

Dr. Amit Khanna

**India Unit Head, Global
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Dr. Amit Khanna has more than ten years experience in Regulatory Affairs, Pharmaceutical R&D, Quality assurance at different companies like, GSK, Biocon & Vitalife laboratories.

Dr. Amit is the 1998 Gold medal winner for M.Pharm and then pursued Ph.D. from Delhi University. He bagged GATE-1996 being All India 1st Rank holder as well as Masters Diploma in Pharmaceutical Management in 1995 with Gold medal from IPER, Pune.

He was the Vice President, Indian Pharmacy Graduates Association during 2003-2007 and is also a Life member of IPA and IHPA. Dr. Amit is an Honorary Faculty Member of IPER (Pune) and NIPER Hyderabad. He also held positions like President of Student's union of College of Pharmacy and was President & Secretary of Rotaract Club. He has guided 2 M.S (Pharm) students on 'Quality by Design' topics at NIPER, Hyderabad.

Dr. Amit has over 10 publications/presentations and has attended over 100 conferences/seminars/ workshops on technical and management topics. His areas of interest include Drug development, Regulatory affairs, Leadership development & Motivation.

Regulatory CMC: Emerging trends:

Regulatory Chemistry, Manufacturing and Controls (Regulatory CMC) is one of the key areas (besides Safety and Efficacy) that the regulators consider for the review and approval of drug applications. Effective CMC strategies and execution may reduce regulatory burden, enable shorter review timelines, and help post-approval maintenance during the product life cycle.

Rapid globalization and significant growth in emerging markets is creating a shift of focus to include LACAN, AMAC, MENA as countries for parallel launch of new drugs and therapies.

Growing needs for quality healthcare in the emerging countries, increasing regulatory requirements, advent of novel therapies (like devices, biologics, therapeutic proteins), new approaches to Quality (ICH Q8, Q9, Q10 & Q11) challenge the conventional approach of submission strategies and offer new opportunities in the RegulatoryCMC environment.