	TITLE	SOP No.	QA-INS-008
	Procedure for Preparation of Risk Based Plan for Inspection of Vaccine Manufacturing Facilities	Effective Date	
		Review Date	
		Supersedes	NA
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Prepared By		Checked By		Approved By		Authorized By	
Name		Name		Name		Name	
Designation	Drugs Inspector	Designation	Tech. Officer	Designation	ADC(I)-QA	Designation	DDC(I)-QA
Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

Control Status

1.0 Purpose

To lay down a procedure for preparation of risk based plan for inspection of vaccine manufacturing facilities

2.0 Scope

This document is applicable for preparation of risk based plan for inspection of vaccine manufacturing facilities by CDSCO(HQ) / Zonal Heads

3.0 Responsibility

3.1 Head-QA / Zonal Head along with concerned ADC(I) / DI shall be responsible for preparation of risk based plan for inspection of vaccine manufacturing facilities.

3.2 DCG(I) shall be responsible for overall compliance of this SOP

4.0 Accountability

Head QA, Zonal Head and DCG (I)

5.0 Procedure

5.1 The site of inspection may be prioritized based on the two different kinds of risk - an intrinsic risk and a compliance-related risk.

5.1.1 The intrinsic risk estimated for a site reflects the complexity of the site, its processes and products as well as the criticality of the products. These items (complexity and criticality) usually remain fairly constant regardless of the compliance status of the site. Therefore, one usually cannot estimate this risk on the basis of inspection deficiencies or compliance history.

5.1.2 The compliance-related risk that is estimated for the site reflects the GMP compliance status of the site immediately following the most recent routine inspection at the site. When this risk is being estimated, number of deficiencies identified at the last inspection are taken into account.

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5.2 Also the areas that were not inspected (or that were not inspected in detail) during the most recent inspection at the site.

5.3 Also AEFI cases, complaints, test results or recalls shall be considered for deciding the inspection

5.4 Major changes in the building, equipment, process, key personnel shall be considered as deciding factors for inspection.

5.5 Factors which may be useful to consider are

5.5.1 Robustness of the Quality Management System, including its approach to Quality Risk Management.

5.5.2 General GMP compliance history, recurring non-compliance issues and failures to address deficiencies following inspections in a satisfactory manner,

5.5.3 Significant failures to address previous GMP deficiencies.

5.6 During the preparation of Risk based inspection plan, it is also to be ensured that, all the vaccine units are included at least once a year. However, in-case of single product vaccine facilities with a history of consistent GMP compliance, prequalified by WHO inspection may be deferred, if required.

5.7 The additional inspection arising out of various applications like renewal, additional products, market surveillance test results, AEFI, complaints, recalls shall be added and revised plan shall be prepared & updated by the zonal officers and forwarded to the CDSCO(HQ) as and when updated.

5.8 The inspection shall be carried out and copy of inspection report shall be submitted by the Zonal Head to the Biological division and QA division of CDSCO(HQ).

Note : The current version of SOPs QA-INS-007 (Procedure for Planning and Preparation of GMP Inspection) and QA-INS-002 (Procedure for Conducting GMP Inspection and Report Writing) shall be used for compliance of this procedure.

6.0 Annexure / Format

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Sign		Sign		Sign		Sign	
Date		Date		Date		Date	

Nil

7.0 References

Doc. No.	Title
1	The Drugs and Cosmetics Act and Rules, 1945.
2	PIC/S : A recommended model for Risk-based inspection Planning in the GMP environment. PI 037-1, 2 Appendices 1 January 2012
3	Guidance Document for Functions and Responsibilities of Zonal, Sub-Zonal and Port Offices of CDSCO, 2011.

8.0 Abbreviation

Acronym	Full Form
QA	Quality Assurance
DI	Drug Inspector
CDSCO	Central Drugs Standard Control Organization
DCG(I)	Drugs Controller General, India
DDC (I)	Deputy Drug Controller, India
ADC (I)	Assistant Drug Controller, India
SOP	Standard Operating Procedure
INS	Inspection
GMP	Good Manufacturing Practices
WHO	World Health Organization

9.0 Revision History

Revision No.	Reason(s) for Revision
00	Created New