9. CERTIFICATE OF PRODUCT REGISTRATION (CPR) OF PHARMACEUTICAL PRODUCTS FOR HUMAN AND USE INCLUDING VACCINES AND BIOLOGICALS THROUGH THE WHO COLLABORATIVE REGISTRATION PROCEDURE (CRP)

This Certificate of Product Registration is granted to Marketing Authorization Holders of drug products upon compliance to the agency-prescribed Quality, Safety, Efficacy standards through the World Health Organization (WHO) **Collaborative Registration Procedure (CRP)** based on FDA Circular No. 2022-009.

It is the approval granted by FDA to market a specific product in the country.

Center/Office/Division	:	Center for Drug Regulation and Research
Classification	:	Highly Technical
Type of Transaction	:	G2B – Government-to-Businesses
Who May Avail	:	All Manufacturers, Distributors, Importers, Exporters, Wholesalers, and Traders of WHO Pre-qualified Pharmaceutical Products • Monitored Release (MR) and Initial for WHO Pre-qualified drug products for human use including vaccines and biologicals
Fees to be Paid	:	AO 50 s. 2001 FDA Advisory No. 2021-2904 New Drug/Monitored Release (for all types of products): Php 33,333.33/5 years + 500.00 (Brand Name Clearance, if applicable) + Php 5,000.00 (clinical review) + Php 2,500.00* [Post-Marketing Surveillance (i.e., Local Phase IV Clinical Trial) Protocol Review] + 1% LRF *If additional PV activity(ies) are necessary based on FDA Circular No. 2021-020 Initial Branded: Php 3,000.00/year + 500.00 (Brand Name Clearance) + 1% LRF Unbranded: Php 2,000.00/year + 1% LRF

		The applicant may apply for 2/5-year CPR validity. 2 year-validity: Branded: Php 6,000.00 + 500.00 (for Brand Name Clearance) = 6,500.00 + 1% LRF Unbranded: Php 4,000.00 + 1% LRF 5 year-validity: Branded: Php 15,000.00 + 500.00 (for Brand Name Clearance) = 15,500.00 + 1% LRF Unbranded: Php 10,000.00 + 1% LRF

ELIGIBILITY CRITERIA
(provided under Sec. V.B. of FDA Circular No. 2022-009)

1. Only FDA-licensed drug manufacturers, traders, and distributors with WHO-prequalified pharmaceutic products and vaccines may apply for registration through this procedure.

2. Prior to the submission of the registration application with the FDA, the applicant shall ensure that the form provided under Appendix 2 of WHO TRS 996 Annex 8, Consent of WHO prequalification holder for WHO to share information with the national regulatory authority confidentially under the Procedure (Annex A), has been duly accomplished and submitted by the Manufacturer or Prequalification Holder to the World Health Organization Prequalification Team (WHO/PQT).

3. The eligible product shall be the same as the product prequalified by the WHO/PQT.
a. All aspects of the drug product's quality, including but not limited to the formulation, manufacturing site/s, release and shelf-life specifications, primary packaging, and commercial presentation must be the same as those currently approved by the WHO/PQT at the time of submission.
b. The proposed indication/s, dosing regimen/s, patient group/s, and/or direction/s for use should be the same as those approved by the WHO/PQT.

4. For post-approval change/s, only applications submitted to FDA not later than thirty (30) calendar days after approval of the change/s by WHO/PQT may be applied through CRP of WHO-prequalified pharmaceutical products and vaccines. Applications for post approval change/s which have not undergone WHO prequalification shall be evaluated through the regular FDA registration pathway following FDA Circular (FC) No. 2014-008, its amendment FC No. 2014-008-A, supplement FC No. 2016-017, and succeeding issuances for the same purposes.

5. The applicant may choose to avail of the CRP of WHO-prequalified pharmaceutical products and vaccines only if the application has not been applied through other types of facilitated review pathway (i.e. abridged review and verification review). If any of the requirements of CRP of WHO-prequalified pharmaceutical products and vaccines cannot be complied with, the application shall not be accepted and the applicant shall be advised to submit their application following the regular review pathway.

