



# GUIDELINES ON GOOD DISTRIBUTION PRACTICES FOR BIOLOGICAL PRODUCTS

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## **1.0 PREAMBLE**

Distribution is an essential activity in the integrated supply-chain management of biological products. Various individuals and entities are generally responsible for the handling, storage and distribution of such products. So it's very important to have adequate controls over the entire chain of distribution. To maintain the original quality of biological products, every party involved in the distribution chain has to comply with the applicable requirement. Each activity in the distribution of biological products shall be carried out according to the principles of Good Distribution Practice (GDP) as applicable (*e.g.* dry ice, cold pack etc). The nature of the risks involved is likely to be similar to that for risks encountered in the manufacturing environment, *e.g.* mix-ups, adulteration, contamination, cross-contamination, spurious besides inherent potential for degradation of such products if not maintained and distributed under specified storage conditions.

## **2.0 OBJECTIVE**

The objective of these guidelines is to assist in ensuring the quality and identity of biological products during all aspects of the distribution process. These aspects include, but are not limited to procurement, purchasing, storage, distribution, transportation, documentation and record-keeping practices.

## **3.0 SCOPE**

These guidelines are intended to be applicable to all persons and outlets involved in any aspect of the storage and distribution of biological products from the premises of the manufacturer of the product to the person dispensing or providing biological products directly to a patient or his or her agent. This includes all parties involved in trade and distribution of biological, including the manufacturers of bulk, finished products, wholesalers, as well as

others such as suppliers, distributors, Government institutions, international procurement organization, donor agencies and certifying bodies, logistics providers, traders, transport companies and forwarding agents and their employees as well as health workers.

#### **4.0 GENERAL PRINCIPLES**

- 4.1 According to Drugs & Cosmetics Act 1940 and Drugs & Cosmetic Rules 1945, Rules 64 and 65 specify the conditions to be fulfilled to sell, stock, exhibit or offer for sale or distribute the drugs.
- 4.2 It shall be the responsibility of all parties involved in the distribution of biological products to ensure that the quality of biological products and the integrity of the distribution chain are maintained throughout the distribution process from the site of the manufacturer to the entity responsible for dispensing or providing the product to the patient or his or her agent.
- 4.3 The principles of GDP shall be applicable both to biological products moving forward in the distribution chain from the manufacturer to the entity responsible for dispensing or providing biological products to the patient and to products which are moving backwards in the chain, for example, as a result of the return or recall thereof and shall be applicable for donated biological products.
- 4.4 There shall be collaboration between all parties including government, custom agencies, law enforcement agencies, regulatory authorities, manufacturers, distributors and entities responsible for the supply of biological products to patients to ensure the quality and safety of biological products and prevent the exposure of patients to spurious biological products.
- 4.5 An agreement shall be in place with all the individual agencies involved in the storage, transportation and distribution.

## **5.0 REGULATION OF THE DISTRIBUTION OF BIOLOGICAL PRODUCTS**

- 5.1 The activities of persons or entities involved in the distribution of products shall be regulated by applicable national legislation.
- 5.2 The distributor or the organization to which the distributor belongs shall be an entity that is appropriately authorized by applicable legislation to perform the function(s) that it intends to perform and the distributor or the organization to which it belongs shall be held accountable for the activities that it performs related to the distribution of products.
- 5.3 Only authorized persons or entities who hold the appropriate license shall be entitled to import or export biological products.
- 5.4 Distributors or their agents shall obtain their supplies of biological products from persons or entities authorized to sell or supply such products to a distributor and shall supply biological products only to persons or entities which are themselves authorized to acquire such products either in terms of an authorization to act as a distributor or to sell or supply products directly to a patient or to his or her agent.
- 5.5 If the activity of a distributor or his or her agent is subcontracted to another entity, the person or entity to which the activity is subcontracted shall be appropriately authorized to perform the subcontracted activity and shall uphold the same standards as the distributor.

## **6.0 ORGANIZATION AND MANAGEMENT**

- 6.1 An adequate organizational structure for each entity in the chain of distribution shall be defined with the aid of an organizational chart. The responsibility, authority and interrelationships of all personnel shall be clearly indicated. An organogram/ organizational chart shall be in place.

