Q&A: CMA Guideline for Raw Materials & Vendor Qualification Questionnaires (VQQ)

This Question and Answer document is designed to assist users of the *CMA's Guideline for Raw Materials used in Complementary Medicines* (the Guideline) by providing answers to frequently asked questions about the Guideline and the supporting Vendor Qualification Questionnaires (VQQs). Where this Document does not address your questions please contact CMA at: standards@cmaustralia.org.au

What is the intention of the Guideline for Raw Materials?

The Guideline aims to define the principles and minimum documentation requirements which need to be adhered to by industry for the quality and safety of raw materials in Complementary Medicines in Australia.

1. Why has this Guideline been developed?

The Guideline has been developed primarily to maintain and enhance the credibility and ensure the sustainability of the complementary medicines industry in Australia.

2. Who are the Guidelines applicable to?

The Guideline provides provisions, requirements and principles that apply to all raw material manufacturers and suppliers, brokers, distributors, re-packers, sponsors and contract manufacturers, and all other parties involved with the manufacture, supply or distribution of complementary medicines.

3. Is compliance with this Guideline mandatory?

Industry is encouraged to adhere to the requirements and principles described within the Guideline. Compliance is therefore voluntary but strongly encouraged as best practice.

4. Is adopting the use of this Guideline and the VQQ forms into my business systems a condition of CMA Membership?

No. CMA strongly encourages its members to use the Guideline and the VQQs to streamline the vendor qualification process, promote efficient decision-making, and ensure consistent quality and safety of all materials to be used for manufacturing complementary medicines in Australia.

5. Are the guidelines available only to members?

No, CMA encourages non-member companies to adopt and use the Guideline and the VQQs. In fact, in some instances the starting material supplier/manufacturer may not be an CMA member. The Guidelines and the Questionnaires are available for public access on our website here.

CMA encourages non-member users of the Guideline and the VQQs to feedback to the continuous improvement of the documents using the Request for Change Form also available on our website. See question 14.

6. When a request for change form is completed for a VQQ, which association will consider it and is there a chance that there could be s separation of the CMA and ASMI VQQ?

For changes to the VQQs, both CMA and ASMI committees will need to review and agree the actions and sign off on completion of the agreed actions. The agreed updated version of the document(s) will be updated on each association's website. The form accommodates joint sign off of the review of the change proposal and the agreed actions.

7. Will there be version control with advice of what has changed for each document?

Yes, a table will be incorporated to the Guideline to document changes. For future versions a document history table will be added to all VQQs to allow users to understand the detail of amendments made for each version.

8. Is there an opportunity to share manufacturer's audits of material manufacturers?

This approach has been deliberately avoided as it does not encourage the relationship of the medicine manufacturer with the supplier or the relationship of the supplier with the material manufacturer. The future vision would be to encourage suppliers to continue to provide a service of a fully qualified supply of a material.

9. Does the VQQ include an element for the commercial assessment of a supplier/material manufacturer?

No. The focus to date has been on the quality assessment. If a standard format is considered appropriate it could be added to the work program as a future opportunity area.

10. Internal company policy states that I must use our global Vendor Qualification Forms.

This is a matter for each individual company. However, the VQQs have been developed incorporating a number of members' questionnaires that were already in use in Australia, with the aim of providing all the information normally sought by companies, and more.

In this way the VQQs may be slotted into the SOPs of an individual company and satisfy most of its requirements.

11. I have a complaint about a competitor's raw material, how do I lodge a complaint?

The Guideline encourages Industry to inform all customers, institutions, healthcare practitioners and other professionals with whom they deal, of the requirements of the Raw Material Guideline. To safeguard consumers and protect the reputation of the complementary medicines industry, there is an obligation for members to raise their concerns about any potential breaches to this guideline by companies that may be adulterating raw materials deliberately, or risking adulteration through poor business practices. This Guideline is not intended to provide or be construed as legal advice.

CMA suggests that complainants first seek to resolve any complaint directly with the company whose behaviour has given rise to the complaint The CMA's Complaints Resolution and Monitoring Committee (CRMC) is established by the CMA Board of Directors pursuant to clause 7.2 of the *CMA Constitution.* The CMA Secretariat on behalf of the CRMC will process all complaints/ issues raised.

