FIELD REGULATORY OPERATIONS OFFICE (FROO)
REGIONAL FIELD OFFICE (RFO)
EXTERNAL SERVICE

1.ISSUANCE OF CERTIFICATE OF COMPLIANCE (COC), RECOMMENDATION FOR DISAPPROVAL (RFD) AND RECOMMENDATION LETTER (RL)

The Certificate of Compliance (COC), Recommendation for Disapproval (RFD), and Recommendation Letter (RL) is the output on the evaluation of documents and/or inspection stating the recommendation of the Regional Field Offices. These will be forwarded to FDA Centers/Offices for processing of the application.

Center/Office/Division	:	Field Regulatory Operations Office (FROO)
Classification	:	Highly Technical
Type of Transaction	:	G2B - Government to Business
Who may Avail	:	Manufacturers, Traders, Distributors (Importers, Exporters, Wholesalers) of health products, drug outlets or retailers and retail outlet for non-prescription drugs, as determined by the FDA
Fees to be paid	:	AO No. 50, s. 2001* + 1% Legal Research Fee (LRF), AO No.18-A, s. 1993 and Republic Act 8172

CHECKLIST OF REQUIREMENTS	**WHERE TO SECURE**
The following requirements shall be presented to the FDA Inspector for examination and review, when required, based on Administrative Order No. 2020-0017:	
Risk Management Plan (RMP) Required for medium and large food manufacturers, and all drug, cosmetics, household urban hazardous substances (HUHS), including household/urban pesticides (HUP) and toys and childcare articles (TCCA), medical device manufacturers, traders and distributors (importer, exporter and/or wholesaler), among others.	Applicant Establishment/ Qualified Person
Site Master File (SMF) Required for drug, cosmetic, HUHS, including HUP and TCCA, medical device and large and medium food manufacturers, among others	Applicant Establishment/ Qualified Person
Refer to the FROO Inspection Agenda of this Citizen's charter for the documents that will be presented to the FDA inspectors during inspection.	Applicant Establishment/ Qualified Person

1.1.THROUGH EPORTAL:

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
	Receives electronic application via FDA e-Portal System or Manual application through FDA-Document Tracking System (FIS-DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	Generates Document Tracking Number (DTN) thru DTS and Encodes in the Internal Database (IDB)	None		Data Controller/ Assigned Personnel Regional Field Office
	Decks and forwards application to Licensing Officer/ Designated Officer	None		Licensing Team Leader Regional Field Office
	Receives application via FDA e-Portal System or thru FIS-DTS	None	2 working days	Licensing Officer/ Assigned Personnel Regional Field Office
If with minor deficiencies,	Evaluates application: If compliant and inspection is not needed, proceed to Step 12 (for RL) If with major deficiencies, proceed to Step 12 (for RFD) If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 working days ***STOP CLOCK***	None		Licensing Officer/ Assigned Personnel Regional Field Office

the applicant needs to submit documents, or records to comply with the deficiencies.	Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5. 4) Note: Non-compliance within the 5 working days grace period shall be treated as major deficiency and shall be a ground for disapproval of application. 5.4 If compliant and inspection is needed, forwards application to Inspection Section			
	Receives Electronic and Manual application thru FIS-DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader Regional Field Office
	Pre -inspection activities: 7.1 Receives application thru FIS-DTS 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Agenda, Inspection Plan 7.5 Forwards prepared documents to the Team Leader (TL)/Supervisor for approval 7.6 Prepare Notice of Inspection (when necessary)	None		FDA Inspectors Regional Field Office

9. If the establishment is non-compliant, the applicant needs to submit documents, or records to comply with the deficiencies.	Conducts inspection as per approved itinerary: If non-compliant, the establishment is given maximum of 15 working days to submit Corrective Action and Preventive Action Plan (CAPA Plan) *****STOP CLOCK***.** The applicant is required to comply with all the deficiencies in 6 months and can be allowed for an extension of 3 months subject for approval.	None	5 working days	FDA Inspectors Regional Field Office
	Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates FIS-DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	Reviews Inspection Report	None	2 working days	Inspection Section Team Leader

	10.1 Updates FIS-DTS and Inspection Database			Regional Field Office
	Forwards Inspection Report to Licensing Section	None		
	Prepares Certificate of Compliance (COC) / Recommendation for Disapproval (RFD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates FIS-DTS 12.2 Forwards to Licensing TL/Supervisor	None	2 working days	Licensing Officer/Assigned Personnel Regional Field Office
	Checks and affixes initials to COC / RFD / RL	None		Licensing Team Leader/ Supervisor Regional Field Office
	Approves/signs COC/RL/ RFD	None		Director/Supervisor Regional Field Office
	Updates Database	None		Data Controller/Assigned Personnel Regional Field Office
	Releases COC/ RFD/RL 16.1 Updates FIS-DTS 16.2 Forwards COC / RFD / RL to Centers	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
TOTAL:		**None**	**20 working days**	

1.2.THROUGH ESERVICES:

CLIENT STEPS	AGENCY ACTION	Fees to be Paid	PROCESSING TIME	PERSON RESPONSIBLE
	Receives electronic LTO application via FDA e-Services Portal and Generates Document Tracking Number (DTN) thru Document Tracking System (FIS-DTS)	None	1 working day	Data Controller/ Assigned Personnel Regional Field Office
	Encodes received application in the Internal Database (IDB)	None		Data Controller/ Assigned personnel Regional Field Office
	Decks and forwards application to Licensing Section (for application not requiring inspection) or to the Inspection and Compliance Section (for application requiring inspection	None		Licensing Team Leader or assigned personnel Regional Field Office
	Licensing Section: Receives application via FDA e-Services System	None	2 working days	Licensing Officer or assigned personnel Regional Field Office

If with minor deficiencies, the applicant needs to submit documents, or records to comply with the deficiencies.	Evaluates application: If compliant and inspection is not needed, proceed to Step 12 (for issuance of Recommendation Letter) If with major deficiencies, proceed to Step 12 (for issuance of Recommendation for Disapproval) If with minor deficiencies, notify applicant thru e-mail/ declared contact no. to comply within 5 working days ***__STOP CLOCK__*** Receives and evaluates compliance: (Follow step 5.1, 5.2 or 5.4) Note: Non -compliance within the 5 working days grace period shall be treated as major deficiency and shall be a ground for disapproval of application 5.4 If compliant and inspection is needed, forwards application to Inspection and Compliance Section	None		Licensing Officer or assigned personnel Regional Field Office
	Inspection and Compliance Section: Receives electronic application thru FIS-DTS and decks to Inspectors	None	2 working days	Inspection Section Team Leader/Supervisor Regional Field Office
	Pre -inspection activities: 7.1 Receives application thru FIS-DTS and claims application through FDA e-Services Portal 7.2 Schedules Inspection 7.3 Reviews Company File 7.4 Prepares Itinerary of Inspection, Attendance Sheet, Inspection Plan and Inspection Agenda	None		FDA Inspectors Regional Field Office

If the establishment is non-compliant, the applicant needs to submit documents, or records to comply with the deficiencies.	Conducts inspection as per approved itinerary: If non -compliant, the establishment is given maximum of 15 working days to submit Corrective Action and Preventive Action (CAPA) Plan *****STOP CLOCK***** The applicant is required to comply with all the deficiencies in 6 months and can be allowed for an extension of 3 months subject for approval.	None	5 working days	FDA Inspectors Regional Field Office
	Post -inspection activities: 9.1 Classifies Deficiencies 9.2 Prepares Risk Assessment 9.3 Submits Inspection Report 9.4 Updates FIS-DTS 9.5 Conducts deliberation for Panel Approval (when applicable) 9.6 Submits to Team Leader 9.7 Evaluates CAPA and/or objective evidence (when applicable) 9.7.1 Submits inspection report with recommendation to TL *Note: If the establishment has not performed any corrective measures within the specified grace period or if the corrective measures made are not acceptable, the inspector recommends disapproval of the application*	None	5 working days	FDA Inspectors Regional Field Office
	Reviews Inspection Report 10.1 Reviews and updates FIS-DTS and Inspection Database	None	2 working days	Inspection Team Leader/Supervisor

	Forwards Inspection Report to Licensing Section	None		Regional Field Office
	Prepares Certificate of Compliance (COC) / Recommendation for Disapproval (RFD) / Recommendation Letter (RL) whichever is applicable 12.1 Updates FIS-DTS 12.2 Forwards to Supervisor	None	1 working day	Licensing Officer or assigned personnel Regional Field Office
	For COC / RL: Approves/signs COC/RL for routing to centers For RFD: Reviews and recommend final decision for routing to Director	None		Supervisor Regional Field Office
	Vets RFD for routing to centers	None	2 working days	Director Regional Field Office
TOTAL:		**None**	**20 working days**	

