VCSMPP Certification

Name of the Organization

(As an example, mentioned as ABC throughout this document)

QUALITY MANAGEMENT SYSTEM MANUAL

Confirming to Clause 5 Certification Process: Option 2 Group Certification

Document Number : X
Issue Number :
Issue Date :

	Reviewed By	Approved By	
Name			
Designation			
Signature			

Disclaimer

. This quality Manual, procedures and other related documents are prepared to the best of our judgment and for the guidance of the users. Please note that these are prepared keeping in view the general requirements of the standard .The user is advised to look at his processes, products, services ,customer requirements and other regulatory requirements while preparing his manuals and other documents. The requirements of the standard will be under constant revision and the user is advised to go through the latest standard updates and visit the standard owner site www.qcin.org

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05	Complaint Handling Register			
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Version No	Release Date	Section No / Pages	Reason for Change	Change Details
00		All	New Document Issue	New Document

Documents to be noted

IMPORTANT PONITS TO BE NOTED

You need to go through the following documents and also visit Quality Council of India website (www.qcin.org) for updates and understanding the requirements of the standard. First your Quality Management System needs to address all the requirements of the VCSMPP Standard and the organization own requirements. Present documents -Version Nois 4.1 and Version Date 01-11-2021. You can find the following referred documents in QCI website,

VCSMPP **VOLUNTARY CERTIFICATION SCHEME FOR MEDICINAL PLANT PRODUCE *CERTIFICATION PROCESS***

1. Certification Criteria
2. Certification Process for Group certification
3. QMS Check List –Annexure C
4. Checklist for self-assessment for Good Agricultural Practices (GAP) for medicinal plants produces. Annexure A
5. Checklist for self-assessment for Good Field Collection Practices Annexure B
6. Permissible levels of contaminants under GAP and GFCP ; Annex D

Section No: ABC/QMSM/C Version No: 00	**Introduction**	Date : Page No:

This Manual is prepared to address the requirements of Voluntary Certification Scheme for Medicinal Plants Products (VCSMPP).

This Manual refers to the QMS system procedures according to which the concerned functionaries carry out the activities in effective manner in order to achieve the QMS objectives of the organization.

Authorized for release by:

_____ *[Name]*

_____ *[Position]*

Date: _____

QMS Manual Soft Copy made available to all concerned personnel

Section No: Version No: 00	**Organization**	Date :

1. **Organization Details**

    - Organization Name :
    - Address :
    - Nature of Activities

2. **Management Team**

3. **Organization's service to farmers and customers**

4. **Any other matter depending on the organization and nature of its activities**

5. Contact Phone Numbers: +91-

6. Email :_____

Section No: ABC/QMSM/G Version No: 00	**Definitions**	Date : Page No:

List out the Definitions as used in the GAP/GFCP standard

Section No: ABC/QMSM/H Version No: 00	**Objective**	Date :

To ensure an objective assessment and certification to the VCSMP Certification

Section No: Version No: 00	**Scope**	Date :

1. This document covers the Group certification of VCSMPP Certification

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Scope Statement:

_____
_____
_____

2. Legality and Structure

2.1 .1 Legality

a. --- is registered as a _____ with Registration No. _____ dated –

b. --has the legal right to carry out production and/or trading of ---------- and can legally contract with and represent the group members ..

- enters Certification Agreement' with CB, and becomes the sole holder of the certificate.

--- It has direct responsibility over the production, handling and ownership of the products and compliance with GAP Standard

2.2 Requirements for Producer Groups

The administrative structure of the producer group is documented and will identify the relationship between the producers and the legal entity through written contract

i. Written contracts are in force between each producer member and legal entity. The contracts include the following elements:

- Legal entity
- Name and/or legal identification of the producer
- Producer contact address and also contact details of another person as an alternative.
- Full residential address and farm address of the producer
- ID proof of the producer (Aadhar or Voter ID)
- Products registered.
- Details of the individual production sites locations (the contract may refer to the -- internal register for this information)
- Details of area (crops) or tonnage (the contract may refer to --group's internal register for this information)
- Producer commitment to comply with the requirements of the VCSMPP. Standard
- Producer agreement to comply with the group's documented procedures, policies and, where provided, technical advice
- Sanctions that may be applied in case of VCSMPP. and any other internal requirements not being met
- Signature(s) of producer and legal entity representatives

Template: Agreement with each Producer Member: End of the Manual

2.3 ABC registered members are legally responsible for their respective production sites, which however takes place under the common QMS of the group.

