacturer. A satisfactory Stage 1 inspection is required in order to proceed to the Stage 2 inspection.

b) The Stage 2 inspection will comprehensively evaluate the effective implementation of the quality management system and implemented production processes through one or more on-site inspection(s).
A preliminary report detailing issues of concern (if any) will be provided on the final day of the inspection. A final inspection report including the classified nonconformities will be issued after the inspection.

5.2. Reinspection

Reinspection of the manufacturing site may occur when required by the Authority to ensure ongoing compliance with registration requirements. This will either be a partial (also known as a surveillance inspection) or full inspection depending on, for example, the type of product, results of inspections by another recognized NRA, feedback from the market such as recalls or complaints, and/or changes to the QMS, manufacturing site or the product(s) since the last inspection. Routine reinspection shall typically occur every <three to five (3–5)> years after registration of the product by the Authority, unless an earlier reinspection is deemed necessary by the Authority.

5.3. Special inspection

A special inspection may be required when, for example:

a) effective implementation of corrective actions to prevent the recurrence of noncon formities needs to be verified in a follow-up inspection, prior to pre-market assessment;

b) substantial changes are made to the design, composition, safety and/or performance of the medical device;

c) serious concerns have been raised about the current quality of the medical device;

d) production has been suspended and later resumed; and/or

e) there is a significant change in the QMS.

5.4. Inspection for an abridged assessment

The Authority will determine eligibility for an abridged inspection on the basis of the documentation provided with the pre-submission form.
If the product qualifies for an inspection with an abridged scope, the manufacturer will not have to submit the full QMS documentation for a Stage 1 inspection. However, at the request of the Authority, the manufacturer must submit an information package to assist the Authority in preparing for the inspection of the manufacturing site(s).

The on-site inspection time will be limited and calculated to cover the selected product(s) and key processes for that site (e.g. risk management, in-use stability under poorly controlled conditions, impact on stability of transportation, information gathered from the market etc., user training and material). An inspection with an abridged scope will

not necessarily include a review of all QMS procedures and processes that are usually inspected, but it will take into consideration the findings of the most recent regulatory audit reports (full and surveillance). There will be a limited sampling of some of the general quality management processes and a follow-up, or clarification of, individual findings identified in the previous report.

5.5. Waiver of manufacturing site inspection

The Authority may waive an inspection of a manufacturing site(s) in defined circumstances, such as a recent inspection with appropriate scope by a recognized NRA or by an auditing organization participating in the Medical Devices Single Audit Program (MDSAP). The requested documentation must be made available to Authority inspection staff members for review. This documentation shall contain sufficient detail on the processes and records related to the type of product in pre-market assessment. The Authority shall take into account any objective evidence contained within an MDSAP audit report that demonstrates compliance with medical device pre-market requirements.

6. Roles and responsibilities of inspectors and manufacturers in an inspection

The lead inspector, who is generally an Authority staff member, has the responsibility for all phases of the inspection and the authority to make final decisions regarding the conduct of, and observations made, during the inspection. The Authority may delegate this role to an external expert appointed by the Authority, when it deems this step appropriate.

Where the lead inspector is not an Authority staff member, all communications with the manufacturer will be the responsibility of the Authority co-inspector participating in the inspection. Further, the Authority co-inspector is responsible for compiling the final report and submitting it for internal Authority review in a timely manner. The manufacturer is required to nominate a contact person for the inspection team, who will ensure that the responsibilities of the manufacturer for the inspection are met.

6.1. Responsibilities of inspectors and lead inspector

Responsibilities of the Authority lead inspector are to:

a) plan and prepare the inspection;
b) communicate with the manufacturer;
c) assist with the selection of the inspection team members;
d) define the scope of the inspection;
e) prepare and/or review the inspection plan, working documents and briefing documents if prepared by a co-inspector;
f) supervise the travel arrangements for the inspectors;
g) represent the inspection team with the manufacturer;
h) supervise inspectors during the inspection;
i) communicate any obstacles regarding the inspection to the manufacturer and to the Authority prior to or during the inspection;
j) after consultation with the other inspectors, prepare and present the general outcome of the inspection of the manufacturing site to the manufacturer at the closing meeting;
k) after consultation with the other inspectors, compile the final inspection report (usually within <one (1)> month) for review and approval by the Authority;
l) submit the report to the manufacturer;
m) follow up on nonconformities; and
n) assist the manufacturer in understanding the Authority's pre-market requirements.

When the lead inspector is not an Authority staff member, some of these responsibilities will be delegated to a member of the inspection team who is an Authority employee.