References:

AO. No. 2014-0029- *Rules and Regulation on the Licensing of Food Establishments and Registration of Processed Foods, and Other Food Products, and for Other Purposes.*

AO No. 2014-0034- *Rules and Regulations on the Licensing of Establishments Engaged in the Manufacture, Conduct of Clinical Trial, Distribution, Importation, Exportation, and Retailing of Drug Products, and Issuance of Other Related Authorization*

AO No. 2014-0038- *Rules and Regulation Governing Household / Urban Pesticides Licensing of Establishment and Operators, Registration of Their Products and for Other Purpose***.**

FDA Circular 2014-025- *Guidelines on Implementation of New Rules and Regulation on Licensing of Drugstore / Pharmacy / Botica and Similar Outlets following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular 2014-026- *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Distributors following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular 2014 -027 *Guidelines on the Implementation of New Rules and Regulations on the Licensing of Drug Manufacturer following Administrative Order No. 2014-0034, dated 13 October 2014*

FDA Circular2014 -028 *Guidelines on the Implementation of New rules and regulation I the licensing of Retail outlet for Non-Prescription Drugs (RONPDs) following Administrative Order No. 2014-0034, dated 13 October 2014*

Amendment to FDA Circular No. 2013-002 *Revised Guidelines in Licensing of Cosmetic Establishments*

Amendment to FDA Circular No. 2013-009 *Revised Guidelines in Licensing of Household Hazardous Substances (HHS) Establishments*

FDA Memorandum Circular No. 2020-001 Interim *Guidelines for the Issuance of Provisional License to Operate (LTO) and Certificate of Product Notification (CPN) for Manufacturers of Rubbing Alcohol Products Under the Center for Cosmetics Regulation and Research*

FDA Circular No. 2020-025 *Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

FDA Advisory No. 2020-1599 Implementation *of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

FDA Advisory No. 2020-2035 *"Update on the Implementation of FDA Circular No. 2020-0025, entitled "Implementing Guidelines for Administrative Order No. 2019-0019, "Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers, or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirement of Prior Registration and/or Notification of Said Products"*

Administrative Order No. 2019-0019 *"Reinstatement of Requirements of Licensing as Importers, Exporters, Manufacturers, Toll Manufacturers, Wholesalers, Distributors, Retailers or Re-Packers of Those Engaged in Certain Household/Urban Hazardous Substances, and from the Requirements of Prior Registration and/or Notification of Said Products"*

FDA Circular 2017-003 "Strict Implementation of the Mandatory Requirement to Secure a License to Operate (LTO), Certificate of Product Registration (CPR) or Any Authorization from FDA Prior to Engaging in the Manufacture, Importation, Exportation, Sale, Offering for Sale, Distribution, Transfer, Promotion, Advertisement and/or Sponsorship of Medical Devices

FIELD REGULATORY OPERATIONS OFFICE INSPECTION AGENDA

Bureau of Customs – For Donation

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
Inspection Report with recommendation for release (Upon validation/inspection of the products)	Simple	Government-to-Business (G2B)	3 days upon receipt of request for inspection from the consignee	FDA Clearance issued by Centers

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)
[3] Based on Current Citizen's Charter Timeline

Bureau of Customs – For Personal Use

Certification	Classification[1]	Type of Transaction[2]	Processing Time[3]	List of Requirements
E-mail Reply (citing Joint Circular No.1)	Simple	Government-to-Business (G2B)	1 day upon receipt of request from the consignee	E-mail Request request (payment, specific information/ complete details needed, photo of product)

Legend:
[1] Classify if Simple, Complex, or Highly Technical Transaction
[2] Classify if Government-to- Citizens (G2C), Government-to-Business (G2B), and Government-to-Government (G2G)

[3] Based on Current Citizen's Charter Timeline

INSPECTION AGENDA FOR HEALTH PRODUCTS HELD AT THE BUREAU OF CUSTOMS/CONSIGNEE'S WAREHOUSE FOR VERIFICATION AND FINAL DISPOSITION

Inspection Activity
Inspection [SITE/LOCATION OF CARGO /SHIPMENT] **Opening Meeting** [BOC Examiner and Consignee/ Consignee's authorized representative] **Actual inspection of the cargo/shipment** 3.1 temperature storage condition 3.2 physical examination of the products [appearance and label] Verification/ validation of the following Documentary Requirements as applicable and necessary vs. actual cargo/shipment **For donations** 4.1 Affidavit/Deed of Undertaking 4.2 *Airway Bill/ Bill of Lading 4.3 *Packing List 4.4 *Proforma Invoice / Commercial Invoice 4.5 *Certificate of Free Sale (CFS) or its equivalent 4.6 Deed of Acceptance 4.7 Deed of Donation **For public auction / products with safety issues /alert** Valid FDA License to Operate [LTO]

Valid Certificate of Product Registration [CPR)]

*applicable documents mentioned above
Certificate of Analysis and other pertinent documents [as applicable and necessary]

Collection of product samples [as applicable and necessary]
Report Writing (Observation and findings/recommendation/directives)
Exit Meeting (discussion observation and findings/recommendation/directives)

INSPECTION AGENDA – FOOD DISTRIBUTOR

Inspection Activity
Opening Meeting
Document Review
-Verification of submitted licensing documentary requirements
2.1 Organization, Management & Personnel
Organizational Chart /Job Description/ Duties and responsibilities
Training Plan/ Records/ Competency evaluation
2.2 QMS & Documentation
Authorization (LTO & CPR)
Risk Management Plan (RMP)
Standard Operating Procedures

Records (Importation/Distribution/Deliveries, complain, recall)

2.3 Contract activities
Quality Agreement with suppliers/sources
GMP Certificate/Free Sale /Phytosanitary Certificate and other equivalent documents
Franchise agreement (if applicable)

III. Walk-through Inspection

3.1 Warehouse facilities (Dry & Cold)
Premises (Sanitation: Sanitation Program/Pest Control /housekeeping/ventilation/Lighting etc.)
Storage fixtures (pallets, steel racks/cabinet)
Storage equipment (Temperature monitors)
Storage area/segregated areas for recalled/damaged/expired/returned products
Storage condition (Stock Rotation and arrangement)
Records (temperature and RH, calibration, Stock Reconciliation/ Inventory, Dispatch)

3.2

Pro

ducts (physical examination / Collection of samples)

3.3

Tra

nsport & Dispatch of products
Vehicle Maintenance, Personnel, Compliance to Storage Requirements

IV. Report Writing (Consolidation of findings)

Exit Meeting (Discussion of findings**)**

INSPECTION AGENDA – FOOD TRADER

Inspection Activity
OPENING MEETING (including Presentation of Inspection Agenda) **DOCUMENTATION REVIEW** License to Operate (if applicable) DTI Certificate / SEC Registration with Articles of Incorporation / Cert. Of Cooperative Development Authority (if Cooperative) Mayor's Business Permit / Brgy. Clearance (if the business name and/or address is different from the registered name and/or address in the DTI / SEC) Notarized Proof of Occupancy / Lease Contract / Transfer Certificate of Title (Office/Warehouse/Stock Room) List of Products and copy of valid Certificate of Product Registration (for LTO renewal/PLI) List of Suppliers / Sources (foreign/local) Franchise agreement (if applicable) Suppliers Documents For Local Supplier Copy of valid LTO of Toll Manufacturer / Repacker Notarized Toll Packing / Food Manufacturing / Repacking Agreement (including warehousing & logistics services) For Importer of Raw Material for own use: Foreign Agency Agreement (Distributorship Agreement / Proforma Invoice / Commercial Invoice / Certificate/Letter of Appointment; Status of Manufacturer (GMP Certificate / Certificate of Free Sale / HACCP Certificate / Phytosanitary Certificate – issued and attested by Health Regulatory Authority / Recognized Association (duly authenticated by the Philippine Consulate from the country of origin)

Distribution Records/Sales Invoice Standard Operating Procedures for: Handling Product Recall, Complaints and Returns Pest Control including Service Records / Contract Stock Management Control Dispatching & Transporting of Products Cleaning & Sanitation Equipment Maintenance including Calibration Records of Temperature Devices (if applicable) Duties and Responsibilities / Trainings of the warehouse personnel Other pertinent documents **Walk Through Inspection** (Office/Warehouse/Stock Room) **REPORT WRITING** **EXIT MEETING**
GDP FOOD INSPECTION AGENDA