- 6.2 There shall be clearly defined duties and responsibilities for individuals and shall be recorded as written job descriptions. At every level of the supply chain, employees shall be fully informed and trained in their duties and responsibilities.
- 6.3 There shall be designated person appointed within the organization, who has defined authority and responsibility for ensuring that a quality system is implemented and maintained.
- 6.4 Managerial and technical personnel shall have the authority and resources needed to carry out their duties and to set up and maintain a quality system, as well as to identify and correct deviations from the established quality system.
- 6.5 It shall be ensured that the responsibilities placed on any one individual shall not be so extensive as to present any risk to product quality.
- 6.6 There shall be arrangements in place to ensure that management and personnel are not subject to commercial, political, financial and other pressures or conflict of interest that may have an adverse effect on the quality of service provided or on the integrity of biological products.
- 6.7 Safety procedures relating to all relevant aspects including the safety of personnel and property, environmental protection and product integrity, shall be in place.

## **7.0 PERSONNEL**

- 7.1 All personnel involved in distribution activities shall be trained and qualified in the requirements of GDP, as applicable. Training shall be based on written standard operating procedures (SOPs). Personnel shall receive initial and continuing training relevant to their tasks, and be assessed as applicable, in accordance with a written training programme. In addition, training of the personnel shall include the topic of

product handling, safety and security, as well as aspects of product identification, the detection of spurious biological product and the avoidance of spurious biological product entering the supply chain. A record of all training, which includes details of subjects covered and participants trained, shall be kept.

- 7.2 Key personnel involved in the distribution of biological products shall have the ability and experience for ensuring that the biological products are properly stored and distributed as per the requirement of the product.
- 7.3 There shall be an adequate number of competent personnel involved in all stages of the distribution of biological products in order to ensure that the quality of the product is maintained.
- 7.4 Personnel involved in the distribution of biological products shall wear garments and adopt other personnel protection measures suitable for the activities that they perform.
- 7.5 Procedures for personnel hygiene relevant to the activities to be carried out shall be laid down and observed. Such procedures shall cover health, hygiene and clothing of personnel.

## **8.0 QUALITY SYSTEM**

- 8.1 All biological product distributors shall establish and maintain Quality System. There shall be documented quality policy describing the overall intentions and requirements of distributors regarding quality, authorized by the management.
- 8.2 There shall be an appropriate organizational structure with defined responsibilities of the personnel recorded as job descriptions.
- 8.3 A responsible person shall be appointed by the management for each distribution site, who shall have defined authority and

responsibility for ensuring that a quality system is implemented and maintained.

- 8.4 Senior management shall ensure that all parts of quality system are adequately resourced with competent personnel and suitable and sufficient premises, equipments and facilities.
- 8.5 There shall be written and approved procedure for all the activities.
- 8.6 A change control system shall be in place for management for changes of critical processes. This system shall incorporate quality risk management principles.
- 8.7 Procedures shall be in place to ensure quality related activities are recorded at the time they are performed.
- 8.8 Procedures shall be in place to ensure safe, transparent and secure distribution system which includes product traceability throughout the supply chain.
- 8.9 There shall be procedures in place to ensure document traceability of products received and distributed, to facilitate product recall.
- 8.10 All parties involved in the supply chain shall be identifiable.
- 8.11 Deviations from established procedures shall be documented and investigated.
- 8.12 Appropriate corrective and preventive action (CAPA) shall be taken to correct deviations and prevent them.
- 8.13 Procedures for procurement and release shall be in place to ensure that appropriate biological products are sourced only from approved suppliers and distributed by approved entities.
- 8.14 Inspection, auditing and certification of compliance with a quality system (such as the applicable International Standardization Organization (ISO) series, or national or international guidelines) by external bodies are recommended.



## **9.0 PREMISES, WAREHOUSING AND STORAGE**

- 9.1 Storage areas shall be maintained or designed to ensure Good storage practices (GSP).
- 9.2 Storage areas shall be suitably secured, structurally sound and of sufficient capacity to allow for the safe storage and handling.
- 9.3 Storage areas shall be provided with adequate lighting to enable all operations to be carried out accurately and safely.
- 9.4 Precautions shall be taken to prevent unauthorized persons from entering storage areas.
- 9.5 Segregated areas shall be designated for storage of the biological products in quarantine and for storage of released, rejected, returned or recalled products as well as those suspected to be spurious.
- 9.6 Storage areas shall be designed or adapted to ensure appropriate and good storage conditions and shall be clean and dry and maintained within acceptable temperature limits. Biological products shall be stored off the floor and suitably spaced to permit cleaning and inspection. Pallets shall be kept in a good state of cleanliness and repair.
- 9.7 Premises and storage areas shall be cleaned regularly.
- 9.8 There shall also be a written programme for pest control and the pest control agents used shall be safe and there shall be no risk of contamination of biological products. There shall be appropriate procedures for the clean-up of any spillage to ensure complete removal of any risk of contamination.
- 9.9 If sampling is performed in the storage area, it shall be conducted in such a way as to prevent contamination or cross-contamination. Adequate cleaning procedures shall be in place for the sampling areas.