6.2. Responsibilities of all inspectors involved

in the inspection

The responsibilities of each inspector, including the lead inspector, who are not staff members of the Authority are to:

a) use established inspection methods to achieve consistency in the inspection process;
b) plan and carry out assigned responsibili ties objectively, effectively and efficiently within the scope of the inspection of the manufacturing site;
c) safeguard confidentiality of documents and information associated with the inspection;
d) comply with the Authority's standard of conduct and conflict of interest rules;
e) comply with the Authority's requirements for inspections, including information in this document;
f) collect, analyse and document objective evidence to establish the extent of compli ance with the quality system and the effec tiveness of its implementation;
g) establish the extent to which the proce dures, documents and other available infor mation is understood and used by the man ufacturer's personnel;
h) cooperate with and support the lead in spector and maintain a means of obtaining prompt guidance during the inspection, if required;
i) bring to the attention of the lead inspector and/or the Authority's inspector(s), in a timely manner, any indications or observa tions that could influence the results of the inspection results, require more in-depth inspection or are an obstacle to the proper performance of the inspection;
j) when applicable, verify that corrective ac tions have been taken and have been effective;
k) minimize disruption to the manufacturer's personnel and processes during the in spection and comply with any health and safety or other requirements of the manu facturer;
l) perform the inspection in a professional manner, without discourteous or intimidating conduct; and
m) assist the lead inspector and/or the Author ity inspector(s) in preparing the inspection report.

NOTE: All notes and other documented evidence gathered in connection with the inspection will be considered confidential and will form part of the Authority's records of the inspection.

6.3. Responsibilities of the manufacturer

The responsibilities of the manufacturer will be communicated to the manufacturer prior to the in-spection. Among other things, the manufacturer's responsibilities will be to:

a) agree the objectives and the scope of the inspection with the Authority team;
b) inform the Authority team of any issues that may affect an effective and efficient inspec tion process;
c) cooperate with the inspectors to ensure that the objectives of the inspection are achieved;
d) identify a person responsible for coordinat ing and facilitating the inspection process on behalf of the manufacturer;
e) inform relevant employees and personnel about the objectives and scope of the in spection;
f) appoint responsible members of staff to ac company members of the inspection team;
g) ensure inspectors are aware of health, safety and other applicable requirements;
h) provide on-site resources, such as a meet ing room, for the inspection team to facilitate an effective and efficient inspec tion process; and
i) provide full and timely access to the manufacturing facilities, documents, records and other evidence as requested by the inspectors to ensure an effective and efficient inspection process and en sure that the inspection timetable can be met.

If nonconformities are identified at the inspection of the manufacturing site these will be notified to and discussed with the manufacturer during the closing meeting. The manufacturer will subsequently receive an inspection report listing the nonconformities. Upon receipt of the inspection report, the manufacturer's responsibilities will be to:

a) determine the root cause of all identified nonconformities;
b) determine actions to correct the noncon formities and the corrective actions to be taken to prevent their recurrence;
c) submit a corrective action plan to the Au thority within <thirty (30)> days of receipt of the final inspection report;
d) implement and verify the effectiveness of the corrective actions in a timely manner;
e) inform the Authority of the completion of these corrective actions, as required; and
f) inform the Authority of any subsequent significant change to the quality system or the product.

7. Inspection team selection

7.1. Composition of the inspection team for a manufacturing site

The inspection team may consist of:

a) the lead inspector;
b) one or more technical inspector(s) who are knowledgeable and experienced in assess ing the relevant medical device, including the product realization processes and re sultant product;
c) a quality management systems inspector who is qualified and sufficiently experi enced to inspect the QMS of the type of manufacturer being inspected (this role may be performed by the Authority inspect or or by a suitably qualified technical in spector);
d) an inspector who is an expert in quality control activities, including the on-site lab oratory, and responsible for activities such as final product release (batch release test ing);
e) inspectors from the local NRA;
f) observers, who may include personnel from other inspection agencies and inspec tion trainees; the observers are not consid ered to be inspectors, but must comply with the same standards of con duct; the number of observers must be lim ited to ensure minimal disruption to the in spection and to the manufacturing process; and
g) qualified interpreter(s) to facilitate com munication between the inspection team and the manufacturer's personnel and sup port open and effective communication throughout the inspection.

NOTE: inspectors may fulfil multiple roles. If more than one product or production line is to be inspected, an additional inspector may be added to the team, to reduce the time spent on site to a maximum of four days.

7.2. Conflicts of interest

Before undertaking work relating to the inspection, each external inspector, assessor or technical expert will be required to complete and sign the Authority declaration of interest form. If, from this declaration of interests, the Authority considers that there is no risk of a real or perceived conflict of interest, or only an insignificant and/or irrelevant conflict of interest, and it is thus deemed appropriate for the assessor or inspector in question to undertake the work relating to the inspection, then he/she will discharge his/her functions exclusively as adviser to the Authority. In this connection, each assessor and inspector is required to confirm that the information disclosed by him/her in the declaration of interest is correct and complete, and that he/she will immediately notify the Authority of any

change in this information.
All inspectors further agree that, at the manufacturer's request, the Authority will advise the manufacturer, in advance, of the identity of each inspector and the composition of the team performing the manufacturing site inspection and will provide the manufacturer with the curriculum vitae of each inspector.

The manufacturer then has the opportunity to express to the Authority possible concerns regarding any of the inspectors before the manufacturing site inspection begins. If such concerns cannot be resolved in consultation with the Authority, the manufacturer may object to a team member's participation in the manufacturing site visit. Such an objection must be sent in writing by the manufacturer to the Authority within <ten (10)> days of receipt of the proposed composition of the team. In the event of such an objection, the Authority reserves the right to cancel all or part of its agreement with, and the activities to be undertaken by, that inspector.

