

Abstract

With the rising of R&D outsourcing, Contract Research Organization (CRO) are increasingly given emphasis and recognition of pharmacy and developing as an indispensable link of pharmaceutical industry chain owing to its professional superiority. Firstly, the development and current status of domestic and overseas CRO were introduced. Subsequently, the potential demands of Chinese medicine (CM) industry to CRO were analyzed. At last, enhancing new drug R&D ability and changing the low level repeat status of CM industry in virtue of CRO were indicated.

Several problems were found in my research, involving (1) Although there're lots of CROs in China, most of them are just starting up and focusing on clinical trials while not R&D of CM; (2) CROs or corresponding branches in overseas have robust R&D networks and management systems, however they cannot supply the R&D service of CM in a short period; (3) Since a long period of time, the majority of R&D resources in China were possessed by universities and research institutions, which undertook the primary R&D works of CM and exerted the analogous functions to CRO. On that basis, a conclusion was drawn that at present CRO is not the best mode in China and it is necessary to explore a new CRO mode in R&D of CM area integrating the facts and status quo.

Virtual research organization has been widely applied in many research fields with shared resources and complementary predominance. Some experts in medical area brought forward a concept i.e. Virtual Contract Research Organization (VCRO) combined virtual research organization with CRO. In this thesis, we introduced this concept into CM area and indicated to stimulate the development of CM industry by establishing VCRO of CM and analyzed the necessity and feasibility. On that basis, the key links of establishing VCRO of CM and project management methods of new drug R&D were deeply explored. In transverse direction, the construction methods of VCRO in CM area were generalized and a set of evaluation index system of choosing cooperative partners was set up through expert consultation to evaluate the

R&D ability and strength of partners in VCRO and offer references for final selection. Secondly, the institutional framework and profit sharing mechanism of VCRO of CM were studied. Finally, the maneuverability and superiority of VCRO in a practical world were proved by case analyzing of “Debio mode”. In longitudinal direction, aiming at the characteristics of VCRO management and CM R&D, the project managements of new drug R&D of CM based on VCRO were discussed according to the project flow of startup, plan, execution, control and ending.

We have achieved research works encircling tightly the theme of “VCRO of CM” in this thesis and expected to promote the development of CM industry via this new organization mode.

Key words: R&D of CM; Virtual Contract Research Organization (VCRO); project management