



**Good Practice in Traditional Chinese Medicine Research in  
the Post-genomic Era**

**GP-TCM**

**223154**

**D.1.6**

**Procedures and recommendations of good practice in quality  
control of CHM**

**(Template: Quality Control)**



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<b>1 PROCEDURES AND RECOMMENDATIONS OF GOOD PRACTICE IN QUALITY CONTROL OF CHM (D1.6)</b>	<b>4</b>
1.1 Introduction	4
1.2 D1.6 Template for quality control procedures	4
<b>2 TOPICS TO BE COVERED</b>	<b>4</b>
2.1 Work shop in Portugal	4
2.2 Template for quality control	5

# 1 PROCEDURES AND RECOMMENDATIONS OF GOOD PRACTICE IN QUALITY CONTROL OF CHM (D1.6)

## 1.1 Introduction

The overall objectives of WP1 are to:

- Design a standard system for the quality control of Chinese herbal medicines (CHM) in the EU
- Design a system that will provide greater transparency about the complexity of TCM nomenclature, thus clarifying plant identities and improving data gathering on CHM species
- Propose guidelines as a basis for the rational development of research methods to authenticate and monitor the quality of TCM plants entering the trade. Guidelines will aim to avoid duplication of research efforts and maximise the use of modern molecular and chemical techniques, especially a functional genomic approach.

## 1.2 D1.6 Template for quality control procedures

To agree the topics to be covered in a quality control document for each selected species.

Output: Template for quality control procedures.

# 2 TOPICS TO BE COVERED

## 2.1 Work shop in Portugal

A joint workshop between members of WP1 and WP2 was held at Brag, Portugal (3/4 Dec 2010). Prof. Alberto Dias hosted the workshop at his university (UMINHO). At the workshop there was a very detailed discussion about the different topics that the quality control procedures should cover. Discussions also took place about how the members might effectively collate and disseminate the relevant information obtained by searching literature on the selected species.

The proposal was to develop a simple Excel based database that could contain appropriate fields that could be filled in when reading through manuscripts. This would enable the members to not only collate information about what is known about the quality control of each species but also review the quality of papers published on the selected species. The outputs from this exercise will assist WP1 and WP2 have a better understanding of the scope of the information available about the quality control for each of the key species as well as support the development of best practise methods. The quality control data discussed at the work shop have been added to the agricultural data discussed at earlier meetings. Once these data are gathered then progress can be made on the next deliverable D1.7 which is a report on the knowledge gaps about quality control for the priority list of plants.

The discussions at the workshop did not cover all aspects of quality control such as those associated with the selection of plants for cultivation and where the plants are grown. More information will need to be gathered about what is known about the genetic and chemical variation within and among populations of a specific species. Information about the genetics of the species as well as Good Agricultural Practice that need to be in place for the supply of quality plants is a feature of quality control that still needs further research, especially with our collaborators in China.

## 2.2 Template for quality control

Main topics that the workshop members would collect data:

### Information about the species

Species name  
Latin binomial + authority and family  
Name used in the Chinese Pharmacopoeia  
Vernacular Chinese names  
Pin Yin name  
Part of the plant used

### Complex drug

Is the species part of a complex mixture with other plants (if yes then what proportion of the specific species is in the “drug”)?  
What is the name of the drug?

### Collection and processing

Collection time  
Collection method  
Processing method after collection  
Drying method  
Primary processing

### Geographical distribution and major production areas

Geographical distribution  
Major production areas

### Plant material

When is the material harvested?  
Is the plant wild harvested or cultivated?  
If wild harvested – what procedures are in place to avoid over-harvesting  
If cultivated - what are the good agricultural practises in place?

Has the material been tested for pesticides, heavy metals, and bacteria?  
What are the levels of heavy metals in the sample (what are the accepted levels)?

### Medicinal uses

What is the plant used for and what scientific data are available to support this use (More data from other WPs)?  
Does the data relate to traditional uses or modern uses of the plant?  
How much of the plant is used (dose)?  
Are adverse responses associated with the plant?  
Are herb-drug interaction reported?

### Chemistry

How are extracts made?  
Do extracts tested relate to those used in traditional methods?  
What is known about the chemistry of the plant?  
Does the chemistry link to known medicinal activity of plant?  
Is there information available about compounds that can be used as markers for identification (chemosystematic markers) or activity (quality markers)?  
What is known about the toxicity of the plant; which compounds?

### DNA-bar-code

Is there information known about DNA sequences of the plant  
Is there a DNA bar code and which sequences are used?



### **Good Agricultural Practice**

Life Cycle and environmental requirements  
Optimal growth conditions  
Cultivation and Planting methods  
Field management  
Pest and disease control

### **Quality control requirements**

National quality specification and requirements of medicinal materials (China and Europe)  
Trade specification  
Determination of Residual heavy metals and organochlorine pesticides

### **Methods for quality analysis**

### **Physicochemical identification**

### **Those members of WP1 and WP2 that attended the Workshop**

Valerian Bunel (for Pierre Duez, WP1)  
Alberto Dias (WP1, WP2)  
Svetlana Ignatova (WP2)  
Andreas Marmann (WP2)  
Jandirk Sendker (WP2)  
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