Central Administration of pharmaceutical institutions licensing
Ceneral Administration of Inspection of pharmaceutical institutions
Central Administration for Pharmaceutical Policies and Market Access

Guideline

Regulatory Guideline for the Regulations and Procedures of Licensing and Operating Research and Development (R&D) and Quality Control Laboratories for Pharmaceuticals and Medical Devices

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1. Introduction:

Based on the strategy of the Egyptian Drug Authority (EDA), which aims to develop work systems within the sectors of the Egyptian pharmaceutical market, and in line with the role entrusted to the Authority by the legislator regarding the Law of establishment of the Egyptian Drug Authority (EDA) No. 151 of 2019 which assigned it the competence to develop and ensure the quality, efficacy, and safety of pharmaceuticals, medical devices, and raw materials, and to undertake these tasks in accordance with scientific developments used in diagnosis or treatment or prevention which requires opening the scope for all research, development, and quality related to pharmaceuticals, medical devices, in a manner that enhances the fulfillment of citizens' rights of healthcare in accordance with the quality standards stipulated in Article (18) of the Constitution which considered its most important determinants is the quality of pharmaceuticals and medical devices. Furthermore, sponsoring the aforementioned research, development, and quality activities represents one form of sponsoring scientific research, which the State is committed to guaranteeing its freedom, encouraging its institutions, sponsoring its researchers, and ensuring effective contribution by the private sector to its advancement, all in accordance with the provisions of Article (23) of the Constitution.

In light of the Authority's competence to license private laboratories related to the scope of the Authority's jurisdiction, regarding the provision of Article (17) of its aforementioned Law, which includes the competence to set the licensing rules for such laboratories, this guide is issued to regulate the regulations and procedures for licensing and operating Research and Development (R&D) and Quality Control (QC) laboratories for pharmaceuticals and medical devices, in accordance with international rules and standards and scientific developments in this regard.

2. Scope of the Guide:

- The provisions of this guide shall apply to Quality Control (QC) and Research & Development (R&D) laboratories for pharmaceuticals and medical devices affiliated with a pharmaceuticals and medical devices factory licensed by the Egyptian Drug Authority, whether located inside or outside the boundaries of the facility, as well as laboratories not affiliated with such factories that independently carry out all or part of the activities and competencies mentioned in this guide.
- Obtaining accreditation from local or international accreditation entities, including EGAC or others, shall not exempt the laboratory from complying with the requirements or licenses mandated by the Egyptian Drug Authority whenever required in accordance with the provisions of this guide.
- All the above shall be without prejudice to the provisions of Law No. 127 of 1955 regarding the Practice of the Pharmacy Profession, Law No. 82 of 2002 regarding the Protection of Intellectual Property Rights, the aforementioned Law No. 151 of 2019, Law No. 214 of 2020 Regulating Clinical Medical Research, and relevant laws and legislation.

- No activity or competency of these laboratories shall be practiced on products containing substances listed in the schedules annexed to Law No. 182 of 1960 regarding combating Narcotics and the Regulation of Their Use and Trade, & products containing psychotropic substances listed under Ministerial Decree No. 172 of 2011 regarding Regulating the Circulation of Psychotropic Medications, as well as raw materials listed under the schedule of explosives, dual-use raw materials, and insecticides.

3. Definitions:

- **Medical/Pharmaceutical Products:** Every product or preparation containing any substance or group of substances used for the purpose of treatment, prevention, or diagnosis in humans or animals, or described as having another medical effect, or aiming to restore, correct, or modify physiological functions through a pharmacological, immunological, or metabolic action in public health, in accordance with applicable references and standards, as well as any products or substances that may be developed according to scientific developments and/or international standards and references.
- **Biological Products:** Products containing one or more active substances produced or extracted from a biological source, including, for example: human vaccines, sera, blood and plasma products and derivatives, as well as products manufactured using biotechnology and similar ones, and any products or substances that may be developed according to scientific developments or international standards and references.
- **Raw Materials:** Active or inactive substances used in the manufacturing of pharmaceuticals and medical devices, excluding materials used in packaging and labeling.
- **Cosmetic Products:** Products intended for use on external parts of the human body, teeth, or mucous membranes lining the oral cavity for the purpose of cleaning, perfuming, protecting, maintaining them in good condition, or altering and improving their appearance, or any other products that exist or may be developed and classified as cosmetic products according to international references.
- **Medical Devices:** A device, instrument, apparatus (means), machine, equipment, appliance, or software, including anything inserted or implanted or in vitro diagnostic reagent or electronic software or material, or other similar or related items, manufactured by the manufacturer intended for human use, whether used alone or in combination, for one or more of the following specific medical purposes:
    - Diagnosis, prevention, monitoring, treatment, or alleviation of disease.
    - Diagnosis, monitoring, treatment, alleviation of, or compensation for an injury.
    - Investigation, replacement, modification, or support of the anatomical or physiological (functional) process.
    - Supporting or sustaining life.
    - Control of conception.
    - Disinfection of medical devices.

- Providing information via in vitro examination of specimens derived from the human body.

Provided that the primary intended action is not achieved by pharmacological, immunological, or metabolic effect in or on the human body, but which may assist the medical device in its intended function by the mentioned effects.

