

## India to soon have national academy for drug regulators

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The proposed academy geared to train regulators both at the Central level as well as in states is expected to be operational from the year, 2016. It will also be extending such facilities for regulators from neighbouring and CIS countries. The academy would become fully functional by 2018 and would have excellent facilities for training and research. This was recently revealed by Mr KL Sharma, joint secretary (regulations), ministry of health and family welfare at CII's 8th Medical Technology Conference held in New Delhi recently.

Mr Sharma exhorted industry to take advantage of the academy by suggesting modules to be included in the course. There would be courses of various durations at the academy, which, he hoped, would create enough manpower for handling the challenging the issues faced by the drug industry in general and medical device sector in particular.

Responding to a query from the floor for having standards and common practices in the industry to evince the interest of the investors, Mr Sharma opined that the proposed academy would take care of many of the perceived challenges of the industry. The government would seek inputs from the industry and hold regular consultations for making the working of the academy to meet the expectations of the stakeholders.

Referring to the large scale e-governance program being launched by the government, Mr Sharma said that the government has outsourced the work of creating e-governance structure to C-DAC and some work is being carried out by NIC. In two-year's time, it would be possible to send replies to stakeholders about their queries through SMS and e-mails.

Responding to another query from the floor about the on line sale of medical devices, Mr Sharma said that he could not comment on the issue since it required some more consultations and clarity in policy. About the need of a single window clearance of applications for license and other procedures, he maintained that the government was working on that by taking views of the stakeholders.

Mr Sharma also mentioned that the Cabinet has approved Rs 2000 crore for setting up new laboratories and for doubling the strength of the regulators across the country. On clinical trials, he said that the government would soon put in public domain a manual for seeking the views of the stakeholders.

The meeting was also addressed by Dr GN Singh, Drug Controller General of India, Central Drugs Standards Organization, who wanted industry to give regular feedback on the organization's working.