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Audit checklist – interpretation guide

Developed in support of the common Audit Checklist of the European Economic Area Joint Audit Programme (EEA JAP), the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Accession and Joint Reassessment Programme and the Health Canada Mutual Recognition Agreement (MRA) evaluation programme.

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MRA/JAP/PIC/S Audit Checklist* - Interpretation guide

Purpose

The interpretations provided in this guide have been written with a view to facilitate the understanding of each indicator, to harmonise expectations and enhance consistency when proceeding with an assessment of a competent authority's Good Manufacturing Practices (GMP) regulatory compliance programme. A GMP regulatory compliance programme is not limited to the GMP inspection process but also includes components such as the supporting infrastructure of legislative and regulatory requirements, GMP standards, inspection/enforcement resources and procedures, performance standards, alert and crisis system, analytical capability, surveillance programme and quality management systems.

The term "Inspectorate" in the context of this document includes all organisational structures in charge of any of the above listed components of a GMP regulatory compliance programme.

Note that the scope of the evaluation, e.g. PIC/S Accession, PIC/S Joint Reassessment Programme (JRP), MRA evaluation, European Economic Area Joint Audit Programme (EEA JAP), will dictate the baseline standard to be used in order to consider the indicator as fulfilled/equivalent.

Product targeted by the evaluation is defined in the checklist's glossary as Active Pharmaceutical Ingredient (API), finished medicinal product, investigational medicinal products, or any intermediate.

Background information:

The GMP regulatory compliance programme checklist is based on 11 components and 38 sub-components comprising a total of 78 indicators.

- There are 8 sub-components considered critical, 14 sub-components considered as very important and 3 sub-components are important (at the time of the creation of the checklist, 13 sub-components were combined with other similar sub-components to facilitate the evaluation).
- There are 48 indicators related specifically to the critical sub-components, 26 indicators for the very important sub-components and 4 for the important sub- components.

* See Audit Checklist

INTERPRETATION GUIDE	
Indicator	

Disclaimer: The content of this document should not be regarded as the only possible interpretation of the indicator, nor does it intend to cover every situation.

Sub-component 1A Legislative and regulatory requirements and scope - Empowering legislation (Critical)	
1	**The legislation identifies key delegations and functions in the organisation(s)/ regulatory authority (ies) assigned for overall responsibility for the GMP regulatory compliance programme.** Interpretation: Documentation review This indicator pertains to the Legal Status of the Authority or Authorities. - Verify if the legislation specifies an authority or authorities responsible for the regulation of medicines at national and/or regional level. - Verify that the legislation details the responsibilities of the authority or authorities with regards to key aspects of the GMP regulatory compliance programme. - If the authority under assessment is responsible for the regulation of both human and veterinary medicinal products, both competencies should be evaluated. Evidence example: National legislation or official orders that have the force of law. If responsibility is shared between authorities, check that there are agreed arrangements in place that ensure the correct functioning of the GMP regulatory compliance programme.

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2	**The authority to designate inspectors is vested in legislation.** Interpretation: Documentation review The designation referred to in this indicator must be seen as assignment of an employee in the role of inspector. It is not related to recruitment of personnel. **-** Verify in the legislation that there is a provision for appointing inspectors and who is authorised to do so. The provision might be of a general character, e.g. that a Director General within the Government / civil service is authorised to designate staff members. **-** Written legal authorisation to appoint designate staff members should be in place. **-** The process for designation of inspectors is verified under sub-component 2A indicator 24.
3	**The identity of designated inspectors and scope of jurisdiction of legislation are available to companies being inspected.** Interpretation: Documentation review

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	- Verify that the inspector is required to produce, upon request by a company, the designation document and the scope of jurisdiction of legislation. - Each inspector may have an ID pass/a written permit or any other form of designation document which signifies authority to carry out inspection on behalf of a competent authority. - The designation document (e.g. ID pass/ written permit or other form of designation) may contain information on the scope of jurisdiction. - Inspected entities can verify the identity of the inspectors and the scope of activities when the information is in the public domain. Evidence examples: Select individual records of a few inspectors for review among the list of designated inspectors
4	**There is legal authority for an inspector to enter at any reasonable time in any place where active pharmaceutical ingredients and / or medicinal products are manufactured, imported and exported.** Interpretation: Documentation review - Verify in the legislation that there is a provision allowing inspectors to access, at any reasonable time, places where manufacturing, packaging, storage, testing, importation and exportation activities are conducted.

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	- There may be cases where inspectors are physically prevented from carrying out the inspection, and may request the help of a law enforcement group (e.g. police or customs department). This situation should be addressed in the legislation or there should be articles in the legislation empowering the said group. Cooperation between the two concerned organisational structures should be defined in appropriate documentation.
5	**There is legal authority for taking samples and submitting them to designated laboratories.** Interpretation: Documentation review **-** Verify in the legislation that there is a provision that allow inspectors to take samples, at any reasonable time, in any place where manufacturing, packaging, storage, testing, importation and exportation activities are conducted. The sample taken may be submitted to a laboratory designated by the competent authority for official testing. **-** The samples in this indicator should not be confused with samples mentioned under sub-component 10A indicators 66 and 67, where sampling is related to the market surveillance programme. Evidence examples: national legislation, competent authority written procedures relating to sampling and sending them to designated laboratories.
6	**There is legal authority for obtaining evidence such as documents, photographs/videos of premises and equipment.** Interpretation: Documentation review

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	- Verify that there is a provision in the national legislation for inspectors to request, view and assess materials at site or to take the originals or copies away, in order to verify compliance with GMP. - The provision for this may be in the national medicines legislation or it may be in other national legislation, e.g. to allow a law enforcement representative (e.g. police or customs officer) to accompany the inspector to obtain these materials. - There should also be provision for actions which the inspector or competent authority can take in situations where the site does not provide the materials following reasonable request by the inspector. - The process for how to deal with these situations should be in a written procedure (may need to link this to the correct handling of materials, possibly as evidence). Evidence examples: national legislation, competent authority written procedures relating to obtaining manufacturer's batch manufacturing documents and other written or electronic records or to take photographs or videos.
7	**There is legal authority to open and examine any article subject to legislation.** Interpretation: Documentation review - Verify that the national legislation provides the right to the designated inspectors to open and examine any article (e.g. medicinal products, APIs, packaging materials, etc.) subject to legislation.

