Meetings International
SciTechnol

Milind Antani, J Nephrol Ren Dis 2018, Volume: 2
DOI: 10.4172/2576-3962-C1-004

WORLD BIOSIMILARS CONFERENCE
&
Annual Conference on
NEPHROLOGY AND UROLOGY

August 20-21, 2018
Chicago, USA

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Similar biologics in India - Impact of regulations on business

Biosimilars, called as Similar Biologics in India have given immense opportunity to industry players not only in India but across the world. The trend in Indian market is very encouraging and India has come on radar for global players. However, the regulatory scenario for biosimilars in India is not robust but is hast evolving. It is important to understand how biosimilars are regulated in India and how to navigate through the regulations. India has to evolve to match global standards. There significant new developments with latest guidelines in place. In the talk the issues, concerns and road blocks for biosimilars in India shall be covered and way forward with this regulation will be discussed charting down the right path to do biosimilars business in India

Biography

Milind Antani leads Pharma & Healthcare practice at multi-skilled, research-based international law firm, Nishith Desai Associates with offices in Mumbai- Nariman Point, Silicon Valley, Bangalore, Singapore, New Delhi, Mumbai – BKC, Munich and New York. He represents clients in JVs, MnAs, VC and Private Equity investments, Collaborations, Regulatory advice, IP, Licensing and Commercialization matters. He has authored and co-authored many articles, publications related to the pharma and healthcare industry including a book on CRAMS. He is a regular speaker and panelist at various national and international forums on the subjects of pharma, Medical Device, biotech, IP, clinical trials, healthcare, CSR and e Health. He has been included as one of the world's leading practitioners in 'Who's Who Legal' for Life Sciences 2014, 2015, 2016, 2017 and 2018 in the 'Regulatory' section as the only lawyer from India. He is also involved in policy making and drafting. He was recently recognized by Economic Times for his commendable contribution to the pharmaceutical industry. He has had his career as an ENT surgeon for 14 years before he changed career to law 14 years ago.

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