Inspection Activity
Ocular Inspection [declared office address] **Premise** [accessibility, suitability, display of FDA License to Operate (LTO)] **Opening Meeting** [Introduction/ Stating Purpose of Inspection/, Presentation of Inspection Agenda, Accomplishment of Attendance Sheet] **Document Review** **Note:** presentation/provision of the following documents will depend or based on the findings noted during inspection [as applicable and necessary] **GENERAL DOCUMENTS**

Proof of payment for renewal and variation/amendment of LTO and CPR in case of change of location/activity/supplier/manufacturer /formulation/label etc.
Organizational Chart
Credentials of the Qualified Person/Compliance Safety Officer
Job Description [JD] / Duties and responsibilities, Training Plan/Training Records/Competency Profile of the Key Personnel involved in the operation
Valid Proof of Business Name Registration / Business Permit
Valid Proof of Occupancy [Office and Warehouse Facility]
Affidavit of Undertaking with the corresponding list of clients [name and complete address of client/s if no warehouse facility is declared
Valid Certificate of Product Registration
Product List indicating the product name, supplier/ manufacturer, registration number and validity, status of registration for new products (initial), renewal, and or amendment
Copy of FDA approved product label; Letter of exhaustion for old labels used
Distribution Records [Proforma/Commercial Invoice/Bill of Lading/ Airway Bill/ Packing List/ Sales Invoice/Delivery Receipt]
Standard Operating Procedures [product recall, complaint, return /damaged/ expired products, disposal/ destruction, compliance to Good Storage and Distribution Practices (GDSP): Sanitation Program, Pest Control Program, Stock Management Control, Dispatch and Transport] etc.]

SPECIFIC DOCUMENTS

For Distributor-Importer

Proforma Invoice /Valid Foreign Agency Agreement/ Appointment/Distributorship Agreement/ Letter of Appointment
Compliance to CGMP [GMP Certificate or its equivalent]
Appropriate Test Result or Certificate of Analysis routinely conducted in country of origin or source that would indicate or show safety of the product

For Distributor-Exporter

Valid notarized Distributorship Agreement or Letter of Appointment between FDA-licensed manufacturer and exporter
Valid CPR

For Distributor -Wholesaler
Valid notarized Distributorship Agreement or Letter of Appointment between the
applicant and FDA-licensed source

For product under Food Fortification and Asin Law
Notarized Affidavit of Undertaking for salt used as industrial
LTO and MOA with the manufacturer for salt and staple food - intended for iodization/re-iodization and fortification/re-fortification
Certificate of Analysis for Vitamin A and /or Iron, Iodine

Ocular inspection of warehouse/s depot [Dry and Cold storage facility/ies following compliance to Good Storage and Distribution Practices (GDSP) within the area of jurisdiction:

Premises [suitability, access/security, sanitation, ventilation, Lighting etc.]
Storage Fixtures Storage fixtures [palettes, steel racks/cabinet]
Storage equipment/s [Temperature monitoring System: Monitoring Device]
Storage area/s for various products
Segregated areas for recalled/damaged/expired/returned products
Stock Management and Control
Physical examination of the product/s
Conformance to Mandatory labeling requirements (pre-packed foods)
Conformance to Mandatory labeling requirements for specific products based on standards [food supplement/s, bottled water, staple products, iodized salt]
Collection of samples when necessary

Ocular inspection of Transport Vehicle

Report Writing (Observation and findings/recommendation/directives) **Exit Meeting** (discussion observation and findings/recommendation/Accomplishment of Attendance Sheet)

INSPECTION AGENDA – DRUG & MEDICAL DEVICE DISTRIBUTOR

Inspection Activity
I. Opening Meeting Introductions Inspection scope Confirmation of Confidentiality Attendance record **Document Review** ***2.1 Organization, Management & Personnel*** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records Competency evaluation of personnel Qualified Person (for medical device) Pharmacist Credentials (for drugs) Pharmacovigilance Officer (for ADRs) ***2.2 QMS & Documentation*** License to Operate Risk Management Plan (RMP)

SOPs
Franchise agreement (if applicable)

Records
Distribution Records

Importation documents

Receipts from suppliers

Receipts issued to customers

Product complaints

Product recall

Product returns

Adverse Drug Reaction (ADR)Reports

Certificates of Product Registration & Notification (for medical device)

Batch Notifications (for antibiotics)

Lot Release Certificates (for vaccines)
List of products per supplier with CPR number and its validities
MDRP (EO 821 & EO 104 / IEC materials) / GMAP / EDPMS
Self-inspection (Internal audit)

2.3 Contract activities

Distribution agreements with suppliers (quality agreements)
With FDA Licenses (for local suppliers) / GMP Certificates / ISO 13485 QMS Certificates (for medical device)-(for foreign suppliers)

Agreement with third party (TP) logistics or carrier (when applicable)

III. Walk-through Inspection

3.1 Warehouse facilities

Restrictions to entry
Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks
Rejects /Returns/Recalled
Quarantined
Facilities & equipment
Pallets /Racks

Calibrated Temperature /RH Monitoring Device

Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Warehouse fixture, equipment, and temperature monitors

Arrangement of stocks (to avoid mix-ups)
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

3.2 Records

Sanitation /Pest Control Records
Recorded temperature and relative humidity (RH) monitoring data

Calibration records of temperature/RH monitors
Stock Reconciliation/ Inventory
Dispatch Records

3.3

Pro

ducts
Labeling requirements
Registration / Notification (for medical device)

3.4 Transport & Dispatch of products
Vehicle Maintenance
Personnel in-charge for transport of products (must be knowledgeable on handling ie. Compliance to Storage requirement for products)
3.6 Other Additional Requirements for TTSPPs

For Temperature-controlled rooms, cold rooms and freezer rooms:
Uninterrupted power supply (UPS)
Calibrated continuous temperature monitoring system
Continuous humidity monitoring devices with sensors located at points representing humidity extremes
Preventive maintenance on all temperature controlled rooms or equipment
Temperature-controlled road vehicles equipped with calibrated temperature monitoring devices
shipping containers
Stabilizing medium: dry ice, ice or gel packs, cool water packs or warm packs, bubble wrap
V. Report Writing
Consolidation of findings

VI. Exit Meeting
Attendance record

Discussion of findings /Signing of Inspection Report

INSPECTION AGENDA – DRUGSTORE

Inspection Activity

I. Opening Meeting

· Introductions
· Inspection scope
· Confirmation of confidentiality
· Attendance record

II. Ocular inspection of Premises / Storage facilities and Products

· Storage and sanitary conditions
· Segregated area for expired, damaged, recalled or returned products
· Equipment – Bioref / dedicated refrigerator, generator Set (if selling TTSPPs)
· Dispensing apparatus including ice packs for dispensing of TTSPPs
· Product compliance to registration and labeling requirements – may collect product

III. Document and Records Review

· License to Operate
· Pharmacist's credentials
· Organizational structure with duties and responsibilities of personnel
· Records of training, competency evaluation of personnel · Attendance to FDA licensing seminar
· Risk Management Plan
· Standard Operating Procedures (SOPs)
· Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
· Stock reconciliation records
· Prescription book – both full and partially filled prescriptions must be recorded in Rx book
· Senior Citizens and PWD records · Generic menu cards

· Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room) · Calibration Certificates of temperature monitoring device/s and/or bioref **IV. Report Writing** · Consolidation of findings; Notice of Violation when necessary **Exit Meeting** · Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA - RETAIL OUTLET FOR NON-PRESCRIPTION DRUGS (RONPD)

Inspection Activity
I. Opening Meeting Introductions Inspection scope Confirmation of Confidentiality Attendance record **II. Ocular inspection of Premises / Storage facilities and Products** Storage and sanitary conditions Segregated area for expired, damaged, recalled or returned products Product compliance to registration and labeling requirements – may collect product (All pharmaceutical products must be OTC) **III. Document and Records Review** License to Operate Pharmacist's credentials List of all RONPDs supervised by the pharmacist with corresponding schedule Attendance to FDA licensing seminar Risk Management Plan

Standard Operating Procedures (SOPs)
Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
Franchise agreement (if applicable)

IV. Report Writing
Consolidation of findings; Notice of Violation when necessary
V. Exit Meeting
Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA – COSMETICS & HOUSEHOLD URBAN PESTICIDES DISTRIBUTOR

Inspection Activity
Opening Meeting Introductions Inspection scope Attendance record **Document Review** **Organization, Management & Personnel** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records and/or Competency evaluation of personnel **QMS & Documentation** License to Operate Proof of Business Registration (DTI / SEC and Business / Mayor's Permit)

