PHARMABIZ.com
india's most comprehensive pharma portal

Industry needs to enhance knowledge across domains to tap burgeoning opportunity in global arena: Expert

Thursday, September 02, 2010 08:00 IST
Nandita Vijay, Bangalore

With drugs going off patent over the next three years valued at around a whopping Rs 3,20,000 crore (US$ 80 billion) and also increased penetration of generics in the global market, Indian pharmaceutical industry sees a great opportunity and various stakeholders are gearing up to obtain a share in the pie that appears to be lucrative. Further, the industry fully realizes that the opportunity that arises could be exploited fully provided critical knowledge gaps could be bridged across the domain.

Going by this, the need of the hour is introduction of value-added courses at the post graduate level and upgradation of undergraduate curriculum by introducing topics like pharmaceutical project management and supply chain management that would help students to acquire skills in documentation, comprehensive understanding of engineering drawings, internal audits, project execution, regulatory aspects and Intellectual Property Rights among others.

According to Kaushik Desai, chairman, Industrial Pharmacy Division, Indian Pharmaceutical Association, there is a need to revise syllabus. This should be done to ensure that ICH Guidelines with new regulatory additions like risk assessment, Q8, Q9 and Q10 are covered.

Likewise, Desai stated that industrial pharmacy graduates need to be armed with know-how on the principles of Quality by Design (QbD), Validation and Calibration processes, in addition to Regulatory Affairs on Guidance documents, Technology Transfer & Pilot Plant Scale-up studies.

There is also need for industrial training for teachers, participation of industry experts in curriculum development, utilization of retired Industry personnel in colleges, and Industry – Institute partnership, he added.

Key strengths of the Indian pharma are the strong manufacturing base, cost competitiveness, R&D infrastructure, highly trained pool of scientists and professionals, solid process development skills, highest quality approvals from regulatory authorities including US FDA, EDQM and MHRA. The country is also an important centre for clinical trials.

The major growth segments are contract research , export of both bulk drugs and formulations, clinical research, pharmacoeconomics , information technology and

Intellectual Property Rights.

According to the IMS Health Market Prognosis, March 2010, the global pharma market in 2002 was US $515 billion and in 2009 was $ 837 billion. The Indian pharma industry in 2009, recorded an annual turnover of Rs 48,000 crore (US$ 12 billion) with a growth rate of 12 per cent. The exports was Rs 38,000 crore (US$ 9.5 billion) with a growth of 20 per cent among 200 countries. In terms of global ranking for volumes India is ranked third and is in the 14th slot in terms of value.

The country has the largest number of US FDA approved facilities outside USA with over 140 plants and more than 1,000 WHO GMP approved facilities. The total number of units are 4,500 with 400 companies in the large and medium sector. There are 60,000 formulations in 60 categories produced in India. The OTC Market is valued at Rs 12,000 crore (US$ 3.0 billion) registering a growth of 31 per cent annually. The fastest growing segments are diabetic, cardiovascular, central nervous system, anti ulcerants, oncology and lipid regulators.

Indian pharma industry turnover is likely to touch Rs 200,000 crore (US $50 billion) by 2015, with domestic formulations expected to account for around Rs 88,000 crore (US $ 22 billion).