7.3. Standards of conduct

All members of the inspection team, as well as all observers and interpreters, must be made aware of and agree to the high standard of conduct expected during the entire inspection process, including pre- and post-inspection activities, confidentiality and absence of conflicts of interest. The conduct required is in keeping with the requirements of the Authority's code of conduct.

8. Logistics, documentation and travel for inspection of the manufacturing site

8.1. Dossier review briefing notes

As part of the Authority's pre-market assessment of medical devices, the pre-submission form and product dossier shall be submitted by the manufacturer to the Authority in accordance with the specified requirements. A briefing note or dossier review summary report will be prepared by the Authority's assessment team and discussed with the Authority inspector. The Authority inspector will share this information with the quality and technical inspectors while preparing the on-site inspection. Other documentation reviewed may include previous inspection reports, the quality management documentation review report and the instructions for use of the product(s) in pre-market assessment. Issues arising from these reports will be noted. Any other relevant documentation or information will be made available to all the participating inspectors for review.

8.2. Dates and times of the inspection

The dates and time allocated for the inspection are to be agreed upon by all participants under the guidance of the Authority inspector and will be documented in an inspection plan.

The manufacturer will be asked to accept the proposed dates for the inspection when:

a) the production line of the product under going pre-market assessment is active; if several products are inspected during the same inspection, the production line for at least one of them must be active;
b) quality control activities are being per formed; and
c) the key personnel for the QMS, quality control and production line are present.

The inspection plan will be provided usually <one to two (1–2)> weeks before the inspection and will include details of the type of inspection to be conducted and the sites and products to be inspected, using the information submitted on the product and the QMS, which includes the quality manual. The plan is a guide only and will be flexible to permit changes in emphasis based on information gathered during the inspection.

The inspection plan will include:

a) scope and purpose of the inspection of the

manufacturing site;

b) identification of inspection team members;
c) date and place of the inspection; and
d) expected time and duration of each inspection activity, including meetings to be held with the manufacturer's management team.

The time allocated to the inspection will be calculated according to the complexity and scope of the inspection, the number of manufacturing technologies involved and the number and type of medical devices in the pre-market assessment. An example of an inspection timetable is provided in the Annex. Inspectors will be allocated tasks by the Authority inspector, according to their expertise and the requirements of the inspection.

8.3. Documentation on subcontractors, outsourced processes and significant (critical) suppliers

The manufacturer must have the necessary documentation available to demonstrate that the processes controlling product supply are effective and meet the relevant quality expectations. This includes, but is not limited to, documentation relating to providers of critical raw material, interim components, packaging services or other services used to make the medical device. The manufacturer shall be responsible for the sufficient control of any critical supplier, including outsourced processes. If this requirement is not adequately met, a nonconformity against the respective ISO 13485 requirement will be issued and an inspection of subcontractor sites may be necessary.

8.4. Working documents for on-site inspection

Inspectors will be provided with briefing notes, as applicable to their area of inspection. The briefing notes may contain information about open questions and/or issues with the product dossier assessment or technical information about the product batches provided for performance evaluation or clinical trials; they do not necessarily define the entire scope of the inspection. Additional items may be included according to the particular requirements of the medical device and the expertise of the inspector. It is expected that inspectors will document in writing their findings in the inspection notes as the inspection progresses. This information will be used to compile the draft on-site report and to describe any nonconformities and shall be handed over to the Authority inspector to gather together all relevant inspection records and to compile the final inspection report.

8.5. Language of the on-site inspection

The inspection will be conducted in <English>. To enable a smooth and effective inspection, the manufacturer shall ensure that all relevant higher-level quality management documents are available in <English>. Translation and/or interpretation needs will be discussed with the manufacturer.

9. On-site inspection

9.1. Opening meeting

The opening meeting (lasting up to one hour) is used to exchange information between the inspection team and the manufacturing team on the inspection process and the manufacturing site, and to confirm the scope, objectives and plan of the inspection and the availability of responsible contact persons on-site. The times indicated in the Annex may act as a guide.

9.1.1. Inspection team

The lead inspector will first:

a) introduce the inspection team;
b) review the scope and objectives of the inspection;
c) provide a short summary of the inspection process as part of the Authority's pre-market assessment of medical devices;
d) confirm the timetable for the manufacturing site inspection;
e) confirm that the resources and facilities needed by the inspection team are available; and
f) allow the manufacturer to ask clarifying questions regarding the inspection process.

9.1.2. Manufacturer

Subsequently, the manufacturer will:

a) introduce its principal staff;
b) provide a current organigram and a written list with contact details of its staff, to facilitate access to key personnel during the inspection process;
c) provide a brief overview of the QMS;
d) provide a brief overview of the on-site manufacturing process, particularly for the product(s) to be assessed;
e) inform the inspection team of any changes since the submission of the product dossier or last inspection for pre-market assessment and/or the submission of the batches for the Authority performance evaluation or clinical studies;
f) provide a manufacturing schedule, including shift times (if applicable), for the inspection days and a diagram of the manufacturing workflow; and
g) present samples of the products in pre-market assessment (final product) for the inspection team to study their content and labelling.

