## 5<sup>th</sup> International Conference and Exhibition on Pharmaceutical Regulatory Affairs

August 03-05, 2015 Orlando, USA

## Investigating problems, applying risk management and creating sustainable solutions

Paul R Kleindorfer

The Wharton School of the University of Pennsylvania, USA

Your value as a leader can be directly measured by the size and complexity of the problems you can solve, the decisions you make and your ability to execute sustainable solutions. The success and sustainability of your company or business depends on you and your management team's ability on making the right decisions. Failure to make the correct decisions can negatively impact your companies' bottom line, profits, staff moral and customer trust in the brand. We all solve problems on a daily basis but many of us tend to only look at problems with a horizontal or surface perspective. Few of us are actually trained on how to apply critical thinking and evaluate issues on a vertical or lateral basis. We often take it for granted that people have an intuitive ability to solve problems. For many situations perhaps we do! However, as we get involved in more and more complex problems our intuitive side alone may not be the best way of identifying the true root cause of a problem and thereby making the right decision on the actions we must take. The key to resolving a problem is to ensure you are dealing with the real problem and not just the symptoms. Understanding the problem correctly also helps you appropriately frame the decision choices you have. Applying a risk management approach to problems lets you understand the level of effort and priority you may need to apply to a problem; it will also help you decide on the urgency of applying a sustainable solution.

kleindorfer@wharton.upenn.edu

## Regulatory hurdles affecting US companies to register and market dietary supplements in the Middle East Region and what US dietary supplement manufacturers need to understand

Reshma Castelino Vitane Pharmaceuticals, UAE

The GCC (Gulf cooperation Council) pharma market (inclusive of Dietary supplements) market is dominated by Saudi Arabia, which accounts for two thirds of the total GCC region in value terms. Along with UAE and Kuwait, these three states account for 91% of GCC dietary supplement sales. These countries however have very stringent regulatory guidelines for both Dietary supplements and Pharmaceutical products. US Dietary supplement companies face significant complexities understanding the guidelines followed in this region. My presentation would be a step by step approach explaining the guidelines, the market size, and the nature of products that qualify as Dietary Supplements in these countries. The objective would be to help companies:-

- a) Dossiers Understand how they need to prepare Dossiers of Dietary supplements.
- b) Labelling I will explain compliance with local laws and,
- c) Process That needs to be followed from product shortlisting to marketing.

reshma@vitanepharma.com