Standard Operating Procedures
Franchise agreement (if applicable)
Records
Distribution Records
Importation documents
Receipts from suppliers
Receipts issued to customers
Product complaints
Product recall
Summary list with status of notification
Recorded temperature and relative humidity (RH) monitoring data (where applicable)
Calibration records of temperature/RH monitors (where applicable)
Stock Reconciliation/ Inventory

Contract activities

Distribution agreements with suppliers (quality agreements)
FDA Licenses (for local suppliers) / GMP Certificates or other equivalent document (for foreign suppliers)
Agreement with third party (TP) logistics or carrier (when applicable)

III. Walk-through Inspection

Warehouse facilities

Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks/Rejects /Returns/Recalled
Facilities & equipment (PPEs for HUPs)
Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Temperature monitors
Sanitation /Pest Control Records
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

Products

Labeling compliance
Status of Notification/ Product registration
Sample collection (as necessary)
Other Requirements
Product Information File for Cosmetic Products
Part I Administrative Documents & product Summary
Part II Quality Data of Raw Materials
Part III Quality Data of Finished Product
Part IV Safety & Efficacy Data

Report Writing
Consolidation and discussion of findings
Exit Meeting
Attendance record
Presentation/ discussion of findings
Signing of Inspection Report

INSPECTION AGENDA – HOSPITAL PHARMACY

Inspection Activity
I. Opening Meeting
Introductions
Inspection scope
Confirmation of Confidentiality
Attendance record
II. Ocular inspection of Premises / Storage facilities and Products
Pharmacy signage
Storage and sanitary conditions
Segregated area for expired, damaged, recalled or returned products

Equipment – Bioref / dedicated refrigerator, generator Set (if selling TTSPPs)
Dispensing apparatus including ice packs for dispensing of TTSPPs
Product compliance to registration and labeling requirements – may collect product (different areas – CSR, OR, DR, ER, Nurse stations/e-carts, others)

III. Document and Records Review

License to Operate
Pharmacist's credentials
Organizational structure with duties and responsibilities of personnel
Records of training, competency evaluation of personnel
Attendance to FDA licensing seminar
Risk Management Plan
Standard Operating Procedures (SOPs)
Invoices issued by suppliers (lot #, exp. Date and transport temp requirement)
Stock reconciliation records
Prescription book – both full and partially filled prescriptions must be recorded in Rx book
Senior Citizens and PWD records
MDRP (EO 821 & EO 104 / IEC materials) /GMAP / EDPMS / Hospital Formulary
Temperature Monitoring records (bioref/ refrigerator if with TTSPPs and room)
Calibration Certificates of temperature monitoring device/s and/or bioref

IV. Report Writing

Consolidation of findings; Notice of Violation when necessary

V. Exit Meeting

Attendance record /Discussion of findings or deficiencies /violation

INSPECTION AGENDA – FOOD MANUFACTURER/ REPACKER/ BOTTLED WATER MANUFACTURER

Inspection Activity
OPENING MEETING
Presentation of inspection agenda, attendance sheet
Company presentation (plant layout, process flow, HACCP Plan, *if any*)
INSPECTION PROPER
Storage/Warehouse facilities (raw materials, packaging materials and finished products)
Premises (Sanitation: Sanitation Program/Pest Control /housekeeping/ventilation/Lighting etc.)
Storage fixtures (pallets, steel racks/cabinet)
Storage equipment (Temperature monitors)
Storage area/segregated areas for recalled/damaged/expired/returned products
Storage condition (Stock Rotation and arrangement)
Records (temperature and RH, calibration, Stock Reconciliation/ Inventory, Dispatch)
Processing area
Laboratory facility *(**If provided;** mandatory to bottled **water processor**)*
Sanitary facilities (**such as but not limited to** gowning area, hand washing, toilet facilities)
Products (physical examination / Collection of samples)
Transport & Dispatch of products
Vehicle Maintenance, Personnel, Compliance to Storage Requirements
DOCUMENTATION REVIEW
Quality Control Procedures/Quality Manual, GMP Manual and/or HACCP Manual
Standard Operating Procedures
Cleaning and Sanitation (production area, equipment, premises)
Rejection/Returns/Disposal
Product Recall
Retention Sample
QC Methods and Procedures / Sanitation & Hygiene Records / Preventive Maintenance Records:

In-house and third-party laboratory analysis (water, finished products) Production Record/Batch Manufacturing Records/Monitoring Records Quality audits (internal/external) Sanitation checklist List of approved suppliers, certificate of analysis of raw materials and packaging materials Calibration of monitoring/measuring instruments/equipment Pest control program and records (including service reports and chemicals used) Personnel training program and records (in-house/third party) Health certificates of personnel Documents relative to subcontracting of manufacturer Verification of submitted licensing documentary requirements Franchise agreement (if applicable) See Administrative Order 153 as reference for Good Manufacturing Practices (GMP) **REPORT WRITING** **EXIT MEETING**
INSPECTION AGENDA- VACCINE AND/OR BIOLOGICALS

Inspection Activity
Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable & Attendance Taking
Company Introduction and Overview/Presentation
Design and Lay-out Review prior to Site Inspection
Warehouse
Production Areas
Cleanroom air classification

Personnel Flow
Material Flow
Waste Flow
Utilities P & ID
Quality Control Laboratory

Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt (Handling and Storage) and Dispatch
Sampling
Method of sampling and inspection
Sampling tools and kits
Storage Areas (quarantine, approved, reject)
Storage condition (temperature and RH monitoring)
Cells/Seed lots
Finished Product Vaccines/Biologicals (Quarantine and Approved/Released/ Lot Release)
Inventory System

Manufacturing Facility
Gowning and Hand washing Procedure (Primary and final)
Dispensing of starting materials (including control measures)
Cell and Seed Cultivation/ Harvest/Disruption/ Purification/ Semi-Finished Product
Serum, Albumin, Media, Buffers etc.
Ultrafiltration/ Virus Inactivation
Drug Product
Formulation
Vial Filling and Sealing
Freeze-Drying

Leak Testing Visual Inspection and Packaging Operations Final Bulk Storage **Utilities** (Site Inspection and Document Review) Air Handling Units Design and Structure-Supply and Return/Exhaust System Operation, Qualification and Maintenance Monitoring and Testing Water System (Pre-treatment, Purification and WFI) Design and Structure Operation, Qualification and Maintenance Monitoring and Testing Compressed Gas/ Sterile Gases Design and Structure Operation and Maintenance Monitoring and Testing Sterile Gases Monitoring and Testing Maintenance
Quality Control QC Laboratory walk through Personnel Qualification and Training Handling of samples, reference standards, microorganism Test Specifications Test Method and Results Tests on seed lots and reagents Test for Adventitious Agents

Method Validation In-process Testing Virus Titration Finished Product Testing Water Analysis QC Instruments (Computer System Validation) Validation of major QC instruments Preventive Maintenance and Calibration Microbiological Testing Production Media Testing and Qualification Environmental Monitoring (Production and QC Lab) Qualification of Sterility Room Bioburden, Sterility, Bacterial Endotoxins Animal House and Animal Testing Stability Studies (On-Going) Out-of- Specification Retention Samples Other related QC tests and records
Qualification and Validation Validation Master Plan Master and Working Cell Qualification Process Validation Cell Culture/ Expansion Purification Validation Sterile Filtration Validation Viral Inactivation Hold Time Studies Aseptic Process Validation

Critical equipment Qualification (PQ)- e.g. Sterilizers/Dry Heat Cold Chain Management and Transport Validation Computer System Validation Cleaning and Disinfectant Validation Studies
Documentation Pharmaceutical Quality System Product Quality Review CAPA System Change Control Deviation Quality Risk Management Supplier Qualification Batch Release Procedure Personnel Organizational Chart Job Description Training Program and records PPE Requirements and Gowning Qualification Health Examination records Batch Manufacturing Record Control of Source material Traceability of materials Line Clearance Reconciliation Release for supply Approved Marketing Authorization

Other relevant documents Procedure for Cleaning and Disinfection of Clean Areas and Equipment Waste Management System Handling of Product Complaints and Recall Pest Control Outsourced Activities Self-Inspection
Exit Meeting Discussion of audit findings CAPA submission instructions **Report Writing**