10. Manufacturing site inspection

10.1. General

The inspection will seek to confirm the adequacy and effectiveness of the manufacturer's documented QMS, with emphasis on the control of production processes and compliance with state-of-the-art practices, including the Authority's technical guidelines. Documents and records from all levels of the quality system will be reviewed. Post-market and market surveillance data, as well as marketing and training material, may be included in the review.

Informal interviews with personnel at all levels and discussions with persons selected by an inspector will form part of the inspection process.

Evidence will be collected on-site, as follows:

a) by examination of documents, including standard operating procedures and records
b) by visual observation of activities
c) by visual observation of environmental conditions
d) by confirmation of statement of fact that is

acquired through interviews

e) (potentially) by random sampling of the product for laboratory quality control testing and

f) (potentially) by means of photographs.

Nonconformities identified during the document review or interviews will be notified to the accompanying representative of the manufacturer and may be verified by additional information where possible. The manufacturer will be given an immediate opportunity to comment on the evidence of nonconformities. Based on this evidence, a nonconformity, even if corrected immediately, will be noted and form part of the final inspection report.

10.2. Quality management system inspection: overview

The QMS inspection will be conducted in a format that follows the production process. ISO 13485 is used as a basis for the inspection; other product- and system-related standards and references may be used by the manufacturer to ensure good practice in the manufacture of the medical device.

The QMS inspection process includes, but is not limited to, the following processes:

a) management: inspection of management processes is intended to ensure that an adequate and effective quality management system is in place, including management review;

b) product documentation, including design and development: inspection of these sections is intended to ensure that the manufacturer has established adequate documented systems and adequate communication of the systems (including change control) to all personnel to ensure a quality product outcome;

c) production and process controls: inspection of these sections is intended to ensure that the manufacturer has established adequate systems (e.g. testing, infrastructure,facilities, equipment and personnel) to ensure a high-quality outcome; to demonstrate that the production and quality units are independent of one another; and to demonstrate that the quality unit controls the release of product batches;

d) corrective and preventive actions, internal audits: inspection of this section is intended to confirm that the manufacturer collects and analyses actual and potential quality problems through investigation and appropriate action;

e) purchasing controls: this section is especially important when significant components are outsourced; the manufacturer must ensure that raw materials, intermediates, components and services provided by suppliers are of an appropriate standard;

f) documentation and records: inspection of this section is intended to ensure that relevant documents and records are defined, established and controlled (for example, by being updated and properly authorized) and to ensure that procedure and process documents are readily available and in routine use by staff as needed;

g) customer-related processes: customers in this context include purchasers and users of the product and relevant regulatory bodies;

h) training of personnel: inspection of this section is intended to ensure that adequate qualifications and training of personnel have been obtained and are appropriate for the tasks required of them and that training records are maintained; and

i) adequate infrastructure and work environment: inspection of this section is intended to ensure the adequacy of facilities, manufacturing, equipment, monitoring and quality control equipment, calibration and maintenance.

10.3. Verification of data supporting the product dossier submission

During the inspection, one of the inspectors will sample quality records and reports that support the data submitted with the product dossier for the Authority assessment. This may include, but is not

limited to, data recorded for the batches submitted for the Authority performance evaluation or clinical testing; data collected in performance studies (internal and independent external); quality control data; and batch manufacturing records. The manufacturer must ensure that the entire product dossier submitted to the Authority is available on site.

11. Meetings of inspectors

Inspectors will meet as necessary throughout the inspection. The meetings described below should, as a minimum, cover:

a) discussion of findings and the progress of the inspection;
b) daily summary (a brief summary of the day's activities and findings);
c) inspection summary: on the last day of the inspection, the inspectors will meet to discuss and summarize the findings to be conveyed to the manufacturer.

11.1. Daily wrap-up meeting

Daily wrap-up meetings will be held between the manufacturer and the inspection team at the end of each day of the on-site inspection. As part of these meetings, the inspection team will present a summary of the daily findings and the manufacturer will be invited to discuss the findings and any issues of concern (potential nonconformities).

During the daily wrap-up meetings, the manufacturer must raise any comments on any issues of concern or the performance of the inspection, indicate its understanding of, or contest, any issues of concern raised, and/or provide additional clarification for the inspection team on the extent or significance of any issue of concern. If the manufacturer contests any nonconformity or issue of concern, a rationale (including supporting evidence) must be supplied by the manufacturer to the inspection team.

11.2. Closing meeting

11.2.1. Summary and draft on-site inspection report

The closing meeting concludes the inspection and will be held in the presence of the complete inspection team and the management team of the manufacturer. Other staff members may be invited by the management, as appropriate.

The lead inspector will summarize the findings and issues of concern from the inspection, in the order of significance, and will present:

a) the outcome of the inspection, including areas covered and not covered, as well as limitations of the inspection; and
b) the list of nonconformities or a draft on-site inspection report, depending on the type of inspection.