- 9.10 Receiving and dispatch bays shall protect biological products from the weather. Receiving areas shall be designed and equipped to allow incoming containers of biological products to be cleaned, if necessary, before storage.
- 9.11 Handling and storage of biological products shall in such a manner as to prevent contamination, mix-ups and cross-contamination.
- 9.12 There shall be a system in place to ensure that the biological products due to expire first are sold and/or distributed first (first expiry/ first out (FEFO)). Exceptions shall be permitted as appropriate, provided that adequate controls are in place to prevent the distribution of expired products.
- 9.13 Arrangement shall be made for withdrawing broken or damaged items from unusable stock and storing separately.

## **10.0 TEMPERATURE, ENVIRONMENT AND STOCK CONTROL**

- 10.1 All biological products shall be stored according to the temperature and storage conditions as described on the label. Adherence to these conditions shall be checked, monitored and recorded.
- 10.2 Storage conditions for biological products shall be in compliance with the recommendations of the manufacturer. This is key to ensure quality of all biological products.
- 10.3 Suitable equipments and procedures shall be in place to for temperature monitoring of storage facilities.
- 10.4 Records of temperature monitoring data shall be available for review. There shall be defined intervals for checking temperature. The equipment used for monitoring shall be checked at suitable predetermined intervals and the results of such checks shall be recorded and retained. All monitoring

records shall be kept for at least the shelf-life of the stored product plus one year.

- 10.5 Storage areas shall be temperature mapped under representative conditions. Temperature mapping shall show uniformity of the temperature across the storage facility. It is recommended that temperature monitors be located in areas that are most likely to show fluctuations.
- 10.6 Equipment used for monitoring of storage conditions shall also be calibrated at defined intervals.
- 10.7 Appropriate alarm system shall be in place to provide alerts when there are deviations from pre- defined storage conditions.
- 10.8 Storage area shall be equipped with backup power source or have alternate storage available in the event of power failure.
- 10.9 Written procedures shall be available for handling of temperatures excursions outside the labeled storage conditions. Such excursions shall be investigated.
- 10.10 Periodic stock reconciliation shall be performed by comparing the actual and recorded stocks. This shall be done at defined intervals.
- 10.11 Stock discrepancies shall be investigated in accordance with a specified procedure to check that there have been no inadvertent mix ups, incorrect issues and receipts, thefts and/or misappropriations of biological products. Documentation relating to the investigation shall be kept for a predetermined period.

## **11.0 TRANSPORTATION**

- 11.1 Biological products shall be transported in accordance with the storage conditions indicated on the packaging information and on the label.

- 11.2 The individuals responsible for the transportation of biological products shall be informed about all relevant conditions for storage and transportation. These requirements shall be adhered to throughout transportation and at any intermediate storage stages.
- 11.3 Biological products shall be stored and transported in accordance with procedures such that:
- 11.3.1 The identity of the product is not lost.
  - 11.3.2 The product does not contaminate and is not contaminated by other products.
  - 11.3.3 Adequate precautions are taken against spillage, breakage, misappropriation and theft. Spillage during transport shall be handled as per type of vaccine (*eg.* live, killed, etc.) according to the standard operating procedures of the manufacturer.
  - 11.3.4 Appropriate environmental conditions are maintained, e.g. using cold chain for thermo labile products.
- 11.4 A written agreement between the manufacturer, Government Institution, agent and Transport Company shall be in place.
- 11.5 Appropriate transport methods shall be employed which may include transport by air, road, sea, rail or a combination of the above. Regardless of the chosen mode, it shall be demonstrated that the products have not been subjected to conditions during transportation that may compromise their quality. A risk based approach shall be utilized when planning transportation routes.
- 11.6 The required storage conditions for biological products shall be maintained during transportation within the defined limits as described on the packaging information.

