



# Quality Control of Medicinal Herbs

## —Has Good Agricultural Practice (GAP) Helped?

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### Abstract

Although GAP, as the overall regulatory practice of safe and high-quality medicinal plant production in China, has experienced negative results and is no longer recommended, it has been replaced by HACCP management system. HACCP system focuses on specific projects of quality and safety assurance, from agricultural production to complex plant requirements, and then to specific technical considerations. GAP plantation can never meet the huge actual demand, but HACCP system can still be carefully checked when it is applied to products collected from different regions to ensure quality and safety. At present, the discussions on establishing the information traceable system of Chinese medicine materials have started. The system relies on extensive literature retrieval, survey results and common quality problems of Chinese Medicinal materials. Collecting the latest information will provide a solid reference framework for the development of Traditional Chinese Medicine (TCM) industry and the supervision of the central government.

### Subject Areas

Agricultural Science, Plant Science

### Keywords

Traditional Chinese Medicine (TCM), Good Agricultural Practice (GAP), Medicinal Herbs, Quality Control

## 1. Introduction

Medicinal herbs have provided good sources of drug development as well as vast choices of ingredients for the provision of health supplements (Leung PC, Cheng

KF 2008) [1]. In China alone over 12,000 species have been reported as medicinal herbs used in traditional and modern supplements. These items belong to 383 families, 2309 genera and 11,146 species (Huang LQ *et al.* 2002b) [2]. Most of these items are originally grown in the wilderness. With their rising demand, they are taken to farmlands to ensure regular productions. For those believed to be best only when grown in the wild areas, over collections have led to the gradual extinction of the species (Huang LQ, *et al.* 2002a) [3]. The natural force of supply and demand has encouraged the agricultural production of the commonly used herbs, especially the expensive items.

Good agricultural practice (GAP) is the source of quality control in the whole production process of Chinese herbal medicine (CHM). GAP for crops of human consumption has been established to provide guidelines on the regular production of food items to ensure rich and quality harvests, while at the same time ruling out commonplace contaminations that may affect production, nutritional value and safety. GAP has been considered appropriate for the growth of medicinal plants (Gao W, Jia W *et al.* 2002) [4].

The botanical and medicinal plant experts in China have realised, since late last century the urgent need for the promotion of agricultural production of herbal plants, and the first national meeting on the issue was held in 1998 (Wang WQ *et al.* 1999) [5] when GAP for medicinal plants was put on the agenda. Drafting of the guidelines started and the first document for trial use was issued by 2002 (Zhan NP, Lin RC. 2002) [6].

Europe also owns a tradition on the use of medicinal plants. Hence at about the same time in 2002, the European Union issued the “New European Union Good Agricultural and Collection Practice Rules” (GACP) (Scholten WK. 2003) [7].

The World Health Organization (WHO), which has been supportive of traditional and native medicine, gave a timely response in 2003 by issuing the WHO GAP recommendations basing on the Chinese and European guidelines (WHO Geneva 2003) [8].

It has been nearly two decades since the establishment of the GAP guidelines on international levels, hence a proper review of the practice is appropriate.

## 2. Has GAP Practice in China Done Well?

Since China must have the greatest need for quality medicinal plants which are essential for the great varieties of prescriptions in Traditional Chinese Medicine practices, and for the production of health supplements, what happened in China since the GAP recommendations would give a genuine view of the situation. China is greatly concerned with the quality control of the medicinal plants. Without the proper standard control, the efficacy of the claimed therapeutic effects cannot be substantiated. The standard control involves assurance of effectiveness as well as safety. It is expected that the proper implementation of a well established GAP could offer the best plant material since the practice covers

seeding, growing, harvesting, collecting, processing, storage and transporting etc. The implementation of GAP in China has initiated the establishment of many GAP plantations. Since 2004, there are 196 GAP bases, owned by 129 companies which have gained proper certifications. The GAP bases are mainly scattered in five provinces: Sichuan, Yunnan, Jilin, Henan, and Shandong, occupying a total of over 0.5 million Mu (1 Mu = 667 m<sup>2</sup>). However, such large agricultural area amounts to only less than 1% of the total areas of medicinal plants being planted in China (Hao-Ming LUO *et al.* 2020) [9].

In 2014, ten years after the implementation of GAP in China, experts analyzed the overall situation and gave their positive, as well as negative views.

The positive views are:

- (i) The Establishment of GAP standards has been satisfactory;
- (ii) The GAP cultivation areas are expanding;
- (iii) The GAP concepts have been better appreciated;
- (iv) GAP practice has improved the agricultural traditions and;
- (v) GAP experts are increasing and their work is well appreciated.

