

# **GMP, GCP & QUALITY CONTROL**

&

# **PHARMACEUTICAL REGULATORY AFFAIRS AND IPR**

September 25-26, 2017 Chicago, USA

## **Role of FSMA (Food Safety Modernization Act) GMP requirements in human and animal food safety**

**Ramakrishnan Narasimhan**

PJRFSI, USA

Consumers all over the globe are increasingly concerned about product safety, including food safety. Food safety is a shared responsibility of producers, processors, distributors, retailers, regulatory bodies and consumers. The concept is easy to understand; however, there are a number of variables in the chain that can affect the safety of food. The responsibilities of regulatory bodies include, protecting consumers from illness or injury caused by food, providing assurance to the public that food is suitable for consumption, providing health education program to communicate principles of hygiene and maintaining confidence in internationally traded foods. While the Codex Alimentarius Commission (CAC) of the World Health Organization (WHO) provides guidelines for food safety, it is the responsibility of the individual regulatory body (example, FDA of USA) to draft rules and regulation for their country. It is this approach that becomes a hurdle to import and export food products. The U S FDA's Food Safety Modernization Act (FSMA) provides robust and comprehensive tools to prevent food safety problems before they occur in human and animal food, rather than trying to identify and react to food safety hazards that have already occurred. For example, the new human and animal food Preventive Controls rules, established as a result of FSMA, require the food industry to systematically identify food hazards needing controls and systematically control those hazards. The US FDA created PC Rules for Human Food within Section 103 of FSMA to help food manufacturing and processing facilities implement a comprehensive and proactive system to ensure food safety. PC Rules for Human Food is a US standard that affects a number of FDA regulated products and facilities exporting products to the US and also domestic food products manufacturers/processors, packers, store houses and distributors. Similarly, the Preventive Controls for Animal Food rule is intended to ensure safe manufacturing, processing, packing and holding of animal food products in the United States. As per the PC Rules the owner, operator, or agent in charge of a facility prepare and implement a written food safety plan. A written food safety plan is essential for the facility to implement the plan consistently, train its employees, and periodically reanalyze and update the plan. The speaker, V P Product Safety & Research of Perry Johnson Registrar, a management system certification body in the US and a lead instructor for the three of the seven rules/regulations of FSMA will explain the role of FSMA (Food safety Modernization Act) GMP Requirements in Human and Animal Food Safety under the following topics: Role of GMP in Hazard analysis of human and animal food; Preventive controls; Corrective action, verification procedures of preventive control rules asnd; Record –keeping. The food processors/manufacturers, packers and holders in the US and also manufacturers of human and animal food exporting products to the US are required to comply with the FSMA regulations. This presentation will help the attendees to understand the provisions of the GMPs of the new regulations.

RNARASIMHAN@PJRFSI.COM