Check List for Prequalification

1. Manufacturer / Supplier Company Profile

i. Name, address, site address & contact details of manufacturer/supplier
ii. Manufacturing experience (no. of years), company history
iii. GMP certificate
iv. International standards of the plant – medical devices

2. Product Information

i. Analytical report of finished product
ii. Analytical report of active pharmaceutical ingredients
iii. Stability data
iv. Annual turnover for the product
v. COPP certificate – pharmaceuticals/free sale certificate for medical devices
vi. NMRA Certificate (certified copy)
vii. Bio Equivalence data

3. Local Agent's Information

i. Name, address & contact details

4. Letter of Authorization from the manufacturer/supplier to represent as the Local agent

5. Manufacturer Financial information for latest 03 years in English

i. Auditor Authorized or signed statement of Cash flow
ii. Auditor Authorized or signed statement of Financial Position or Balance sheets
iii. Auditor Authorized or signed statement of Income & statement of Profit & Loss
iv. Authorized or signed Independent Auditors' reports

v. If the Subsidiary company submitting Financial statement of parent company's or Mothers company should attach the proof documents or certified letter from parent company and claim that subsidiary does not prepare separate financial statements.

vi. Other necessary documents.

General Remarks.

- GMP certificate & COPP **for the pharmaceutical items** should be certified as true copies by the Sri Lankan Embassy in the country of manufacture. (If the originals are not submitted)
- ISO & Free Sale certificates **for the surgical items** should be certified as true copies by the Sri Lankan Embassy in the country of manufacture. (If the originals are not submitted)
- ISO certificate web link of the accreditation body can be submitted instead of the authorization of the Sri Lankan ambassador.
- All pages of the documents submitted with the application should be numbered. A list of documents submitted with folio numbers to be included as the first page.(Index)
- The prequalified suppliers are removed from the PQ list once their NMRA registration is expired. The prequalification status would be reinstated once a certified copy of re-registration certificate is submitted. Certificate should be certified by an attorney at law/JP.
- Stability data should be submitted for different dosage forms of the same product.
- Copies of COPP and registration certificates of evidence countries should be submitted.
- Each SR number will be considered as a separate item and payment should be made for each SR number.
- One guideline should be filled for each SR number.