If a complaint is identified as a therapeutic good or substance that is a quality, safety or efficacy risk, or a therapeutic good that is not entered on the Australian Register of Therapeutic Goods (ARTG) the complaint is referred to the Therapeutic Goods Administration (TGA). Complaints may also be forwarded to state health authorities or the Australian Competition and Consumer Commission (ACCC), depending on the nature of the complaint.

12. How were the requirements for specifications and C of As determined?

The requirements for Certificates of Analysis were determined though the summation of various documents including the *Australian Code of Good Manufacturing Practice for Medicinal Products August 2002 Annex 7- Manufacture of Herbal Medicinal Products*, and the TGA's *Australian Regulatory Guidelines for Complementary Medicines* (ARGCM), among others listed in Appendix 3 of the Guideline.

13. Who was involved in the development of this Guideline?

CMA's Raw Material Suppliers Committee was pivotal in the development of this Guideline in consultation with members of CMA's Manufacturing and GMP Committee and relevant external stakeholders.

14. Will the provision of a completed vendor qualification questionnaire automatically result in approval to supply a medicine manufacturer?

No, the provision of a completed questionnaire is the start of the vendor qualification process.

15. How do I assess the response to the VQQ?

The completed questionnaires should be reviewed and assessed by an experienced Quality Professional. Many manufacturers and multinational companies already have in place their own assessment criteria. The VQQs are predicted on a level of understanding and of trust. They provide an overall picture of the Supplier's/Manufacturer's site(s), processes and capabilities and must be considered in the context of the material being sourced.

After review the Supplier/Manufacturer may need to request further data or ask additional questions to finalise their assessment e.g.TSE Questionnaire and Free From Questionnaire. The questionnaires allow for a basic comparison of Suppliers/Manufacturers.

Therefore it is recommended that Sponsors/Manufacturers develop their own:

- Assessment criteria prior to conducting any assessments.
- Cover page for review and assessment of the completed questionnaire.

After assessment it is anticipated that the Supplier/Material Manufacturer will be either:

- Approved;
- Approved with specific conditions communicated;
- Approval subject to further consideration; or
- Rejected as unsuitable.

16. How regularly should completed VQQs be reviewed by the supplier/material manufacturer?

Completed questionnaires should be reviewed and reissued when a change to the site details occur or every three years.

17. Why are Material Specifications, Acceptable Quality Limits (AQL) and Key Performance Indicators (KPIs) not included in the VQQ?

The VQQ are Site specific rather than Material Specific.

The suitability of the technical specification of the material must be confirmed concurrently with the suitability of the site. The Sponsor Manufacturer should develop a technical file for the material.

The AQLs can only be negotiated with the Material Manufacture. The supplier can assist solely as a conduit in the negotiation.

KPIs will form part of the commercial considerations of the Supplier Agreement between the Sponsor/Manufacturer and the Supplier.

18. Can some of the forms be consolidated? For example, along the lines of the Australian Food and Grocery Council (AFGC) forms – including the allergen and additive questions into one of the main questionnaires.

The vendor qualification questionnaires are manufacturing site specific and not intended to address product specific issues, which is why the free from/allergen/additive forms are separate/standalone documents. At the next review, the Free From Information questionnaire can be checked to ensure that all allergens listed in the AFGC Product Information Form (PIF) are included.

19. We have already received vendor approval from a medicine manufacturer for our manufacturing site. Do we need to provide an updated vendor qualification questionnaire in the new format immediately to maintain approved status?

This will be at the discretion of the medicine manufacturer. In many cases vendors are requalified on a periodic basis. At the point you make a change to your site details or when an updated VQQ is due would seem a reasonable timeframe.

20. We are already approved as a medicine manufacturer for our manufacturing site with one medicine manufacturer. Does this mean we will be automatically approved at other medicine manufacturers if we provide a completed vendor qualification questionnaire?

No, each medicine manufacturer will assess the VQQ according to their own criteria and risk assessment for the material.

21. How can I suggest amendments to the Guideline and Vendor Qualification Forms?

The Request for Change Form is available on the CMA website:
http://www.cmaustralia.org.au/CHC-Guidelines

All users of the Guideline and VQQs are encouraged to complete the form as suggestions to improve or update the Guideline or Questionnaires arise.

The Guideline and VQQs will be reviewed every three years with consideration of all suggestions for change by the CMA Raw Material Supplier/Manufacturing Working Group. The form also allows for members to indicate if a change is urgent/ important and requires immediate review.