

India Pharma/Device Regulators (1)

□ **Drug Controller General India (DCGI):**

- DCGI is the key official in the Central Drug Standards Control Organization (CDSCO) and works under the Director General of Health Services, Ministry of Health & Family Welfare (MOHFW), Government of India (the Ministry also has several specialized drug testing laboratories).
- CDSCO is headquartered in New Delhi and has 4 regional offices – meant to help local governments.
- **Functions of DCGI/CDSCO:**
- Approval of manufacture of certain drugs (vaccines, large volume parenterals, blood products, r-DNA derived), specific devices and new drugs.
- Registration certificate for manufacturer, facility and product for all imported drugs/specific devices and import licenses.
- Clinical trials for any drug/device.
- Standards and quality.