FOOD AND DRUGS AUTHORITY

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Governing Board/ CEO, Food and Drugs Authority

Guideline on Licensing of Drug Manufacturing Facilities

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Document Revision History

Date of Revision	Version Number	Changes made and/or reasons for revision
15/03/2019	01	Initial issue
26/06/2019	02	Inclusion of section 3.7, 3.8, & 3.9
16/09/2024	03	i. General review to align to current guideline template and to conform to current organogram. ii. Inclusion of Sections 3.2, 4, 5, 6 and Annex 1

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Acknowledgements

It is acknowledged that, in the development of this Guideline, reference was made to the following sources:

- All WHO Guidelines related to Good Manufacturing Practices (GMPs)
- Public Health Act, 2012 (Act 851)

Executive Summary

This document is a guideline that prescribes how applications for the licensing of drug manufacturing facilities shall be made to the Food and Drugs Authority Ghana.

The guideline highlights the format of the application and the processes involved leading to licensing of a manufacturing facility, including the facility inspection and timelines for each activity in the licensing process.

The objective of this guideline is to serve as a guide to applicants, increase transparency in the FDA's operations and build confidence and accountability in the licensing structure via public availability of information on the licensing process.

1. INTRODUCTION (BACKGROUND)

The Food and Drugs Authority (FDA) is an agency of the Ministry of Health (MoH), mandated under the Public Health Act, 2012, Act 851 to ensure the quality, safety, and efficacy/performance of health products. The FDA executes this mandate through Registration, Inspections, Licensing, Surveillance and Clinical Trial activities.

To enhance the inspections and licensing functions of the FDA, this guideline is hereby made to provide prospective applicants with information on the requirements for the registration and licensing of premises or facilities for the manufacture of drugs in Ghana and for the renewal of already licensed drugs manufacturing facilities.

This Guideline is hereby promulgated for information, guidance, and strict adherence by all concerned.

1.1 Legal Basis

1.1.1 The following sections of the Public Health Act 2012, Act 851 mandates the Authority to carry out inspections and licensing of manufacturing facilities to achieve the desired safety, quality, and efficacy of the products for human and animal use regulated by the Authority.

- Section 115: Control of manufacturing
- Section 130: Registration of premises
- Section 131: Licences and permits.

1.1.2 Section 148 of The Public Health Act, 2012, Act 851 further mandates the Authority to issue guidelines and codes of practice in connection with products regulated by the Authority to persons in the industry and are required to comply. It is based on this legal provision that this guideline has been developed.

1.1.3 In accordance with Section 130(1) of the Public Health Act, 2012 (Act 851), the manufacturing of drugs shall not be carried out except in premises registered (licensed) by the Food and Drugs Authority (FDA) for that purpose.

1.1.4 Pursuant to Section 118(1), drugs manufactured by business entities are required to be registered with the Authority before placing them on the Ghanaian market.

1.1.5 As per Section 115 of the Public Health Act 2012, Act 851, the manufacturing process in the facilities shall be carried out under the supervision of a person having appropriate knowledge and qualification in the product being manufactured.

1.2 Scope

1.2.1 This Guideline applies to all business entities duly registered by the Registrar-General Department with intention to establish drugs manufacturing facility in Ghana and to continue manufacturing this product.

1.2.2 This guideline applies to manufacturing facilities that produces drugs or pharmaceutical or nutraceutical dosage forms. This includes oral tablets., oral liquids, suppositories, topical preparations, parenterals, inhalers, patches etc.

1.2.3 Foreign manufacturing entities will be inspected to confirm compliance to the Authority's guideline on Good Manufacturing Practice (GMP) requirements for drugs and other applicable regulatory requirements for drugs.