Members of ABC are not legal certificate holders. They do not market any products under their name with reference to the group certificate. All products that are sold without reference to the certificate are recorded in the group mass balance system.

2.4 Producer

i. A register is maintained of all contracted group member producers and of all the applicable sites used for production in accordance with the Standard.

Template: Producer Register: End of the Manual

ii. A declaration is issued to the members of the group to indicate that they are the members of the group only if they are listed on the certificate annex. This declaration is not being used to replace a certificate or to trade with.

iii.

Template: Declaration issued to the members of the group: End of the Manual

Requirements of Producer Register

All producers in --- internal register will be registered individually.

i. The register contain the following information for each producer, at the least:

- Name of producer
- Name of contact person
- Full address ,residential and farm addresses
- Contact data (telephone number, e-mail, if available)
- Other legal entity ID (Aadhar or Voter ID
- Products registered
- Growing/production area in Ha and/or quantity for each registered product
- Certification body(ies) if a producer makes use of more than one CB
- Producer status (internal status as a result of the last internal inspection: approved, suspended, etc.)
- Date of last internal inspection

Those producers of the legal entity who do not apply for GAP certification listed separately

3 Management and Organization

The QMS ensures that the group's registered members or production sites comply in a uniform manner with the VCSMPP Standard requirements.

3.1 Structure

a. The structure enables the appropriate implementation of a QMS across all registered producer members or production sites.

b. --- has management structure and sufficient suitably trained resources (management and technical capacity) to effectively ensure that the requirements of VCSMPP are met by all producers and at all production sites.

c. Members of management annually conduct a documented management review and make necessary changes. The management reviews are generally in the form of an annual staff meeting, where food safety resources, the status of actions from previous management reviews, external and internal changes that are relevant to the quality management system, and effectiveness of the quality management system are reviewed. Evidence of this management review is available and can be verified by the external CB auditor.

Record: Management Review Minutes (Refer to Procedures Manual)

d. The organizational structure is documented and includes individuals responsible for:

- Managing the QMS; which is independent from the sites and producers?
- The internal inspections of each producer member and/or production site annually (i.e.internal inspector(s)).
- The internal audit of the quality management system and verifying the internal inspections (i.e. internal auditor). At least one person in the QMS structure (e.g. internal auditor) is responsible and able to train the internal inspectors and producers.
- Technical advice to the group (depending on the scope of the group)

Template: Organizational Structure/Chart: End of the Manual

e. The management has given internal auditors and inspectors sufficient authority to make independent and technically justified decisions during the internal controls.

3.2 Responsibilities and Duties

The duties and responsibilities of all personnel involved with the compliance of VCSMPP requirements are documented and an individual who holds position of

sufficient seniority and resources to serve as the overall responsible person will be nominated for maintenance of IndG.A.P certification

4. Competency and Training of Staff

a. The competency requirements, training and qualifications for key personnel are defined and documented. These qualification requirements also apply to external consultants.

   Template: Competency, Training, Qualifications of Key Personnel: End of the Manual

b. The management ensured that all personnel with responsibility for compliance with the VCSMPP. Standard are adequately trained and meet the defined competency requirements:

   - Internal auditor competence is maintained
   - Internal inspector competence is maintained
   - Where the internal auditor does not have the necessaryG.A.P. training, but only QMS training/experience, another person with these qualifications (and identified in the QMS) shall form part of the “audit team” to perform the approval of the farm inspections.

c. Records of qualifications and training are maintained for all key personnel (managers, auditors, inspectors, etc.) involved in compliance with VCSMPP. Requirements to demonstrate competence.

d. If there are more than one internal auditor or inspector, they undergo training and evaluation to ensure consistency (calibration) in their approach and interpretation of the standard (e.g. by documented shadow audits/inspections).

e. Systems are in place to demonstrate that key staff is informed and aware of development, issues, and legislative changes relevant to the compliance to the VCSMPP. Standard. Evidence of induction and annual refreshment trainings for key staff as defined above is available.