If a draft on-site inspection report is presented, the report will describe the main findings and issues of concern and will summarize the general outcome of the inspection. Significant issues of concern will be discussed in detail with the manufacturer. The inspectors will be available to provide additional clarifications concerning the inspection, if so requested by the manufacturer.

The manufacturer's management team will have the opportunity to comment on and to seek clarification from the inspection team on items in the draft on-site inspection report. If the manufacturer contests any issue of concern, a rationale for this, including supporting evidence, must be supplied to the inspection team.

The list of nonconformities or a draft on-site inspection report will allow the manufacturer to start working on any corrections that are immediately required. A time frame for the issuing of the final inspection report and the implementation of corrective actions should be agreed at the closing meeting, if possible. The lead inspector will advise the manufacturer that the corrective action plan (CAP) has to be submitted within <thirty (30)> days of receipt of the final inspection report.

12. Report for a manufacturing site inspection

12.1. Overview

The purpose of the inspection report is to:

a) provide the manufacturer with information on nonconformities found at the inspection. To be eligible for the Authority assessment of the medical device inspected, the identi fied examples of nonconformity must be corrected by the manufacturer and investi gated to determine correction actions that are intended to prevent recurrence of the nonconformity;

b) provide information to the manufacturer upon which to base improvements to the quality of the manufacturing system;

c) provide a permanent record of the findings of the inspection; and

d) provide the Authority team with a recommendation of actions following the inspection.

NOTE: A more detailed list of the purpose of the inspection report is found in guidance such as IMDRF/MDSAP WG/N24 FINAL: 2015 Medical device regulatory audit reports (12) and ISO 19011:2011 Guidelines for auditing management systems (13).

The Authority inspector will prepare the inspection report and is responsible for its accuracy and content. A final inspection report will be issued by the Authority to the manufacturer, generally within <thirty (30)> days of the inspection, although this time may be extended to <two (2)> months during periods of high workload and/or vacation. If a final inspection report cannot be issued within this <thirty (30)>-day time frame, the manufacturer will be notified of the delay.

The manufacturer understands and agrees that the Authority will have absolute, exclusive and unrestricted control over the manner in which the inspection is carried out, including the publication of the results of the inspection, regardless of the outcome. The manufacturer also understands and agrees that the Authority reserves the right to share the manufacturer's assessment application and related information, as well as the results of the inspection and the full inspection reports, including any drafts thereof and including (subject to appropriate obligations of confidentiality) any confidential information to which the Authority may gain access in the course of the pre-market assessment process and/or inspection, with the relevant authorities of any interested international organizations, with interested NRAs, and with relevant intergovernmental organizations. As used in this document, the term "confidential information" means confidential intellectual property, know-how and trade secrets (e.g. formulae, processes or information contained or embodied in a product, unpublished aspects of trademark, patents); and commercial confidences (e.g. structures and development plans of a company).

Inspection reports shall be broadly of two types, as detailed below.

12.1.1. Reports with no requirements

The inspection report with no requirements will be a consensus report compiled by the lead inspector. The participating inspectors may be asked to review the report for accuracy. Following approval by the Authority's authorized approver; the report shall be submitted to the manufacturer.

12.1.2. Reports with requirements relating to nonconformities

The inspection report with requirements relating to nonconformities will be a consensus report compiled by the lead inspector. Following authorization by the Authority's authorized approver, the report will be submitted to the manufacturer. This type of report will include a description of the nonconformities found during the manufacturing site inspection, their severity, the findings that contributed to each decision of nonconformity, the relevant specific ISO 13485 requirements (individual clause or subclause) and the evidence of nonconformity

(e.g. manufacturer's procedure).

12.2. Nonconformities

During the on-site inspection, nonconformities may have been identified with respect to:

a) QMS inspection criteria and/or
b) verification of data supporting the product dossier claims.

Both types of nonconformity, as well as the objective evidence contributing to the nonconformity, including the inspection criterion that was not met, will be individually stated and described in the manufacturing site inspection report. Additional findings on the same requirement may contribute to the severity grading of a nonconformity and raise its level.

The severity of nonconformities will be classified according to the document GHTF SG3 N19:2012 (9). Nonconformities may be graded between level 1 and level 5, with level 1 being the lowest level and level 5 the most critical level of nonconformity. The QMS shall be considered critically deficient if the following findings occur:

a) one (1) or more level 5 nonconformity(ies) or
b) seven (7) or more level 4 nonconformities.

If any nonconformities are included in the final inspection report, a CAP shall be submitted to the Authority by the manufacturer within <thirty (30)> days of receipt of the final inspection report. For each identified nonconformity, the CAP shall include:

a) a root cause analysis
b) the corrections required for the identified nonconformities
c) the corrective actions required to remove the cause and to prevent recurrence
d) a timeline for implementation of corrections and corrective actions
e) the resources responsible for implementation and
f) evaluation of the effective implementation of the corrective action(s).

The manufacturer must provide the CAP to the Authority in an editable format, e.g. a Word document or Excel spreadsheet. This enables improved communication about approval, rejection or a request for additional information and documents by the Authority.