GENERAL REQUIREMENTS

1. Accomplished application form as per FC No. 2014-003, as prescribed in FA No. 2022-0001, or any future issuance providing for its amendment, repeal, or modification;
2. Complete International Council for Harmonization of Technical Requirements for Pharmaceutical for Human Use (ICH) Common Technical Document (CTD) or ASEAN Common Technical Dossier (ACTD) data requirements following existing guidelines (Refer to Annex 8.2 Checklist of Requirements for MR/Initial Applications of Vaccines and Biologicals).
3. Appendix 3, Part A of WHO TRS 996 Annex 8, *Expression of interest to the national regulatory authorities (NRAs) in the assessment and accelerated national registration of a World Health Organization (WHO) prequalified pharmaceutical product or vaccine)* (Annex B). If the applicant company is not the original WHO PQ holder, the applicant company must submit an authorization letter that indicates agreement of the original WHO PQ holder, following the prescribed format in Appendix 3, Part A of WHO TRS 996;
4. Country-specific requirements such as:
    a. Current Good Manufacturing Practice (cGMP) Clearance of Foreign Drug Manufacturers issued by Philippine FDA;
    b. Labeling materials consistent with country-specific requirements;
    c. Stability studies conducted under Climatic Zone IVb (hot and humid) for applicable products;
    d. Tabulated summary of WHO/PQT post-approval change/s prior to the registration application through CRP of WHO-prequalified pharmaceutical products and vaccines, obtained by the manufacturer/prequalification holder;
    e. Risk Management Plan (RMP) and RMP Philippine-specific Annex, with Periodic Safety Update Reports (PSUR)/Periodic Benefit-Risk Evaluation Report (PBRER), as applicable;
    f. Representative sample with corresponding Certificate of Analysis (upon request of the evaluator); and
    g. Additional requirements for vaccines and biological products:
        i. Identification of the medical director who will monitor event/s reactions, and prepare appropriate report to be submitted to FDA;
        ii. Person/s responsible for production and control of the product (Name/s, Position, Department, and Sample of Signature);
        iii. Information/procedure on the numbering system of the lots or batches;
        iv. System for the reprocessing of the product in event of rejection of the lot or batch by the manufacturer's Quality Assurance/Quality Control;
        v. Demonstration of lot-to-lot consistency from three (3) consecutive lots or batches;

vi. Description of the cold-chain procedures employed from the origin to the port of entry and storage in the Philippines (how and where);
vii. Summary Lot Protocol (for vaccines, toxoids, and immunoglobulins only);
viii. List of countries where the product is already licensed and the date of approval (for vaccines only); and
ix. Head-to-head comparability studies (for biosimilars only).

CHECKLIST OF REQUIREMENTS FOR NEW CHEMICAL ENTITIES/MONITORED-RELEASE REGISTRATION OF PHARMACEUTICAL PRODUCTS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
ASEAN Common Technical Dossier Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information 8. Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 9. Letter of Authorization (where applicable) 10. Certifications For contract manufacturing: d. License of pharmaceutical industries and contract manufacturer e. Contract manufacturing agreement f. GMP certificate of contract manufacturer For manufacturing "under-license" d. License of pharmaceutical industries e. GMP certificate of the manufacturer f. Copy of "under-license" agreement	Applicant Company/Manufacturer (For the whole Part I) FDA Website & Cashier

For locally manufactured products: c. License of pharmaceutical industries d. GMP certificate (country specific) For imported products d. License of pharmaceutical industries/importer/wholesaler (country specific) e. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format f. Foreign GMP Clearance 11. Site Master File 12. Labeling 13. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 14. Product Information c. Package Insert d. Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 2.2. Description of Manufacturing Process and Process Controls S 2.3. Control of Materials S 2.4. Control of Critical Steps and Intermediates S 2.5. Process Validation and/or Evaluation S 2.6. Manufacturing Process Development S 3 Characterization	Applicant Company/Manufacturer (For the whole Part II: Quality)