INSPECTION AGENDA – STEM CELL

Inspection Activity
Opening Meeting Introduction from FDA Lead Inspector Discussion of Scope, Inspection Plan and GMP Standard Timetable Attendance Sheet Company Introduction and Overview **Design and Lay-out Review prior to Site Inspection** (Storage Area, Production Areas, Utilities, Quality Control Laboratory) **Site Inspection** **Storage Area** Storage of cells *(cryogenic vessels)* Cell bank system *(if applicable)* Cryopreservation Temperature and Nitrogen level monitoring Preventive Maintenance of cryogenic vessels Alarm system of cryogenic vessels Backup system in case of power failure

Contingency plan in case of equipment break down

Processing Area

Gowning and Handwashing Procedures

Receiving of cells

Cell Culture Area

Contamination control measures

In-process checks

Handling of cultured cells

Labeling of finished product

Waste Disposal

Quality Control Laboratory

Donor Testing

Handling of Reagents and Media

Sterility Room Qualification

Quality Control checks *but not limited to:* ***(specifications and records)***

Cell Characterization

Cell Count and Viability

Endotoxin

Sterility Test

Microbial Contamination Testing

Mycoplasma

Out of Specification Procedure

Documentation

Quality System

Quality Risk Management

Release Procedure

Change Control

Deviation

CAPA
Supplier Qualification
Handling of reject cells
Qualification and Validation
Air Handling Unit System
Cleanroom Qualification
Biosafety cabinet
Biosafety level
Quality Control Instruments
Water System *(if applicable)*
Computer System *(if applicable)*
Patient Record
Source of cells (*autologous or allogenic*)
Unique numbering system
Donor Selection
Donor Screening
Patient Monitoring Sheets
Release controls prior to administration of product to patient
Other relevant documents
Collection of cells from donor (*procedure*)
Freezing and thawing of cells *(procedure)*
Handling of Product Complaint, ADR/ADE
Clinical Protocol
Outsourced Activities
Self-Inspection
Report Writing
Discussion of audit findings

INSPECTION AGENDA – TRADITIONAL MEDICINES

Inspection Activity
Opening Meeting Introductions, Attendance record, Inspection standard and scope Major Changes Key personnel Brief description of the company Buildings and facilities overview (for initial; if applicable) Floor plan / Lay-out plan Product and personnel flows **On-site inspection** Plant Tour Warehouse (starting materials, packaging materials and finished goods) Production Cutting and drying* Expression of plants* Distillation* Comminution, processing of exudates, extraction from plants, fractionation, purification, concentration or fermentation of herbal substances* Processing into dosage form Packaging Quality Control Laboratory Utilities Water HVAC

Compressed Air

Document Inspection

Establishment Records:

License to Operate
List of Products Manufactured
Site Master File

Registered Pharmacist's Records:

PRC ID, PTR

Pharmaceutical Quality System:

Quality Manual
Quality Risk Management
Finished Product Release procedure
Product Quality Review
Supplier Qualification including audits
Manufacturing Authorization of the supplier
Validation Master Plan
Process Validation
Cleaning Validation
Computer Validation*
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action

Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations including eye check-ups

Premises and Equipment:
Warehouse (Starting Materials, Packaging Materials and Finished Goods)
Receipt, handling & storage
Identification
Storage areas – quarantine, release, reject
Approval for use (materials)
Temperature & humidity monitoring
Dispatch
Inventory control
Storage for rejects, returns and recall
Production areas
Dust extraction
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Equipment
Storage
Cleaning
Qualification

Repair and Maintenance
Calibration
Compatibility from the extraction solvent*
Engineering and Services:
Pest Control
Housekeeping
Back-up system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results including trending)
Maintenance
HVAC
Lay-out
Qualification
Environmental Monitoring and Testing (method, specifications and results including trending)
Maintenance
Compressed air
Lay-out
Specifications of filters
Monitoring and Testing
Maintenance and Cleaning

Documentation:
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for starting materials (sample of the dried plant)
Certification from National Museum for the plant with a reference authentic specimen

Documentation for herbal substances / preparations:
Binomial scientific name of plant (genus, species, subspecies / variety and author (e.g. Linnaeus); other relevant information such as the cultivar name and the chemotype
Details of the source of the plant (country or region of origin and where applicable, cultivation, time of harvesting, collection procedures, possible pesticides used, possible radioactive contamination, etc.)
Part(s) of the plant is/are used
Drying system used, when a dried plant is processed
Description of the herbal substance and its macro and microscopic examination
Suitable identification tests including, where appropriate, identification tests for constituents with known therapeutic activity, or *markers*. Specific distinctive tests are required where an herbal substance is liable to be adulterated / substituted. A reference authentic specimen should be available for identification purposes
Water content for herbal substances, determined in accordance with the relevant Pharmacopoeia
Assay of constituents of known therapeutic activity or, where appropriate, of markers; the methods suitable to determine possible pesticide contamination and limits accepted in accordance with relevant Pharmacopoeia methods or, in absence of thereof, with an appropriate validated method, unless otherwise justified
Tests to determine fungal and/or microbial contamination, including aflatoxins, other mycotoxins, pest-infestations and limits accepted, as appropriate
Tests for toxic metals and for likely contaminants and adulterants, as appropriate
Tests for foreign materials, as appropriate
Any other additional test according to the relevant Pharmacopoeia general monograph on herbal substances or to the specific monograph of the herbal substance, as appropriate
SOPs
Delivery documents
Lot Numbering System
Records
Specifications
Distribution records

Production:
Process Flow
Sorting*
Cleaning*
Drying*
Crushing and sifting*
Extraction*
Gowning procedures
Inspection procedures
Sampling
Method of sampling and inspection
Sampling tools and kits
Dispensing / Weighing
Processing
Formulation
Batch processing documentation
In-process and Line clearance checks
Rework/reprocessing
Packaging
Storage of bulk product
Control of labels & pre-printed packaging materials
In-process controls
Line clearance checks
Reconciliation
Batch packaging documentation
Storage of packed product
Control of materials (starting, in-process, finished and returned materials)

Quality Control:
Sample receipt
Method validation
QC Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Reference Standards and reagents
Markers
Reference standards from the authentic reference sample
Analysts work books/records & test results (if available)
Training & assessment
Particular expertise and experience in herbal substances, herbal preparations and/or herbal medicinal products (especially inspectors and samplers)
Retention samples
Stability program
Identification test procedure and specifications of starting materials
Pesticide residue testing
Heavy metals testing
Microbiology Laboratory testing
Equipment / Laminar Flow hood
Testing procedure, references and results
Media preparation
Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis

Identification tests
Passage (procedure and records)
Storage

Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others

Complaints and Product Recall (procedure and records)

Self-inspection (procedure and records)

Report Writing
Exit Meeting

INSPECTION AGENDA – DRUG TRADER

Inspection Activity

Opening Meeting
Introductions, Attendance record,
Inspection standard and scope
Confirmation of Confidentiality
Major Changes

On-site and Document Inspection	*Registered Pharmacist's Records:*
Establishment Records:	PRC ID, PTR
License to Operate	Certificate of Attendance to Licensing Seminar
List of Toll Manufacturers and Activities	Number of LTO and products being handled
Franchise agreement (if applicable)	

Pharmaceutical Quality System:
Quality Manual
Quality Risk Management / RMP
Finished Product Release procedure (including Batch Notification control) including filing of Certificates of Analysis and Batch Notification (if available)
Personnel:
Duties and Responsibilities
Training (SOP and Records): GMP and GDP, GSP (if warehouse was handled by the company)
Premises and Equipment (Warehouse; if applicable):
Inventory control including Computer System (if applicable)
Pest Control and Cleaning (Procedure and Records)
Temperature monitoring device calibration and records of monitoring including temperature mapping (if applicable)
Storage for rejects, returns and recall
Storage of retention sample

Documentation:

Contract of Lease or TCT (office and warehouse; if applicable)
LTO and GMP Certificates of toll manufacturer
Certificate of Product Registration and list of products status
Audit to toll manufacturer and Vendor rating of PM and RM Suppliers (procedure and records)
System of Distribution
Dispatch Records (Sales Invoice, etc)
Monitoring of transport conditions
SOPs:
Receipt and Dispatch
Handling of rejects and returns
Destruction
Batch Notification control

Outsourced Activities: Contract Manufacturing Agreement LTO and contract if distributors were available Agreement with Pest Control Provider (if applicable) *Complaints and Product Recall* (procedure and records) *Pharmacovigillance system and records of PV activities* **Report Writing** **Exit Meeting**