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	Evidence example: related pieces of the national legislation.
8	**There is the legal authority to seize or detain any article believed to be in violation.** Interpretation: Documentation review - Verify in the legislation that there is a provision allowing inspectors to seize or detain any article (e.g. medicinal products, APIs, packaging materials, etc.) connected with an offence or to prevent offences (in particular at places where manufacturing, packaging, storage, testing, importation and exportation activities are conducted) where there may be non-compliance with GMP. - There may be cases where inspectors are not allowed to seize or detain articles and may request the help of a law enforcement group (e.g. police or customs department). This situation should be addressed in the legislation or there should be provisions empowering the law enforcement group. Cooperation between the two concerned organisational structures should be defined in an appropriate documentation. The seizure procedures/mechanisms and records are to be assessed under sub-component 7B indicator 55.
9	**The legislation allows entry to a private dwelling.** Interpretation: Documentation review

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	- Verify if the legislation allows entry to the private dwelling when required such as when suspected illegal manufacturing operations occur. - This may not necessarily be in the medicines legislation but in other national legislation. In some instances, the help of a law enforcement group (e.g. police or customs department) may be requested. Cooperation between the two concerned organisational structures should be defined in an appropriate documentation.
10	**Legislation requires that the person who has the responsibility of the site where active pharmaceutical ingredients and medicinal products are manufactured, imported and exported, to cooperate and not obstruct an inspector.** Interpretation: Documentation review - Verify in the legislation that the person, who has the responsibility for the site where active pharmaceutical ingredients and / or medicinal products are manufactured, imported and exported, have to cooperate and not obstruct an inspector. - The "person" could be also indicated as the authorised manufacturer, Senior Management, the person designated for quality or any other legal person with GMP responsibilities. - There may be cases where this provision is not specifically addressed in the national legislation. In this case, the auditor should evaluate if the same principle is addressed in a different way in the legislation and if the approach provides the inspector with an equivalent level of cooperation.

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Indicator 1.1	**Legislation requires a marketing authorisation holder and/or a manufacturer of medicinal product to report to the regulatory authority any serious adverse medicinal product reactions.** Interpretation: Context This indicator has originally been added to the audit checklist to address the requirement included in the MRA agreement Appendix 4 under component 10-Surveillance programme; "Adverse reaction reporting system/procedures" but, as specified under sub-component 10D-Adverse reaction reporting system/procedures are not to be evaluated as they are not considered within the scope of a GMP regulatory compliance programme. It is considered as an element of a Pharmacovigilance programme. However, it is expected that the legislation includes a requirement for the marketing authorisation holder and/or the manufacturer to report any serious adverse reaction. Documentation review - Verify that there is a provision in the legislation for the marketing authorisation holder and/or the manufacturer to report serious adverse drug reactions (ADRs). - In the situation where the ADR is due to a quality defect, it is expected that the competent authority does the appropriate follow- up with the manufacturer on possible GMP deficiencies. - An adverse reaction to a defective medicinal product may also result in a complaint. The competent authority should proceed with an investigation and take the appropriate actions. The consumer complaint procedure/system and records are assessed under the sub-component 10C.

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12	**Legislation requires the marketing authorisation holder and a manufacturer of active pharmaceutical ingredients or medicinal product to assess, investigate and document any product defect impacting quality.** Interpretation: Documentation review **-** Verify that there is a provision in the legislation that stipulates that any complaint or information received concerning a quality defect shall be recorded and investigated by the marketing authorisation holder and the manufacturer of active pharmaceutical ingredients or medicinal product. Note that this indicator does not pertain to the reporting of product quality defects to the competent authority. **-** Defective product may result of faulty manufacture, out-of-specification (OOS) result, product deterioration, detection of falsification, or any other serious quality problems. **-** GMP standards must define competent authority's expectations in terms of management of product complaints or suspected defective product information received, its assessment, its investigation and corrective/preventive measures taken. This is to be verified under sub-component 3A indicator 27.
13	**Legislation requires the marketing authorisation holder and/or the manufacturer to notify a competent regulatory authority before or upon commencement of a recall of medicinal product and to submit pertinent information.** Interpretation: Documentation review

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	- Verify that there is a provision in the legislation for the marketing authorisation holder (MAH) and/or the manufacturer to notify the competent authority upon commencement of a recall of medicinal product from the supply chain. **-** The requirement for the MAH or manufacturer to inform the competent authority about the reason for the recall should also be stated in the legislation.
14	**All companies that manufacture, import, export medicinal products or active pharmaceutical ingredients, are required to hold a manufacturing authorisation or be a registered company for active pharmaceutical ingredients.** Interpretation: Documentation review **-** Verify in the legislation that there is a provision for a person/company engaged in the activities mentioned above to hold an authorisation or to be registered. Note: The authorisation must be required for total as well as partial manufacture (intermediates) and for products/intermediates intended for export only (ref. indicator 21). **-** The exportation and distribution activities are included in the indicator when it is part of other activities covered by the authorisation. When these activities are standalone, they are not within the scope of this indicator. **-** For the licensing of the contract laboratories two different approaches can be accepted. Either they can hold a separate manufacturing authorisation/establishment licence (EL) or they can be named on the manufacturing authorization/ EL of the company to whom they provide services.

