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Background

GMP in western pharmaceutical production internationally has been operating for decades, during these times there were substantial upgrades in the requirement. These upgrades were generally supported by both quality management and technological advancements. The Hong Kong GMP guideline published in 2003 for proprietary Chinese medicine (pCM) was an encouraging initiative that ignited both industry and Department of Health (DoH) to develop specific GMP for pCM and certification requirement respectively, given there are numerous challenges. These challenges include but not limiting to product characterisation, testing, modernisation of manufacturing technology, product registration, in addition to GMP hardware requirement.

The first GMP guideline by the Chinese Medicine Council offers sufficient space for GMP development, and subsequently 12 local manufacturers have so far achieved GMP certification. Without doubt, both the manufacturers and DoH have worked tremendously to achieve higher GMP standard while GMP for pCM is at a developing/infant stage. It is reasonable to expect a gap between western pharmaceutical and pCM GMPs, due to the complexity of pCM together with some of the challenges highlighted above. For example, pCM with simple formulation and where QC technology is available as in western pharmaceutical, the gap would be smaller. However, while most of pCM are multi-ingredients, it is conceivable that the technology and skills are not currently available to achieve the same GMP standard as in western pharmaceutical.

Similar to international GMP development on pharmaceutical, as our quality management workforce and technologies advances in pCM production, the GMP standard will be shifted higher progressively. But until then, it is neither possible nor economically justifiable to achieve equivalent international GMP standard such as PIC/s in the majority of pCM production.

Specific GMP for pCM from Hong Kong and future prospect in international regulatory framework

Already, the outcome of 12 pCM GMP manufacturers have begun paving specific GMP for pCM in Hong Kong. This achievement should be affirmed by industry wide GMP implementation. With an appropriate implementation plan, industry should

adopt basic quality management at first. Then, the subsequent progression will take industry to explore both available and affordable tools and technology for specific GMP implementation. We envisage that the former will have a positive impact on product assurance, while the latter will realise best practice to the specific GMP for pCM.

Due to the diverse products from the industry, and technological challenges in pCM, the establishment of industry best practice and acceptable specific GMP may require substantial R&D, and eventually regulatory review. Therefore, the overall implementation time is likely to be over 5 years, and subject to significant resources in both DoH and R&D support are most certain. Nevertheless, the ultimate specific GMP for pCM will relevant to the capability of Hong Kong at high standard. Furthermore, as the Department of Health is becoming a member of PIC/s in 2015, and the specific GMP developed for pCM by Hong Kong can a creditable representation to the PIC/s organization.