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Regulatory affairs for pharmaceuticals

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The current Pharmaceutical Industry is well organized, systematic and compliant to international regulatory standards for manufacturing of Chemical and Biological drugs for human and veterinary consumption as well as medical devices, traditional herbal products and cosmetics. Stringent GMPs are being followed for blood and its derivative as well as controlled manufacturing for Traditional Herbal Medicines, Cosmetics, Food and Dietary products which was otherwise differently a century before. Each regulatory system had faced certain circumstances which led to current well-defined controlled regulatory framework. This has resulted into systematic manufacturing and marketing of safe, efficacious and qualitative drugs. With the growth of industry, the legislations from each region have become more and more complex and created a need for regulatory professionals.

I propose to cover below aspects in my presentation:

1) Evolution of regulatory framework in USA, EU and India and major regulations
2) Brief regulatory environment of Emerging Markets i.e. Brazil, Russia, Mexico, South Africa, Thailand and GCC
3) Drug Regulatory Affairs and Global, Regional and National Regulatory Network
4) Key Organizations for Harmonization of regulatory requirements i.e. WHO and ICH
5) Regional Regulatory Network and its regulations i.e. GCC, ASEAN, APEC, PANDARH, SADC, EU
6) Roles of Regulatory Affairs Professional in Health Authorities as well as Pharmaceutical Industry
7) Regulatory Affairs Network in Pharmaceutical Industry

Above presentation would provide global insight of regulatory framework to all participants.

Biography

Ms. Hasumati has 18 years of rich experience in Pharmaceutical Regulatory Affairs for Regulated as well as Emerging Markets. She has expertise in filing NDA, NCE as well as Branded Generic products across the globe. She has successfully interacted with various regulatory authorities and prepared regulatory strategy for new market entry. She possesses comprehensive knowledge on global regulatory landscape and well verse with on-going regulatory changes. Currently, her firm, METINA COSNULTANTS is offering consultancy services for Emerging markets to Pharmaceutical Industry and covers end to end regulatory and business development activity covering strategy development, due diligence of dossier, in –license/ out-license of dossiers, Submission Management to Health Authorities, GMP audits Personal meeting with Health Authorities and product market launch.

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