

# 4<sup>th</sup> International Conference on Pharmaceutical Regulatory Affairs

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## Regulatory affairs in herbal products - Indian perspective

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Out of ca 17500 plant species in India, approx. 3000 species are used in Indian system of medicine including around 30 in modern medicine. About 90% of these medicinal herbs are collected from the wild. Safety and quality of herbal medicines have become increasingly important as no standard process is followed for the collection and the collectors are not sufficiently trained. Market potential is curtailed by lack of standardization of many herbal medicines. Quality lacks in raw material production, garbling, packing, labeling etc. There is no validation of efficacy and safety. Presence of extraneous matter (adulterants), microbial contamination and production of toxic materials are also the matter of concern. Genetic variants, geographical and nutritional factors and seasonal changes are some of the factors influencing the physico-chemical profile of medicinal plants. Authentication of medicinal herbs is a vital issue. Good agricultural and collection production address some of the issues. In herbal products, quality is wholesome which should have some statutory requirements, market expectation and technical experience. Some newly emerging techniques viz., Herbopoint capillary electrophoresis (HPLC finger print, electrophoresis) and DNA analysis (RAPD, AFLP, RFLP and ISSR) are successfully employed for characterization of semi processed and processed herbal drug materials. Good agricultural practices (GCP), good manufacturing practices guidelines have now become an intrinsic part of quality assurance system. Realistic quality control in medicinal and aromatic plants involves GAP, GCP and GMP and considers the entire processes from raw material to final products.

### Biography

D D Patra, who did his PhD at Indian Agricultural Research Institute, New Delhi, India in 1982-83, is presently working as the Chief Scientist and Head Crop Production at CSIR-Central Institute of Medicinal and Aromatic Plants, Lucknow, India. Fellow of several academies, he has published more than 100 research papers in reputed journals. His present area of working is Agrotechnology of high value medicinal and aromatic plants following standard agropractices, utilization of salt affected soils, phytoremediation of heavy metals, utilization of metal rich tannery sludge for cultivation of aromatic plants and quality evaluation of medicinal and aromatic herbs.

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