- 11.7 If a deviation has occurred during transportation, this shall be reported to the distributor and recipient of the affected biological products.
- 11.8 In cases where the recipient notices the deviation, it shall be reported to the distributor. Where necessary, the manufacturer of the biological product shall be contacted for information about appropriate steps to be taken.
- 11.9 It is the responsibility of the distributor to ensure that vehicles and equipment used to distribute, store or handle biological products are suitable for their use and appropriately equipped to prevent exposure of the products to conditions that could affect their quality and packaging integrity, and to prevent contamination of any kind.
- 11.10 Damage to containers and any other event or problem that occurs during transit shall be recorded and reported to the relevant department, entity or authority, and investigated.
- 11.11 There shall be procedures in place for the operation and maintenance of all vehicles and equipment involved in the distribution process, including cleaning and safety precautions. Particular attention shall be paid to the fact that cleaning agents shall not have an adverse effect on product quality.
- 11.12 Equipment used for temperature and humidity monitoring (Data Logger) during transport within vehicles and/or containers, shall be maintained and calibrated at regular intervals at least once a year or earlier depending upon the criticality of the product.
- 11.13 All monitoring records shall be kept for a minimum of the shelf-life of the product distributed plus one year or as required by National legislation.
- 11.14 Records of monitoring data shall be made available for inspection by the Regulatory Authority.

- 11.15 Dedicated vehicles and equipment shall be used, where possible, when handling biological products. Procedures shall be in place to ensure that the quality of the biological product shall not be compromised where non-dedicated vehicles and equipment shall be used.
- 11.16 No defective vehicles and equipment shall be used and shall either be labeled as such or removed from service.
- 11.17 Appropriate documents shall accompany biological products in transit.

## **12.0 CONTAINERS, PACKAGING AND LABELING**

- 12.1 Biological products shall be transported in containers that have no adverse effect on the quality of the products, and that offer adequate protection from external influences, including contamination.
- 12.2 Selection of a container and packaging shall be based on the storage and transportation requirements of the biological products; namely the space required for the amount of products; the anticipated external temperature extreme; the estimated maximum time for transportation including transit storage at customs and the validation status of the packaging and shipment containers.
- 12.3 Labels on the containers shall bear sufficient information on handling and storage requirements and precautions to ensure that the products are properly handled and secured at all times. The containers shall enable identification of the contents of the containers and the source.

## **13.0 TEMPERATURE CONTROL DURING TRANSPORT**

- 13.1 Validated temperature-control systems (e.g. thermal packaging, temperature-controlled containers, and refrigerated vehicles) shall be used to ensure that correct transport conditions are maintained between the distributor and customer.
- 13.2 If refrigerated vehicles are used, the temperature monitoring equipment used during transport shall be maintained and calibrated at regular intervals or at a minimum of once a year. This includes temperature mapping under representative conditions and shall take into account seasonal variations. Customers shall be provided with data to demonstrate that products remained within the required temperature storage conditions during transportation, if requested.
- 13.3 If cool-packs are used in insulated boxes, they need to be located such that the product does not come in direct contact with the cool-pack. Staff must be trained on the procedures for assembly of the insulated boxes (seasonal configurations) and on the reuse of cool-packs.
- 13.4 Special care shall be taken when using dry ice in shipment containers.
- 13.5 The process for delivery of sensitive products and control of seasonal temperature variations shall be described in a written procedure. This procedure shall also cover unexpected occurrences such as vehicle breakdown or non-delivery. A procedure shall also be in place for investigating and handling temperature excursions.

## **14.0 DISPATCH AND RECEIPT**

- 14.1 Selling or distribution of biological products shall be done to persons or entities that are authorized to acquire such products in accordance with the applicable national, state and

international legislation. It is required to obtain written proof of such authority prior to the distribution of products to such persons or entities.