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	- For active substances intended for the manufacture of human medicinal products, there must be a provision that manufacturers, importers, exporters or distributors to be registered with the competent authority. A provision to hold a manufacturing authorisation/ EL for API manufacturers is considered to be equivalent to registration. Evidence example: related authorisations or registrations should be checked on a random basis (in line with indicator 16).
15	**The holder of the manufacturing authorisation is required to notify the regulatory authority of significant changes or of conditions, which may affect the quality, safety or efficacy of a medicinal product.** Interpretation: Documentation review **-** Verify that there is a provision in the legislation for the manufacturing authorisation/ establishment licence holder to inform the relevant competent authority where changes to the authorisation are considered. Significant changes or conditions that differ from the original authorisation are required to be reported. **-** The requirement to notify the competent authority before introducing changes may also be included in the legislation.
16	**Legislation requires that the manufacturing authorisation include: the address of each site, the manufacturing activities, the category of medicinal product, and the dosage form.**

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	Interpretation: Documentation review - Verify that information required to be indicated on the manufacturing authorisation/ establishment licence (EL) is specified in the legislation. It must include, as a minimum, each site's address, the activities for which they are authorised (e.g. manufacture, package, test, import, export, distribute), the category of medicinal products and the dosage form (i.e. scope of the authorisation). - In the case where the information to be included on the manufacturing authorisation/ EL is not specified in the legislation, the legislation should refer to an official document that details all of the above.
17	**Legislation prohibits the processing and sale of active pharmaceutical ingredients or medicinal products under unsanitary conditions or leading to adulteration.** Interpretation: Documentation review - Verify that there is a legal text which ensures that authorised sites for APIs and medicinal products follow rules and guidance to maintain premises, equipment facilities and processes for the handling, control, manufacture, labelling / packaging, storage and distribution of APIs and medicinal products in order to maintain their quality. Evidence example: National legislation that describes the above, details may be in other official documents.

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	For reference: Adulterate definition: make poorer in quality by adding or substituting another undeclared substance; product consists in whole or in part of any filthy, putrid or decomposed substances, not pure or genuine.
18	**Good Manufacturing Practices are legal requirements.** Interpretation: Documentation review - Verify that there is a legal text which enforces current GMP in the national regulation (including national language or specific indication authorising the enforcement of a text written in another language). - Verify that national legislation details the above in a general or specific way.
19	**The legislation specifies that a manufacturer and / or a person is liable for a defective medicinal product and provides for prosecution and/or penalties upon conviction.** Interpretation: Documentation review - Verify in the legislation that a person can be legally held responsible for a defect in a medicinal product. - The liable "person", i.e. authorised manufacturer, Senior Management, the person designated for quality or any other legal person with GMP responsibilities may be prosecuted and/or may have penalties upon conviction.

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20	**There is legislative authority to suspend, revoke or amend a manufacturing authorisation.** Interpretation: Documentation review **-** Verify that the legislation provides the authority to suspend or revoke a manufacturing authorisation/ establishment licence (EL). **-** The authority to revoke part of a manufacturing authorisation/EL may be interpreted as amending a manufacturing authorisation/EL.
21	**Active pharmaceutical ingredients and medicinal products intended for export only are covered by the same or equivalent legislation as the products intended for the domestic market.** Interpretation: Documentation review - Verify that there is a provision in the legislation that active pharmaceutical ingredients and medicinal products intended for export only are manufactured in accordance with the same or equivalent standards as those for the domestic market. There should be no exceptions for APIs or medicinal products intended for export.
Sub-component 1B Legislative and regulatory requirements and scope – conflict of interest (Very important)	
22	**A policy/guideline exists that details the situations regarded as conflict of interest.**

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Indicator	
	Interpretation: Documentation review - Verify that a document exists and is implemented that requires the competent authority's employees to adhere to a conflict of interest policy to maintain public confidence in the objectivity of the public service by preventing and avoiding situations that could give the appearance of a conflict of interest, result in a potential for a conflict of interest or result in an actual conflict of interest. - The policy/guideline should outline how to prevent/avoid conflict of interest and specifically with regards to assets/liabilities, outside employment/activities, gifts/hospitality and solicitation. - The document should explain the process when a real or an apparent conflict of interest is declared and any restrictions taken.
23	**Employees are required to declare their compliance with the conflict of interest policy.** Interpretation: Documentation review - Verify that there is a provision that requires employees involved in the GMP regulatory compliance programme, to declare on a regular basis their compliance with the conflict of interest (CoI) policy and to report any potential conflict. - Reporting requirements should be defined i.e. upon hiring, on a regular basis thereafter and every time a major change occurs in the employee's personal affairs or public duties. On-site Evaluation at the Inspectorate and at the Laboratory

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	- Verify CoI declarations for a few staff involved in the GMP regulatory compliance programme. If there are any conflict of interests declared, verify if appropriate measures have been taken.
Sub-component 2A Regulatory directives and policies – Procedures for designating inspectors (Very Important)	
24	**A process for designation of inspectors exists.** Interpretation: Documentation review The designation referred to in this indicator must be seen as assignment of an employee in the role of inspector. It is not related to recruitment of personnel (as stated under indicator 2). - Verify that there is a process for assigning inspectors defined in a written document such as in the legislation or in a procedure. The procedure should also include provisions for withdrawal of designation, e.g. resignation, change in job position, etc. Examples of the designation of an inspector are verified under sub-component 1A indicator 3.
Sub-component 2B Regulatory directives and policies – Enforcement Policies	
Included under sub-component 7B Enforcement powers and procedures – Non-compliance management	
Sub-component 2C Regulatory directives and policies – Code of conduct (Very important)	
25	**A policy/guideline exists that details situations regarded as Code of Conduct.**

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	Interpretation: Documentation review - Verify that there is a document available which defines the Code of Conduct that the employees involved in the GMP regulatory compliance programme have to follow. This document should outline the values and expected behaviours that guide employees in all activities related to their professional duties. Employees should be periodically reminded of their obligations/responsibilities with respect to the Code of Conduct. - Verify if an actual Code of Conduct is available i.e. within the quality management system or publicly.
Sub-component 2D Regulatory directives and policies – Training certification policies/guidelines	
Included under sub-component 4C Inspection resources – Training programme	
Sub - component 2E Regulatory directives and policies – Alert/crisis management policies/procedures/guidelines	
Included under sub-component 8A Alert and crisis systems – Alert mechanisms	
Sub-component 2F Regulatory directives and policies – Organisational structure	
Included under sub-component 11A Quality management system	
Sub-component 3A GMP Standards - Details/ scope of GMP (Critical)	
26	**(this indicator has been combined with ind. 27)**