S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 4.5. Justification of Specifications S 5 Reference Standards or Materials S 6 Container Closure System S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients	

P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/Equivalence Evidence (if applicable) Part III: Nonclinical Document Sec. A Table of Contents Sec. B Nonclinical Overview 1. General Aspect 2. Content and Structural Format Sec. C Nonclinical Written and Tabulated Summaries 1. Nonclinical Written Summaries 1.1. Introduction 1.2. General Presentation Issues 2. Content of Nonclinical Written and Tabulated Summaries 2.1. Pharmacology 2.1.1. Written Summary 2.1.1.1. Primary Pharmacodynamics 2.1.1.2. Secondary Pharmacodynamics 2.1.1.3. Safety Pharmacology 2.1.1.4. Pharmacodynamic Drug Interactions 2.1.2. Tabulated Summary 2.2. Pharmacokinetics	Applicant Company/Manufacturer (For the whole Part III: Nonclinical Document)

2.2.1. Written Summary 2.2.1.1. Absorption 2.2.1.2. Distribution 2.2.1.3. Metabolism 2.2.1.4. Excretion 2.2.1.5. Pharmacokinetic Drug Interaction (Nonclinical) 2.2.2. Tabulated Summary 2.3. Toxicology 2.3.1. Written Summary 2.3.1.1. Single-Dose Toxicity 2.3.1.2. Repeat-Dose Toxicity 2.3.1.3. Genotoxicity 2.3.1.4. Carcinogenicity 2.3.1.5. Reproductive and Developmental Toxicity 2.3.1.5.1. Fertility and Early Embryonic Development 2.3.1.5.2. Embryo-Foetal Development 2.3.1.5.3. Prenatal and Postnatal Development 2.3.1.6. Local Tolerance 2.3.1.7. Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3. Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption	

3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity 4.1.3. Genotoxicity 4.1.3.1. In vitro Reports 4.1.3.2. In vivo Reports 4.1.4. Carcinogenicity 4.1.4.1. Long Term Studies 4.1.4.2. Short- or Medium-Term Studies 4.1.4.3. Other Studies 4.1.5. Reproductive and Developmental Toxicity 4.1.5.1. Fertility and Early Embryonic Development 4.1.5.2. Embryo-Foetal Development 4.1.5.3. Prenatal and Postnatal Development 4.1.5.4. Studies in which the Offspring are Dosed and/or further Evaluated 4.1.6. Local Tolerance 4.1.7. Other Toxicity Studies (if available) 4.1.7.1. Antigenicity 4.1.7.2. Immunotoxicity 4.1.7.3. Dependence 4.1.7.4. Metabolites 4.1.7.5. Impurities 4.1.7.6. Other Sec. E List of Key Literature References Part IV: Clinical Document Sec. A Table of Contents	

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4.1.3. Demographic and Other Characteristics of Study Population 4.2. Adverse Events 4.2.1. Analysis of Adverse Events 4.2.1.1. Common Adverse Events 4.2.1.2. Deaths 4.2.1.3. Other Serious Adverse Events 4.2.1.4. Other Significant Adverse Events 4.2.1.5. Analysis of Adverse Events by Organ System or Syndrome 4.2.2. Narratives 4.3. Clinical Laboratory Evaluations 4.4. Vital Signs, Physical Findings, and Other Observations Related to Safety 4.5. Safety in Special Groups and Situations 4.5.1. Patient Groups 4.5.2. Drug Interactions 4.5.3. Use in Pregnancy and Lactation 4.5.4. Overdose 4.5.5. Drug Abuse 4.5.6. Withdrawal and Rebound 4.5.7. Effects on Ability to Drive or Operate Machinery or Impairment of Mental Ability 4.6. Post-Marketing Data Appendix 4 5. Synopses of Individual Studies Sec. D Tabular Listing of All Clinical Studies Sec. E Clinical Study Reports (if applicable) 1. Reports of Biopharmaceutic Studies 1.1. Bioavailability (BA) Study Reports 1.2. Comparative BA or Bioequivalence (BE) Study Reports 1.3. In vitro-In vivo Correlation Study Reports 1.4. Reports of Bioanalytical and Analytical Methods for Human Studies 2. Reports of Studies Pertinent to Pharmacokinetics Using Human Biomaterials 2.1. Plasma Protein Binding Study Reports 2.2. Reports of Hepatic Metabolism and Drug Interaction Studies 2.3. Reports of Studies Using Other Human Biomaterials 3. Reports of Human Pharmacokinetic (PK) Studies	

