Friends, Ladies and gentlemen,

Good morning and welcome you all to this seminar titled, “Evolving trend in the Supply Chain Management.’

As we know, globally the pharmaceutical industry is going through a metamorphosis. The types of changes that are taking place today globally, perhaps has no precedence ever in the past.

The key drivers of these changes are mainly the following:

1. A large number of patent expiration hugely impacting the top-line growth
2. Research pipeline is drying-up
3. The cost of bringing a new molecule from ‘the mind to market’ has now touched around U.S$ 1.75 billion
4. Regulatory requirement to get the marketing approval is getting more and more stringent, basically for patients’ safety, making clinical development more expensive and time consuming.
5. Cost containment measures of various governments around the world is putting an immense pressure on product price, significantly affecting the profit margin.

All these are triggering other sets of consequential strategic events of enormous significance. Among those, following key corporate strategic steps indeed stand out:

1. More mergers and acquisitions of various size and scale to achieve both revenue and cost synergy, with new products and newer types of resources

2. Transformation in the fundamental operating models, e.g R&D focused companies like Pfizer, GSK, Sanofi Aventis are extending their business interest in the pharmaceutical generics space, as well

3. Increasing globalization and more focus on the emerging markets of the world like, Brazil, Russia, India, China, Turkey, Mexico

4. Growing emphasis on partnering, as we see in India, like for example, between Pfizer and Aurobindo, Claris, GSK with Dr. Reddy’s Lab (DRL).

5. Global outsourcing in the ‘Contract Research and Manufacturing Services (CRAMs)’’ space, mainly to rationalize costs and deliver the bottom lines, when the top line is under pressure.

The changing requirements of all types, in sales and marketing, manufacturing and research and development, have created a challenging, if not a rather volatile operating environment. In this type of business situation supply chain will increasingly play a key

role to ensure that the right product is available at the right place, at the right time, at a right price and following the right process…always.

There is at the same time, a new trend emerging for increased outsourcing initiative, especially from countries like India and China. This initiative, which in turn is in the process of making these two countries the key global outsourcing hubs, is definitely not all due to just cost advantages. It encompasses increased integrated value proposition for the customers. Cost is just one of the key factors, others being quality, speed and suppliers' reliability. Nothing in this value chain is mutually exclusive. Supply Chain will need to go through a set of complex algorithms to strike a right balance between all these vital parameters.

In the days to come by one of the greatest challenges in supply chain management will be **to improve the supply chain integrity and security.**

An appropriate definition of integrity for supply chains is:

"the requirement that *the system performs its intended function in an unimpaired manner, free from deliberate or inadvertent manipulation."*

A safe and secure supply chain is definitely not a new requirement. However, in the list of priority of importance, it has now come up significantly compared to what it was just a few years back.

Though the issue of improving the supply chain integrity and security has now assumed global importance, unfortunately, any uniformity in national regulatory requirements for this vital parameter is glaringly missing. Such a lack of regulatory uniformity clearly highlights that the pharmaceutical companies, engaged in manufacturing, are still not aligned with each other on what will be the right way to ensure absolute integrity, safety and security in the supply chain operating process to guarantee patients' safety.

Globally many Pharmaceutical Companies are getting engaged in improving supply chain integrity, security and patient safety with the introduction RFID. This, as many may know, is an inventory tracking system for improved product traceability, which in turn extends some protection to its customers with genuine products from the genuine pharmaceutical manufacturers. It is worth noting that RFID is just one component of overall patients' safety initiative.

Along with high tech measures like RFID, to improve supply chain integrity, I reckon, pharmaceutical companies will need to further enhance their respective supplier qualification process.

The process of supplier audits should include all important and critical areas of manufacturing, testing and quality, related to each individual product. Only a stringent

supplier qualification process will be able to guarantee integrity, safety and the quality of products from the suppliers.

Before I conclude, I would like reinforce my recommendation with the example of Heparin tragedy where the supply chain integrity was violated and seriously challenged thereafter.

In the beginning of 2008, there were media reports on serious adverse drug events, some even fatal, with Heparin, a highly-sulfated glycosaminoglycan of Baxter International. Heparin is widely used as an injectable anticoagulant. Baxter voluntarily recalled almost all their Heparin products in the U.S. Around 80 people died from contaminated Heparin products in the U.S. The US FDA reported that such contaminated Heparin was detected from at least 12 other countries.

A joint investigation conducted by Baxter and the US FDA ascertained that the Heparin used in batches associated with the serious adverse drug events was contaminated with over sulfated chondroitin sulfate (OSCS). It was reported that his Heparin was supplied to Baxter by Scientific Protein Laboratories, Changzhou, China.

The cost of OSCS is just a fraction of the ingredient used in Heparin. Being driven by the criminal profiteering motive the manufacturers in Changzhou, China had reportedly used OSCS for highly-sulfated glycosaminoglycan as the former could not be detected by the pharmacopeia test in use, until 2008. This is because OSCS mimics Heparin in the pharmacopeia test and thus could not be detected in the case in question.

Post this criminal event, at present, all over the world more specific pharmacopeia test methods have been adopted for Heparin.

Let us all ensure that such a tragedy does not get repeated in future due to a breach in the supply chain integrity, anywhere in the world...for the patients' sake.

In today's deliberations I am sure this issue will be touched upon to ponder over the possible implementable steps to address such future threats effectively.

Thank you.