2. DEFINITIONS AND ABBREVIATIONS

2.1 Abbreviations

i. CAPA: Corrective action and Preventive action
ii. EPA: Environmental Protection Agency
iii. GMP: Good manufacturing Practices
iv. QMS: Quality Management System
v. SMF: Site Master File

2.2 Definitions

In this Guideline, unless the context otherwise requires, the following terms have the assigned meanings:

2.2.1 **Applicant:** Product owner or licence holder. May either be the trademark owner or person authorized by him, who has rights to sell a product and is responsible for placing the product on the Ghanaian market. Representatives of licence holders may not hold themselves as applicants unless they are the Marketing Authorization Holder of the product.

2.2.2 **Authority:** Food and Drugs Authority, Ghana

2.2.3 **Authorized/Qualified Person**: A person with appropriate knowledge and qualification who can ensure the purity, quality and wholesomeness of products regulated by the Authority and is required to supervise the manufacture of same

2.2.4 **Authorized Representative (or Local Agent):** Legal person established within the jurisdiction who has received a written mandate from the manufacturer to act on his behalf for specified tasks with regard to the latter's obligations under the jurisdiction's legislation.

2.2.5 **Corrective action and preventive action (CAPA) Report:** A report stating the steps taken to eliminate the causes of the deficiency or other undesirable situations raised during GMP inspection by the FDA.

2.2.6 **Correction:** Action to eliminate a detected deficiency. A correction can be made in conjunction with a corrective action.

2.2.7 **Corrective Action:** Action to eliminate the cause of a detected deficiency or other undesirable situation. Corrective action is taken to prevent recurrence.

2.2.8 **Drugs:** Drugs includes

(a) a substance referred to in a publication mentioned in the Fourth Schedule of the public Health Act 2012, Act 851

(b) a substance or mixture of substances prepared, sold or represented for use in

(i) the diagnosis, treatment, mitigation or prevention of disease, disorder of abnormal physical state or the symptoms of it, in man or animal, or

(ii) restoring, correcting or modifying organic functions in man or animal, and nutritional supplements

2.2.9 **Entity:** Any legal person, engaging in the manufacture, importation, exportation, storage, transportation, and wholesale distribution of drugs.

2.2.10 **Label:** instructions for use, and any other information that is related to identification, technical description, intended purpose and proper use of the drug, but excluding shipping documents.

2.2.11 **Major variation (Vmaj):** Changes that could have major effects on the overall safety, efficacy and quality of the finished product.

2.2.12 **Manufacturing:** Production of products or engaging in any part of the process of producing the product or bringing the products to their final stage. This includes processing, assembling, packaging, repackaging, labelling, storage, sterilizing, testing or release for supply of the products or of any component or ingredient.

2.2.13 **Manufacturer:** Any entity that does manufacturing.

2.2.14 **Minor variation (Vmin):** Changes that may have minor effects on the overall safety, efficacy and quality of the finished product.

2.2.15 **Notification:** Changes to a manufacturing facility that could have minimal or no adverse effects on the overall safety, efficacy and quality of the finished product. Annual notification (AN) does not require prior acceptance but must be notified to FDA within 12 months following implementation of the change.

2.2.16 **Product:** result of a process.

2.2.17 **Preventive Action:** Action to eliminate the cause of a potential deficiency or other undesirable situation.

2.2.18 **Packaging/ Packaging material:** The container and other materials including printed material in which drugs are supplied. Primary packaging materials are those that are in direct contact with the product.

2.2.19 **Packaging process/Operations:** All operations, including filling and labelling, that a bulk product has to undergo in order to become a finished packaged product.

2.2.20 **Quality policy:** The overall intentions and direction of a manufacturer with respect to quality, as established by management with executive responsibility (or top management).

2.2.21 **Quality management system (QMS):** A formal system that documents the structure, processes, roles, responsibilities and procedures required to achieve effective quality management.

2.2.22 **Quality manual:** A document which fully describes the quality management system of an organization.

2.2.23 **Site master file**: A document prepared by a manufacturer containing specific and factual GMP information about the products and/or control of the manufacturing conditions carried out at the site. (Refer to WHO TRS on writing of site master file).

