FORMING OF THE PROCESS MODEL OF CRO LOGISTIC ACTIVITY IN CLINICAL TRIALS AREA

Khromykh A.G., Posylkina O.V.
National University of Pharmacy, Kharkiv, Ukraine
kaf.ep.nfay@rambler.ru

According to the research, efficiency of contract research organizations (CRO) activities in clinical trials (CT) mostly depend on reasonable logistic strategy and logistics-based management. Logistic approach in management allows increasing both profit and quality of logistic service, guarantying effectiveness of CRO flow processes management in order to get more competitive advantages in world CT market. So far as effectiveness of logistic services in CT influences the CT quality, it becomes necessary to develop the process model of CRO logistic activity. The necessity of process technologies implementation inclinical trials management in order to ensure their quality is stated in ISO standards as well.

While forming the process model of CRO logistic activity each business-process should be considered as a unit of the whole logistic mechanism of organization functioning. In this connection the compatibility and interaction of particular processes within CRO process system should be investigated. Based on the analysis it had been justified that effective logistic activity of CRO requires the integration of main business-processes in through supply chain management in order to facilitate compliance with ISO and GxP.

The most important rule to be followed while forming the supply chain logistic business-processes is concentration of all CRO logistic management functions in one subunit. This allows to ensure the optimal resources flow taking into account the dynamics of both external and internal medium, and also changes in inner through processes. Only in this case CRO enables handling of logistic in order to ensure provision of clinical center with essential medicines and biological samples in certain quantity and assortment at certain time guaranteeing the quality of all processes.