

# **List of Document to Support the Application**

*to be submitted in English*

- I National legislation enabling inspections, licensing, sampling and testing and recalls**
- II Information requested from companies prior to undertaking GMP Inspections e g Site Master File**
- III GMP standard if different from PIC/S, EU or WHO GMP Guides**
- IV A list of manufacturers/wholesalers currently inspected and licensed showing type of products manufactured**
- V Copy of Quality Manual**
- VI List of SOPs**
- VII Programme for introduction and ongoing training for inspectors.**
- VIII Names of inspectors carrying out GMP-inspections on full-time or part-time bases including any specialist inspectors**
- IX CVs for each inspector**
- X SOP for how to carry out inspections**
- XI Report format if different from PIC/S format**
- XII Statistical information on numbers of inspections carried out**