- **Quality Control (QC):** All procedures that must be followed to ensure the compliance of raw materials, intermediate products, and finished products with pre-established specifications, starting from approving specifications, through sampling, performing required testing and analysis, up to issuing and reviewing reports and certificates of analysis.
- **Research & Development (R&D):** A systematic process of discovering and addressing new knowledge and applying it to innovate new pharmaceutical products or formulations, or to improve existing products.
- **Chemical Testing:** Tests performed to determine or measure the chemical composition of a substance or product, or the content of active pharmaceutical ingredients (APIs), impurities, and related substances, in order to verify compliance with approved specifications and standards.
- **Physical Testing:** Tests performed to evaluate the physical properties of a substance or product, such as appearance, color, texture, density, weight, volume, viscosity, particle size, and other relevant physical characteristics.
- **Microbiological Testing:** A set of laboratory procedures aimed at evaluating the microbial load of a substance, ensuring it is free from specific pathogenic microorganisms, measuring preservative efficacy, or verifying product sterility.
- **Biotechnical Testing:** Tests performed using biological systems or materials to evaluate the biological activity, potency, safety, or identity of a substance or product, including bioassays, immunological tests, cell culture assays, and other tests used for biological or biotechnological products.
- **Laboratory Affiliated with pharmaceuticals or medical devices factory:** An independent pharmaceutical facility separated from the main factory whether located inside or outside its boundaries, as the case may be affiliated with a factory licensed by the Egyptian Drug Authority, and it is specialized according to its license in performing chemical, physical, microbiological, cell-based tests/ research and development (R&D).
- **Private Laboratory:** An independent pharmaceutical facility not affiliated with a factory, and it is specialized according to its license in performing chemical, physical, microbiological, cell-based testing/ research and development (R&D) for pharmaceuticals and medical devices that fall within the scope of the Authority's jurisdiction.
- **Research & Development (R&D) and Quality Control (QC) Laboratory License:** The license issued by the Egyptian Drug Authority for a Research & Development and QC laboratory, which specifically details the types of research, development, or quality control

activities licensed for practice, as well as the associated laboratory testing, related analysis, and the pharmaceutical institutions to which the laboratory is permitted to provide its services.

- **Licensee:** The pharmaceutical factory, or the natural or legal person desiring to practice all or part of the R&D and QC laboratory activities, whether for himself or for third parties, in accordance with the provisions of this guide.
- **Responsible Laboratory Manager:** The pharmacist responsible for managing the laboratory and supervising its activities, who holds a license issued by the Egyptian Drug Authority.
- **License Application:** The form designated by the Egyptian Drug Authority to apply for licensing a Research & Development (R&D) and Quality Control (QC) laboratory.
- **Laboratory layout:** A schematic layout showing the different areas and activities within the laboratory, illustrating the personnel flow, testing samples flow, waste flow, as well as cleanliness or sterility classification when the activity requires that.
- **WHO Good Laboratory Practices (GLP):** The guidelines issued by the World Health Organization regarding good laboratory practices.
- **ISO/IEC 17025:2017:** An international standard specifying the general requirements for the competence of testing and calibration laboratories, ensuring that laboratories operate efficiently and consistently produce accurate and reliable results; according to this standard accreditation reflects the laboratory's commitment to the highest professional and technical quality standards.
- **Documentation of Results:** Recording, archiving, and approving test and analysis results alongside their associated raw data, in a manner that ensures data integrity, traceability, verification, and retrievability when needed.

4.Activities and Competencies of Research & Development (R&D) and Quality Control Laboratories:

Research & Development and Quality Control laboratories shall carry out all or part of the following activities and competencies:

1. Research & Development (R&D): Includes the following activities:

- Designing and developing new pharmaceutical formulations, whether compendial or proprietary.
- Improving and developing marketed compendial or proprietary pharmaceutical formulations to meet or enhance quality, safety, and efficacy requirements.
- performing stability studies related to research and development to evaluate finished product stability under various conditions (temperature, humidity, light) and documenting the results.
- performing comparability studies for biosimilars.
- performing R&D activities, including pre-clinical studies on laboratory animals within R&D laboratories, in compliance with the applicable regulatory guidelines and the relevant references cited in this guideline.

2. Quality Control (QC): Includes the following activities:

- Testing and analysis of raw materials, intermediate products, finished products, and packaging materials, including the following tests:
  - Chemical testing
  - Physical testing
  - Microbiological testing
  - Conformance testing, such as cell-based bioassays

3. Services and Contracts:

Includes laboratory contracting with any of the pharmaceuticals or medical devices factories licensed by the Egyptian Drug Authority, or companies licensed by the Egyptian Drug Authority for toll manufacturing to perform any of the aforementioned activities related to research, development, and quality control, in addition to performing tests within the laboratory's scope of competence on behalf of those factories or companies.

5. Technical Requirements and Conditions for Licensing:

5.1 General Conditions for All Laboratories:

1. Must fulfill all health and technical conditions set forth in this guide.
2. The laboratory must be suitable regarding area and building design.
3. Must have independent boundaries that do not overlap with any other pharmaceutical activities.
4. Must have a designated responsible manager, dedicated full-time to managing and supervising its activities and competencies, who shall not practice any other tasks or roles, even if affiliated with the licensee.

5.2 Special Conditions for Private Laboratories:

1. The license applicant must be a natural person or a legal entity licensed in its establishing document to practice the activities subject to this guide.
2. The natural person or the individual responsible for the actual management of the legal entity must be of good conduct and reputation, possess full legal capacity, and must not have been convicted by a final judgment in a felony or a misdemeanor involving moral turpitude or dishonesty, unless rehabilitated.

5.3 Health and Technical Conditions Specific to Quality Control Laboratories:

- **Location and Facility:**
  - The laboratory site and environmental conditions must be suitable for laboratory activities and must not adversely affect the validity of results.
  - The laboratory must be suitable in terms of building design.