3.1. Healthy Subject PK and Initial Tolerability Study Reports 3.2. Patient PK and Initial Tolerability Study Reports 3.3. Population PK Study Reports 4. Reports of Human Pharmacodynamic (PD) Studies 4.1. Healthy Subject PD and PK/PD Study Reports 4.2. Patient PD and PK/PD Study Reports 5. Reports of Efficacy and Safety Studies 5.1. Study Reports of Controlled Clinical Studies Pertinent to the Claimed Indication 5.2. Study Reports of Uncontrolled Clinical Studies 5.3. Reports of Analyses of Data from more than One Study, Including any Formal Integrated Analyses, Meta-Analyses, and Bridging Analyses 5.4. Other Clinical Study Reports 6. Reports of Post-Marketing Experience 7. Case Report Forms and Individual Patient Listing Sec. F List of Key Literature References Additional Requirements: 1. Risk Management Plan – which shall include the following: h. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems i. RMP Philippine-Specific Annex (as applicable) j. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 2. Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020] Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	

	Applicant Company /Manufacturer Applicant Company /Manufacturer FDA (Applicant Company)

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
CHECKLIST OF REQUIREMENTS FOR INITIAL REGISTRATION OF PHARMACEUTICAL PRODUCTS (PRESCRIPTION – HUMAN DRUGS) **ASEAN Common Technical Dossier** Part I: Administrative Data and Product Information Sec. A Introduction Sec. B Overall ASEAN Common Technical Dossier Table of Contents Sec. C Guidance on the Administrative Data and Product Information 1. Duly accomplished and notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. 2.Letter of Authorization (where applicable) 3. Certifications For contract manufacturing: a. License of pharmaceutical industries and contract manufacturer	Applicant Company/Manufacturer (For the whole Part I) FDA Website & Cashier

b. Contract manufacturing agreement c. GMP certificate of contract manufacturer For manufacturing "under-license" a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of "under-license" agreement For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific) For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance 4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet) Part II: Quality Sec. A Table of Contents Sec. B Quality Overall Summary Sec. C Body of Data Drug Substance (S) S 1 General Information	Applicant

S 1.1. Nomenclature S 1.2. Structural Formula S 1.3. General Properties S 2 Manufacture S 2.1. Manufacturer(s) S 3 Characterization S 3.1. Elucidation of Structure and Characteristics S 3.2. Impurities S 4 Control of Drug Substance S 4.1. Specifications S 4.2. Analytical Procedures S 4.3. Validation of Analytical Procedures S 4.4. Batch Analyses S 5 Reference Standards or Materials S 7 Stability Drug Product (P) P 1 Description and Composition P 2 Pharmaceutical Development P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation	Company/Manufacturer (For the whole Part II): Quality Document