   Records: Training Records

5. Quality Manual

All the requirements of VCSMPP standard have been documented in quality manual. Policies and procedures are documented in procedures manual and made available to registered members and key staff.
Quality manual will be reviewed once in a year and also whenever the standard requirements changes ,that will affect the implementation of the standard.

6.1 Document Control

a. All documentation relevant to the operation of the QMS for VCSMPPare adequately controlled.
b. The quality manual
    - Operating procedures
    - Work instructions
    - Recording forms
    - External standards,
c. Policies and procedures are sufficiently detailed to demonstrate compliance checks of the requirements of the VCSMPP. Standard.

d. Policies and procedures are made available to relevant staff and producer group registered members.

e. The contents of the quality manual are reviewed annually to ensure that it continues to meet the requirements of the Standard and those of the applicant.

6.2 Document Control Requirements

- There is a written procedure defining the control of documents.

- All documentation are reviewed and approved by authorized personnel before issue and distribution.
- All controlled documents are identified with an issue number, issue date/review date, and be appropriately paged.

- Any changes in these documents are reviewed and approved by authorized personnel prior to their distribution. Wherever possible, an explanation of the reason and nature of the changes are given.

- A copy of all relevant documentation is made available at any location where the QMS is being controlled.

- There is a system in place to ensure that documentation is reviewed and that following the issue of new documents, obsolete documents are effectively rescinded.

Procedure: Document Control (Refer to Procedures Manual)

7. Records

- Records are setup with effective control and implementation of the QMS and compliance with the requirements of the . Standard.

- Records are kept for a minimum of 3 years. However in case of first implementation, requirement is three months.

- Records that are established and maintained are genuine, legible, stored and maintained in suitable conditions, and are accessible for inspection as required.

- Records that are kept online are valid. It is a password protected. The electronic records are available during inspections. Back-ups are available at all times.

8 Complaint Handling

- The applicants have a system for effectively managing customer complaints and the relevant part of the complaint system is made available to the producer members and customers

- Procedure is established to record how complaints are received, registered, identified, investigated, followed up, and reviewed.

- The procedure is made available to customers as required.

- The procedure covers both complaints against the applicant as well as individual producers or sites.

Procedure: Complaint Handling

9.1 Internal Quality Management System Audit

a. The QMS for the VCSMPPis audited annually or per crop cycle, whichever is earlier and Internal auditors comply with the requirements .It is ensured that the internal auditors are independent of the area being audited.
b. Internal auditors comply with the requirements of the standard

c. Records of the internal audit, audit findings, and follow up of corrective actions resulting from an audit are maintained and available.

d. The completed QMS checklist with comments for every QMS control point is made available on site for review during the audits.

   The central management, in lieu of this commitment for the organization and for all its members by completing and signing one declaration at QMS level, which is attached to the QMS checklist used for the internal audit.

e. In cases where the internal audit is not performed in one day but continuously over a 12-month period, a pre-defined schedule is kept in place.

Procedure: Internal Audit (**(Refer to Procedures Manual)**

9.2 Internal Producer and Production Site Inspections

a. Inspections are carried out at each registered producer (and corresponding production sites) or production site at least once per year or per crop cycle , whichever is earlier against all the relevant VCSMPP. Control Points and Compliance Criteria.

b. Internal inspections timing follow the rules defined in the General Requirements and scope specific rules.

c. Internal inspectors comply with the requirements set by the group

d. It is ensured that the internal inspectors are independent of the area being inspected. Internal inspectors do not inspect their own daily work.

e. New members of the group and new production sites of the Option 1 multisite are always internally inspected and approved prior to entering into the internal Inspections Register.

f. The original Inspection Reports and Notes are maintained and are made available for the CB inspection.

g. The Inspection Report contains the following information:

- Identification of registered producer and/or production site(s)
- Signature of the registered producer or production site responsible
- Date
- Inspector name
- Registered products
- Evaluation result against each VCSMPP. control point
- The checklist includes details in the comments section for the Major Musts control points that are found to be compliant, Major Musts and Minor Musts control points that are found to be non-compliant, and Major Musts and Minor Musts control points that are found to be non-applicable; This is needed to enable the audit trail to be reviewed after the event.
- Details of any non-compliances identified and period for corrective action
- Inspection result with calculation of compliance
- Duration of the inspection
- Name of internal auditor who approved the checklist

h. The internal auditor (or audit team; see point 2.2 b)) reviews and makes the decision on whether the producer or site is compliant with the VCSMPP. Requirements, based on the Inspection Reports presented by the internal inspector.

i. In caseswhere there is only one internal auditor who also performs the internal inspections, another person, e.g. management representative identified in the QMS, will approve the internal inspections.

j. Where the internal inspections take place continuously over a 12-month period, a predefined schedule is kept in place.

Procedure: Internal Inspection (**Refer to Procedures Manual)**

9.3 And 11 Non-Compliances, Corrective Action, and Sanctions

a. A procedure is established to handle non-compliances and corrective actions, which resulted from internal or external audits and/or inspections, customer complaints or failures of the QMS.

b. The documented procedure addresses the requirements for the identification and evaluation of non-conformances and non-compliances to the QMS by the group or by its members, respectively.

c. Corrective actions following non-compliances are evaluated and a timescale defined for action.

d. Responsibility for implementing and resolving corrective actions is defined.

e. A system of sanctions and non-conformances that meets the requirements defined in the VCSMPP are operated with producers or production sites. In case of contractual non-conformances (e.g. not complying with one of the QMS internal policies), sanctions are decided by the QMS.

f. Mechanisms are in place to notify the VCSMPP. Approved certification body immediately of suspensions or cancellations of registered producers or production sites.

g. Records shall be maintained of all sanctions including evidence of subsequent corrective actions and decision-making processes.

Procedure: Non-compliances, Corrective Actions (Refer to Procedures Manual)

10. Product Traceability and Segregation

a. A documented procedure is established for the identification of registered products and to enable traceability of all products, both conforming and non-conforming, to the applicable production sites. A mass balance exercise is carried out, at least annually, per product to demonstrate compliance within ABC (see points e) to k)).

b. Products meeting the requirements of the VCSMPP Standard and marketed as such are handled in a manner that prevents mixing them with non VCSMPP approved products. An effective system is in place to ensure segregation of certified and noncertified products. This is done via physical identification or product handling procedures, including the relevant records.

c. Effective systems and procedures are in place to negate any risk of mislabelling of VCSMPP certified and non-VCSMPP. Certified products. VCSMPP products entering the process (either from producer members/production sites or from external sources) are immediately identified with reference that is clearly explained in the company policy and provides a unique reference to the certification status. This reference is used on the smallest individually identified unit.

d. A final document check is in place to ensure correct product dispatch of certified and non-certified products.

e. It is ensured that all transaction documentation (sales invoices, other sales related, dispatch documentation, etc.) related to sales of certified product includes the name of the certificate holder and contains a reference to the VCSMPP. certified status.

f. Sales details of certified and non-certified products are recorded, with particular attention to quantities delivered/sold as certified and descriptions provided. Records are maintained.

g. Quantities (including information on volumes or weight) of certified and non-certified incoming, outgoing and stored products are recorded and a summary is maintained so as to facilitate the mass balance verification process. The documents demonstrate the consistent balance between certified and non-certified input and the output. The frequency of the mass balance verification is once in a year or per crop cycle, whichever is earlier and is appropriate to the

scale of the operation, which is done per product. Documents to demonstrate mass balance shall be clearly identified.

h. Conversion ratios are calculated and available for each relevant handling process. All generated product waste quantities shall be recorded.

i. This section is audited both internally and externally at PHU level, while PHUs are in operation.

j. In case of any suspensions or cancellations of the members, the group will notify the CB immediately

Procedure: Product Traceability and Segregation (Refer to Procedures Manual)

12 Withdrawal Of Certified Product

a. Documented procedures are in place to effectively manage the withdrawal of registered products.

b. Procedures identify the types of event that may result in a withdrawal, persons responsible for taking decisions on the possible withdrawal of products, the mechanism for notifying customers and the VCSMPP approved certification body, and methods of reconciling stock.

c. The procedure is capable of being operated at any time.

d. The procedure is tested in an appropriate manner at least annually or per crop cycle to ensure that it is effective, and records of the test retained.