- Provide an adequate ventilation and a design that facilitates cleaning and sterilization, with environmental monitoring systems to control temperature, humidity, and lighting.
- Provide an independent water supply source and an independent drainage system for the laboratory.
- It is essential to provide a water source suitable for various analytical purposes according to the testing requirements subject to the license.
- Effective separation between areas with incompatible laboratory activities according to the risk assessment study for each activity, as well as relevant international requirements in this regard.
- Design, construction, and maintenance of laboratories in a manner that prevents the entry of insects and rodents, in addition to preventing cross-contamination.
- Internal surfaces (walls, floors, and ceilings) must be smooth, free from cracks, and allow easy cleaning and sterilization.
- Provide an adequate space and equipment to perform necessary testing, in addition to basic utilities such as water, electricity, and gas.
- The ventilation system must ensure a dust-free environment.
- Laboratories must be provided with adequate lighting and ventilation, and, if necessary, air conditioning to maintain appropriate temperature and relative humidity levels that do not adversely affect the testing and storage of pharmaceuticals & medical devices, or the performance accuracy of laboratory equipment or instruments.
- Drainage system facilities must be designed to facilitate proper maintenance and prevent water accumulation in the laboratory.
- Bench surfaces must be made of materials resistant to acids, alkalis, and solvents, and must be smooth and free from cracks.
- The area classification must be appropriate according to the requirements of the activities performed in the laboratory according to the license.
- Destruction and treatment of all biomedical laboratory waste.
- Provide an adequate space with appropriate storage conditions within the laboratory for preserving (archieving) reference standards and working standards.
- In microbiology laboratories, airborne microbial counts are controlled via a dedicated Air Handling Unit (AHU) for the laboratory, with providing a Laminar Airflow (LAF) in the area designated for sterility testing and certain other tests (e.g., microbial limit test, pathogen test, GPT).
- dedicated storage areas should be provided for retained samples.

- **Personnel:**
  - Laboratory personnel must possess the necessary qualifications, appropriate training, and sufficient experience to perform their assigned duties.
  - Maintaining a training record for all personnel.
  - The laboratory manager must hold qualifications and experience in the analysis of medical products within the licensed scope of activity and in laboratory management, and shall be responsible for:

1. Ensuring the control and maintenance of documentation, including the quality system in accordance with regulatory authority requirements, which includes all raw data, Standard Operating Procedures (SOPs), documentation, protocols, and training schedules.
2. Planning and organizing quality system audits, as well as initiating and following up on corrective actions, if any.
3. Investigating technical complaints and bearing ultimate responsibility for recommending any regulatory action in case of non-compliant laboratory samples.

- **Equipment and Instruments:**
  - The laboratory must be equipped with the necessary instruments and operating software required for laboratory activities according to the scope of competence to be licensed, provided they are in valid operating condition with calibration logs and documentation evidencing qualification and validation.
  - The laboratory must have a procedure for handling equipment, including transportation, storage, operation, maintenance, and scheduled calibration to ensure proper performance and to prevent contamination or deterioration.
  - Supplying the laboratory with all necessary instruments, equipment, and technical installations required to practice the activities subject to licensing in accordance with approved international standards and specifications, including—without limitation—the instruments and equipment required to enable the laboratory to execute all tests and analyses within the requested scopes of work efficiently and effectively.

Instruments for Physical and Chemical Laboratories:

Analytical balances, pH meter, spectrophotometer (UV/Vis/IR), High-Performance Liquid Chromatography (HPLC), Gas Chromatography (GC), Fourier-Transform Infrared Spectrophotometer (FTIR), melting point apparatus, refractometer, viscometer, analyzer /moisture balances, drying ovens/hot air ovens, hot plates, magnetic stirrers, distillation unit, general glassware (beakers, volumetric flasks, test tubes, cylinders, funnels, pipettes), fume hood, refrigerator, water bath, polarimeter, potentiometer, conductivity meter, Karl Fischer apparatus, dissolution testing equipment/apparatus, and disintegration tester.

Instruments for Microbiology Laboratories:
Microscope, incubators with controlled temperature ranges for microbial growth (60–70°C, 30–35°C, 20–25°C, 55°C), sterilization and decontamination equipment (steam autoclave), Laminar Flow Hood / Biosafety Cabinet (BSC), centrifuge, colony counter, deep freezer/refrigerator, water bath, vortex mixer, hot air oven, bacterial identification system (such as VITEK), pH meter, antibiotic zone reader, filtration pump, air sampler, UV spectrophotometer, and balance.

Testing Instruments for In-Process/Intermediate Formulations:
Weight variation testing equipment, pH meter, viscometer, moisture content analyzer, tablet hardness tester, friability tester, content uniformity testing equipment, torque tester, leak test apparatus, disintegration tester, and dissolution testing apparatus.

Instruments for Biotechnology Laboratories:
Instruments may vary from one laboratory to another based on the nature of the tests performed; examples of required equipment for a biotechnology laboratory include, but are not limited to: microscope, refrigerator/freezer, incubators with controlled temperatures tailored to the nature of testing, liquid nitrogen tanks, cell counter, CO2 cylinders, Laminar Flow Hood / Biosafety Cabinet tanks, plate readers , fluorescence/absorbance software, centrifuges and vortex.

- Placing analytical instruments in a dust-free environment, with continuous monitoring and routine& regular recording of temperature and humidity within approved limits to ensure the maintenance of suitable operating conditions for the instruments.
- Maintaining the cleanliness and tidiness of instruments, workbenches, and surrounding areas at all times.
- Instruments requiring calibration must be calibrated at regular intervals, with calibration and maintenance records preserved, alongside providing written instructions in the form of Standard Operating Procedures (SOPs) for instrument operation, maintenance, and calibration.
- Equipment records must be maintained and should include the following: calibration records, standard operating procedures for preventive maintenance of machines, equipment, or devices.
- Other equipment, such as weight boxes and thermometers, shall be thoroughly checked to verify calibration accuracy before acceptance for use.
- Maintenance procedures must be prepared as Standard Operating Procedures (SOPs), and routine maintenance must be conducted by a qualified maintenance engineer or specialist technician.
- Equipment and instruments producing abnormal or defective results shall be tagged as "Out of Service" until repaired; following repair, they must be calibrated prior to use.
- Maintenance of utility equipment (e.g., electricity, gas, water, steam, compressed air) must be carried out by a qualified person.
    - Steam sterilizers (autoclaves) must satisfy specified requirements for operation, safety, and calibration procedures.