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27	**The GMP regulatory framework covers all GMP requirements including but not limited to: quality management, premises, equipment, personnel, sanitation, raw material testing, manufacturing control, quality control department, complaints, product recalls, packaging material testing, finished product testing, records, samples, stability and sterile products.** Interpretation: Documentation review - Verify that regulated GMP, as stated under sub-component 1A indicator 18, are supported by current version of GMP standards/guidelines for medicinal products and for active pharmaceutical ingredients used as starting materials. - All the elements listed above should be included and should be sufficiently detailed to ensure the adequate manufacture of medicinal products and APIs. The requirements are fully endorsed and implemented to ensure that the most up to date version is enforced. - A mechanism for the updating of GMP has been defined and is followed.
Sub-component 3B GMP Standards – Process validation	
Included under sub-component 3A GMP Standards – Details/scope of GMP	
Sub-component 4A Inspection resources – Staffing: Initial qualification (Very important)	
28	**The minimum qualifications for GMP inspection staff are defined.**

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	Interpretation: Documentation review This indicator relates to the initial qualifications for hiring staff, in particular GMP inspectors. - Verify that there is a document that describes the minimum prerequisite competencies (including education and experience) for GMP inspectors and staff involved in the inspection process. - Review recruiting documentation that specifies prerequisites for inspectors and other staff. Review vacancy announcement, curriculum vitae, resume, and minimum qualifications listed in the job description. The verification of qualification evidences is under sub-component 4A indicator 30.
29	**Duties of staff involved in the GMP regulatory compliance programme are defined.** Interpretation: Documentation review - Verify that there is a document (job description, SOP) describing the functions of each type of role related to the GMP regulatory compliance programme. On-site Evaluation at the Inspectorate - Verify that job description forms and evidence of acknowledgement of the key functions by the personnel involved in the GMP

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	regulatory compliance programme are available. - Select a few key positions for review.
30	**Evidence exists that the GMP inspectors meet the minimum qualifications.** Interpretation: On-site Evaluation at the Inspectorate **-** Verify that records/ evidence are available to demonstrate that all GMP inspectors meet the minimum qualifications. Minimum qualifications are defined under sub-component 4A indicator 28. **-** Select individual records of a few inspectors for review e.g. qualifications of the inspectors assigned for the observed inspections.
Sub-component 4B Inspection resources – Number of inspectors (Very important)	
31	**The number of inspectors dedicated to the GMP inspection programme is sufficient to meet the prescribed inspection frequency/inspection programme.** Interpretation: Documentation review - Verify that the number of inspectors is sufficient to perform the inspections prescribed by the inspection programme. A

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	significant number of overdue inspections could be an indication that perhaps the number of inspectors is insufficient. - Verify the inspection plan and individual records for planned and performed inspections for each inspector. On-site Evaluation at the Inspectorate - Verify individual records to ensure that the number of inspections/inspection days represent a reasonable workload for each inspector and that all inspections allocated and related activities (e.g. issuance of the report) have been performed or planned for. Consider that inspectors might be involved in other work not directly related to inspections. - Verify if the competent authority has the capacity to meet the inspection programme and if there is a backlog of inspections. Note that this indicator is linked to sub-component 5A indicators 34 and 35.
Sub-component 4C Inspection resources – Training (Very important)	
32	**A training programme for inspectors is established and records are maintained.** Interpretation: Documentation review - Verify that a procedure is available describing the training program for inspectors. The procedure should describe the training for new inspectors as well as for experienced inspectors. It should describe if there are different levels of inspectors, which require specific levels of training (e.g. non-sterile, sterile, biopharmaceuticals, ATMP's, herbals etc.). The procedure should also describe how training is recorded and how (re) qualification for all levels is monitored.

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	On-site Evaluation at the Inspectorate - Review the training procedure and training program/records/database, including qualification status of inspectors. - Select a few GMP inspector's training files for review e.g. training files of the inspectors assigned for the observed inspections.
33	**A mechanism to evaluate the effectiveness of training exists.** Interpretation: Documentation review - Verify that a documented mechanism exists whereby the effectiveness of the training followed by GMP inspectors is evaluated. - Verify that the principle for effectiveness evaluation and examples of possible evaluation are described in the procedure on training. - Possible ways to evaluate effectiveness are: test at the end or after the training, feedback survey at the end of the training, report on the training, presentation on the training to colleagues, observation by or discussion with mentor or manager. On-site Evaluation at the Inspectorate - Verify that the mechanism of effectiveness evaluation of training is in place and followed. - Verify the training records of a few GMP inspectors, e.g. the inspectors of the observed inspection, and check if the effectiveness of the training for the inspector was evaluated and documented (link with indicator 32).

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Sub-component 4D Inspection resources – QA mechanism to assure effectiveness of training programme	
Included under sub-component 4C Inspection resources – Training programme	
Sub-component 5A Inspection procedures – Inspection strategy (Very important)	
34	**Documents that describe the work expected, anticipated results and resources applied to fulfil the functions of GMP inspections are available.** Interpretation: Documentation review - Verify that a documented planning process exists that outlines the steps that must be taken to establish the deliverables, associated targets/milestones and resource requirements to fulfil the GMP inspection program for a given period of time. - The plan should be updated when necessary and senior management should be made aware of the status of the plan. On-site Evaluation at the Inspectorate - Select a work plan for review and verify that the elements listed in the indicator are covered. - Verify that available resources of GMP inspectors are sufficient to fulfil the GMP Inspection program Note that this indicator is linked to indicator 31 and the performance of the plan is to be verified under sub-component 11A indicator 74.

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35	**A scheduling system identifies companies due for inspections within a set time frame.** Interpretation: Documentation review - Verify that there is an inspection planning system in place. The system lists companies, the inspection intervals, appointed inspector(s) and is prepared according to risk management principles. Inspection plan should be prepared for a given period of time. On-site Evaluation at the Inspectorate - Verify the scheduling system used to plan inspections. Ensure that companies due for inspection and the inspection frequency are in line with the internal processes. - Verify also consistency with sub-component 4B indicator 31.
Sub-component 5B Inspection procedures – Pre-inspection preparation (Very important)	
36	**A procedure details the requirements for pre-inspection activities, and is followed.** Interpretation: Documentation review - The pre-inspection activities referred to in this indicator relate to preparations for inspection after the inspection has been