2.2.24 **Risk:** A combination of the probability of occurrence of harm and the severity of that harm.

2.2.25 **Specification:** Any requirement with which a product, process, service, or other activity must conform.

2.2.26 **Variation:** Substantive changes made to the details of the manufacturing facility, manufacturing process and/or product.

3. REQUIREMENT

3.1 Application Preparation Guidance

3.1.1 An application to register and license a new facility for the manufacture of drugs shall be made in writing by submitting a completed application form with a cover letter addressed to: The Chief Executive Officer

Food and Drugs Authority
P.O. Box CT 2783
Cantonments – Accra
(GPS: GA-237-7316)

3.1.2 The application form shall be completed in duplicate, and shall be dated, signed, and stamped by an authorized representative of the firm. It shall provide the following minimum information as part of the licence acquisition:

(a) General information of the company or facility which shall include the name, full business address, location/site address and telephone numbers (including mobile numbers) of the applicant as well as the addresses, telephone numbers, and the names of contact persons for all facilities used by the applicant for the manufacture of drugs.
(b) The products/product categories manufactured.
(c) Brief description of the manufacturing process
(d) Key persons responsible for production, quality control and quality assurance
(e) Number and category of employees engaged.
(f) Specification of the plant
(g) Water supply, treatment, and waste disposal
(h) Contract manufacture, where applicable

3.1.3 The completed application form shall be accompanied by:

(a) Proof of payment of the prescribed fee (non-refundable) for licensing of the facility as specified in the FDA's Fee Schedule
(b) Copy of a valid business registration certificate
(c) Quality Manual/Site Master file or a related document that describes an organisation's Quality Management System and provides specific, factual information about the production and control of manufacturing operations where applicable.
(d) Permit from the Environmental Protection Agency (EPA), where applicable.
(e) Basic conceptual design showing plant installation, where applicable

3.1.4 In situations where the manufacturing site is more than one, a separate application is required in respect of each premise, except where a group of buildings on one or more sites are engaged in making the same kind of product under the same direct production and quality control management.

3.1.5 A copy of the submitted documents shall be endorsed by the FDA and returned to the applicant.

3.2 Submission of Application

3.2.1 An application for licensing of a manufacturing facility can be submitted at any of the offices of the FDA (as per Annex 1).

3.2.2 Applications received at any of the FDA offices shall be evaluated for completeness to ensure all relevant documents have been attached.

3.2.3 All applications submitted to the district and regional offices shall be forwarded to the head Office within ten (10) working days for further processing.

3.2.4 If additional documents are required, clients shall be informed within five (5) working days after the review.

3.3 Evaluation of Applications Submitted

3.3.1 Applications received shall be reviewed by the FDA officers to ensure compliance with both administrative and technical requirements.

3.3.2 Based on the outcome of the evaluation in 3.3.1 additional or supplementary documentation may be requested by the FDA.

3.3.3 The Authority shall consider, as a minimum, the following factors in reviewing the application:

(a) Any convictions of the applicant relating to FDA-regulated products.
(b) The applicant's history of regulatory compliance in the manufacture, importation, exportation, or distribution of FDA-regulated products, where applicable.
(c) The applicant’s information provided to the Authority, which is found to be misleading, false, or fraudulent in respect of its application for FDA-regulated products.
(d) Information on whether the applicant’s licence has been suspended or revoked by the Authority for violation of any FDA law; and
(e) Any other requirements the FDA may from time to time prescribe.

3.3.4 The Authority may approve, defer, or refuse an application following assessment and shall be duly communicated to the applicant.

3.4 Withdrawal Of a Submitted Application

3.4.1 At any point, if a company does not wish to proceed further with the application, the company is able to withdraw a pending application through writing to the Authority.

3.5 GMP Inspection of the Facility

3.5.1 A successful evaluation of the completed application form and the accompanying documentations shall be followed by GMP inspection of the facility.