The Authority inspector will request, and the inspection team will review, submissions from the manufacturer relating to correction of the nonconformities. Thereafter, one of the following outcomes may occur, as applicable:

a) if the submissions are acceptable to the Authority, the Authority inspector will notify the manufacturer by letter that the inspection and follow-up are complete;
b) if the manufacturer's CAP submissions are not acceptable to the Authority, the Authority inspector will request an improved CAP and may ask the manufacturer for further evidence; in such cases, both the improved CAP and the additional evidence must be presented by the manufacturer to the Authority within <thirty (30)> days from the date the first review report on CAP is sent to the manufacturer;
c) if the effective implementation of corrective actions cannot be evaluated by document review, a follow-up inspection will be required before the nonconformities can be closed out.

Before the manufacturing site inspection is finalized, all nonconformities identified in the inspection report must have been satisfactorily corrected by the manufacturer (as determined by the Authority).

However, if a satisfactory outcome is not reached, for example if:

a) the manufacturer does not submit (in time or at all) a CAP to the Authority; or
b) the manufacturer is unable to implement all agreed corrections and corrective actions during the agreed time period; or
c) more than <six (6)> months have elapsed after the initial inspection and the manufacturer has still not provided the Authority with

satisfactory responses to the identified nonconformities then the manufacturer's application for the Authority pre-market assessment of the product(s) inspected will be terminated by the Authority and a new application will be required.

Any subsequent application for the Authority pre-market assessment will not be accepted unless and until the manufacturer submits sufficient evidence demonstrating that the nonconformities have been properly corrected. If the manufacturer's QMS is found to be critically deficient, a re-inspection and review of any available additional data will take place before the inspection component can be completed.

13. Notice of concern

A notice of concern (NOC) is a letter that is issued by the Authority to a manufacturer to remind the manufacturer of its obligation to maintain quality assurance procedures and practices, as well as to inform suppliers and procurement agencies of any potential risks associated with a given product or manufacturer.

An NOC lists observations made during an inspection that are considered to be:

a) critical or major noncompliances with the Authority's norms, requirements and stan dards that are of concern in relation to quality management or quality assurance; or
b) critical or major noncompliances with the Authority's norms, requirements and stan dards that were not satisfactorily ad dressed in the response from the manufac turer to an inspection.

An NOC is not necessarily a cause for public concern. However, if the Authority does identify a public health risk linked to a given product or manufacturer, then the Authority will take appropriate additional steps, including provision of advice for the public. These steps may include:

a) suspension of products included on the Au thority list of approved medical devices;
b) issuing of a compulsory variation to tempo rarily or permanently suspend the use of a manufacturing site;
c) recall of batches of products on the Author ity list of approved medical devices that have been supplied by the manufact urer concerned; and/or
d) rejection of applications for pre-market as sessment submitted by the manufacturer.

An NOC may be issued by the Authority to a manufacturer if:

a) observations were made during an inspec tion that indicate poor compliance or fail ure to comply with the applicable Authority norms, standards or requirements;
b) the response to the observations noted in an inspection report, detailing the correc tive actions taken or proposed to be taken, is considered by the lead inspector to be insufficiently robust and unlikely to resolve the underlying root cause of a critical or major nonconformity; this may include not providing suitable objective evidence of corrective action;
c) the requested response to the observa tions noted in an inspection report, detailing the corrective actions taken or proposed to be taken, was not received by the Authority on or before the due date (i.e. 30 days from the inspection date);
d) if a manufacturer refuses inspection of a manufacturing site by the Authority.

If immediate public health concerns have been identified during the inspection, or if the inspection observations relate to mis representation of data, falsification or ma nipulation of data with the intent to deceive, the NOC will be posted immediately on the Authority website. The Authority has a ze-

ro-tolerance policy in relation to such activities, since they indicate a serious quality system failure that should be urgently addressed by the senior management of the manufacturer.

An NOC will remain on the Authority website until adequate and appropriate corrective actions have been implemented effectively by the manufacturer concerned and verified by the Authority.

13.1. NOC appeal rights

An NOC contains the factual observations made during an inspection. These will have been discussed during the inspection and listed in the inspection report. Generally, the facts that form the basis of the observations are not in dispute. However, the manufacturer may disagree that a risk exists, or disagree with the level of risk identified by the Authority that has resulted in the issuing of the NOC. If the manufacturer disagrees with any aspect of the inspection report and subsequent NOC, it should send information to the Authority providing the basis for its disagreement. The matter will then be investigated, and a response provided within <fifteen (15)> days. All feedback will be treated in confidence and without prejudice.

14. Contents of the report for the inspection of a manufacturing site(s)

The main components of the inspection report shall include:

a) purpose, scope and objectives of the in spection, including the manufacturing site(s), processes and product(s);
b) details of the inspection team;
c) details of the areas covered in the inspection;
d) limitations of the inspection;
e) details of nonconformities (and their relative severity) and date for submission of any required corrective action;
f) comments and conclusions about the effectiveness of the manufacturer's quality system in meeting quality objectives;
g) summary of conclusions; and
h) authorized signature and date of the report.