P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Product Interchangeability/equivalence evidence (if applicable) Note: • ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions.	
CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE (MR)/MONITORED RELEASE EXTENSION (MRE) TO INITIAL APPLICATIONS: 1. ACTD Parts I & II (same as above) 2. Risk Management Plan 3. Periodic Safety Update Report (PSUR) or Phase IV Clinical Study Report (whichever is applicable) 4. Other post-approval commitments (if any, based on the Special Conditions at the back page of the CPR and accompanying letter)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
Additional Requirement for Dangerous Drugs (as per RA 9165 and Dangerous Drugs Board): -License to Handle Dangerous Drugs	Philippine Drug Enforcement Agency (PDEA)
Note: As per FDA Circular No. 2020-003, Submission of Risk Management Plan for a generic drug is	Applicant

not required, but it is expected that the Marketing Authorization Holder (MAH) will continue to evaluate the safety of their products on a regular basis and must be readily available upon request of FDA in case-to-case basis, such as but not limited to: • In response to a safety concern arising from a new route of administration; • As a result of a new safety concern associated with a new indication that may require additional PV activities; If the innovator or reference product has safety concerns that have been identified to require additional local PV activities.	Company/Manufacturer

CHECKLIST OF REQUIREMENTS FOR MONITORED RELEASE AND INITIAL REGISTRATION OF VACCINES AND BIOLOGICALS

CHECKLIST OF REQUIREMENTS	WHERE TO SECURE
AO No .47-a, series of 2001 Rules and Regulations on the Registration, including Approval and Conduct of Clinical Trials, and Lot or Batch Release Certification of Vaccines and Biological Products	Applicant Company
ASEAN Common Technical Dossier	
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Sec. B Overall ASEAN Common Technical Dossier Table of Contents	Applicant Company
Sec. C Guidance on the Administrative Data and Product Information	Applicant Company
1 . Notarized Integrated Application Form (in excel and pdf formats) (with proof of payment) 2. Letter of Authorization (where applicable)	FDA Website Applicant Company/ Manufacturer
3. Certifications For contract manufacturing:	
a. License of pharmaceutical industries and contract manufacturer b. Contract manufacturing agreement c. GMP certificate of contract manufacturer	Applicant Company /Manufacturer Applicant Company/ Manufacturer

	Applicant Company/ Manufacturer
For manufacturing "under-license" a. License of pharmaceutical industries b. GMP certificate of the manufacturer c. Copy of "under-license" agreement	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For locally manufactured products: a. License of pharmaceutical industries b. GMP certificate (country specific)	Applicant Company/ Manufacturer Applicant Company/ Manufacturer
For imported products a. License of pharmaceutical industries/importer/wholesaler (country specific) b. Certificate of Pharmaceutical Product (CPP) issued by the competent authority in the country of origin according to the current WHO format c. Foreign GMP Clearance	Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer
4. Site Master File 5. Labeling 6. Representative Sample with corresponding Certificate of Analysis (upon request of the evaluator) 7. Product Information a. Package Insert b. Summary of Product Characteristics (Product Data Sheet) 8. Risk Management Plan (RMP) which shall include the following: a. RMP compliant with latest EMA838713/2011 Guideline on Good Pharmacovigilance Practices (GVP) Module V – Risk Management Systems b. RMP Philippine-Specific Annex (as applicable) c. RMP Philippine-Specific Annex annotated version (with tracked changes) (as applicable) OR instead of a core or country specific annex, an RMP specifically developed for the Philippines may be submitted 9. Periodic Safety Update Report (PSUR)/Periodic Benefit Risk Evaluation Report 10. List of Countries where the product is already licensed and the date of approval (for vaccines) 11. Names of the medical director of the importer/distributor and local manufacturer who will monitor	Applicant Company /Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer Applicant Company/ Manufacturer

event/s reactions and prepare appropriate report to be submitted to FDA 12. Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature) 13. Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)	
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Drug Product (P)	