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	scheduled. - Review the procedure(s) that specify the various task elements that inspectors should complete prior to the start of the inspection. Elements such as sending notification (or not) to the company, reviewing relevant documents, developing an inspection plan, etc. Verify if there is sufficient detail in the procedure(s) to ensure a consistent approach towards inspection preparations and that the activities are recorded. On-site Evaluation at the Inspectorate/observed inspection - Verify if the pre-inspection activities for the observed inspection(s) have been completed and review the relevant records or database if used.
37	**The inspection plan is based on the company's GMP compliance history, critical activities and type(s) of dosage forms or products manufactured.** Interpretation: On-site Evaluation at the Inspectorate - Verify that the inspection plan follows a risk-based approach. - Verify that a quality risk-management tool is in place taking into account the company's compliance history, complexity of the site, critical activities and dosage forms to determine the risk-based inspectional approach. Observed inspection

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	- Verify that an inspection plan is available for the observed inspection. - The intrinsic risk of the site is checked/ proved during inspection. After the inspection the risk status of the site has to be confirmed or amended using the foreseen template.
Sub-component 5C Inspection procedures – Format and content of inspection reports (Very important)	
38	**A procedure for the format and content of inspection reports is available.** Interpretation: Documentation review - Verify that there is a procedure that specifies the format and content of inspection reports. - Review the inspection report templates, to ensure the content include all requirements as specified in the procedure such as information on the production operations of the inspected facility including but not limited to: list of products manufactured, description and assessment of the manufacturing processes, and an explanation of observations/deficiencies and associated risk.
39	**Observations are factual and are based on proper interpretation of applicable legislation.** Interpretation: Observed inspection - This indicator is to be verified during the "observed" part of the evaluation.

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	- The inspectors must be able to demonstrate that the observations are based on facts (e.g. evidences) and are fully justified according to the GMP requirements or other legislative requirements. - The inspector should be able to identify if any observations have an impact on product/patient safety and determine if the issue is systemic or if it is an isolated case. - The auditors must pay attention to the observation noted, the moment of detection, the questions posed by the inspector and the discussions that occur with the inspectees. - The inspector should be consistent in their approach.
40	**Observations are classified/categorised according to risk.** Interpretation: Documentation review -Verify that the competent authority has defined a classification/ categorisation system for observations according to risk. Observed inspection - Verify through the observed inspections and the review of inspection reports (randomly) that observations made during inspections are appropriately classified/ categorised according to risk. - The inspector should be consistent in their approach.

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41	**Assessment of the company's overall compliance status is in line with the inspection findings.** Interpretation: - Assess this indicator in line with indicator 37 Observed inspection - Verify if the compliance status from the observed inspection(s) are in line with the findings. The relevant inspection procedures should require assessment of the overall compliance and recording of this status in the report as well as relevant databases after each inspection. - It is preferred to assess the overall compliance status assigned from the observed inspection(s); however, this can also be achieved through the review of previous/recently completed inspection reports.
42	**Inspection reports are completed in the required reporting format and timeframe.** Interpretation: Observed inspection - Verify that reports of the inspection are completed in the format that is described in the procedure in indicator 38. The timeframe for completing the report should be realistic and reflect the requirements described in the inspection procedure. - It is preferred to review the inspection reports issued for the observed inspections to evaluate if the requirement for the format and timelines are met. However, this can also be achieved through the review of previous/recently completed inspection reports.

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Sub-component 5D Inspection procedures – Inspection methodology	
Included under sub-components 5E Inspection procedures – SOP for conducting inspections	
Sub-component 5E Inspection procedures - SOP for conducting inspections (Critical)	
43	**A procedure details the requirements for conducting inspections, and is followed.** Interpretation: Documentation review - Verify that procedure(s) is/are present providing sufficient details and guidance on the breadth and depth of individual inspections. - Verify that procedure(s) describe(s), as a minimum, the following steps for conducting inspections: • opening meeting • plan tour • documentation review • observation of on-going activities • closing meeting Observed inspection

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	- The adherence to the procedure by the inspectors is verified by observation of inspection(s).
44	**Critical stages and parameters of manufacturing processes are assessed.** Interpretation: Observed inspection - This indicator is to be verified during the "observed" part of the evaluation and is linked to the inspection plan/agenda. - The inspector should select and assess critical stages and parameters related to the manufacturing processes of the inspected site. This may also include review of the process used by the manufacturing site for defining "critical stages" and "parameters".
45	**Qualification and validation are assessed**. Interpretation: Observed inspection - This indicator is to be verified during the "observed" part of the evaluation and is also linked to the inspection plan/agenda. - The inspector should select and assess validation reports for critical manufacturing and cleaning processes as well as equipment/utilities qualification reports related to the operations of the inspected site. This may also include review of the validation master plan, test method validation and the qualification of computerised systems.

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46	**The inspection plan/agenda is adjusted, where warranted, based on the findings of the inspection.** Interpretation: Observed Inspection - This indicator is to be verified during the "observed" part of the evaluation. - Observe if the inspectors are modifying their plan in order to address situations seen/found during the course of the inspection, as necessary.
47	**The depth of the inspection is appropriate and based on the findings of the inspection.** Interpretation: Observed inspection - This indicator is to be verified during the "observed" part of the evaluation and is also linked to the inspection plan/agenda. - Verify that significant issues found on site are followed up in depth and that insignificant issues are not dwelt upon – so to avoid a checklist approach where all findings are given equal weight.
Sub-component 5F Inspection procedures – Post-inspection activities (Very important)	
48	**A procedure details the requirements for post-inspection activities, and is followed.**

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	Interpretation: Documentation review - Verify that a documented system exists describing the activities to be performed by the members of the inspection team and inspectorate staff and/or managers after the inspection. - Verify the description of at least the following topics: • Inspection report preparation, review and finalisation; • Request for comments and CAPA plan from the inspected company; • Assessment of the CAPA plan and follow-up of the CAPA implementation; • Risk management for next inspection; • Handling of GMP non-compliance; • Archiving of inspection documents (link with indicator 50). On-site Evaluation at the Inspectorate - Verify that the system is in place and followed. - During the preparation of the observed inspection, verify for the previous inspection at the company that all post-inspection activities were performed as per the procedure. Review the relevant records and databases, if used. Observed inspection

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	- At the end of the observed inspection(s), verify that the planned post-inspection activities are in line with the procedure. However, this can also be achieved through the review of previous/recently completed inspections.
49	**Inspection findings and conclusions are subject to an internal review.** Interpretation: Documentation review **-** Verify that a process exists for the review of the inspection report before its finalisation and issuance to a company. The process should describe the review and approval steps. The review could be conducted either by a peer, a supervisor or any other person with appropriate expertise. The goal is to ensure: • uniformity and consistency among inspectors; • the content of the written observations is valid and supported by the regulations; • observations/deficiencies are properly risk rated; • conclusion is in line with the observations noted. On-site Evaluation at the Inspectorate **-** Select inspection records for review and verify that the internal review process has been followed. Observed inspection **-** Verify that the review process has been followed for the sites selected for the observed inspections. However, this can also be achieved through the review of previous/recently completed inspections.