- Fume Hoods: Work involving the emission of harmful or foul-smelling vapors must be performed inside a fume hood. The exhaust system of the fume hood must be inspected periodically to ensure its integrity. An internal drainage system must be provided within the fume hood and inspected periodically to prevent water accumulation and ensure integrity.
- Validation of computerized systems, such as Laboratory Information Management Systems (LIMS), that capture, process, generate, maintain, distribute, or store electronic records.
- Reviewing and auditing activities to ensure compliance with Good Manufacturing Practice (GxP) data integrity requirements, and validating systems and their interfaces to ensure data integrity during inter-system transfer.
- Provision of an Uninterruptible Power Supply (UPS) or generator, with verification of operational efficiency.

- **Chemicals and Reagents:**
  - Chemicals and reagents must be stored and handled in a manner that accounts for their physical and chemical properties and associated hazards, ensuring proper segregation of hazardous and flammable materials.
  - All reagents and solutions in the laboratory must be properly identified using labels.
  - The laboratory must maintain a standardization record that includes raw data and Standard Operating Procedures (SOPs) for the preparation and standardization of volumetric and standard solutions, specifying storage conditions.
  - Containers of concentrated and standard solutions must bear the following details:
    - ✓ Name of the analytical chemist who prepared the solution;
    - ✓ Date of preparation;
    - ✓ Each volumetric solution must have an expiration date according to solution stability, storage conditions, date of opening, and shelf life after opening;
    - ✓ Standardization records.
  - Transferring chemicals and hazardous substances from one container to another must be carried out using appropriate equipment, taking safety into account and avoiding temporary or hazardous practices.

- **Cleanliness, Safety, and Waste Disposal:**
  - General and specific written safety instructions shall be circulated to all personnel and reviewed periodically as needed (e.g., posters, audiovisual materials).
  - Standard Operating Procedures (SOPs) for safety and cleanliness shall be established, including the provision of Safety Data Sheets (SDS) to personnel prior to conducting tests and on a routine basis.
  - Eating, drinking, and smoking are strictly prohibited in laboratories.

- Laboratory coats or other protective clothing—including gloves, face masks, and eye protection—must be worn when required.
- Laboratories must be equipped with a first aid kit and adequate fire-extinguishing equipment located in appropriate areas according to each laboratory's scope of specialization.
- Personnel shall be aware of and trained in the use of fire-fighting equipment, including fire extinguishers, fire blankets, and gas masks.
- Personnel performing sterility testing must wear sterile garments, including head covers, face masks, and footwear.
- Personnel shall be trained in first aid techniques and emergency care.
- Safety rules must be observed when handling compressed gas cylinders; personnel must be familiar with relevant color codes and follow protective precautions to be taken within laboratories.
- Emergency safety showers must be installed in suitable locations within laboratories.
- Rubber suction bulbs/pipette fillers must be used on manual pipettes and tubes.
- Written warnings, precautions, and instructions must be provided for working with violent, uncontrollable, or hazardous reactions (e.g., mixing water with acids or handling biological substances).
- Provision of adequate facilities for the collection, storage, and disposal of waste.
- Safe disposal methods for corrosive or hazardous substances must be implemented via neutralization or inactivation, with mandatory complete disposal of mercury and its salts.
- A Standard Operating Procedure (SOP) must be established for handling, collecting, and disposing of chemical and biological waste.
- Provision of personal protective equipment (PPE), fire suppression systems, and alarm and emergency systems within the laboratory.
- Monitoring and documenting waste disposal operations in compliance with waste disposal rules based on a risk assessment study; treatment must be tailored to the hazard level of all waste generated by each laboratory, and disposal may be carried out via an external contract with a specialized entity, provided that responsibilities are clearly specified in the contract.

- **Maintenance, Calibration, and Equipment Documentation:**
  - All equipment, instruments, and other tools used in laboratories uses appropriate methods and procedures for all testing or calibrations and must be regularly calibrated and documented. Calibration intervals may vary from one instrument to another.

- For most equipment and instruments, the laboratory must establish Standard Operating Procedures (SOPs) for calibration along with a calibration schedule, and every laboratory must maintain a logbook to properly document calibration results.

- **Reference Materials:**
  - Reference materials are essential for testing and/or the calibration of equipment, instruments, or other devices, and all such materials must be traceable.
  - The laboratory shall prepare a working standard by comparing it against reference standards, and it must be routinely tested for purity by evaluating criteria such as identity, loss on drying or water content, impurities, and assay.
  - Any new reference material entering the laboratory shall be assigned a unique identification number, which must be recorded in the laboratory notebook and the analytical worksheet. Similarly, working standards must be assigned an identification code.
  - The laboratory must maintain a dedicated register for reference materials. The following details may be specified in this register:
    a. Source of supply
    b. reference material identification number
    c. Date of receipt
    d. Batch number or supplier's identification number
    e. Analytical details such as assay value, water content, or any other available information
    f. Storage conditions of the material
    g. Expiration date, if applicable, and manufacturing date if applicable
  - All working standards shall be verified at appropriate intervals or prior to use to ensure they have not deteriorated or degraded during storage, and these observations must be recorded in a logbook.
  - All reference and working standards shall be stored under suitable storage conditions according to the nature and specific storage requirements of each material.
  - **Regarding Microbiological Cultures:** The laboratory is committed to establishing and implementing Standard Operating Procedures (SOPs) for the maintenance of subculturing and microbial cultures .
  - If any culture is found to be non-viable or mutated, approved procedures for culture disposal via steam sterilization must be followed under the supervision of a person authorized to perform biological testing. Subculturing shall not exceed five passages. All activities related to microbiological cultures must be conducted within aseptic areas by authorized personnel only. Laboratories are obligated to perform standard biochemical testing on subcultures in accordance with approved references—specifically *Annex 2, WHO TRS 961, 2011 "WHO good practices for pharmaceutical*

microbiology"—to continuously verify the viability and purity/integrity of these cultures.
- The laboratory is committed to adhering to updates in scientific references as well as internationally and locally approved applicable standards.

