CENTER FOR DRUG REGULATION AND RESEARCH
LIST OF REQUIREMENTS FOR REGISTRATION OF BIOLOGICAL PRODUCTS

A. Initial Application

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2. Letter of Authorization (where applicable)
3. Certifications
4. Labeling
5. Product Information

Sec. C Guidance on the Administrative Data and Product Information
1. Application Form
2. Letter of Authorization (where applicable)
3. Certifications
   For contract manufacturing:
   a. License of pharmaceutical industries and contract manufacturer
   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
   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 issued by the competent authority in the country of origin according to the current WHO format
4. Labeling
5. Product Information
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- S 2.2. Description of Manufacturing Process and Process Controls
- S 2.3. Control of Materials
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- S 2.6. Manufacturing Process Development

S 3 Characterization
- S 3.1. Elucidation of Structure and Characteristics
- S 3.2. Impurities

S 4 Control of Drug Substance
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S 5 Reference Standards or Materials

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- P 2.4. Manufacturing Process Development
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- P 2.6. Microbiological Attributes
- P 2.7. Compatibility

P 3 Manufacture
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- P 3.2. Manufacturing Process and Process Control
- P 3.3. Controls of Critical Steps and Intermediates
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- P 4.2. Analytical Procedures
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- P 4.4. Novel Excipients

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     - 3.1.6. Pharmacokinetic Drug Interaction (Nonclinical)
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     - 4.1.6. Local Tolerance
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   - 1.1. Background and Overview
   - 1.2. Summary of Results of Individual Studies
   - 1.3. Comparison and Analyses of Results across Studies

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4.6. Post-Marketing Data

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5. Synopses of Individual Studies

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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
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   3.1. Healthy Subject PK and Initial Tolerability Study Reports
   3.2. Patient PK and Initial Tolerability Study Reports
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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) Representative Sample with corresponding Certificate of Analysis
2) Risk Management Plan
3) For imported products:
   (a) Foreign GMP Clearance
4) For Vaccines:
   (a) List of Countries where the product is already licensed and the date of approval

(b) Names of the medical director of the importer/distributor and local manufacturer who will monitor event/s reactions and prepare appropriate report to be submitted to FDA
(c) Person/s responsible for production and control of the product (Name/s Position, Department, and sample of signature)
(d) Information on the number system of the lots or batches
(e) System for the re-processing of the product in event of rejection of the lot or batch by the manufacturer's QA/QC
(f) Summary Lot Protocol
(g) Lot to Lot Consistency from three (3) consecutive batches
(h) Description of the cold-chain procedures employed from the origin to the port of entry and in the Philippines (how and where)

B. Renewal Application

1) Integrated Application Form
2) Periodic Safety Update Report (PSUR) and Risk Management Plan (RMP)
3) Certification that there were no changes during the 5-year period. If there were any, the summary changes made by the manufacturer for the 5-year period shall be incorporated
4) Labeling Materials (actual/commercial labels)
5) Actual commercial sample

Additional Requirements:

1) Post-marketing commitments (if any)
2) For vaccines:
   (a) Summary Lot Protocol
   (b) List of Countries where the vaccine is already licensed and date of approval
   (c) Adverse event following immunization report (Summary of Annual Reports)
3) MR/E to Initial:
   (a) Risk Management Plan (RMP)
   (b) Periodic Safety Update Report (PSUR)

Notes:

- All documentary requirements must be in PDF format to be submitted to PAIR
- Image files should be at least 150 dots per inch (dpi)
- A hard copy of the integrated application form is required
- Samples may be submitted at a later date, e.g. when the application has already been decked as indicated in the Document Tracking System
- ICH Common Technical Document format is acceptable provided that the products are approved in ICH member countries/ regions