INSPECTION AGENDA – DRUG, MEDICAL DEVICE and COSMETIC REPACKER/ PACKER

Inspection Activity
Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable
Attendance Sheet
Company Introduction and Overview
Design and Lay-out Review prior to Site Inspection
(Warehouse, Repacking/Packing Area)
Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt
Sampling
Storage area (quarantine, approved, reject, cool room)
Storage condition (temperature, humidity)
Approval for use / release prior to repacking or packing
Dispatch

Premises and Equipment
Plan or description of manufacturing areas with scale
Nature of construction and finishes
Special areas for the handling of highly toxic, hazardous and sensitizing materials
Production
Brief description of production operations using flowsheets and charts, if possible, specifying important parameters
Arrangements for the handling of starting materials, packaging materials, bulk and finished products, including sampling, quarantine, release and storage
Arrangements for reprocessing or rework
Arrangements for the handling of rejected materials and products
Brief description of general policy for process validation Repacking / Packing Facility
Building Maintenance and Structure
Gowning Areas / Changing Rooms
Repacking/Packing Area
Storage condition (temperature, humidity)
Line Clearance
In-process controls
Cross contamination prevention measures
Equipment (status: cleaning, maintenance, calibration)
Control of labels and pre-printed packaging materials
Coding
Storage of finished goods
Retention Sample

Utilities and Engineering Services (if applicable)
Air Handling Units
Design and Structure
Operation and Maintenance

Monitoring

Pest Control and Waste Disposal

Documentation
Pharmaceutical Quality System / Quality Management System
Quality Risk Management
Change Control
Deviation
CAPA
Supplier Qualification
Batch Release Procedure
Personnel
Organizational Chart
Job Description
Training and Assessment
Personnel Hygiene
Health Examination
Arrangements for the preparation and revision and distribution of documentation
Description of the documentation system
Responsible for the preparation, revision and distribution of documents
Storage of the master documents
Procedures on the preparation of the documents
Control of the documentation
Related to Product Quality
Equipment specification
Training procedures
Documentation control of process deviations

Calibration and test documents
Validation documents
Reconciliation of batches of raw materials, major packing components
Personnel Hygiene
Health Examination
Batch Packaging Records Review
Packaging Specifications

Other Relevant Documents
Standard Operating Procedures
Receiving and Dispatch
Cleaning and Sanitization of Premise and Equipment
Storage conditions to each category of materials
Quality Control check
Reprocessing / Reworking
Handling of excess packaging materials
Out-of-Specifications Product Complaint and Recall Outsourced Activities Self-Inspection
Franchise agreement (if applicable)
Report Writing
Discussion of audit findings

INSPECTION AGENDA –HOUSEHOLD REMEDY/EXTERNAL OTC

Inspection Activity

Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Agenda and GMP Standard

Timetable of activities
Attendance Sheet
Company Introduction and Overview

Design and Lay-out Review prior to Site Inspection
(Warehouse, Production Areas, Utilities, Quality Control Laboratory)

Site Inspection
Warehouse (Starting Materials and Finished Goods)
Receipt
Sampling
Storage area (quarantine, approved, reject, cold room)
Storage condition (temperature, humidity)
Approval for use / release to production
Dispatch
Production Facilities
Building Maintenance and Structure
Dispensing
Gowning Areas / Changing Rooms
Bulk Manufacture (including in-process controls)
Cross contamination prevention measures
Equipment (status: cleaning, maintenance, calibration)
Packaging Operations
Control of labels and pre-printed packaging materials/ prevention of mix-up
Line Clearance
Coding
Reconciliation
Storage of finished goods

Utilities and Engineering Services
Air Handling Units (where applicable)
Design and Structure
Operation and Maintenance
Monitoring and testing
Water System (where applicable)
Design and Structure
Operation and Maintenance
Monitoring and Testing
Pest Control and Waste Disposal

Quality Control Laboratory
Laboratory Design
Laboratory Staff Training and Assessment
Handling of QC Samples
Specifications and Testing Procedures including results
Raw material, packaging materials and finished product
Instrumentation Room (status: calibration, maintenance, logbooks)
Stability Program
Handling of Out-of-Specifications
Retention Samples
Micro laboratory (where applicable)
Media Preparation and controls
Reference Cultures
Testing (Products, Environmental Monitoring, Water)
LAF or BSC (calibration and maintenance)

Documentation
Pharmaceutical Quality System
Quality Risk Management
Product Quality Review
Change Control
Deviation
CAPA
Supplier Qualification
Product Dossier
Batch Release Procedure
Personnel
Organizational Chart
Job Description
Training and Assessment
Personnel Hygiene
Health Examination
Qualification and Validation
Validation Master Plan
Utilities Qualification (HVAC, Water, Gases)
Equipment Qualification
Process verification
Computer System Validation
Cleaning Validation
Batch Manufacturing Records
BMR Review
Product Dossier
Release for supply

Other Relevant Documents
Product Complaint and Recall
Outsourced Activities
Self-Inspection
Report Writing
Discussion of audit findings
INSPECTION AGENDA – MEDICINAL GAS

Inspection Activity
Opening Meeting
Introductions, Attendance record, Inspection standard and scope
Major Changes
Key personnel
Buildings and facilities overview (for initial; if applicable)
Floor plan / Lay-out plan
Product and personnel flows
On-site inspection
Plant Tour
Warehouse
Production
Quality Control Laboratory
Document Inspection
Establishment Records:
License to Operate
List of Products Manufactured
Site Master File
Registered Pharmacist's Records:

PRC ID, PTR
Pharmaceutical Quality System:
Quality Manual
Quality Risk Management
Finished Product Release procedure
Procedure, Records and logs:
Deviation
Change control
CAPA
Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations
Premises and Equipment:
Warehouse (Packaging Materials / Cylinders and Finished Goods)
Housekeeping & Pest control
Receipt, handling & storage
Identification and avoidance of mix-ups
Sampling
Storage areas – quarantine, release, reject
Approval for use
Temperature & humidity monitoring
Dispatch
Inventory control

Storage for rejects, returns and recall
Equipment
Storage of starting material (cryogenic tank) specification (dedicated)
Cleaning and Purging
Qualification of pipelines and manifolds (for shared equipment of different gases)
Repair and Maintenance
Delivery tankers (incl. Maintenance and Qualification records)
Storage of pipelines, manifolds, tester, valves and other equipment
Calibration
Air separation unit*
Air inlet
Position
Sequence
Repair and Maintenance including Cleaning
Filters & /Molecular Sieves
Type / Specifications
Regeneration and Maintenance
Installation
Integrity test
Air compressors
Maintenance frequency (incl. oil used, checking of bearings, etc.)
Change and consumption of oil
Water quality
Pressure
Separation Columns
Proper design (valves, sensors)
Maintenance
Usage and Specifications (Liquid levels, pressure)

Calibration of in-line processing monitors
Engineering and Services:
Pest Control
Housekeeping
Quality of water used for testing (e.g. hydrostatic testing)
Back-up system
Documentation:
Batch Record/Production Record Review
Document control (history, issuing, superseded, obsolete)
SOPs
Delivery documents
Records
Specifications
Distribution records
Production:
Process Validation (shared manifold for medicinal and industrial gases)
Process Flow
Air separation/ LOX vaporization
Unloading of bulk gas
Filling of gas
Inspection of cylinders
Control of materials (starting, in-process, finished and returned materials)
Line Clearance Procedures
Traceability of valves and cylinders
Quality Control:
Sampling and receipt of samples
QC or line Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance

Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Analysts work books/records & test results (if available)
Training & assessment
Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others
Complaints and Product Recall (procedure and records)
Self-inspection (procedure and records)
Report Writing
Exit Meeting

INSPECTION AGENDA – STERILE DRUG AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity

Opening Meeting
Introduction from FDA Lead Inspector
Discussion of Scope, Inspection Plan and GMP Standard
Timetable of Activities
Attendance Sheet
Company Introduction and Overview

Design and Lay-out Review prior to Site Inspection
(Warehouse, Production Areas, Utilities, Quality Control Laboratory including cleanroom air classification, material and process flow)

Site Inspection
Warehouse (Starting & packaging materials, Bulk &Finished Goods)
Receipt (Handling and Storage)
Storage Areas (quarantine, approved, reject)
Storage condition (temperature and RH monitoring)
Approval for use
Dispatch
Label reconciliation

Production Facilities
Building maintenance and structure
Gowning and hand washing
Dispensing of starting materials (including control measures)
Bulk Manufacture (formulation and/or filtration) and Staging
Cross contamination and Contamination prevention measures/ control strategies
Preparation of packaging materials (e.g. washing of containers, sterilization of packaging materials, garments, equipment parts)
Filling operations (aseptic process implementation)
In process checks

