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DoP proposes Cluster Development scheme to enhance quality, productivity of SMEs

Tuesday, June 01, 2010 08:00 IST **Ramesh Shankar, Mumbai**

Direct link to the News/Story:-

<http://www.pharmabiz.com/article/detnews.asp?articleid=55728§ionid=>

Aiming to catalyze and encourage quality, productivity and innovation in SME pharma sector and to enable them to play a leading role in a competitive global market, the Department of Pharmaceutical (DoP) proposes to formulate a scheme called Cluster Development Proforma for Pharma Sector (CDP-PS).

The scheme proposes adoption of cluster development approach as a key strategy for enhancing productivity and competitiveness as well as capacity building of SMEs located in clusters. For this, world class quality manufacturing facilities with high level of productivity and innovative capabilities are required. The DoP proposes this scheme as these are on one hand very capital intensive and cannot be established and opened by pharma SMEs on their own, due to financial constraints, and on the other global level technical expertise is an adverse handicap.

The scheme proposes to support the common facilities on a need-based basis. Under the Formulation Development Facilities, the scheme proposes to set up GLP for calibrating and validating important equipments like testing facilities such as analytical lab, toxicology centre, process & product validation laboratory, raw material testing, standardization laboratory etc which will enable better quality assurance & control; to set up common incinerator; to set up common ETP (Effluent Treatment Plant); to set up training centre for imparting training for appropriate documentation for pharma sector; and to support the first level processing facilities such as cleaning, drying, sorting, storing, extracting, packaging etc.

Under the scheme, the DoP proposes to set up facilities for tableting, capsulation, packaging and labelling; standardization of raw materials and finished products; development of references and standards; adoption of new technologies and processes; application of ERP and other IT tools; assistance for ISO, WHO GMP, GLP, US FDA, EU GMP, Australian TGA and other standards and compliances; and development of DMF1 for the purpose of registration with regulatory bodies overseas.

The common facilities under the scheme also include studies/surveys; preparation of DPRs; sensitization/awareness creation/skill development at entrepreneurial level, managerial level and worker level; and hiring of cluster development executives (CDEs).

Specific needs of the cluster regarding technology up-gradation, lean manufacturing technology benchmarking (international and national), certification system (WHO/other International), productivity and quality development requirements would be done through a Detailed Diagnostic Report (DDR). This DDR would be funded by DoP with wide participation of industry concerned. The DDR will detail Implementation Action Points.

The CDP-PS also intends to intervene in the existing clusters for purposes of providing common facilities to them. The DoP has issued a detailed concept paper on the scheme asking the industry to make suggestions and comments.