Procedure: Withdrawal of Products (Refer to Procedures Manual)

Template: Products Withdrawn Register: End of the Manual

13. Subcontractors

a. In cases where any services are subcontracted to third parties, procedures exist to ensure that these activities are carried out in accordance with the requirements of the VCSMPP Standard.

b. Records are maintained to demonstrate that the competency of any subcontractor is assessed and meets the requirements of the standard.

c. Subcontractors work in accordance with the applicant's QMS and relevant procedures and this is specified in service level agreements or contracts.

Procedure: Subcontractors (Refer to Procedures Manual)
Template: Sub Contractors Evaluation and Activities: End of the Manual

14. Internal Auditor and inspector Requirements

All the internal inspectors and internal auditors will be qualified based on Educational qualifications, Technical skills & qualifications, food safety and GAP trainings, Crop specific training and other requirements as mandated by VCSMPP standard

END OF QUALITY MANUAL

1. Agreement with Producer Member (Clause 2.3)

This agreement is entered by and between

Producer Group Name…… Address…….. Represented by……

And

Farmer Name……. s/o…….. Aged about year resident of …… (Aadhar or voter Id No…..). This agreement is entered between the producer group and the farmer in connection with implementation of VCSMPP Standard for the crop….. Under the direction and supervision of the producer Group.

1. Name and Legal identification of the farmer
2. Name of the contact person and also alternate name with contact Nos
3. Residential Address
4. Farm Address
5. Framer code allotted by the producer group if any and Aadhar card no or voter id No.
6. Products or Crops Registered
7. Details of Individual Production location with full address
8. Details of areas (in Ha) on which crop is growing
9. Any other terms

   Farmer agree to comply with all the applicable requirements of the VCSMPP standard and the requirements (Producers, Policies etc) and directions of the producer group. Farmer undertakes to inform the producer group in case of any non compliance during the implementation of the standard and producer group requirements. Farmer also agree not sell the farm produce output outof the cultivated area to third parties without taking prior approval of the producer group.

   This agreement is valid for one year

Signature:	Signature:
Name of the Farmer:	Name of the representative of producer group
	Producer Group Stamp:
Place:	
Date:	

2. Producer Register (QM Clause 2.4)

1. Name of Producer :
2. Producer code allotted if any :
3. Name of contact person :
4. Full Address (Residential /Farm):
5. Contact Details :
6. Email Id:
7. ID Proof (Aadhar or Voter) :
8. Contract Signed : **Yes :** or **No:**
9. Produce Register :
10. Produce Growing area in Ha :
11. Land Ownership : **Tenant:** or **Own :**
12. Sowing Date :
13. Expected Harvest Month :
14. VCSMPP
15. Relationship of Legal entity with Produce Group :

3. **Organization Chart**
(Producer Group)-Indicative (QM Clause 4)

4. COMPETENCY NEEDS FOR IDENTIFIED POSITIONS (QM Clause4)

Competency needs are determined for operational activities and the personnel are deployed after evaluation

S. No	Name	Designation	Key Activity	Minimum Education Qualification	Technical Knowledge & Experience	Training	Compliance

5. Complaint Handling Register (QM Clause 8)

S.N	Description of Complaint	From whom Received	Date	Responsible Person	Root cause for the Complaint	Corrective Action Taken	Date	Information to the complaint	Date	Feedback from the complaint	Date	Status of the complaint closed or open

1. Depending upon the nature and seriousness of the complaint certification body and scheme owner to be informed

6. Products Withdrawal Register(QM Clause 12)

S.NO	Product withdrawn	Customer Name or Market from where the product is with drawal	Date	Reason for withdraw al	Corrective Action Taken	Date	How the product is disposed	Who are informed to the final summary	Whether entered in the Mass Balance Register

7. Sub-contractor Activities and Evaluation (QM Clause 13)

(This is needed only if the subcontractor is engaged for the farm activities)

Sub-Contractor Name:

S.No	Activities Assigned	Competency requirements for the assigned activities	Subcontractor compliance Level	Service level agreement signed with subcontractor		Activities Performed by the subcontractor	
				Yes	No	Date	Activity