- **Analysis:**
  - Reviewing analytical methods for raw materials and finished products in accordance with internationally and locally applicable references.
  - Method validation of analytical procedures.
  - Testing and analyses of water sample according to Standard Operating Procedures (SOPs) and ensuring compliance with required standards.
  - environmental monitoring related to production and microbiology laboratories and ensuring compliance with required standards.
  - Approved or validated analytical methods must be utilized.
  - When changes are introduced to an approved (validated) method, the impact of such changes must be determined; if the changes are found to affect the original validation, re-validation of the method must be conducted.
  - Performance characteristics of approved (validated) methods, as evaluated for the intended use, must be relevant to customer needs and compliant with specified requirements.
  - The laboratory must maintain the following records regarding method validation:
    a) The validation procedure used;
    b) identification of requirements.
    c) Determination of the performance characteristics of the method;
    d) Results obtained;
    e) A statement on the validity of the method, detailing its suitability for the intended use.

- **Sampling:**
  - Written sampling procedures must be established.
  - The laboratory must maintain records of sampling data that form part of the testing or calibration performed. These records shall include, where applicable:
    a) Reference to the sampling method used;
    b) Date and time of sampling;
    c) Data identifying and describing the sample (e.g., number, quantity, name);
    d) Identification of personnel who performed the sampling;
    e) Identification of equipment used;
    f) Environmental or transportal conditions;
    g) Diagrams or equivalent means to identify the sampling location, where appropriate;

h) Deviations, additions, or exclusions from the sampling method and plan.

- **Quality Procedures:**
  - Using an integrated quality management system complied with ISO/IEC 17025 standards, WHO GLP guidelines, as well as ICH guidelines.
  - Following Standard Operating Procedures (SOPs) for all operations and activities.
  - The laboratory must use an electronic system for issuing technical and financial reports and all related procedures, provided that the electronic system complies with data integrity and security requirements.
  - Procedures must adhere to standard criteria when documenting laboratory results for certificates issued for pharmaceutical and medical devices originating from contract factories or companies.
  - Test and analysis results, as well as technical reports issued by the laboratory, must be documented in accordance with approved procedures to ensure data integrity, traceability, and auditability.
  - The quality system must be designed to achieve the following objectives: ensuring that measurements and calibrations comply fully with reference standards; adhering to validated methods based on verification protocols; effectively providing necessary assurances that activities, processes, techniques, or practices comply with planned arrangements; and facilitating early detection and correction of non-conformities, with appropriate corrective actions taken based on observations from internal and external inspections.

5.4 Health and Technical Conditions Specific to "Research & Development (R&D) Laboratories":

The same requirements specified for Quality Control laboratories must be applied, in addition to the following:

1. Accurate data collection and analysis.
2. Safe handling of active compounds and hazardous materials, in accordance with safe disposal practices.
3. An efficient workflow to accelerate the development of pharmaceutical and medical devices.
4. Availability of necessary equipment for laboratory activities in accordance with international standards, including: High-Performance Liquid Chromatography (HPLC) systems, dissolution testing apparatus, disintegration testers, friability testers, hardness testers, microscopes, and balances.

5. Availability of processing equipment, including stability chambers simulating various temperature and humidity conditions for short-term and long-term product testing, refrigerators, and drying ovens.
6. Equipment capable of conducting R&D processing operations (e.g., mixers, granulators, coating machines, capsule filling machines, among others).
7. Secure networks, data management systems, and workstations.
8. Calibration and validation of instruments, methods, and processes to ensure reliable results (method validation).
9. Documentation: Archiving and retention of all records, data, and procedures in secure archives.
10. Adhering to Good Manufacturing Practices (GMP) and Good Laboratory Practices (GLP) relevant to its scope of work, in proportion to the nature of the research and development activities conducted, and in a manner that ensures data and result integrity, personnel safety, safe handling of materials and samples, traceability, and documentation.
11. Data and information related to equipment, instruments, manufacturing, and testing must be provided at an appropriate level of detail, traceable, and available.

- In the event that an R&D laboratory conducts quality control testing in addition to its research and development activities, it will be subject to the technical, regulatory, and routine inspection requirements applicable to private quality control laboratories.
- When conducting pre-clinical studies within R&D laboratories, compliance is mandatory with the regulatory requirements governing such activities and the international standards for conducting pre-clinical studies on laboratory animals in accordance with the references cited in this organizational guide.

6. Licensing Procedures:

Licensing includes defining the scope of activities, tests, and technologies authorized for the laboratory to practice, based on the technical capabilities, instruments, and personnel submitted with the license application and no activity or test outside the licensed scope may be practiced without prior approval from the Authority.

The laboratory must create an account on the Egyptian Drug Authority's electronic system and complete its profile data.

First: Procedures for Licensing an R&D and QC Laboratory Affiliated with an EDA-Licensed Factory and/or Licensing a Private R&D and QC Laboratory

1. An application is submitted to the General Administration of Factories Licensing in the Central Administration for Licensing Pharmaceutical Establishments on the designated form, detailing the requested scope of licensing for the laboratory, accompanied by the following documents:

- ✓ A copy of the technical license of operation of the factory to which the laboratory is affiliated (for laboratories affiliated with a licensed factory).
- ✓ A copy of the proof of possession document for the laboratory.
- ✓ A copy of accreditation certificates obtained by the laboratory (if any).
- ✓ A copy of a letter from the local district authority stating that the unit is licensed for commercial activity; inspection of the issued unit license stating commercial activity shall suffice, with a copy retained.
- ✓ A copy of the company's commercial register, provided it includes the testing activities for which the laboratory seeks licensing.
- ✓ A copy of the laboratory's electricity meter bill demonstrating an independent electricity meter.
- ✓ A copy of an independent water meter bill for the laboratory.
- ✓ A copy of the engineering layout drawing of the laboratory.
- ✓ List of laboratory equipment/instruments.
- ✓ Documents related to the Responsible Laboratory Manager (of Egyptian nationality – full-time):
    - ➢ Copy of graduation certificate (holding a Bachelor's degree in Pharmacy) in the case of laboratories affiliated with pharmaceutical and biological products activity.
    - ➢ Copy of graduation certificate (holding a Bachelor's degree in Pharmacy / Bachelor of Science / an academic degree related to the same field) in the case of laboratories affiliated with cosmetic or medical device facilities.
    - ➢ Copy of National Identification Card.
    - ➢ Copy of Syndicate Membership Card.
    - ➢ Copy of manager's experience certificates (minimum of 10 years of experience in quality control for laboratories affiliated with pharmaceutical and biological products activity, and a minimum of 5 years for laboratories affiliated with cosmetic and medical device activity).
    - ➢ Certificate stating the pharmacist's mandatory public service status (Takleef) issued by the General Administration of Certificates and Licensing Follow-up at the Central Administration of Pharmaceutical institutions Licensing (in the case of a pharmacist manager).