3.5.2 The GMP inspection shall be conducted in accordance with the Authority’s guideline on GMP requirements for drug manufacturing facilities.

3.5.3 The outcome of the inspection shall be communicated to the company.

3.5.4 The applicant shall submit a Corrective Action and Preventive Action (CAPA) with regards to the deficiencies identified. The CAPA shall indicate amongst others the following:

(a) Description of the deficiency
(b) Investigations & Analysis carried out on the deficiency including root cause(s) and of the deficiency.
(c) Impact assessment of the deficiency on company's operations
(d) Timelines within which the applicant intends to complete each of the deficiencies identified.
(e) Responsible person for the CAPA
(f) Correction taken
(g) Corrective action taken
(h) Preventive action taken
(i) Status of the CAPA
(j) Review of the Effectiveness of the CAPA

3.5.5 Upon successful implementation of the CAPA, a follow-up inspection may be conducted by the inspection team to ascertain the effectiveness of the implementation (where necessary).

3.5.6 There shall be three (3) CAPA cycles before a final decision is taken on the GMP status of the facility.

3.5.7 The facility that fails to respond to inspection deficiencies through CAPA submission (where required), for a maximum of six (6) months, the inspection shall be considered closed with or without notification of the company.

3.6 Licensing of Facility

3.6.1 A manufacturing facility shall only be licensed or issued with a GMP certificate after the inspection report and CAPA (where applicable) have been reviewed and found to be satisfactory.

3.6.2 The licence/certificate will only be valid for the period stated provided there are no quality and safety issues on the product manufactured during the period of validity of the manufacturing licence.

3.6.3 The Authority shall exercise the right to cancel or suspend a licence in accordance with the law.

3.7 Post license inspection

3.7.1 Within the period of validity of a manufacturing licence, a licensed facility may be subject to a post license inspection (announced or unannounced) in accordance with provisions of the **Public Health Act, 2012, Act 851 of the Republic of Ghana**.

3.7.2 Violations or alleged violations of local and international laws of which FDA Ghana subscribes which bear on the quality, safety and efficacy of the drugs manufactured by the facility may attract a post-license inspection of the facility.

3.8 Renewal of Manufacturing Licence/GMP Certificate

3.8.1 Manufacturing Licences shall be renewed annually. GMP certificates shall be renewed in accordance with their validity period.

3.8.2 An application for renewal of manufacturing licence shall be made at least 3 months before the expiry of the existing licence by submitting the following with a cover letter:

(a) Duly completed application form

(b) Non-refundable application fee in accordance with the FDA fee schedule

3.8.3 The application shall capture details of any variation (as stated in **appendix 2**) within the period. Documents that have already been submitted in respect of the variation need not be submitted for the second time.

3.8.4 The applicant's compliance with GMP requirements shall be a key determinant to the renewal of the manufacturing licence/GMP certificate.

3.9 Foreign Manufacturing Entities

3.9.1 Foreign manufacturing entities shall be required to pay facility inspection fee (refer to the FDA fee schedule) for the conduct of GMP inspection in addition to other documentations as part of the processes to provide quality assurance to imported products.

3.9.2 Where applicable, GMP inspection of some manufacturing facilities can be waived on submission of the required documents as outlined in Waiver Notification.

3.9.3 A foreign manufacturing entity would be issued a GMP certificate following a satisfactory inspection.

3.9.4 Foreign manufacturing facilities shall be inspected **every 5 years** provided there are no safety and quality issues related to the facility's products during this period.

3.9.5 If an applicant for the registration of drugs to be marketed in Ghana is not a registered entity in Ghana, the applicant is required to appoint a local agent (authorised representative) and duly notify the Authority.

4. VARIATION/CHANGES TO LICENSED FACILITIES

4.1 The manufacturing licence holder shall inform the Authority of any changes(variations) made in the facility and its operations.

4.2 A variation application shall be submitted along with a declaration letter undersigned by the company that declares there is no other change except for the proposed variation.