Monitoring (air cleanliness and environment)
Cleaning of premises and equipment
Packaging operations
Control of labels and pre-printed packaging materials
In-process checks
Coding
Line Clearance
Reconciliation
Sterilization (*terminal*)

Utilities
Air Handling Units
Design and Structure
Operation and Maintenance
Monitoring and testing
Water System
Design and Structure
Operation and Maintenance
Monitoring and testing
Compressed Gas and other gas
Design and Structure
Operation and Maintenance
Monitoring and testing

Quality Control Laboratory
Laboratory Staff training and assessment
Sampling

Handling of samples, reference standards, microorganism
Test Specifications
Method Validation
In-process Testing
Finished Product Testing
Instrumentation Room (status: CSV, calibration, maintenance, logbooks)
Validation of major QC instruments
Qualification of Sterility Room
Water Analysis
Microbiological
Environmental Monitoring (Production and QC Lab)
Stability Studies (Accelerated and Real Time)
Out-of- Specification
Retention Samples
Other related QC tests and records

Documentation
Pharmaceutical Quality System
Quality Risk Management
Product Quality Review
Change Control
Deviation
CAPA
Supplier Qualification
Batch Release Procedure
Personnel
Organizational Chart
Job Description

Training Program and records
Gowning qualification
Personnel hygiene
Health examination records

Qualification and Validation
Validation Master Plan
Process Validation
Cleaning Validation
Validation of aseptic process
Washers
Sterilizers (autoclave; dry heat)
Filters (integrity and microbial)
Container Closure integrity
Utilities Qualification (HVAC, Water, Gases)
Computer System
Batch Manufacturing and Packaging Record Review
Traceability of materials
Line Clearance
Reconciliation
Release for supply
Approved Marketing Authorization
Product Dossier

Engineering Services (procedure and records)
Preventive Maintenance
Calibration
Pest Control

Waste Disposal Key Control Other relevant documents Process Simulation / Media Fill Document control *(history, issuing, superseded, obsolete)* Handling of Product Complaints and Recall Outsourced Activities (qualification of suppliers) Self-Inspection **Report Writing** **Discussion of audit findings**
INSPECTION AGENDA – NON-STERILE DRUG AND MEDICAL DEVICE MANUFACTURERS

Inspection Activity
OPENING MEETING Introductions, Attendance record, Inspection standard and scope Brief description of the company (identify key personnel) Buildings and facilities overview (for initial; if applicable) Floor plan / Lay-out plan Product and personnel flows Major changes from the last inspection (if applicable) **ON-SITE INSPECTION** Warehouse (starting materials, packaging materials and finished goods) Receipt (Handling and Storage) Storage Areas (quarantine, approved, reject) Storage condition (temperature and RH monitoring)

Approval for use
Dispatch
Label reconciliation
Production
Dust extraction
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Sampling
Dispensing
Processing
Packaging
Quality Control Laboratory
Utilities
Water
HVAC
Compressed Air

DOCUMENT REVIEW
Establishment Records
License to Operate
List of Products Manufactured (CPR)
Site Master File

Registered Pharmacist's Records:
PRC ID, PTR

Pharmaceutical Quality System:

Quality Manual
Quality Risk Management
Hormone / Steroid facilities shared with general production
Risk assessment
Cleaning validation
Finished Product Release procedure
Product Quality Review
Supplier Qualification including audits
Validation Master Plan
Process Validation
Cleaning Validation
Computer Validation (if applicable)
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action (CAPA)

Personnel:
Organizational Chart
Consultants' credential (if applicable)
Duties and Responsibilities/Job Description
Training
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Medical and Health Examinations

Premises and Equipment:

Warehouse (Starting Materials, Packaging Materials and Finished Goods)
Receipt, handling & storage
Quarantine, approval/release, reject
Including hazardous materials (if applicable)
Temperature & humidity monitoring records
Dispatch
Inventory control
Equipment
Storage
Cleaning
Qualification
Repair and Maintenance
Calibration
Engineering and Services
Pest Control
Housekeeping
Key control
Back-up system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results, including trending)
Maintenance
HVAC
Lay-out
Qualification
Environmental Monitoring and Testing (method, specifications and results, including trending)
Maintenance

Compressed air
Lay-out
Specifications of filters
Monitoring and Testing
Maintenance and Cleaning

Documentation
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for:
starting materials
packaging materials
bulk product
finished product
SOPs
Delivery documents
Lot/Batch Numbering System
Distribution records
Qualification of suppliers

Production (Process Flow)
Gowning procedures
Sampling
Method of sampling and inspection
Sampling tools and kits
Dispensing / Weighing
Laundry
Processing

Formulation
In-process and Line clearance checks
Rework/reprocessing
Packaging
Storage of bulk product
Control of labels & pre-printed packaging materials
In-process controls
Storage of packed products (quarantine/awaiting approval)

Quality Control
Sample receipt
Method validation
Testing Procedure and Results (starting materials, bulk, finished products)
Identification test procedure
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Reference Standards and reagents
Special storage and directions
Traceability of primary and secondary standards
Analysts work books/records & test results (if available)
Training & assessment
Retention samples
Stability program
Microbiology Laboratory testing
Equipment / Laminar Flow hood/ BSC
Testing procedure, references and results
Media preparation

Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis
Identification tests
Passage (procedure and records)
Storage

Outsourced Activities (Contract Manufacturing Agreement, Testing laboratories agreement, others)

Complaints and Product Recall (procedure and records)
Mock recall

Self-inspection (procedure and records)

REPORT WRITING

EXIT MEETING

INSPECTION AGENDA – RADIOPHARMACEUTICALS

Inspection Activity
Opening Meeting Introductions, Attendance record, Inspection standard and scope Major Changes Key personnel

Brief description of the company
Buildings and facilities overview (for initial; if applicable)
Floor plan / Lay-out plan
Product and personnel flows

On-site inspection
Plant Tour
Warehouse (starting materials, packaging materials and finished goods)
Production
Reactor/Cyclotron Production** - Non-GMP
Chemical synthesis
Purification
Processing, formulation and dispensing
Aseptic or final sterilization
Packaging
Quality Control Laboratory
Utilities
Water
HVAC

Document Inspection
Establishment Records:
License to Operate
List of Products Manufactured
Site Master File
Necessary licenses from PNRI
License to Construct

License to Operate for commissioning
Radioactive material license
LTO for controlled facility

Registered Pharmacist's Records:
PRC ID, PTR

Pharmaceutical Quality System:
Quality Manual
Quality Risk Management
Determine the extent of qualification/validation, focusing on a combination of Good Manufacturing Practice and Radiation Protection
Usage of closed or open equipment
Pressure differences, air flow direction and air quality
Finished Product Release procedure
Assessment by a designated person of batch processing records
Assessment of the final analytical data
Radionuclides with long half-lives
Product Quality Review
Supplier Qualification including audits
Validation Master Plan including protocols and reports
Prospective Process Validation
Cleaning Validation
Computer Validation
Procedure, Records and logs:
Deviation
Change control
Corrective Action and Preventive Action (CAPA)

Personnel:
Organizational Chart
Duties and Responsibilities / Job Description
Training:
Training program
Training records & traceability of training history
Assessment of effectiveness of training
Training on radiation safety and cleaning and maintenance of radiopharmaceuticals
QA / Plant manager / Key personnel
Training on Radiation protection
Training on radiopharmaceutical specific aspects of the quality management system
Medical and Health Examinations including eye check-ups
Personnel monitoring
Radiation activity
Equipment used
Disinfection / Decontamination of personnel

Premises and Equipment:
General
Controlled (environmental and radioactive) areas
Self-contained facilities for radiopharmaceuticals
Thickness of wall and non-straight line building walls for facilities with reactor / cyclotron production
Detection of radioactivity contamination
Prevention of cross-contamination from personnel, materials, radionuclides
Closed or contained equipment
Open equipment
Gowning area
Procedure

Appropriate gown / suits
Personnel protective equipment such as ring badge, pendosimeter
Warehouse (Starting Materials (excipients), Packaging Materials)
Receipt, handling & storage
Storage areas – quarantine, release, reject
Approval for use (materials)
Temperature & humidity monitoring
Dispatch
Inventory control
Production areas
Surfaces and finishes
Lighting and Ventilation
Dedicated premises / areas
Air locks
Environmental monitoring
Radioactivity
Particle
Microbiological quality
Equipment
Storage
Cleaning
Qualification
Hot cells – filtered feed air
Isolator / Laminar
Repair and Maintenance
Calibration and reading of radiation monitor devices
Engineering and Services:
Pest Control