2. The General Administration of Factories Licensing shall review the submitted documents within 10 working days from the application submission date.
3. The initial inspection date shall be set within 30 days from the application submission date to verify the implementation of health and technical requirements of the laboratory in accordance with the requested scope of licensing.
    - o If the laboratory is confirmed to be fully prepared and compliant with health and technical requirements, the license shall be granted.
    - o In the case of non-compliance, the laboratory shall be granted a grace period of eight months to rectify observations and fulfill all requirements.

- At the end of the grace period, a second licensing inspection of the laboratory shall be conducted. If compliance with requirements is established, the license shall be issued within 7 working days from the date of completing all required licensing documents; in case of continued non-compliance, the application shall be archived.
- In all cases, the validity period of the license shall be three years for a private laboratory, and five years for a laboratory affiliated with a licensed manufacturing facility.

License Delivery Procedures:

- After verifying the fulfillment of health and technical requirements in the laboratory and the completion of all documents, the General Administration of Factories Licensing shall issue the license for the laboratory affiliated with a licensed facility / issue the license for the private laboratory.
- The laboratory license shall be received by virtue of an authorization letter or a special power of attorney notarized by the Real Estate Registration Office, authorizing a person designated by the license applicant to deal with the Egyptian Drug Authority and submit/receive all documents pertaining to the applicant, provided that the authorization letter is authenticated with a bank signature verification from an authorized signatory.
- A list of tests authorized for the laboratory to perform shall be specified during the licensing process to ensure compatibility with contracts executed with manufacturing facilities—which are reviewed during the inspection phase—according to the nature of the products and analyses authorized for performance. The laboratory shall not have the right to perform any tests not registered on the list or not authorized to practice.

Renewal Procedures for Research & Development (R&D) and Quality Control (QC) Laboratory License Affiliated with an EDA-Licensed Facility and/or Renewal of Private R&D and QC Laboratory License

1. An application shall be submitted to the General Administration of Factories Licensing for the purpose of renewing the laboratory license at least 6 months prior to the expiration of the mentioned license validity period, using the designated form.
2. The General Administration of Factories Licensing shall review the submitted documents.
3. An inspection shall be conducted by the Egyptian Drug Authority to ensure compliance with the laboratory's technical requirements, which must align with the authorized scope.
4. After verifying the fulfillment of technical requirements in the laboratory and the completion of all documents, the General Administration of Factories Licensing shall issue the license renewal for the laboratory affiliated with a licensed facility / private laboratory.

The renewed laboratory license shall be received by virtue of an authorization letter or a special power of attorney notarized by the Real Estate Registration Office, authorizing a person designated by the

license applicant to deal with the Egyptian Drug Authority and submit/receive all documents pertaining to the applicant, provided that the authorization letter is authenticated with a bank signature verification from an authorized signatory.

Amendment Procedures for Research & Development (R&D) and Quality Control (QC) Laboratory License Affiliated with an EDA-Licensed Facility or Amendment of Private R&D and QC Laboratory License

1. An application shall be submitted to the General Administration of Factories Licensing for the purpose of amending the laboratory license, attached with the documents related to amending the laboratory data or scope of competence, using the designated form.
2. The General Administration of Factories Licensing shall review the submitted documents.
3. A licensing inspection shall be conducted by the Egyptian Drug Authority, if necessary, to ensure compliance with the laboratory's technical requirements.
4. After verifying the fulfillment of technical requirements in the laboratory and the completion of all documents, the General Administration of Factories Licensing shall issue the amended license for the laboratory affiliated with a licensed facility / private laboratory.

The amended laboratory license shall be received by virtue of an authorization letter or a special power of attorney notarized by the Real Estate Registration Office, authorizing a person designated by the license applicant to deal with the Egyptian Drug Authority and submit/receive all documents pertaining to the applicant, provided that the authorization letter is authenticated with a bank signature verification from an authorized signatory.

7. Inspection Procedures:

The Central Administration for Inspection of Pharmaceutical Establishments (General Administration of Facility Inspection) shall be responsible for periodic inspection of licensed R&D and Quality Control laboratories, which encompasses inspecting the licensed facility and its technical and health requirements, excluding the R&D operations carried out therein and the associated tracking of raw materials used.

- Periodic inspection shall be executed based on risk assessment evaluated by (complexity degree, critical importance, level of compliance) after the laboratory obtains the license.

- In the event that the laboratory complies with Good Analytical Practices during the operational phase, the Central Administration for Inspection of Pharmaceutical Establishments shall issue a Good Laboratory Practice (GLP) certificate. If the laboratory fails to comply with the requirements, the certificate shall not be issued, and licensed manufacturing facilities

contracted with it shall be notified to suspend contracting due to non-compliance with Good Analytical Practices.
- Compliance with international standards such as: OECD GLP, ISO/IEC 17025, ICH Q9, PIC/S, and WHO GBT.
- The Periodic inspection includes the following procedures:

1. Review of General Information
- Verifying the identity and contact details of the establishment (name, address, telephone number, e-mail).
- Verifying laboratory licenses and their analytical activities.
- Verifying any contracted activities and reviewing contracts between the laboratory and contracting entities.