4.3 Each information on any variation to the FDA Ghana shall be accompanied by the requisite documentations as indicated in Annex 2 of this guideline.

4.4 Minor Variation – Notification

4.4.1 If the application fulfils the requirements (conditions and supporting documents as per Annex 2) of minor variation – notifications, the following actions will be taken:

(i) Receipt of the application shall be acknowledged as a valid notification.

(ii) The notification shall be responded to within a period of 20 working days after receipt of the application.

(iii) The applicant can continue to do business provided such variations have been filed with the FDA Ghana not more than twelve months after implementation.

4.5 Minor Variation – Prior Approval

4.5.1 If the application fulfils the requirements (conditions and supporting documents as per Annex 2) of a minor variation – prior approval, MFD shall issue approval in the form a written letter for the proposed change.

4.5.2 The MFD shall issue the approval to the minor variation within a period of 30 working days after receipt of the application.

4.5.3 The manufacturer/marketing authorization holder shall implement/commence implementation of the variation within the next 30 days after receipt of approval from the FDA. This 30 days' allowable period for commencement of implementation shall be indicated in the letter of approval.

4.6 Major Variation

4.6.1 If the application for variation fulfils the requirements (conditions and supporting documents as per Annex 2) of a major variation,

(i) An approval in the form of written letter for the proposed change shall be issued

(ii) The approval to the major variation shall be done within 60 working days after receipt of the application. This timeline may be reviewed downwards to 40 working days based on the urgency of the variation, for example if it borders on safety. The timeline may also be adjusted upwards based on scientifically justifiable evidence.

(iii) The manufacturer/marketing authorization holder shall implement/ commence implementation of the variation within the next 30 days after receipt of approval from the FDA. The allowable period of implementation shall be indicated in the letter of approval.

4.7 The FDA reserves the right to re-categorize the application type, where it's deemed appropriate.

4.8 Where a re-categorization of the variation is done by the FDA, it shall be communicated to the manufacture/marketing authorization holder only where additional conditions and documentations are required as per appendix 2. This shall be done within 15 working days after receipt of the application.

4.9 Stakeholder Meetings/Trainings

The Authority will periodically conduct appropriate stakeholder meetings/training for manufacturers to enhance their level of compliance.

4.10 Contract Manufacturing

Where the applicant for the registration of drugs to be marketed in Ghana is not the manufacturer, a contract agreement between the applicant and the manufacturer will be required.

5. TIMELINES

Refer to **Annex 4** for a flow chart showing the licensing process and the corresponding timelines.

5.1 Conducting the inspection

Inspection of manufacturing facilities shall be carried out after notification to the manufacturer for pre-licensing and re-licensing inspections. Facilities to be inspected shall be notified at least three days to the inspection day depending on the circumstances (for foreign facilities the notification shall be upon management's approval and such as to be able to reach consensus on the final inspection date).

5.2 Unannounced Inspections

Notwithstanding '5.1' above, the Authority shall, when it deems it necessary, conduct unannounced inspections. No prior notification of the manufacturing facility shall be given.

5.3 Communication of Inspection findings

The inspection observations shall initially be communicated to the manufacturer during the closing meeting of the inspection. This shall be followed by a formal inspection communication within 45 working days from the end date of the inspection.

5.4 Response to inspection findings/nonconformities

The manufacturer is required to formally respond to the deficiencies/nonconformities identified in the inspection as officially communicated within a specified timeframe (usually 25 working days on receipt of the formal inspection deficiencies/nonconformities letter, these 25 working days may be varied depending evaluated circumstances).

5.5 Issuing of manufacturing licenses/GMP certificates

A manufacturing facility that undergoes an inspection by the FDA, satisfactorily addresses deficiencies sited as part of the inspection and has no outstanding statutory obligations to fulfil shall be licensed and/or issued a GMP certificate. It shall take 10 working days from the date of granting approval, to issue a license /certificate to a manufacturing entity.