P 1 Description and Composition P 2 Pharmaceutical Development P 2.1. Information on Development Studies P 2.2. Components of the Drug Product P 2.2.1. Active Ingredients P 2.2.2. Excipients P 2.3. Finished Product P 2.3.1. Formulation Development P 2.3.2. Overages P 2.3.3. Physicochemical and Biological Properties P 2.4. Manufacturing Process Development P 2.5. Container Closure System P 2.6. Microbiological Attributes P 2.7. Compatibility P 3 Manufacture P 3.1. Batch Formula P 3.2. Manufacturing Process and Process Control • Information on the number system of the lots or batches • System for the re-processing of the product in the event of rejection of the lot or batch by the manufacturer's QA/QC P 3.3. Controls of Critical Steps and Intermediates P 3.4. Process Validation and/or Evaluation P 4 Control of Excipients P 4.1. Specifications P 4.2. Analytical Procedures P 4.3. Excipients of Human and Animal Origin P 4.4. Novel Excipients P 5 Control of Finished Product P 5.1. Specifications P 5.2. Analytical Procedures P 5.3. Validation of Analytical Procedures P 5.4. Batch Analyses • Summary Lot Protocol (for vaccines, toxoids and immunoglobulins) • Lot to Lot Consistency from three (3) consecutive batches	

P 5.5. Characterization of Impurities P 5.6. Justification of Specifications P 6 Reference Standards or Materials P 7 Container Closure System P 8 Product Stability P 9 Head to Head Comparability – for Biosimilars	
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2.3.1.1.Single-Dose Toxicity 2.3.1.2.Repeat-Dose Toxicity 2.3.1.3.Genotoxicity 2.3.1.4.Carcinogenicity 2.3.1.5.Reproductive and Developmental Toxicity 2.3.1.5.1.Fertility and Early Embryonic Development 2.3.1.5.2.Embryo-Foetal Development 2.3.1.5.3.Prenatal and Postnatal Development 2.3.1.6.Local Tolerance 2.3.1.7.Other Toxicity Studies (if available) 2.3.2. Tabulated Summary 3.Nonclinical Tabulated Summaries Sec. D Nonclinical Study Reports 1. Table of Contents 2. Pharmacology 2.1. Written Study Reports 2.1.1. Primary Pharmacodynamics 2.1.2. Secondary Pharmacodynamics 2.1.3. Safety Pharmacology 2.1.4. Pharmacodynamic Drug Interactions 3. Pharmacokinetics 3.1. Written Study Reports 3.1.1. Analytical Methods and Validation Reports 3.1.2. Absorption 3.1.3. Distribution 3.1.4. Metabolism 3.1.5. Excretion 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical) 3.1.7. Other Pharmacokinetic Studies 4. Toxicology 4.1. Written Study Reports 4.1.1. Single-Dose Toxicity 4.1.2. Repeat-Dose Toxicity	

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Sec. F List of Key Literature References Additional Requirements: 1. For MR, Post Marketing Surveillance (PMS) Protocol [as post-approval requirement if additional activity(ies) are necessary based on FDA Circular No. 2021-020]	Applicant Company/Manufacturer

CLIENT STEPS	AGENCY ACTION	FEES TO BE PAID	PROCESSING TIME	PERSON RESPONSIBLE
1. Secure a schedule of appointment / submission to FDAC E-mail submission: Submits the application for pre-assessment through fdac.pacd.cdrr@fda.gov.ph	1. Sends the scheduled date of submission for pre-assessment	None		FDAC *Personnel*
	2. Pre-assesses the completeness of the application. If the application is acceptable, informs the client of the result of the pre-assessment and instructs the client to proceed with payment. If the application did not satisfactorily pass the pre-assessment, advises client to secure a new appointment schedule for pre-assessment and new Document Tracking Number	None		CDRR *Personnel*

2. For accepted applications, pays the required fee through any of the following: • BANCNET • Landbank OnColl • Landbank Link.bizPortal Sends proof of payment to the FDAC.	3. Upon receipt of the proof of payment, endorses the application to CDRR for evaluation.	See Table Above	Day 1 1 working day	FDA Cashier/ Landbank FDAC *Personnel*
	4. Receives the application from FDAC and encodes/updates the database.	None	Day 2 1 working day	Center for Drug Regulation and Research (CDRR) – Central Receiving and Releasing (CRR) Unit
	5. Decks/Assigns the application to the assigned evaluators of Registration Section and/or Clinical Research Section*. *Decking to CRS is only applicable for Monitored release and Initial (Vaccines) applications	None	Day 3 1 working day	CDRR *Director*