2. Quality Assurance System (QA)
- Reviewing the Quality Policy and Quality Manual.
- Verifying the organizational structure and responsibilities.
- Following up on supplier management operations and internal assessments (audits, supplier assessment).
- Reviewing risk assessment, change control, Corrective and Preventive Actions (CAPA), management reviews, testing results, deviations, traceability, Out-of-Specification (OOS) results, and ensuring the safe handling and disposal of sample remainders.
- Proficiency Testing: Verifying the laboratory's participation in external performance evaluation programs to ensure the accuracy and reliability of results.

3. Contracts and Contracted Activities
- Reviewing contracts between the laboratory and contracting entities, and ensuring the presence of valid, written contracts.
- Verifying that the contracted laboratory is licensed at the time of contracting.
- Ensuring that the Scope of Work is clearly documented and aligned with the quality policy, encompassing samples, types of analysis, and quality requirements.
- Ensuring the existence of initial evaluation and periodic re-evaluation of the laboratory's performance level by the contracting entity.
- Ensuring clarity of responsibilities between both parties, deviation management, confidentiality and impartiality, and report quality to guarantee result compliance with standards.

Contracts must clearly define:
  - Responsibilities of each party
  - Sampling and sample transport procedures
  - Management of deviations and OOS/OOT (Out-of-Trend) results
  - Change control system

- Retention of records and reference samples
- Sample Disposal: Contracts must clarify responsibilities for sample disposal following the completion of analysis, provided regulatory procedures for destruction via the Drug Authority outlined in the organizational guide are followed, including chemical substances and finished products, while complying with environmental and health standards as well as local and international laws. Ensuring that the contracting entity and the laboratory have agreed upon documented procedures for safe and responsible disposal, and that they form part of the laboratory's Standard Operating Procedures (SOPs).

- Under no circumstances shall batches be released at medical product and device manufacturing plants except pursuant to applicable procedures and controls established by the Egyptian Drug Authority in this regard.
- In all cases, if the company or manufacturing plant contracts with a laboratory subject to the scope of this guide to perform any quality control testing, the company is obligated to attach a copy of the operating license issued to the laboratory by the Egyptian Drug Authority within the product file submitted for analysis at the Central Administration for Pharmaceutical Control.

4. Documentation

- Reviewing laboratory documents: SOPs, testing instructions, result logbooks/records, and laboratory notebooks.
- Verifying data traceability and raw data to ensure complete traceability of samples and standards. Reviewing analytical methods and method validation.
- Ensuring the integrity of electronic documents, access authorizations, data backup, and enabling Audit Trail and computerized systems (where applicable), such as Chromatography Data Systems (CDS) and Laboratory Information Management Systems (LIMS).
- Issuance of certificates and reports: Certificate of Analysis (COA) and OOS investigation reports.

5. Personnel and Analysts

- Reviewing the qualifications, numbers, and distribution of personnel and analysts across different departments.
- Verifying training programs, training effectiveness evaluations, and scheduling periodic re-assessments.

6-Premises and Equipment

- Verifying laboratory layout design and separation between clean and contaminated areas.
- Ensuring environmental monitoring (temperature, humidity, ventilation) and storage integrity.
- Inspection of equipment: qualification process ([DQ] / [IQ] / [OQ] / [PQ]), routine calibration, maintenance log books, and cleaning procedures.

- Ensuring protection of sensitive documents and equipment, continuous monitoring of storage conditions.

Risk Classification and Inspection Periodicity

Laboratories shall be classified into three categories (High – Medium – Low) based on:

- Type of testing (stability, chemical, microbiological, biotechnology).
- Impact of results on regulatory decisions.
- Historical compliance record (observations, complaints, Out-of-Specification [OOS] results).
- Accreditation level (ISO/IEC 17025, GLP).
- Activity volume and annual number of tests.

Inspection System and Procedures

Inspection encompasses the following stages:

1. **Pre- Preparation:** Document collection and scoping of inspection based on risk assessment.
2. **Notification:** Issuing the inspection agenda via official email (unless unannounced).
3. **Opening Meeting:** Clarifying the scope, responsibilities, and activities.
4. **On-site Field Activities, including:**
    - Reviewing the Quality Management System (SOPs, deviations, Corrective and Preventive Actions [CAPA], management reviews).
    - Inspection of facilities, equipment, and calibration logs.
    - Reviewing analytical methods and method validation.
    - Sample management and chain of custody.
    - Data integrity and computerized systems (Audit Trails, Chromatography Data System [CDS], Laboratory Information Management System [LIMS]).
    - Microbiology operations and environmental monitoring.
    - Issuance of certificates and reports (Certificate of Analysis [COA], OOS investigations).
5. **Closing Meeting:** Presenting observations, providing an opportunity for clarification, and establishing response deadlines.
6. **Reporting and Classification:** Classifying observations into (Critical – Major – Minor).
7. **Follow-up and Execution:** Reviewing CAPA plans and taking escalatory measures when necessary.

Classification of Findings and Regulatory Actions

Critical: A deficiency directly affecting product safety, thereby impacting patient safety, device safety, or result integrity, requiring immediate action such as suspension of data acceptance or accreditation
Major: Failures affecting result integrity and requiring urgent follow-up
Minor: Improvements required without an immediate impact on safety.

- Where a medical device or in vitro diagnostic facility contracts a licensed external laboratory to conduct a stability study, inspection shall be conducted using the checklist approved by the specialized Medical Device Registration Committee, pursuant to the resolution of the specialized Medical Device Registration Committee.
- If any violations or deficiencies in safety or applicable systems are established, necessary regulatory measures shall be taken according to the type and severity of the violation and in accordance with relevant regulatory decrees issued in this regard.

8. Regulatory Procedures for Destruction and Disposal of Samples:

- **The applicant must initiate destruction procedures by:**
  - Submitting an initial electronic request via the official portal of the Egyptian Drug Authority through the approved link.
  - Preparing a complete physical hard-copy dossier containing all required documents and submitting it to the Central Administration for Inspection of Pharmaceutical institution at the Egyptian Drug Authority within a period not exceeding five working days from the date of electronic submission.