6. SANCTIONS

6.1 Cancellation / Suspension / Withdrawal /Revocation of licences

6.1.1 The Authority shall cancel, suspend, withdraw or revoke a licence of a facility if:

(a) The facility contravenes GMP requirements.
(b) Any of the conditions under which the license was issued no longer exist.
(c) The information on which the approval was given is later found to be false.
(d) The circumstances under which the approval was given no longer exist.

6.1.2 Where the licensure is suspended, withdrawn, or cancelled, the Authority shall issue a notice to the management of the facility.

6.1.3 The Authority shall take steps to ensure that the manufacturing facility is stopped from manufacturing until otherwise decided by the Authority. Measures towards enforcing this may include the publication of the FDA's action on its website and other relevant media.

6.2 Penalties

6.2.1 The Authority shall impose an administrative fine in accordance with the approved fees and charges Act applicable to the FDA if:
(a) The facility contravenes GMP requirements.
(b) Any of the conditions under which the license was issued no longer exist.
(c) The information on which the approval was given is later found to be false.
(d) The circumstances under which the approval was given no longer exist.

6.2.2 Other penalties as provided for in section 129 of the Public Health Act, 2012, Act 851, related to contraventions to the provisions of this guideline may be imposed.

6.2.3 Other penalties as provided for in section 129 of the Public Health Act, 2012, Act 851, related to contraventions to the provisions of this guideline may be imposed.

ANNEXURE 1: LIST OF REGIONAL OFFICES

OFFICE	ADDRESS	CONTACT
Head Office	No. 17 Indian Ocean Street, Nelson Mandela Avenue, Shiashie P.O, Box CT 2783 Accra. GPS: GA–237–7316	03022 35100
Western Regional Office	Adjacent Fidelity Bank, Ghana Post Building, Takoradi Harbour P. O. Box MC 2129, Takoradi GPS: WS-406-1927	031 202 7558, 0544 338 829
Volta Regional Office	GWCL Building (Same Building with Cool FM) Private Mail Bag, Ho GPS: VH–0016–3748	03620 26659, 0244399632, 0247 978 956
Upper West Regional Office	Controller Block, Ministries, P. O. Box 291 Wa. GPS: SW–022–9492	03920-20111, 0244 470 413
Upper East Regional Office	Regional Administration Building, P. O. Box 612, Bolgatanga GPS: UB-0034-4017	0247 717 744
Northern Regional Office	Regional Administration Building, P. O. Box TL 1763, Tamale GPS: NT–0066–3381	03672024935
Eastern Regional Office	Hospital Road, Opposite Assemblies of God Church, P. O. Box KF 2431, Koforidua GPS: EN-011-2579	0277 705 752
Central Regional Office	UCC Credit Union Building Adjacent, CEDECOM Building, Pedu Junction P. O. Box CC 1373, Cape Coast GPS: CC-097-0402	033090110, 0245839521, 0504422905

Bono Regional Office	House No. 61A, Nkwabeng Extention, Sunyani. Near St. Mary's School. Opposite Goode Goode Spot. Postal address PMB, Sunyani GPS: BS-0054-2542	0352028791, 0265062697
Ashanti Regional Office	Regional Coordinating Council (RCC), next to Electoral Commission's Office P. O. Box ST 402, Kumasi GPS: AK-133-7324	0302-203-6027/70, 0507-187-420/1/2