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Sub-component 5G Inspection procedures – Storage of inspection data (Important)	
50	**A policy/procedure is available for the storage of inspection data.** Interpretation: Documentation review - Verify that a process exists establishing how to store inspection data. This process should ensure that a comprehensive documentation system is maintained. The policy/procedure should determine responsibilities (who), coverage (what), storage location (where) and timeframes (how long).
51	**An inspection report database (or archive) is maintained in a secure and controlled manner.** Interpretation: On-site Evaluation at the Inspectorate **-** Verify if access to the report filing system or database is restricted or controlled. Verify that inspection reports are protected i.e. cannot be modified or removed when finalised. **-** Select one or two reports to verify they can be retrieved.
Sub-component 6A Inspection performance standard – Performance standards (Very important)	
Included under sub-component 11A Quality management system – Quality management system	

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Sub-component 7A Enforcement powers and procedures – Provision for written notice of violations	
Included under sub-component 7B Enforcement powers and procedures – Non-compliance management	
Sub-component 7B Enforcement powers and procedures - Non-compliance management (Critical)	
52	**There is provision for written notice of violations to be sent to the company.** Interpretation: Documentation review This indicator pertains to informing the regulated party of failure to comply with the legislation. This is applicable, for example, to GMP inspection outcome or to the result of a complaint investigation or to any other violations noted including those of criminal nature. - Verify that procedures are in place detailing the activities to be performed for implementing the legislative provisions and the related timeline. - Ensure that adequate communication channels are in place in cases where different departments within the competent authority are responsible to notify the site in violation. On-site Evaluation at the Inspectorate - Select few files for review. Verify forms, letters, or any other documents issued by the competent authority to inform companies of violations noted.

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	- When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.
53	**Recall procedures/mechanisms and records are available.** Interpretation: Documentation review **-** Verify if there are mechanisms in place for overseeing the recall processes of medicinal product from the market. Assess if the processes are sufficiently described in the procedures. On-site Evaluation at the Inspectorate **-** Review the documentation of at least one recent recall case and verify that records are maintained which include details regarding the decisions taken and timelines applied. **-** When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.
54	**GMP certificates, manufacturing authorisation suspension/withdrawal procedures/mechanisms are available and a list of suspended/withdrawn authorisations/GMP certificates is maintained**. Interpretation:

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	Documentation review This indicator supports sub-component 1A indicator 20. - Verify that there are procedures in place, which describe the process of suspension and withdrawal of GMP certificates (or equivalent) and manufacturing authorisations/ establishment licence. Assess if the suspension/withdrawal mechanisms are sufficiently described in the procedures. - Verify that the competent authority has a notification process in place to inform regulatory partners of non-compliant inspection rating. On-site Evaluation at the Inspectorate - Verify that there is a list, register or database of suspended and withdrawn authorisations and GMP certificates (or equivalent). - Select few files for review and verify that processes were followed.
55	**Seizure procedures/mechanisms and records are available.** Interpretation: Documentation review

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	This indicator supports sub-component 1A indicator 8. - Where inspectors are empowered to seize products, verify that there are procedures in place, which describe the process of seizure. Assess if the seizure mechanisms are sufficiently described in the procedures. - Where inspectors are not allowed to seize or detain articles and the responsibility is delegated to a law enforcement group, e.g. police or customs department verify the communication process in place. On-site Evaluation at the Inspectorate - Review examples of records related to seizures and verify if the processes were followed. - Verify the communication process in place in cases where inspectors are not allowed to seize or detain articles and the responsibility is delegated to a law enforcement group e.g. police or customs department. - When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.
56	**Prosecution procedures/mechanisms and records are available.** Interpretation: Documentation review - Verify whether the competent authority has the legal tools and that mechanisms exist to initiate the prosecution process in case

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	of breaches of the legislation by a company. Specifically, details are provided on how to handle these cases, the decision- making process, how to escalate and formats of notification letters. Records of decision on whether to prosecute or not are maintained and available for review. - The legal liability of the manufacturer/person is covered under sub-component 1A indicator 19. On- site Evaluation at the Inspectorate - Review examples of prosecution records and verify that processes were followed. - When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.
Sub-component 7C Enforcement powers and procedures – Appeal mechanism (Important)	
57	**Appeal procedures/mechanisms and records are available.** Interpretation: Documentation review - An appeal mechanism should be set up so that decisions of the competent authority can be subject to appeal. - Verify that there is an actual document available dealing with how to process appeals, including keeping records of appeals.

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	On-site Evaluation at the Inspectorate - Verify if appeals are dealt with according to procedures and that records are maintained.
Sub-component 7D Enforcement powers and procedures – Other measures	
Included under sub-components 7B Enforcement powers and procedures – Non-compliance management	
Sub-component 8A Alert and crisis systems - Alert mechanisms (Critical)	
58	**Two-way alert procedures/mechanisms and records are available.** Interpretation: Documentation review The legislative provision to notify the competent authority of a recall is covered under sub-component 1A indicator 13. **-** Verify that there are procedures in place that describe the process to evaluate the information received regarding defects in medicinal product/API and to transmit the information within applicable timelines. When urgent action is required to protect public or animal health by means of a rapid alert relating to the recall of medicinal products/API, which have quality defects or which are falsified, or to transmit other information, such as cautions-in-use, product withdrawals for safety reasons or for any follow-up messages to competent authorities. On-site Evaluation at the Inspectorate **-** Verify that a list/register or database exists and is maintained for the transmission of the information to the relevant competent

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	authorities. - Verify that the processes were followed by selecting and reviewing examples of Two-way alert records.
Sub-component 8B Alert and crisis systems – Crisis management mechanisms	
Included under sub-component 8A Alert and Crisis systems – Alert mechanisms	
Sub-component 8C Alert and crisis systems – Alert performance standards (Important)	
59	**Performance standards for the transmission of two-way alert are established and are followed.** Interpretation: Documentation review - Verify process established for ability to review, respond and issue notifications for quality defects as well as the Key Performance Indicators (KPI) defined for the process. - Verify that procedures or program exist and include metrics, timeframes, and a program for review. On-site Evaluation at the Inspectorate - Verify that a system is established to handle quality defects within a defined timeframe.