	6. Evaluator verifies the registration pathway of the application if indeed for Collaborative Review/Registration Procedure (CRP). The evaluator shall inform the WHO/PQT and the applicant of its consent to apply the procedure through Appendix 3, Part B of WHO TRS 996 Annex 8, Decision on acceptance by the NRA to apply the Procedure to a specified WHO-prequalified product and request for access to product-specific information and documentation (Annex C). The regulatory time is stopped (stop clock) until the WHO/PQT has provided the FDA with the requested product-related information and documentation, through the restricted-access website.	None	Day 4-8 5 working days	FDRO I/II/III
	For human vaccines, toxoids and immunoglobulins, Summary Lot Protocol shall be referred to CSL.	None	Day 9-38 30 working days	Food-Drug Regulation Officer (FDRO) I/II (Junior Evaluator)/FDRO III (Senior Evaluator)
	7. Evaluates the application according to requirements and prescribed standards	None		FDRO *I/II/III*

If an electronic notice of deficiencies (E- NOD) was issued by the evaluator, submits complete compliance documents to the evaluator	8. **a. Clinical Research Section (Safety and Efficacy evaluator)** Prepares a worksheet with Recommendations on the evaluated safety and efficacy dossier, RMP, and PMS protocol (if any), then forwards this to the Quality evaluator of the Registration Section. **b. Registration Section (Quality evaluator)** Prepares a worksheet and drafts Certificate of Product Registration (CPR) issuance when the approval of the application is recommended (Quality, and Safety & Efficacy received from the CRS)	None		FDRO *I/II/III*
	Prepares a worksheet and Letter of Disapproval (LOD) when the application does not merit an approval recommendation (Quality, and Safety & Efficacy received from the CRS) *Any minor deficiencies/ clarifications will be communicated to the clients through electronic communication **step 8a is only applicable for Monitored Release and Initial (Vaccines) applications.			
	9. Reviews the evaluated application bearing the recommendation of the Junior Evaluator.	None	Day 39-58 20 working days	FDRO III

	10. Prepares the final output document (CPR/LOD), affixes initial, and forwards it to the senior evaluator (FDRO III) If with post-approval commitment/s, prepares a letter, signs, and forwards it together with the CPR For Dangerous Drugs, prepares a letter/notification to PDEA for its recommendation on the application particularly on the formulation and labeling	None	Day 59 1 working day	FDRO I/II/III
	11. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Section Supervisor.	None		FDRO III
	12. Reviews the final output document, affixes initial on the worksheet, and forwards it to the Licensing and Registration (LRD) Chief.	None	Day 60 1 working day	FDRO IV (Supervisor)
	13. Checks and recommends the decision of the evaluators and supervisor by affixing signature.	None	Day 61 1 working day	LRD Chief
	14. Signs and approves the final decision	None	Day 62 1 working day	CDRR Director

	15. Encodes/Updates the Database and endorses the final output document (CPR/LOD/Letter) to the CDRR-Records Section	None	Day 63 1 working day (per batch of applications)	CDRR-CRR Unit Personnel
	16. Scans, barcodes the final output document (CPR/LOD/Letter); and endorses the final output document to the FDAC Releasing Section	None	Day 64 1 working day (per batch of applications)	CDRR-Records Personnel
3. Receives the CPR/LOD/Letter	17. Releases the CPR/LOD/Letter to the client	None	Day 65 1 working day	AFS - Releasing Section Personnel
	18. Notifies the WHO/PQT of the regulatory decision (CPR/LOD/Letter)	None	Within 20 working days upon release of the regulatory decision (CPR/LOD/Letter)	FDRO I/II/III
(Service is covered under FDA Circular No. 2022-009).		**TOTAL:**	**65 working days**	