ANNEXURE 2: VARIATION REQUIREMENTS

MINOR VARIATION – NOTIFICATION		
No.	**Details of Variation**	**Supporting documents required**
1	Change of business name without change in business location	a. Notification letter b. Updated SMF
2	Change in the number/name of the street/building without a physical change in location	a. Notification letter b. Document issued by the local authority as proof of zonal change c. Updated SMF
MINOR VARIATION – PRIOR APPROVAL		
No.	**Details of Variation**	**Supporting documents required**
1	Removal of Pharmaceutical Dosage Form	(a) Updated SMF - *Ensure that the company either holds a Storage Facility Licence for the finished product or all the remaining stock of the product has already been sold/distributed before removing the dosage form from* Manufacturer's Licence.
2	Deletion of one or more lines of the manufacturing premises	Updated SMF with the new premises' layout
3	Update of contract testing laboratories' particulars or type of tests performed	(a) Updated SMF (b) Manufacturer's assessment on the suitability and compliance of the contract lab for the proposed testing to GMP requirements (c) Written contract agreement if available
	Addition / deletion of contract testing laboratories	
MAJOR VARIATION		
No.	**Details of Variation**	**Supporting documents required**
	Addition of Pharmaceutical Dosage Form for manufacturing	(a) Specify the proposed manufacturing operations (b) Provide the technical details of the new manufacturing activity and the site address(es) where each operation is carried out (where applicable) (c) Updated SMF
2	Change in location of a licensed facility.	(a) Application letter (b) Payment of fees for inspection and licensing of new site

		(c) Proof of business registration reflecting the new location address (d) Updated SMF
3	Addition of warehouse(s) for the storage of: (a) Raw materials (b) Intermediate products (c) Bulk products (d) Retention/reference samples (e) Products in quarantine / pending batch release (f) Critical Process Consumables (e.g., Columns, Resins) (g) Addition of cold rooms for the storage of materials listed above	(a) If the storage is outsourced to contract warehouse which holds a valid Storage Facility Licence for storage of regulated products, the licence of the contract warehouse can be submit as supporting document for assessment of the change (b) Updated SMF with the new layout of the premises (where applicable) and updated list of products and materials stored in the new warehouse and their respective storage conditions
4	Addition or deletion of other product comprising highly sensitising materials (e.g., penicillin, cephalosporins, hormones, steroids, etc.) or non-medicinal products manufactured in same Premises	(a) Updated SMF with the new premises layout (where applicable) (b) Information on how segregation and cross-contamination/ decontamination is controlled/performed
5	Additional building(s) or unit(s) or room(s) where the manufacturing address remain unchanged	(a) Provide the details of the proposed use of the buildings/ rooms (b) Updated SMF with the layout and the intended use of the new facilities
	Addition of manufacturing process step (e.g., introduction of film coating, serialization)	(a) Specify the proposed manufacturing operations (b) Provide the technical details of the new production process and the address(es) where each operation is carried out. (c) Updated SMF
6	Change of Qualified Person(s)	*Curriculum Vitae* (CV) and training records of the newly nominated Qualified Person(s)
7	Installation of equipment	(a) Risk assessment report (b) Updated SMF

ANNEXURE 3: APPLICATION DOCUMENTS

LIST OF DOCUMENTARY REQUIREMENTS FOR LICENSING OF A PHARMCEUTICAL MANUFACTURING FACILITY

Initial Application

1. Application letter
2. Application form
3. Proof of Business name registered
4. Credentials of pharmacist
5. Site mater file
6. Location plan
7. Proof of payment

