Quality Management Systems Assessment Checklist for New Manufacturers: **Medicines & Medical Devices**

Instructions: The Quality Management Systems Assessment checklist will gather relevant information to confirm the Good Manufacturing Practice (GMP) status of the manufacturing facilities. This assessment should be conducted with Quality Assurance personnel at the product manufacturer.

☐ **Collect the following product information:**

- Name (scientific and branded)
- Description & Intended Use/Indication
- Dose, Dosage Form, and Route of Administration (Only for Medicines)
- Ingredients (API and excipients for Medicines; components for Medical Devices)
- Class (Only for Medical Devices)

☐ **Collect the following manufacturer information:**

- Name
- Contact Information
- Copy of the Free Sales Certificate

  NOTE: *US-FDA does not issue Free Sales Certificates. For medical devices manufactured in USA, the Certificate to Foreign Governments should be used in-lieu of the Free Sales Certificate (Only for Medical Devices).*
- Manufacturer License issued by the authorities in the Country of Origin
- Copy of the Site Master File

☐ **Collect the following information about the Quality Management System:**

- Copy of the valid ISO 13485:2016 Certificate (Only for Medical Devices)
- Copy of the GMP Certificate

  NOTE: *US-FDA does not issue GMP Certificates. For medicines manufactured in USA, the Certificate of Pharmaceutical Product (CPP) should be used in lieu of the GMP Certificate (Only for Medicines).*
- Copy of the Certificate of Pharmaceutical Products (CPP) according to the World Health Organization format (Only for Medicines)
- Open sections of the Active Pharmaceutical Ingredient (API) Manufacturer Drug Master File (DMF) (if applicable)
- Copy of the latest Manufacturer Establishment Inspection Report issued by the applicable National Regulatory Authority (NRA)
- List of the active Standard Operating Procedures (SOPs)

- [ ] **Collect a copy of the Product Dossier** according to the International Conference on Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) Common Technical Document for the Registration of Pharmaceuticals for Human Use (Only for Medicines)
- [ ] **Collect a copy of the Technical File** (Only for Medical Devices)
- [ ] **Collect a copy of the available product registration** certificates issued by NRAs
- [ ] **Collect a copy of the Product Labeling,** including:
  - Primary Packaging
  - Secondary Packaging
  - Patient Information Leaflet (Only for Medicines)
  - Summary of Product Characteristics (Only for Medicines)
  - Instructions for Use (Only for Medical Devices)
- [ ] **Establish a Quality Agreement**
- [ ] **Establish a Safety Data Exchange Agreement**
- [ ] **Request product samples for technical evaluation**
- [ ] **Perform due diligence prior to contracting.** This should include a search for warning letters and inspection history on stringent regulatory authority (e.g., FDA, EMA, MHRA, etc.) websites. Request inspection reports from the past 5 years from the manufacturer. Consider visiting the manufacturer in-person, if feasible. If conducting an in-person or remote GMP inspection, consult relevant (e.g., SRA-specific) guidelines for GMP inspection checklists. In the absence of specific guidance, refer to the Pharmaceutical Inspection Co-operation Scheme (PIC/S) Audit Checklist and Interpretation Guide.