The Pre-meeting Workshop for the Quality Control Interest Group (QCIG) of the 5th GP-TCM RA Meeting

2016.08.08
Hong Kong Baptist University, HKSARg, PR China

Professor Kelvin Chan PhD DScFRSM  https://www.researchgate.net/profile/Kelvin_Chan4
Chair: Kevin CHAN; Co-Chair: Yuan-Shiun CHANG

15:30-15:45 Kelvin CHAN “Update of progress of the QCIG & future focus on QC standards of TCM products”
15:45-16:00 Yuan-Shiun CHANG from China Medical University, Taichung: “Overall QC of TCM products in Taiwan”
16:00-16:15 Gerhard FRANZ (EDQM): “Phytoequivalence of commercial granules with the corresponding TCM herbal drug and decoctions made of”
16:15-16:30 Monique SIMMONS* (Kew Garden, UK): “Progress of QC requirement of herbal products prescribed by CM practitioners in the UK” (*To be confirmed)
16:30:18:00 90 minutes Debate and participation from audience
Some historical background of the Interest Groups


Inherited from the EUFP-7 Project GP-TCM in the post-genomic era

- 2012.04.15-18: At the founding and 1st meeting of GP-TCM RA, University of Leiden, The Netherlands; 5 Interests Groups were established
- 2013.08.26-31: 2nd meeting at University of Graz, Austria; linked with CGCM
- 2014.07.18-20: 3rd meeting at China Pharmaceutical University, Nanjing, PR China
- 2015.07.12-15: 4th meeting at University of Mons, Belgium
- 2016.08.08-10: 5th meeting at Hong Kong Baptist University, Hong Kong
Discussion topics proposed in previous meeting-workshops

- Require QCIG members’ active inputs and participation.
- Promote good practice related to quality of CMM used as food, medicines or research materials.
- Understand the science behind processing of CMMs and their impacts to quality, efficacy and toxicity
- Explore methodology for assessing differences between CMM decoction pieces and granules (from aqueous extracts) supplied to TCM practice.
- To provide advice on harmonisation of regulatory requirement for source materials - Pharmacopoeia standards
- To develop home page for members’ input on latest publications on related topics
Initial QCIG objectives on website for members’ inputs and discussions—Not much responses received

- To develop national and international collaborations and investigations on GAP of medicinal plants within and outside China, including contaminants of CMM and PCM: Aflatoxins, heavy metals, microbials, pesticides and sulphur dioxide traces; Dealt with by most pharmacopoeia; members can access
- To develop national and international collaborations and investigations in order to understand geographic influence on quality of CMM and the requirement and science of processing of CMM; A very difficult issue; China is leading a current effort on this
- To develop national and international collaborations and investigations on quality of CMM/PCM to keep up with advances in technology – instrumental analysis, fingerprinting, multivariate analysis, and omics-based technologies; Many published papers in the literature needed help to collect and consolidate
- To develop national and international collaborations and investigations in order to develop monographic standards of CMM/granules (Keli) in Europe and other regions. Urgent need to focus on this topic since the GP-TCM FP7 project
- To develop the understanding on the challenges in the supply of TCM with increased changes in land use and the potential increase in trade in CMM; Shortage of CMM need advice from experts in China – The 13th 5year Plan
- To discuss action for developing home page for QCIG; Not many visits from members on GP-TCM RA website (?), The Newsletters may be a better venue
Types of TCM products

- Chinese materia medica are key starting materials for TCM practice.
- Parts of medicinal plants (mainly), animals (some) and minerals (few).
- After processing they are presented as decoction pieces for TCM practitioners for prescribing herbal formulae consisting of multiples CMM, known as ‘Fufang, 複方’.
- CMM decoction pieces are used in manufacturing of proprietary Chinese medicines (PCM), often known as ‘patent medicines, 中成藥’, which are prescribed by TCM practitioners or for OTC purchase.
- Decoction pieces are often substituted by ‘dried aqueous extracts of CMM in the form of dried granules, often know as ‘prescription Keli, 處方粿粒’ intended for TCM prescription.
# Harmonization of Pharmacopoeia monographic standards of CMM

(Adopted from *BMC-Chinese Medicine* 2009; 4:18)

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The 13th 5-year plan at the home of TCM

- Future development of pharmacopoeia
- International trade standards for TM
- Requirements in herbal pharmacopoeia.
- ISO quality of monographs
- Forming global alliance with EMA on monographs
中药饮片面临的质量困境及应对措施

摘要 目的：揭示中药饮片质量面临的困境，分析其根源，提出应对建议；方法：利用市场调查、文献检索，收集并分析中药饮片存在的问题 结果与结论：中药饮片及中药饮片存在的染色、增重、掺假等质量隐患。在深入研究之后，提出市场准入、诚信生产、实施批准文号管理，维护中药饮片质量和产业等措施。

关键词：中药饮片；饮片质量；中药生产企业；质量困境；药品监管

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Countermeasures against Quality Dilemma of Chinese Herbal Decoction Pieces

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Abstract Objective: To reveal the quality dilemma of Chinese herbal decoction pieces, analyze the causes of the difficulties and put forward suggestions. Methods: The methods of market investigation and literature search were used to collect and analyze the existing problems of Chinese medicinal materials and Chinese herbal decoction pieces. Results and Conclusion: Quality problems exist among Chinese medicinal materials and Chinese herbal decoction pieces such as dyeing, weight gaining, adulteration, illegal operation and illegal processing. The in-depth study suggests the countermeasures such as market regulation, production with integrity, implementation of approval number and maintenance of quality of Chinese medicinal materials and Chinese herbal decoction pieces.

Keywords: Chinese herbal decoction pieces; quality of decoction pieces; traditional Chinese medicine manufacturer; quality dilemma; supervision of drug quality
Suggestions to strengthen quality management of herbal decoction pieces
—— based on production chain of herbal decoction pieces

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Abstract: With the development of society and the improvement of people's living standards, the effect of Chinese medicine is more and more prominent. The herbal decoction pieces are the important part of Chinese medicine, it can be applied directly to clinical treatment, and it's also the raw material of Chinese patent medicine. Therefore, the quality of herbal decoction pieces is quite important. The parts of the production of herbal decoction pieces are numerous, and there are possibilities of adverse effects on the quality of the herbal decoction pieces in every part. In this paper, we based on the production chain of herbal decoction pieces, analyzed the main problems that affect the quality of herbal decoction pieces in the part of selection of Chinese herbal medicine, planting, purchasing, processing, packaging, storage and transport, such as the non-quality of seed and seedlings of plantation Chinese medicines, some plants lost their place of origin and have been introduced to the place that is not suitable for this kind of plant, the insufficient growth time and the excessive herbage vaccination. The purchasers and the accepters lack of professional knowledge and professional ethics. The mechanism of processing is not clear, the standards can not be enforced, and lack of qualified persons in processing, etc. So we suggest:

1. Establish the quality management system of herbal decoction pieces; to ensure the quality of the products from end to end.

2. Strengthen the selection of Chinese herbal medicine, establish the quality management system of the seed and seedlings of plantation Chinese medicines, and ensure the quality of seed and seedlings of plantation Chinese medicines.

3. Improve the method of planting and the establishment of plantation Chinese medicine, establish the large-scale plantation bases, and ensure the quality of planting Chinese medicine.

4. Establish the quality management system of the entire production process, ensuring the quality of the final products.

5. Establish the quality management system of the entire production process, ensuring the quality of the final products.

6. Establish the quality management system of the entire production process, ensuring the quality of the final products.

Key words: herbal decoction pieces; quality management; quality; suggestions.