Renewal of application

1. Application letter
2. Application form
3. Copy of initial certificate issued
4. Proof of payment

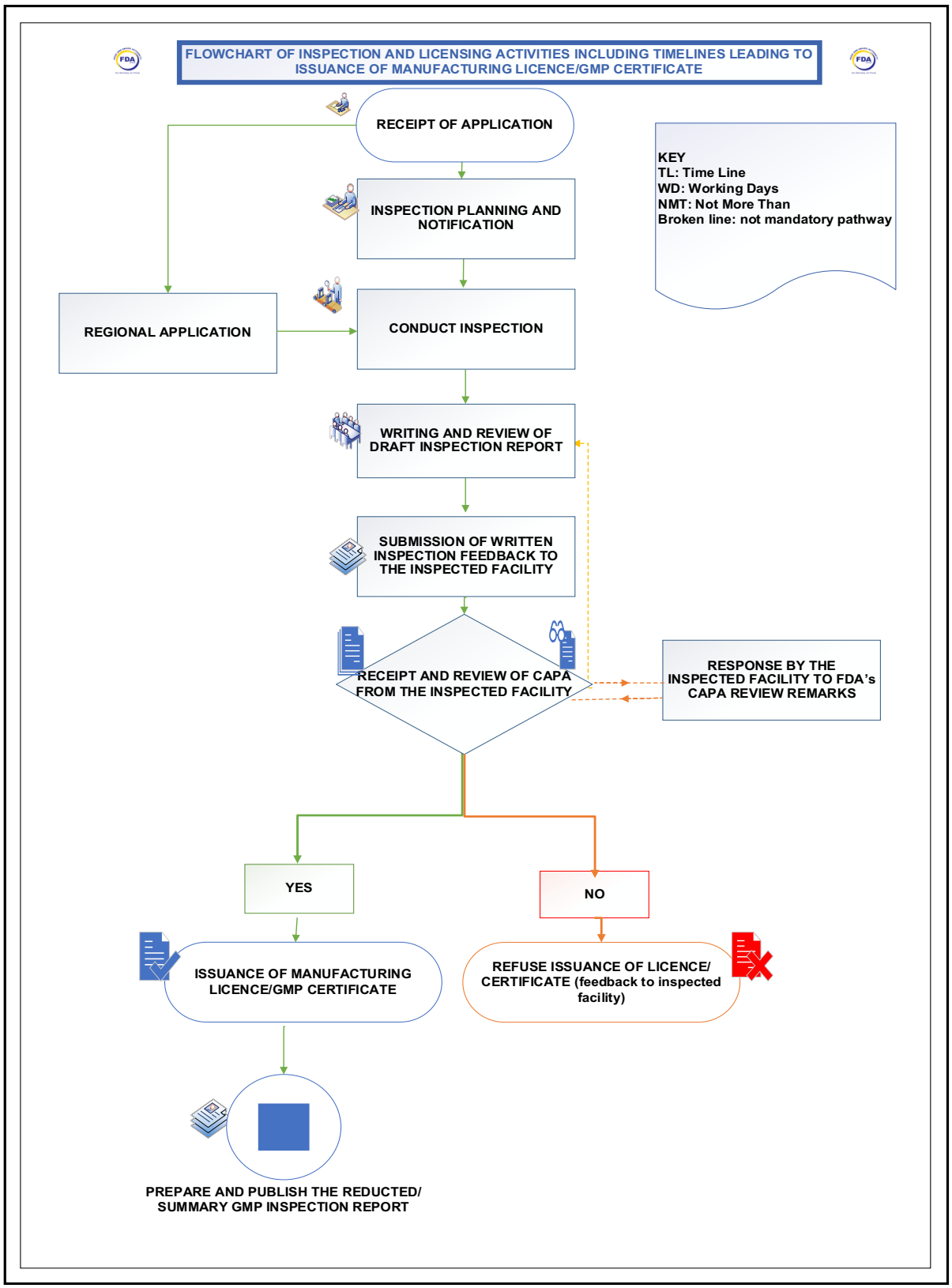
Reissuance of Lost Certificate or Destroyed Certificate

1. Letter of request
2. Affidavit of loss or destruction
3. Proof of payment

Voluntary cancellation of license

1. Letter of request
2. Original license

ANNEXURE 4: FLOWCART



TIMELINES

LOCAL FACILITIES: NMT 1 months af **FOREIGN FACILITIES**: NMT 6 months after receipt (Dependent on management approval)

NMT 5 WD

NMT 45 WD after the conduct of inspection

COMPANY: 25 WD to respond. (*may be varied*)
FDA: 20WD to review.

FOLLOW-UP INSPECTION REQUIRED: 20 WD after CAPA review.

NMT 10WD on approval

NMT 40 WD on issuance of licence/certificate.