- 14.2 The supplier shall ensure that the person or entity, e.g. the contract acceptor for transportation of the biological products, is aware of the biological products to be distributed and complies with the appropriate storage and transport conditions prior to the dispatch of biological products.
- 14.3 Only after the receipt of a valid delivery order or material replenishment plan, the dispatch and transportation of biological products shall be undertaken, which shall be documented.
- 14.4 Written procedures for the dispatch of biological products shall be established. Such procedures shall take into account the nature of the product as well as any special precautions to be observed. Biological products under quarantine shall require release for dispatch by the person responsible for quality.
- 14.5 Records for the dispatch of biological products shall include at least the following information:
  - Date of dispatch;
  - Complete business name and address (no acronyms), type of entity responsible for the transportation, telephone number and names of contact persons;
  - Complete business name, address (no acronyms), and status of the addressee (e.g. retail pharmacy, hospital or community clinic);
  - A description of the products including, e.g. name, dosage form and strength (if applicable);
  - Quantity of the products, i.e. number of containers and quantity per container (if applicable);
  - Applicable transport and storage conditions;



- A unique number to allow identification of the delivery order; and Assigned batch number and expiry date (where not possible at dispatch, this information shall at least be kept at receipt to facilitate traceability).

14.6 It shall be ensured that records of dispatch contain enough information to enable traceability of the biological product. Such records shall facilitate the recall of a batch of a product, if necessary, as well as the investigation of spurious or potentially spurious biological products; the assigned batch number and expiry date of biological products shall be recorded at the point of receipt to facilitate traceability.

14.7 It shall be ensured that the volume of biological products ordered does not exceed the capacity of storage facilities at the destination.

14.8 There shall be no supply or receipt of biological products after their expiry date, or so close to the expiry date that this date is likely to be reached before the products are used by the consumer.

14.9 Incoming shipments shall be examined to verify the integrity of the container/closure system, to ensure that tamper-evident packaging features are intact, and that labeling appears intact.

## **15.0 DOCUMENTATION**

15.1 Documentation comprises all written procedures, instructions, contracts, records and data, in paper or in electronic form.

15.2 Written instructions and records which document all activities relating to the distribution of biological products, including all applicable receipts and issues (invoices) shall be available.

15.3 Distributors shall keep records of all biological products received. Records shall contain at least the following information:

- Date;
- Name of the biological product, batch no, manufacturer's name.
- Quantity received, or supplied; and
- Name and address of the supplier.

15.4 Procedures shall be established and maintained for the preparation, review, approval, use of and control of changes to all documents relating to the distribution process.

15.5 The contents of documents shall be clear and unambiguous. In particular, instructions and procedures relating to activity that may have an impact on quality of biological products shall be designed, completed, reviewed and distributed with care.

15.6 Documentation shall be approved, signed and dated by appropriate authorized persons, as required. It shall not be hand-written; although, where documents require the entry of data, sufficient space shall be provided for such entries.

15.7 Any alteration made in the documentation shall be signed and dated; the alteration shall permit the reading of the original information. Where appropriate, the reason for the alteration shall be recorded.

15.8 Documents shall be retained for a period of 1 year after expiry of the product.

15.9 Documents shall be reviewed regularly and kept up to date.

15.10 Records shall be kept either in the form of purchase/sales invoices, delivery slips, or on computer or in any other form, for any transaction in biological products received or supplied.

15.11 Records shall be made at the time each operation is taken and in such a way that all significant activities or events are traceable.

15.12 If electronic copies/data are stored then validation of computers and database management system shall be in place.

15.13 All records shall be readily retrievable, and be stored and retained using facilities that are safeguarded against unauthorized modification, damage, deterioration and/or loss of documentation.

15.14 Backup shall be maintained to prevent any accidental data loss where the records are generated and kept in electronic form.

## **16.0 COMPLAINTS**

16.1 Written procedure shall be in place for the handling of complaints. A distinction shall be made between complaints about a biological product or its packaging and those relating to distribution. In the case of a complaint about the quality of a product or its packaging, the original manufacturer and/ or marketing authorization holder shall be informed as soon as possible.

16.2 There shall be written procedure for reviewing carefully all complaints and other information concerning potentially defective and potentially spurious biological products describing the action to be taken, including the need to consider a recall where appropriate.

16.3 Any complaint concerning a material defect shall be recorded and thoroughly investigated to identify the origin or reason for the complaint.

- 16.4 A risk based consideration shall be given to whether other batches of the biological product shall also be checked if a defect relating to a biological product is discovered or suspected.
- 16.5 Appropriate follow-up action shall be taken after investigation and evaluation of the complaint where necessary. A system shall be in place to ensure that the complaint, the response received from the original product manufacturer, or the results of the investigation of the complaint, are shared with all the relevant parties.
- 16.6 There shall be documentation of product quality problems or suspected cases of spurious products and sharing of the information with the appropriate national and/or state regulatory authorities.