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	- Verify the actual implementation and adherence to established program. - Verify that established timelines are met. - Verify if KPIs are met (in line with indicators 58 and 74).
Sub-component 9A Analytical capability - Access to laboratories (Critical)	
60	**The regulatory authority has access to laboratories capable of conducting necessary analyses for the purpose of official testing.** Interpretation: Documentation Review - Verify that there is a laboratory, or laboratories with sufficient expertise to conduct tests as required by the competent authority. This can include routine samples such as; samples taken at inspection, samples taken from market surveillance or for other tests required by legislation - For laboratories conducting test on samples for prosecution purposes, which may include customs and other law enforcement agencies, the laboratory needs to be capable of handling samples in a forensic (e.g., fully traceable, avoidance of contamination) manner. - If the laboratory is not part of the competent authority, verify that an agreement or similar exists (refer to ind. 61).

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	On-site Evaluation at the Laboratory - Proceed with an evaluation of the testing capabilities of the laboratory (ies). - Select few test records for review. It may not be necessary to proceed if the capability of the laboratory has been assessed within the last 5 years, supported by an ISO17025 or EDQM accreditation, and the scope of the accreditation includes all tests required under the responsibility of the competent authority.
61	**Regulatory Authority's or contract laboratories are qualified according to a recognised standard.** Interpretation: Documentation Review - Verify that an accreditation/qualification regarding the activity related to quality control of medicinal products and API exists (e.g. ISO17025, EDQM attestation of OMCL). In this field, it is important to determine if the scope of the qualification/ accreditation is covering all tests for products under its responsibility. On-site Evaluation at the Laboratory - Verify the official qualification document. - If a contract laboratory is used, verify that:

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	• qualification document is available to the competent authority; • records for tests are available and reviewed by the competent authority; • technical agreement or similar exists; • confidentiality arrangement exists and there is no conflict of interests.
62	**All reported product defects obtained in the laboratory are documented and investigated.** Interpretation: Documentation Review Product defects under this indicator pertain to out-of-specification (OOS) results/product failures obtained in the laboratory. - Verify that there is a process in place that requires OOS/product failure observed in the competent authority's laboratory be investigated and documented. This should apply to all non-compliant test results obtained from the analyses performed by the laboratory. - The investigation should include the review of the data, calculations, adherence to the test method, review of instruments, glassware, reference standards, reagents utilised, etc. Verifications should be documented. - Role and responsibilities should also be clearly defined. - When the investigation reveals no identified laboratory error there should be a process in place to communicate the non-compliant result to the Inspectorate for further investigation/follow-up with the manufacturer of the affected medicinal product/API.

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	On-site Evaluation at the Laboratory - Verify that the procedure is in place and if it is followed. - Select and assess documentation generated in support of an OOS/product failure result. Note: If the competent authority decides to rely on a qualified contract laboratory, the competent authority should have access to all of the above information, i.e. copy of the OOS procedure, investigation reports, etc. Refer to indicator 60: it may not be necessary to verify in detail if the above elements have already been assessed within the last 5 years through the ISO17025 or EDQM accreditation process.
Sub-component 9B Analytical capability – SOPs for analytical support (Very important)	
63	**Documents are available that detail the work expected, anticipated results and resources applied to fulfil the functions of the laboratories.** Interpretation: Documentation review - Verify that a documented planning process exists that outlines the steps that must be taken to establish the deliverables, associated targets/milestones and resource requirements to fulfil the activities of the laboratory for a given period of time. - The plan should be updated when necessary and senior management should be made aware of the status of the plan.

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	On-site Evaluation at the Laboratory - Select a work plan for review and verify that the elements listed in the indicator are covered. Refer to indicator 60: it may not be necessary to verify in detail if the above elements have already been assessed within the last 5 years through the ISO17025 or EDQM accreditation process.
64	**Procedures covering all elements of laboratory operations are available and are followed.** Interpretation: Documentation review: Verify that the laboratory procedures are defined and integrated in the quality management system. On-site Evaluation at the Laboratory - Select a few laboratory procedures for review and verify that they are followed. Refer to indicator 60: it may not be necessary to verify all laboratory procedures in detail if the laboratory has been assessed within the last 5 years through the ISO17025 or EDQM accreditation process.

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Sub-component 9C Analytical capability – Validation of analytical methods (Very important)	
65	**The test method validation guideline is equivalent to the ICH standard and records are available.** Interpretation: Documentation review: - Verify that the approach used, for method validation is equivalent to the ICH standards. Note: In some instances, complete method validation may not be required but rather method verification (e.g. pharmacopeia methods). On-site Evaluation at the Laboratory - Verify a few examples of protocols and reports from performed method validations. Refer to indicator 60: it may not be necessary to verify all laboratory procedures in detail if the laboratory has been assessed within the last 5 years through the ISO17025 or EDQM accreditation process.
Sub-component 10A Surveillance programme – Sampling and audit procedure (Very important)	
66	**The market surveillance programme for active pharmaceutical ingredients and medicinal products is developed involving at least the inspection and laboratory departments using risk management principles and covers dosage forms of different medicinal product types.**

