Appendix 9

Example of a standard operating procedure for planning of inspections

1. Title

Inspection, planning of site inspections

	Signature	Date
Prepared by		1 July 2006
Authorized by		

2. Policy and objective

2.1 Manufacturing sites should be inspected as part of the prequalification process. To enable the procurement agency to perform the inspections, they should be properly planned.

2.2 The objective is proper planning of site inspections to ensure that products will be sourced only from manufacturers that comply with international standards.

2.3 Proper planning of inspections should save time and resources (e.g. financial and human) through procurement agency planning.

3. Responsibility

Head of the Section or Department
Project Manager
Evaluator

4. Action

4.1 When assessing product information, make a list of all the products received (see Addendum A). Complete the table.

4.2 On the basis of the outcome of the assessment of the product information, decide which manufacturers should be inspected for prequalification.

4.3 Dossiers lacking information, or of unacceptably low quality, may lead to the manufacturing site failing to qualify for the inspection.

4.4 Group all the manufacturers in one country together to ensure that when a trip is undertaken to one country, more than one manufacturer can be included in the inspection trip where relevant.

4.5 Consult a map to see where the sites are located and plan the trip so as to prevent unnecessary loss of time through travelling.

4.6 Plot the sites on a table (calendar) and allocate at least 3 days for inspection of each manufacturing site, depending on the dosage forms manufactured and the size of the facilities.

4.7 Write a letter to the company informing them of the tentative date allocated for the site inspection. Request the company to indicate whether the dates are suitable to them, and also request them to submit a site master file.

4.8 Appoint inspectors for the inspection team. There should be at least two inspectors on the team, including the representative from WHO.

4.9 Send a letter to the national regulatory authority inviting an inspector from the inspectorate to participate in the inspection.

4.10 Inform the inspectors of the proposed dates for the inspection.

4.11 When the manufacturer confirms the dates for inspection confirm the date with the company and request the information listed in Addendum B.

4.12 Confirm the dates with the inspectors.

4.13 Send the inspectors copies of the SOPs needed to perform the inspections, as well as the terms of reference, confidentiality clause, no conflict of interest declaration and agreement for performance of work.

4.14 Make the relevant bookings (air travel, transport in the country where the inspection will be performed and hotel accommodation).

5. Addenda

Addendum A: Summary list of dossiers received

Addendum B: Manufacturer information

6. Distribution and retrieval

The record of distribution and retrieval of the SOP should be entered in a table; see the model below.

	Distribution		Retrieval	
Name	Signature	Date	Signature	Date

7. History

The history of changes to the SOP should be entered in a table; see the model below.

Date	Reason for change

Addendum A: Summary list of dossiers received

No	API	Strength	Dosage form	Supplier/ Manu-facturer	Manu-facturing site	Country	Sample

Addendum B:Manufacturer information

1. General information

Name	
Physical address of head office	
Postal address	
Telephone number	
Fax number	
Contact person	
E-mail address	

2. Manufacturing licence

Please attach the manufacturing licence.

3. Product list

Please attach a list of products manufactured at this particular manufacturing site.

4. Inspections by the national regulatory authority

Date of last inspection by the national regulatory authority (NRA)		
List the NRA of other countries that have inspected the site, and dates of inspection	Country	Date

5. Manufacturing and testing

Physical address of manufacturing sites for the products indicated in the submission	
Telephone number	
Fax number	
Physical address of quality control laboratories (chemical and microbiological) used for testing the products in the submission	
Telephone number	
Fax number	
E-mail	

6. Recalls

Please list the products and reasons for implementing a product recall in the last 5 years.

Product and batch number (INN, strength and dosage form)	Reason	Date of recall

7. Complaints

If the company has had any product complaints in the last year, please complete the table below.

Products and batch number (INN, strength and dosage form)	Complaint and source	Corrective action taken

8. Site master file (SMF)

If the SMF for the manufacturing site was submitted previously:

Date submitted	
SMF number	

If the SMF has not yet been submitted to WHO, please attach it now. Please note that the SMF must conform to the requirements specified previously.

9. Audit/inspection

We herewith grant WHO permission to perform the inspection of the manufacturing site to assess compliance with good manufacturing practice, for the purpose of the prequalification of the manufacturing site and product.

I declare that the information given above is true and correct.

_____ _____

Signature: Date:

Name: _____

Position: _____