The hard-copy dossier must contain all documents listed in the electronic form, in addition to the following mandatory documents:

Official Authorized Cover Letter:
An official letter addressed to the Egyptian Drug Authority (Central Administration for Inspection of Pharmaceutical institution), stamped with the applicant's official seal, including:

- An explicit request for destruction
- Specification of the proposed location and method of destruction
- Email address of the service applicant

Detailed Product Inventory List
Specifying for each item the following:

- Product name (finished pharmaceutical product / medical device / raw material / testing supplies / IVD / in vitro diagnostic product)
- Batch/Lot number
- Expiration date
- Quantity per batch
- Total weight for disposal (calculated according to the approved conversion factor)
- Specific reason for disposal associated with each product or batch
-

Approval from the Ministry of Environment

- Recent official approval issued by the Ministry of Environment for the proposed destruction site.

Notification Letter of Authorized Representative

- Including the name of the company's authorized representative responsible for documents and attending the execution of the destruction process.

Legal Undertaking

- A written undertaking stating that the products requested for destruction are not subject to any ongoing legal proceedings or pending judicial cases.

- **Application Review and Decision-Making**
  - If all documents satisfy the Authority's requirements, the applicant shall be notified by email within five working days. The applicant must schedule the destruction date within fourteen days from the notification date; otherwise, the request shall be automatically canceled.
  - In case of document deficiencies, the applicant shall be notified to rectify them within five working days. Following re-submission, the final review shall be completed within two working days.
  - In the event of application rejection, detailed grounds for rejection shall be communicated, and the applicant may re-submit after implementing necessary corrective actions.

- **Planning and Formation of the Destruction Committee**

The applicant is obligated to coordinate the execution of the destruction process. A committee shall be formed to supervise the destruction process, comprising representatives from:

  - Central Administration For Pharmaceutical Inspection
  - Central Administration For Market Surveillance
  - The applicant entity

- **Supervision of Sorting and Sealing at the Storage Location**

Authority inspectors shall proceed to the storage site to supervise sorting operations conducted by the committee, where they shall:

  - Verify the product types, quantities, and expiration dates against the approved list.
  - Ensure alignment of items with submitted documents.
  - Seal all items with the official inspector's seal, whether inside a designated separate room within the warehouse or inside transport vehicles dedicated for destruction.

- **On-Site Supervision and Execution of Destruction**

Authority inspectors shall proceed to the approved destruction site at the scheduled time, where they shall:

  - Ensure seal integrity and absence of tampering.

- Execute destruction in accordance with the approved location and method.
- Require full attendance of all committee members.
- In case of broken seals or unauthorized alterations in quantities or destruction methods, the process shall be stopped immediately, an official report shall be drafted, and the applicant shall be required to submit a written justification within 24 hours.

- **Final Report and Documentation**

Upon verifying complete and safe destruction of all items, the Authority inspector shall prepare the official destruction report, which serves as an approved official document evidencing execution of the process in compliance with applicable regulatory controls.

9. Sample Importation Procedures:

- The importation of pharmaceutical raw material samples, reference standards, finished pharmaceutical product samples, and necessary chemicals for performing R&D and Quality Control (QC) activities in these laboratories shall be permitted in light of the license issued by the Egyptian Drug Authority in this regard, provided that the procedures outlined in the organizational guide are followed in compliance with the rules and regulations governing the importation process and medical customs clearance for medical products, their raw materials, and packaging supplies.
- Samples imported from medical devices, in vitro diagnostic reagents, finished products, raw materials, and production inputs related thereto shall be subject to the rules and procedures regulating the importation and exportation of these samples in accordance with the regulatory guide on the rules and procedures governing the importation and exportation of medical device, in vitro diagnostic samples, laboratory and diagnostic reagents, finished products, raw materials, and production inputs related thereto through customs ports.

10. References:

- Law No. 127 of 1955 on the Practice of the Pharmacy Profession.
- Law No. 151 of 2019 Establishing the Egyptian Drug Authority and Its Executive Regulations.
- Requirements of the Egyptian Drug Authority Regarding Medical Device Manufacturing Plants.
- ISO/IEC 17025:2017 Requirements for International Standards for Laboratories.
- WHO good practices for pharmaceutical quality control laboratories (WHO TRS 1052 Annex 4)
- WHO good practices for pharmaceutical microbiology laboratories (WHO TRS 961 Annex 2)
- ISO 22716 Cosmetics Good manufacturing practices GMP
- Validation of Analytical Procedures: ICH Q2 (R1)
- Analytical Procedure Development: ICH Q14
- Quality Risk Management: ICH Q9 / Q9 (R1)
- Pharmaceutical Development: ICH Q8 (R2)

- Manual and Guidance Documents: WHO GBT (Global Benchmarking Tool)
- Appendix: Guidance on Good Manufacturing Practices – Inspection Report (WHO TRS 996 Annex 1), Inspection Report Template
- PIC/S Aide-Memoire on Inspection of Pharmaceutical Quality Control Laboratories (PI 023-2)
- FDA Guide to Inspections of Pharmaceutical Quality Control Laboratories
- FDA – Bioresearch Monitoring (BIMO) Program Technical Guidance (in case inspection scope includes research activities or clinical computerized data)
- EMA Compilation of Union Procedures on Inspections & Exchange of Information (CoUP)
- EMA Guidance for the Conduct of GCP Inspections Annex II: Clinical Laboratories
- WHO / TRS / ISPE Compendia Guidance Bundles on Inspection Methods and Report Formats
- WHO Technical Report Series No. 1010 (2018), Annex 9: Guidance on Good Practices for Desk Assessment of Compliance with GMP, GLP, and GCP for Regulatory Decisions
- WHO Technical Report Series No. 986 – Annex 2: WHO good manufacturing practices for pharmaceutical products: Main principles
- WHO Technical Report Series No. 1044 – Annex 2: WHO good manufacturing practices for sterile pharmaceutical products
- Guide for the care and use of laboratory animals, committee for the update of the guide for the care and use of laboratory animals, USA
- CCAC guidelines: Laboratory animal facilities