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	Interpretation: Documentation review - Verify that a procedure is in place describing the process of how the surveillance sampling plan for APIs and medicinal products is compiled in a structured way, taking into consideration the principles of risk management involving the concerned departments, e.g. inspection and laboratory department and covering dosage forms of different medicinal product types. It is important that samples pulled from the distribution chain are representative. The plan could be a rolling plan or encompass a certain period (e.g. yearly plan). On-site Evaluation at the Inspectorate and the Laboratory - Verify the market surveillance programme as well as the sampling plan. For each sampling plan, the rationale and risk evaluation need to be documented and presented.
67	**The market surveillance programme performance is reviewed annually and records of review are available.** Interpretation: Documentation review - Verify that a process exists to review at least on an annual basis the performance of the market surveillance programme and that these reviews are documented. The Inspection department and/or other departments/divisions in charge of handling quality defects should be part of this review. - Verify the description of at least the following topics:

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	• comparison of the number of samples and analysis planned versus performed • description of reasons for deviation from the programme • review of results (in particular negative outcomes – out of specification results) • recommendations for next year's programme On-site Evaluation at the Inspectorate and the Laboratory - Verify that the system is in place and if it is followed. - Verify that the report from, at least, last year's review is available.
Sub-component 10B Surveillance programme – Recall monitoring	
Included under sub-component 7B Enforcement powers and procedures – Non-compliance management	
Sub-component 10C Surveillance programme - Consumer complaint system (Critical)	
68	**A consumer complaint system/procedure and records are available.** Interpretation: Documentation Review - Verify that there is a consumer complaints system and that all complaints related to medicinal products/API are processed and documented according to a procedure. On-Site Evaluation at the Inspectorate

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	- Verify that records of the handling of consumer complaints do exist at the competent authority and that complaints are handled appropriately according to the established processes e.g. may result in a recall/two-way alert (refer to indicators 53 and 58). - When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.
69	**Issues of high risk are investigated immediately.** Interpretation: On-Site Evaluation at the Inspectorate These are for investigations of complaints received from consumers (e.g. patients, clinical trial subjects, healthcare professionals, employees, whistle blowers, anonymous source, etc.). - Verify that there is a formal documented system for the receipt, assessment and risk classification of consumer complaints, with appropriate timelines for action. - Review whether consumer complaints are being recorded in a timely manner and that timeline targets are being met (these are possible Key Performance Indicators (KPIs) for the regulator-refer to indicator 74). - When different divisions/ departments are involved in this process, the relevant procedures should be defined and implemented accordingly.

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	- Verify that the procedure covers weekends and public holidays.
70	**Compliance staff and / or inspection staff can access complaint information.** Interpretation: On-site Evaluation at the Inspectorate - Verify that complaints and/or quality defect information is filed so as to facilitate review by GMP inspectors. If relevant, the information should be taken into consideration during the preparation for GMP inspections.
71	**All product defects reported (e.g. through the complaint and two-way alert systems) are documented and investigated.** Interpretation: On-site Evaluation at the Inspectorate **-** Verify that there is a documented system in place to receive, register and assess any suspected product defects including initiating any necessary actions. **-** Verify a few records of investigations including, e.g. testing records.
Sub-component 10D Surveillance programme – Adverse reaction reporting system/procedures	
Not evaluated – not considered within the scope of a GMP regulatory compliance programme	
Sub-component 10E Surveillance programme – Drug product defect reportint system/procedures	

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Included under sub-component 10C Surveillance programme – Consumer complaint system	
Sub-component 11A Quality management system - Quality management system (Critical)	
72	**The quality management system is based on a recognised international standard.** Interpretation: Documentation review - Verify that a quality management system covering all components of the GMP regulatory compliance programme* is established and maintained according to International standards (e.g. ISO 9001, ISO 19011, ISO 17020, ISO 17025 etc.). The system is described in the quality manual (or equivalent) of the competent authority and other internal documents. *The definition in the glossary enumerates the components of a GMP regulatory compliance programme.
73	**The quality manual covers all elements of GMP regulatory compliance programme.** Interpretation: Documentation review - Verify that the competent authority has an up-to-date quality manual(s) that incorporates all the elements of a GMP regulatory compliance programme.

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74	**Key performance indicators (KPI) for the overall GMP regulatory compliance programme are established and available.** Interpretation: Documentation review On-site Evaluation at the Inspectorate and the Laboratory - Verify that the competent authority defines, implements and evaluates quality metrics to measure the performance of all elements of the GMP regulatory compliance programme. The Key performance indicators (KPI) can be qualitative and quantitative. Quality metrics are used to monitor e.g. the GMP quality system, inspection and authorisation processes, management of quality defects, two-way alerts, etc. and can be used to identify, where performance of quality management is meeting the desired standards or where performance requires amendments. Examples of quality metric could be: time for issuing the inspection report after the inspection, number of inspections performed vs inspections planned, etc.
75	**The quality management system has been implemented and is followed.** Interpretation: On-site Evaluation at the Inspectorate and the Laboratory - Verify that a documented quality management system is present with evidence that it is followed at a national and, if appropriate, local level(s) in order to ensure that adequate quality standards are consistently achieved and maintained. Where more than one level exists, these systems should be linked and consistent. For reference: From ISO 9000:2015, quality management system: - Comprises activities by which the organisation identifies its objectives and determines the processes and resources required to achieve desired results.

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	- Manages the interacting processes and resources required to provide value and realize results for relevant interested parties. - Enables top management to optimize the use of resources considering the long and short term consequences of their decision. - Provides the means to identify actions to address intended and unintended consequences in providing products and services.
76	**A documentation control system is in place.** Interpretation: On-site Evaluation at the Inspectorate and the Laboratory - Verify that a system exists to control documents and records. - Assess how the system is organised; verify the review and approval process and how changes are controlled. - Verify that employees have access to the system and that only current and approved quality documents are used. - Verify the storage of quality documents and records.

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77	**Quality audit plans and records are available.** Interpretation: On-site Evaluation at the Inspectorate and the Laboratory - Verify that quality audit plans for the GMP regulatory compliance programme are developed and are periodically reviewed. - Ensure that all activities covered by the GMP regulatory compliance programme are audited according to the plan. - Review examples of audit records and verify that processes were followed.
78	**Management reviews the performance of the quality management system on an annual basis.** Interpretation: On-site Evaluation at the Inspectorate and the Laboratory - Verify that a procedure for an annual management review of the GMP regulatory compliance programme is implemented. - Verify that a system and structure for the evaluation of information do exist. - Verify that quality system issues noted are addressed. Proposed actions should be satisfactorily implemented.