Housekeeping
Back-up system
Radioactive waste disposal
Drainage system
Water
Lay-out
Qualification
Monitoring and Testing (method, specifications and results including trending)
Maintenance
HVAC
Lay-out
One-pass air
Exhaust filter (Carbon filters)
Alarm system
Qualification – Classification should be the same with sterile production
Environmental Monitoring and Testing (method, specifications and results including trending)
Maintenance

Documentation:
Batch Record Review
Document control (history, issuing, superseded, obsolete)
Specifications for starting materials
Specifications of packaging materials
Specifications of bulk product
SOPs
Delivery documents
Lot Numbering System
Records of equipment

Usage
Cleaning
Sanitization / Sterilization
Specifications
Starting materials
Packaging materials
Critical items (such as process aids, gaskets, sterile filtering kits)
Distribution records
Acceptance criteria
Criteria for release
Shelf-life (chemical identity of the isotope, radioactive concentration, purity, and specific activity)

Production:
Process Flow
Gowning procedures
Preparation
Processing
Assembly of sterilized equipment under aseptic conditions
Formulation
Filter sterilization (aseptic)
Integrity testing with radiation protection and maintenance of filter sterility
Process simulation (Media fill)
Batch processing documentation
Sterilization processes
Labelling
In-process and Line clearance checks
Packaging
Control of labels & pre-printed packaging materials

In-process controls
Line clearance checks
Reconciliation
Batch packaging documentation
Storage of packed product
Control of materials (starting, in-process, finished and returned materials)

Quality Control:
Sample receipt
Method Validation
QC Testing Procedure and Results (bulk gas, finished products)
Equipment Calibration and Maintenance
Handling of OOS
Test Methods & References (i.e. official pharmacopeia) and Specifications
Radioactivity decay
Identification of radionuclide
Identification of radiopharmaceutical
Reference Standards and reagents
Special storage and directions
Traceability of primary and secondary standards
Analysts work books/records & test results (if available)
Training & assessment
Period of validity (finished product)
Reference and Retention Samples
Stability program
Identification test procedure and specifications of starting materials
Microbiology Laboratory testing
Sterility tests

Bacterial Endotoxin test
Equipment / Laminar Flow hood
Testing procedure, references and results
Media preparation
Growth Promotion Testing
Storage of Reagents
Strains
Receipt
Certificate of Analysis
Identification tests
Passage (procedure and records)
Storage

Outsourced Activities: Contract Manufacturing Agreement, Testing laboratories agreement, others

Complaints and Product Recall (procedure and records)

Self-inspection (procedure and records)

Report Writing
Exit Meeting

INSPECTION AGENDA – TOYS AND CHILDCARE ARTICLES MANUFACTURER

Inspection Activity
OPENING MEETING
Presentation of Inspection / Audit Plan
Presentation of Floor Plan and Plant Lay-Out

Scope of Inspection

PLANT INSPECTION
Premises & Equipment
Production areas
Sampling Area
Packaging
Maintenance of facilities
Cleaning of equipment
Maintenance/Calibration of Equipment
Pest Control
Waste Disposal

Warehouse
Raw Materials
Packaging Materials
Finished Goods

DOCUMENTATION REVIEW
Duly Accomplished Integrated Application Form
DTI / SEC Registration
Business Permit / Ma
yor's Permit
Contract of Lease of Office or Proof of Ownership (TCT) or Certificate of Occupancy
Contract of Lease of Warehouse or Proof of Ownership (TCT) or Certificate of Occupancy
Training Certificates
Internal Audit
201 File of Technical Person / Authorized Person

Standard Operating Procedures (if applicable)
Certificate of Analysis of Finished Goods (Third Party)
Disposal Plan
Recall Plan
Incoming Delivery Receipts and Distribution Records
Franchise agreement (if applicable)

REPORT WRITING
EXIT MEETING

INSPECTION AGENDA – COSMETICS & HOUSEHOLD URBAN PESTICIDES DISTRIBUTOR

Inspection Activity
<u>Opening Meeting</u> Introductions Inspection scope Attendance record **<u>Document Review</u>** **Organization, Management & Personnel** Organizational Chart Job Description / Duties and responsibilities of personnel involved in supply chain Training Plan Training Records and/or Competency evaluation of personnel **QMS & Documentation** License to Operate Proof of Business Registration (DTI / SEC and Business / Mayor's Permit) Standard Operating Procedures

Franchise agreement (if applicable)
Records
Distribution Records
Importation documents
Receipts from suppliers
Receipts issued to customers
Product complaints
Product recall

Summary list with status of notification
Recorded temperature and relative humidity (RH) monitoring data (where applicable)
Calibration records of temperature/RH monitors (where applicable)
Stock Reconciliation/ Inventory

Contract activities

Distribution agreements with suppliers (quality agreements)
FDA Licenses (for local suppliers) / GMP Certificates or other equivalent document (for foreign suppliers)
Agreement with third party (TP) logistics or carrier (when applicable)

III. <u>Walk-through Inspection</u>

Warehouse facilities

Adequate/ sufficient and labeled or identified areas for products:
Commercial stocks/Rejects /Returns/Recalled
Facilities & equipment (PPEs for HUPs)
Storage conditions (must be in compliance with the recommendations of manufacturer or instructions on the label)
Temperature monitors
Sanitation /Pest Control Records
Stock Rotation ((first expiry/first out (FEFO) system must be observed)

Products

Labeling compliance Status of Notification/ Product registration Sample collection (as necessary) **Other Requirements** **Product Information File for Cosmetic Products** Part I Administrative Documents & product Summary Part II Quality Data of Raw Materials Part III Quality Data of Finished Product Part IV Safety & Efficacy Data **Report Writing** Consolidation and discussion of findings **Exit Meeting** Attendance record Presentation/ discussion of findings Signing of Inspection Report

INSPECTION OF MANUFACTURER/REPACKER – COSMETICS/HOUSEHOLD URBAN PESTICIDES /TOYS AND CHILD CARE ARTICLES (TCCAs)

INSPECTION AGENDA		
Presence of all Key Personnel	**Opening Meeting** Introduction from FDA Lead Inspector Discussion of Scope, Inspection Plan Attendance Sheet Company Introduction and Overview Design and Lay-out Review prior to Site Inspection	GMP Cosmetics Team
Company Key Person Assigned	**Site Inspection**	

	QUALITY MANAGEMENT SYSTEM Quality Manual Suppliers of materials/ accreditation Site Master File **PERSONNEL** Organizational Chart/ number of personnel Qualification Responsibilities Training/records **PREMISES** Location Plant Construction & Design Changing rooms and facilities Toilets Defined areas Materials receiving. Material Sampling Incoming goods and quarantine. Starting materials storage. Weighing and dispensing. Processing. Storage of bulk products. Packaging. Quarantine storage before final release of products. Storage of finished products. Loading and unloading.	

	Laboratories. Equipment washing. Wall, Ceiling & Floor Drains Air Intakes and Exhausts Lighting & Ventilation Laboratories Storage Areas Cleaning and Maintenance of facilities Water System (Lay-out, Monitoring / records) **EQUIPMENT** Design and Construction Installation and Location Maintenance Calibration Cleaning Records **SANITATION & HYGIENE** **Personnel** Medical Examination Records Hygienic Practices Gowning & de-gowning procedures **Premises** Employee's hand washing facilities	

	Locker facilities Cleaning and Maintenance Waste Material Pest Control **Equipment and Apparatus** Cleaning Procedure and records **PRODUCTION** Control of Starting Materials Water Verification of Materials Rejected materials Batch Numbering System Weighing and Measurement Procedures and Processing Dry products Wet products Labeling and Packaging Finished Product: Quarantine and Delivery to Finished Stock **QUALITY CONTROL** Quality Control System Reprocessing (Procedure and records) Returned Products (Procedure and records) **DOCUMENTATION** Documentation Control System	

	Specifications Raw and packaging materials Bulk and finished products Documents for Production Master Formula BMR Records of Quality Control Standard Operating Procedures Distribution Records **INTERNAL AUDIT** Inspection Program and Procedure Records **STORAGE** Stock Handling and Control (Inventory system) Receiving Control Reject/return materials Segregated storage area for flammable and toxic substances (if applicable) **CONTRACT MANUFACTURING AND ANALYSIS** Written Contract between the principal and the contract manufacturer Duties and responsibilities Quality of product **PRODUCT COMPLAINTS** Procedure Responsible Person Handling Complaints	

	Records **PRODUCT RECALL** Procedure Responsible Person in Execution and coordination of Recalls Records	