However, negative observations on the same items co-exist. The low comparative benefit and imperfect market mechanism limit the development of GAP. Moreover, the narrow-minded farmers and peasants have been trying to resist general GAP principles. (Lo L, Pun GK. 2005) [10] It is therefore obvious that GAP in China, after the ten years of implementation, has failed to offer genuine improvement in the quality control of medicinal plants. GAP practice for individual plants could have been successful and very much welcome, however, it cannot be widely implemented because of the vast demand on medicinal plants: their huge varieties and volumes.

On March 18, 2016, the China National Food and Drug Administration announced the official removal of GAP requirements (CFDA 2016) [11].

Obviously the Administration is reluctant to enforce a legal recommendation on GAP, which, after a decade of practice, has proven null and void due to its high cost and immature cultivation techniques leading to high risk in the process of large-scale production. However, the removal should not be taken as a denouncement of the need for the control of medicinal plants, from agricultural production to quality supply (Wu J 2004) [12].

### 3. A Practical Substitutions for GAP in China—GACP

China has to carefully study how European Countries and WHO deal with the agricultural production of the medicinal plants, and in particular, how to maintain an international standard of the Marketed Chinese Medicinal herbs: from planting, harvesting, processing, packaging, transporting and related staff training and equipment provisions.

Both European Union (EU) and WHO have been using Good Agricultural and Collection Practice (GACP) rules for specific items and such rules cover both cultivated and wild species of plant material (Wu J 2004) [12].

In Japan the GACP recommendations are copied and practiced, emphasizing on essential procedures for the maintenance of quality. The Japanese herb companies, which have been growing medicinal plants in China, have followed rigidly and effectively such GACP rules in the past years. They have gained very satisfactory experience and assurances (Japan Jincun Co., Ltd 2011) [13].

#### 4. Another Practical Enhancement of Quality Control

There is another internationally recognized system of management for the safety and quality assurance of raw materials: from their serial production, assemblance to transportation. Originally, this system is not created for living items like plants, and cannot be considered a GAP substitute. This system: Hazard Analysis Critical Control Point (HACCP) has earned extensive trust in the risk management armamentarium for bio-organism, chemical and physical safeties. It has been popular in the Food and Agriculture Organization (FAO) and Pharmaceutical areas. China has applied HACCP for Nutritional supplements, and has just started its utilization for agricultural products (Li L, Jiang GH 2018 [14]; WHO 2003 [15]).

The Current Requirements in China for the quality control of medicinal materials used in the development of new drugs including medicinal plant related Chinese Medicine have been issued under a trial package issued on October 12, 2020 (ZHANG Wen-jin *et al.* 2021) [16]. The requirements are clearly defined and the provisions include:

- (i) Accurate information about the medicinal effects of the plant product;
- (ii) Agricultural source of the product;
- (iii) Details of growth and maturation of the plant product;
- (iv) Environmental details for the best production of the plant product;
- (v) Packaging details, and
- (vi) Risk management for genomic accuracy and quality stability.

It is believed that with the practical application of the HACCP system, the whole process of quality control for medicinal plants, from harvesting raw material to finished product could be realized, so that the potential exogenous harm from Chinese Medicinal material can be reduced to the lowest level, and the safety of such material is ensured (Li L, Jiang GH 2018 [14]; WHO 2003 [15]).

#### 5. Conclusions

While GAP as an overall regulatory practice for the production of safe and quality medicinal plants in China has experienced a negative outcome and is no longer recommended, it is replaced by the HACCP management system. The HACCP system focuses on specific items with the aim of quality and safety assurance, from the agricultural production along the complicated line of botanical requirements to specific technical considerations. GAP cultivating fields will never meet the vast practical need, but the HACCP system, applied to products collected from widely divergent areas, could still administer the careful checks to

ensure quality and safety (Huang LF, Chen XL 2011) [17]. GAP is only a link in the traditional Chinese medicine industry chain. Good Supply Practice (GSP) and Good Manufacturing Practice (GMP) are equally important in the development of traditional Chinese medicine. However, this article does not cover these two aspects.

Currently discussions on the construction of an Information Traceable System for Chinese Medicine Material have started. The system relies on extensive literature search, investigation results and common quality problems of Chinese Medicinal materials. An update collection of information would provide a solid framework of reference for the development of Chinese Medicine Industry and Central Government regulation (Li C, Qu 2020) [18].

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### Conflicts of Interest

The authors declare no conflicts of interest.

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