## **17.0 RECALLS AND RETURNS**

- 17.1 There shall be a written procedure for the management of recalls of defective biological products with a designated person responsible for recalls. .
- 17.2 The system of recall shall comply with the guidance issued by National or State Regulatory Authority
- 17.3 In the event of recall the original manufacturer and/or marketing authorization holder shall be informed. Consultation with the original manufacturer and /or marketing authorization holder shall take place, where possible, before the recall is instituted in case recall is instituted by an entity other than the original manufacturer.
- 17.4 National or State Regulatory Authority shall be shared with information on recall.
- 17.5 Recall operations shall be capable of being initiated promptly and at any time.

- 17.6 The distributor shall follow the instructions of a recall message, which shall be approved, if required, by the competent authorities.
- 17.7 Any recall operation shall be recorded at the time it is carried out and records shall be made available to the competent authorities.
- 17.8 The distribution records shall be readily available to the person(s) responsible for the recall, and shall contain sufficient information on distributors and directly supplied customers (with addresses, phone and/or fax numbers inside and outside working hours, batches and quantities delivered).
- 17.9 Recalled biological products shall be identified and stored separately in a secure area while awaiting a decision on their disposition.
- 17.10 All customers and competent authorities of all countries to which a given biological product may have been distributed shall be informed promptly of any intention to recall the product because it is, suspected to be defective.
- 17.11 All records shall be readily available to the designated person(s) responsible for recalls containing sufficient information on biological products supplied to customers (including exported products).
- 17.12 The progress of the recall process shall be recorded and a final report shall be issued, including reconciliation between the delivered and recovered quantities of the biological products.
- 17.13 Rejected biological products and those returned to a distributor shall be appropriately identified and handled in accordance with a procedure which involves at least:- the physical segregation of such biological products in quarantine in a dedicated area; or other equivalent (e. g electronic) segregation.

17.14 Destruction of biological products shall be done in accordance with international, national and local requirements regarding disposal of such products, and with due consideration to protection of the environment.

17.15 Records of all returned, rejected and/or destroyed biological products shall be kept for a predetermined period.

## **18.0 SPURIOUS BIOLOGICAL PRODUCTS**

18.1 Spurious biological products if found in the distribution chain shall be completely segregated from other biological products, clearly labeled as not for sale and national regulatory authorities and manufacturer of the original product shall be informed immediately.

18.2 The sale and distribution of a suspected spurious biological product shall be suspended and the national regulatory authority shall be notified without delay.

18.3 A formal decision shall be taken on its disposal, ensuring that it does not re-enter the market upon confirmation of the biological product being spurious and the decision shall be recorded.

## **19.0 IMPORTATION**

19.1 Consignments of biological products shall be stored under suitable conditions for as short a time as possible, at the port of entry.

19.2 Importers shall take all reasonable steps to ensure that biological products are not mishandled or exposed to adverse storage conditions at wharves or airports.

19.3 Procedures shall be in place for quality assessment of imported biological products.

19.4 Customs, enforcement agencies and regulatory agencies responsible for supervision of biological products shall establish means for cooperation and information exchange in order to prevent importation of spurious biological products.

## **20.0 CONTRACT ACTIVITIES**

20.1 Only parties appropriately authorized to distribute a biological product shall be delegated to perform any activity relating to distribution of such product and in accordance with the terms of a written consent.

20.2 The responsibilities of each party including observance of the principles of GDP and relevant warranty clauses shall be defined in the contract. It shall also include responsibilities of the contractor for measures to avoid the entry of spurious biological products into the distribution chain, such as by suitable training programme.

20.3 The requirements in these guidelines shall be complied with by all contract acceptors.

20.4 Under certain conditions and subject to the written approval of the contract giver, subcontracting may be permissible, provided that the subcontractors shall be authorized for the function.

20.5 There shall be periodic audit of contract acceptors.

## **21.0 SELF-INSPECTION**

21.1 Self-inspections shall be included in the quality system. These shall be conducted to monitor implementation and compliance with the principles of GDP and, if necessary, to trigger corrective and preventive measures.

21.2 A designated, competent person shall conduct self-inspection in an independent and detailed way.

21.3 There shall be records of self inspection results which shall contain all observations made during the inspection and if required proposal for corrective measures. There shall be an effective follow-up programme and evaluation of inspection report and corrective action taken by the management.