PIC/S
Explanatory Notes for Pharmaceutical Manufacturers on the Preparation of A Site Master File
PE008-4

2.5 Product Quality Reviews

- Brief description of methodologies used

3. PERSONNEL

- Organisation chart showing the arrangements for quality management, production and quality control positions/titles in Appendix 5, including senior management and Authorised Person(s) / Qualified Person(s);
- Number of employees engaged in the quality management, production, quality control, storage and distribution respectively.

4. PREMISES AND EQUIPMENT

4.1 Premises

Draft SMF Template prepared by PMDA

2.5 Product Quality Reviews

Product quality review is done for each product once a year.

Quality Assurance Department is responsible for product quality review and approval.

(i) A review of starting materials including packaging materials used in the product, especially those from new sources and in particular the review of supply chain traceability of active substances;

(ii) A review of critical in-process controls and finished product results;

(iii) A review of all batches that failed to meet established specification(s) and their investigation;

(iv) A review of all significant deviations or non-conformances, their related investigations, and the effectiveness of resultant corrective and preventive actions taken;

(v) A review of all changes carried out to the processes or analytical methods;

(vi) A review of Marketing Authorization variations submitted, granted or refused, including those for third country (export only) dossiers;

(vii) A review of the results of the stability monitoring programme and any adverse trends;

(viii) A review of all quality-related returns, complaints and recalls and the investigations performed at the