The report shall include the following comment: "This report contains the collective views of the inspection team performing this inspection and does not necessarily represent the decisions or the stated policy of the Authority".

14.1. Retention of inspection reports

The Authority and the manufacturer shall retain inspection reports and associated documentation for a period of <three (3)> consecutive inspections and for <five (5)> years following the last inspection.

15. Review of corrective action plans to remedy nonconformities

The Authority inspector will be responsible for requesting, reviewing and reporting on the manufacturer's responses to nonconformities observed during the inspection.

The manufacturer will have a maximum of <two (2)> opportunities to supply the Authority with the necessary information to correct nonconformities and implement corrective actions to prevent recurrence in a timely manner. The manufacturer will supply such information and correct the nonconformities identified during the inspection within <thirty (30)> days of the request for information, unless the Authority agrees in writing (given the nature of the nonconformities) to grant the manufacturer a longer time period to supply the requested information. Consideration may be given to justifiable requests for an extension of time to respond.

In certain cases, the Authority may agree, at its sole discretion, to permit the manufacturer to correct specific nonconformities after-market authorization, provided that the manufacturer commits itself in writing to correcting them by an agreed deadline. Such a commitment to pre-market authorization will be reflected in the Authority's pre-market authorization public report and will be verified during the reinspection. Failure to comply with pre-market authorization commitments within agreed deadlines will result in delisting from the Authority's list of authorized medical devices.

16. Completion of the inspection of a manufacturing site(s)

When the identified nonconformities have been corrected, corrective actions to prevent recurrence have been implemented by the manufacturer as requested by the Authority, and the results accepted by the Authority, the manufacturer will receive a letter advising it of the completion of the inspection process.

The reinspection period will be determined by the Authority, using a risk management approach, after all of the information from the product dossier review, performance evaluation and inspection has been collated.

17. Criteria for not recommending pre-market authorization

The consensus view of the inspectors, confirmed by a review by the Authority, may be that a product should not be recommended to an Authority-authorized approver for inclusion in the Authority list of approved medical devices. The criteria or reasons for not recommending a product inclusion may include (examples only; not exhaustive):

a) failure to maintain an adequate QMS (deficient QMS);
b) falsification of data or submitted evidence or deliberate misrepresentation of facts regarding the manufacturing and quality system (level 5 nonconformity);
c) excessive number of level 4 nonconformities identified;
d) failure to implement appropriate action when post-market data have identified a pattern of defects;
e) failure of the product to meet the manufacturer's own specifications; and/or
f) failure of the manufacturer to respond adequately to requests for submissions relating to nonconformities.

18. Authority internal review of the inspection process

An internal review of the inspection documents and process for a manufacturing site shall be carried out by the Authority to maintain the high quality of the inspections.
The internal review assesses the consistency of the work relating to manufacturing site inspections within the Authority assessment team.

References

1. Principles of conformity assessment for medical devices (document GHTF/SG1/N78:2012). Global Harmonization Task Force Study Group 1; 2012 (*https://mdpharmacourses.com/ghtf-global-harmonization-task-force-guidelines/*, accessed 26 July 2021).

2. Guidelines for regulatory auditing of quality management systems of medical device manufacturers – Part 2: regulatory auditing strategy (document GHTF/SG4/N30:2010). Global Harmonization Task Force Study Group 4; 2010 (*http://www.imdrf.org/ghtf/ghtf-archives-sg4.asp*, accessed 26 July 2021).

3. Guidelines for regulatory auditing of quality management systems of medical device manufacturers – Part 1: general requirements (document GHTF/SG4/N28R4:2008). Global Harmonization Task Force Study Group 4; 2008 (http://www.imdrf.org/docs/ghtf/archived/sg4/technical-docs/ghtf-sg4-guidelines-auditing-qms-part-1-general-requirements-080827.pdf#search=%22n28r4%22, accessed 26 July 2021).

4. Principles of conformity assessment for medical devices (document GHTF/SG1/N78:2012). Global Harmonization Task Force Study Group 1; 2012 (*http://www.imdrf.org/documents/doc-ghtf-sg1.asp*, accessed 26 July 2021).

5. Guidelines for regulatory auditing of quality management systems of medical device manufacturers – Part 3: regulatory audit reports (document GHTF/SG4/N33R16:2007). Global Harmonization Task Force Study Group 4; 2007 (*http://www.imdrf.org/docs/ghtf/archived/sg4/technical-docs/ghtf-sg4-n33r16-quality-management-systems-part-3-071002.pdf*, accessed 26 July 2021).

6. Definition of the terms ‘medical device’ and ‘in vitro diagnostic (IVD) medical device’ (document GHTF/SG1/N071:2012). Global Harmonization Task Force Study Group 1; 2012 (*http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n071-2012-definition-of-terms-120516.pdf*, accessed 26 July 2021).

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8. Quality management system – medical devices – guidance on corrective action and preventive action and related QMS processes (document GHTF/SG3/N18:2010). Global Harmonization Task Force Study

Group 3; 2010 (*http://www.imdrf.org/documents/doc-ghtf-sg3.asp*, accessed 26 July 2021).

