	TITLE	Division Name	QMS Monitoring Division
	Procedure for Qualifying Inspector for inspection of Vaccine/ Biological Manufacturing Facilities	Document No.	QMS-INS-001
		Revision No.	00
		Effective Date	30/12/2022
		Page No.	1 of 4

Prepared By		Approved By		Authorized By	
Name	Saurabh Garg	Name	V. Rajappan	Name	Dr. V.G. Somani
Designation	Drugs Inspector	Designation	ADC(I)	Designation	DCG(I)
Sign		Sign	V. Rajappan	Sign	
Date	12/12/22	Date	14/12/22	Date	23/12/22

Control Status

1.0 Purpose

To lay down a procedure for qualifying inspector for the inspection of Vaccine/ Biological Manufacturing Facilities.

2.0 Scope

This document is applicable for qualifying inspectors for the inspection of Vaccine/ Biological Manufacturing Facilities.

3.0 Responsibility

3.1. Head of CDSCO Zonal/ Sub-zonal offices shall be responsible for recommending the names of the Inspectors to be qualified.

3.2. QMS Monitoring Division shall be responsible to assess the performance of the inspectors whose names are recommended by Head of CDSCO Zonal/ Sub-zonal offices to be qualified as Qualified Inspector.

3.3. DCG(I) shall be responsible for designating the Qualified Inspector.

4.0 Accountability

Head of CDSCO Zonal/ Sub-zonal offices, Head of QMS Monitoring Division and DCG(I)

5.0 Procedure

5.1. Pre requisite for Qualified/ Lead Inspector

5.1.1. Drugs Inspector(s) who have not less than 18 months experience in the manufacture or testing of at least one of the substance specified in Schedule-C of Drugs & Cosmetics Act and Rules or who have gained experience of not less than three years in the inspection of firm manufacturing any of the substances specified in Schedule-C of Drugs & Cosmetics Act and Rules during the tenure of their services as Drugs Inspectors.

5.1.2. Drugs Inspectors who have undergone at least two GMP training (General GMP training and GMP training in the area of vaccines/ sterile products) shall be considered.

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5.1.3. Drugs inspector who has accompanied a Qualified Inspector as a member of inspection team for a minimum of three inspections of Vaccine / Biological Manufacturing Facilities.

5.1.4. Drugs Inspectors shall be deputed for inspection along with Senior Inspector who may be Zonal Head and experienced in inspection of Vaccine / Biological Manufacturing Facilities.

5.1.5. Drugs Inspector who shall inspected Vaccine / Biological Manufacturing Facilities as a Lead Inspector for at least two inspections under the supervision and monitoring of the Zonal head after the three accompanied inspections.

5.2. Drugs inspector who have satisfactorily performed in the inspections of Vaccine/ Biological Manufacturing Facilities for at least five inspections (according to point No 5.1.3 and 5.1.5) and meet basic experience and training requirements as per current version of SOP No. QMS-INS-001 may be recommended by the Head of Zonal/ Sub-zonal offices to QMS Monitoring Division as per the current version of Annexure-I of this SOP to be designated as a Qualified Inspector.

5.3. Drugs inspector of CDSCO (HQ) who meets entire "Pre-requisite for Qualified Inspector" shall be recommended by Head of Biological Division/ QMS Monitoring Division to be designated as Qualified Inspector in case of inspection for pre-authorization and post approval.

5.4. QMS Monitoring Division in consultation with Head of Biological Division shall assess the qualifying criteria and performance of the Drugs Inspectors whose name was recommended by the Head of Zonal/ Sub-zonal offices on the basis of review of inspection report, documentation, review procedures, etc.

5.5. DCG(I) shall designate the Drugs Inspector(s) as Qualified Inspector as per the recommendations of the Head of QMS Monitoring Division and Head of Biological Division.

5.6. QMS Monitoring Division shall publish list of Qualified/ Lead Inspector on CDSCO website as per current version of Annexure-II of SOP No. QMS-INS-001.

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5.7. **Requalification of Inspector:**

5.7.1. If the qualified inspector at the supervisory level has not conducted any GMP inspection in 03 years or has not attended any refresher training then he/she shall be disqualified and the list of the qualified inspector shall be updated accordingly. Such inspectors, if they intent to remain as qualified inspector shall be re-qualified after passing the written examination conducted by the QMS Monitoring Division or by participating in 02 inspections as a team. The list of Qualified Inspector or Lead Inspector shall be updated accordingly.

5.7.2. In case of other Qualified Inspector or Lead Inspector, minimum 5 GMP inspections in 03 years shall be the criteria for requalification of the inspector as Qualified Inspector or Lead Inspector.

6.0 Annexure / Format

Annexure / Format No.	Title
Annexure-I (QMS-INS-001)	Format for "List of Drugs Inspectors recommended by zonal/ sub-zonal Head to be qualified as Qualified/ Lead Inspector"
Annexure-II (QMS-INS-001)	Format for "List of Qualified Inspectors or Lead Inspectors for Vaccine/ Biological Manufacturing Facilities"

7.0 References

Doc. No.	Title
1	The Drugs and Cosmetics Act and Rules

8.0 Abbreviation

Acronym	Full Form
SOP	Standard Operating Procedure
DCG(I)	Drugs Controller General (India)
DDC (I)	Deputy Drugs Controller (India)
QMS	Quality Management System

9.0 Revision History

Revision No.	Reason(s) for Revision

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Annexure-I of QMS-INS-001

Format for "List of Drugs Inspectors recommended by zonal/ sub-zonal Head to be qualified as Qualified/ Lead Inspector"

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi -110002

S.No.	Name of Drugs Inspector(s)	Details of Basic and Advanced GMP training attended	Name and address of Vaccine/ Biological Manufacturing Facilities	Name of Qualified/ Lead Inspector who accompanied in inspection	Remarks, if any

Signature of Head of Zonal/ Sub-zonal Head

Annexure-II of QMS-INS-001

Format for "List of Qualified Inspectors or Lead Inspectors for Vaccine/ Biological Manufacturing Facilities"

Central Drugs Standard Control Organization

Directorate General of Health Services, Ministry of Health and Family Welfare, Government of India
FDA Bhavan, ITO, Kotla Road, New Delhi -110002

S.No.	Name	18 months experience in manufacturing/ testing or 3 year experience in inspection of manufacturing sites of products specified in Schedule-C & C1 (Yes/No)	Training completed on GMP-Basic and Advanced (Yes/No	Whether minimum inspections of vaccine manufacturing site completed as per SOP No. QMS-INS-001 (Yes/No)	Whether name of Drugs Inspector(s) recommended by the Zonal/ Sub-zonal Head	Qualified Lead Inspector for manufacturing of Vaccine/ Biological Manufacturing Facilities

QMS Monitoring Division **Biological Division** **Drugs Controller General (India)**