

## Sourcing generic formulations & OTC drugs from Indian pharmaceutical manufacturers: A GMP fiasco waiting to happen?

**Ram Balani**

FDA Smart Inc, 7 Barlow Court, New York

According to the Generics Pharmaceutical Healthcare Association (GPhA), “Every other day, generics save consumers and the US Healthcare System, \$ 1 Billion US dollars ! Did you know 80% of drug prescriptions in the US are written for generic drugs?

Out of this 80%, one (1) out of every four (4) or 25% of US generic drugs comes from India and though India is 3<sup>rd</sup> in terms of volume in the drug industry, it ranks a low 14<sup>th</sup> in dollar terms, i.e. a testament to the efficient and very competitive, LOW-COST Indian drug manufacturing industry. India relies heavily on generics domestically as well and the generics drug Market in India is projected to grow at a CAGR of around 17 % between 2010-11 and 2012 and 2015.

In his presentation, Ram Balani will focus on opportunities and challenges to sourcing generic formulations or OTC drugs from India with focus on GMP manufacturing regulatory compliance.

India claims to have the most US FDA approved drug manufacturing yet recent negative events point to deficiencies with global GMP standards due to various reasons that include its tolerant work culture with very ‘forgiving’ best practices and lack of appreciation that GMP is a constant mind-set instead of a mere series of short-term rules you can check-off from a list, etc.

Ram Balani will trace with how India became the 800-lb pharma industry “gorilla” specially with generics, discuss topics on how to navigate the Indian drug manufacturer supply chain channels, cover the two (2) types of GMP deficiencies that include lack of enforcement or training to deliberate criminal intent with counterfeits, etc.

New US FDA initiatives to safeguard American pharmaceutical supply chain will also be covered including GDUFA, FDASIA, etc and how that will affect the Indian pharmaceutical industry with US markets.

Ram Balani will present strategies & options to challenges with sourcing from India as the country continues to evolve its role as “pharmacy to the world” and will briefly discuss the changing biotech/biologics focus of Indian pharmaceutical industry.

### Biography

Ram Balani has a wide range of experience in various life sciences areas that includes pharmaceuticals, medical research, real-time IT and software development, LIMS, robotics and automated retrieval systems specifically. He is also well versed with US FDA, MHRA and Health Canada pharmaceutical industry regulatory compliance with manufacturing and sourcing specifically. FDASmart, the latest company he founded, provides pharmaceutical regulatory compliance consulting & manufacturing/supply chain intelligence to assist emerging regions create new markets. In U.S. Ram actively assists SMEs (Small/Medium Enterprises) with sourcing drugs (generics, OTCs) or contract manufacturing services from emerging regions including China, India, Bangladesh etc. For emerging regions, FDASmart assist with ANDA partnering search, in-licensing, out-licensing, etc.

rbalani@fdasmart.com