

# Understanding U.S. FDA Regulatory Requirements

*An exclusive 2-Day Seminar providing an overview on how the U.S. Food and Drug Administration regulates drugs and biological products, discussions of the latest developments on biosimilars, 510(k) submissions for diagnostic, therapeutic and hybrid medical devices, and FDA's oversight of marketing. This seminar is designed for company officials who are seeking to bring new drugs or biologicals, branded generics, biosimilars, or medical devices/diagnostics before the FDA for approval.*

India's pharmaceutical companies enjoy an unparalleled record of success in the U.S. market. The Indian industry has been very successful in navigating the complex FDA process in submitting INDs, NDAs, BLAs and ANDAs. The new U.S. health care law will increase demand for cost-effective therapeutic options, including branded and unbranded generics and new devices and diagnostic products. The FDA now is in the early stages of new standards for biosimilars, and is addressing the need for changes in the 510(k) device process. This 2-day Seminar provides an overview on basic U.S. FDA requirements, and an overview on key developments of importance for Indian companies seeking to enter the U.S. market.

## Course Highlights

✓ U.S. FDA Regulatory requirements: INDs, NDAs, BLAs, ANDAs

✓ Emerging Issues: A New Pathway for Biosimilars; Proposed ANDA Fees

✓ Overview of Diagnostic, Therapeutic, and Hybrid Medical Devices

✓ How to Successfully Navigate FDA Processes

✓ Marketing and Advertising Oversight/REMS Requirements

✓ Crisis Management

## Featured Topic 1: How the Approval Process Really Works

Expert views on how companies can best navigate the intricate and ever-changing FDA submission processes for new drugs and biological products, including branded and unbranded generic drugs. What insights may save Indian companies valuable time and money in compiling their applications?

## Featured Topic 2: Changes on the Horizon

FDA experts will discuss impact of a new U.S. law authorizing U.S. FDA review and approval for biosimilars following expiration of exclusivity periods, increased FDA scrutiny for Diagnostic Testing Products, and how tightened enforcement of advertising and promotion regulations and implementation of Risk Evaluation and Mitigation Strategies affects product submissions.

For details contact Ms. Anjami Nayyar, India Project Manager 095-5254-9858  
[anjami@finstonconsulting.com](mailto:anjami@finstonconsulting.com) • [www.finstonconsulting.com](http://www.finstonconsulting.com)