9. Quality management system – medical devices – nonconformity grading system for regulatory purposes and information exchange (document GHTF/SG3/N19:2012). Global Harmonization Task Force Study Group 3; 2012 (*http://www.imdrf.org/documents/doc-ghtf-sg3.asp*, accessed 26 July 2021).

10. Essential principles of safety and performance of medical devices (document GHTF/SG1/N68:2012) Global Harmonization Task Force Study Group 1; 2012 (*http://www.imdrf.org/docs/ghtf/archived/sg1/technical-docs/ghtf-sg1-n68-2012-safety-performance-medical-devices-121102.pdf*, accessed 26 July 2021).

11. Clinical evidence for IVD medical devices – key definitions and concepts (document GHTF/SG5/N6:2012). Global Harmonization Task Force Study Group 1; 2012 (*http://www.imdrf.org/docs/ghtf/final/sg5/technical-docs/ghtf-sg5-n6-2012-clinical-evidence-ivd-medical-devices-121102.pdf*, accessed 26 July 2021).

12. Medical device regulatory audit reports (document IMDRF/MDSAP WG/N24 FINAL: 2015). IMDRF MDSAP Working Group; 2015 (*www.imdrf.org/docs/imdrf/final/technical/imdrf-tech-151002-mdra-audit-report.docx*, accessed 26 July 2021).

13. Guidelines for auditing management systems (ISO 19011:2018). Geneva: International Organization for Standardization; 2018.

Other reference documents

Reference documents not included in the reference list.

Clinical and Laboratory Standards Institute

1. Evaluation of stability of in vitro diagnostic reagents: approved guideline (document CLSI EP25A, Vol.29, No. 20). Annapolis Junction (MD): Clinical and Laboratory Standards Institute; 2009 (https://clsi.org/standards/products/method-evaluation/documents/ep25/, accessed 26 July 2021).

European Commission

1. The standards listed at the following website are harmonized standards and thus lead to presumption of conformity with the relevant essential requirements:
(https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards/medical-devices_en, accessed 26 July 2021).

2. Common technical specifications on IVD are published under Other amending and implementing legislation at https://ec.europa.eu/health/sites/default/files/md_sector/docs/md_imp_measures_dir_key_docs.pdf, accessed 26 July 2021).

Global Harmonization Task Force (GHTF)

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IMDRF Medical Device Single Audit Program documents used in the piloting programme
All documents available at https://www.fda.gov/medical-devices/medical-device-single-audit-program-mdsap/mdsap-audit-procedures-and-forms.

1. MDSAP_AU_P0008: Audit time determination procedure.
2. MDSAP_AU_F0008.1: Audit duration calculation form.
3. MDSAP_AU_P0019: Medical device regulatory audit reports policy.

International Organization for Standardization (ISO)
All standards available at https://www.iso.org/standards.html.

1. ISO 13485:2016 Medical devices – quality management systems – requirements for regulatory processes.
2. ISO 14971:2019 Medical devices – application of risk management to medical devices.
3. ISO 9000:2015 Quality management systems – fundamentals and vocabulary.
4. ISO 23640:2011 In vitro diagnostic medical devices – evaluation of stability of in vitro diagnostic reagents.
5. ISO 15223-1:2016 Symbols to be used with medical device labels, labelling and information supplied. Part 1 General requirements.
6. ISO 2859-10:2006 Sampling procedures for inspection by attributes. Part 10: Introduction to the ISO 2859 series of standards for sampling for inspection by attributes.

Annex. Example of inspection timetable for a manufacturing site

The table below is an example of a timetable for an NRA inspection of a manufacturing site. Times may be modified to comply more fully with the daily production routine. The length of the on-site inspection will vary according to inspection requirements.

Day	Time	Inspection activity
Day 1	9:00–10:00	Opening meeting
		Introduction of personnel and overview of the manufacturing site
		Inspection by the Authority lead inspector; overview of manufacturing process, principal staff and quality system by manufacturer
	10:00–11:30	Facility tour
	11:30–13:00	Inspection of one or more of the following processes:
		quality system: management responsibility, including interviews with senior management
		planning of product manufacture, customer-related processes, design and development, purchasing
		quality system: quality management system
		production and service provision, control of monitoring and measuring devices
		quality system: resource management, measurement analysis and improvement
	13:00–13:45	Lunch break (on-site)
	13:45–16:45	Inspection (continued): one or more of the above QMS processes
	16:45–17:00	Daily wrap-up meeting: inspectors report briefly to manufacturer on the day's findings
Days 2–3	All day	Short opening meeting to schedule activities
		Inspection continued as above and as required, including breaks
		Daily wrap-up meeting
Final day	9:00–12:30	Inspection (continued)
	12:30–13:15	Lunch break (on-site)
	13:15-16:00	Inspectors meeting: discuss findings, prepare draft on-site report
	16:00–17:00	Closing meeting: present outcome and draft report of the inspection of the manufacturing site(s), and discuss findings with manufacturer