



# PHARMA HIGHLIGHTS

## Industry Visit to Sanofi

The Department of Pharmacy, BRAC University had an amazing opportunity to visit the Manufacturing Plant of Sanofi Bangladesh Limited located at Tongi on Sunday, 21<sup>st</sup> December 2014. A group of 37 students along with 6 faculty made a visit to Sanofi, one of the leading multinational pharmaceutical companies in the world. This manufacturing plant of Sanofi is a neat and clean industrial zone consisting of green and colorful flora and fauna. With the help of their friendly and efficient personnel, the students were segregated into 2 groups and they were shown the antibiotic and non antibiotic manufacturing unit along with the warehouses and quality control units. It was not only giving the students an overview of how pharmaceutical company carries out its daily work of producing different dosage forms available in the market systems but also providing them an insight of how in future they will have to put themselves into the shoes of these efficient employees and carry out their assigned responsibilities of a pharmacist.



Last but not least the session ended with a sumptuous lunch and a Question/Answers session. Several new terms were learnt, such as 'Lean'. To conclude, the industrial visit was a thorough learning experience where the students could learn beyond books and also could relate their theoretical knowledge with practical implementation.

-Nausheen Sayeera

### Lean Manufacturing System

Lean is a word that can be interpreted as 'just what is necessary'. Lean is not a tool or a method, it is a system which includes a continuous improvement in the state of mind! Currently, lean is a very interesting topic to discuss in the industrial sector. But most of us have an ambiguity about the concept and its real application. Following are a few reasons for the requirement of this system:

- Causing organizations to move beyond "Scientific Excellence" to "Business Excellence"
- Increasing pressure to reduce COGS (cost of goods sold)
- Forcing processes to become more efficient and flexible
- Requiring the capability to "do more with less"

This is being implemented in Sanofi Bangladesh Limited.

### A New Pharmaceutical Company in Dhaka!

M. M. Ispahani Group and Alliance Holdings Limited is setting up a state of the art OSD (Oral Solid Dosage) manufacturing pharmaceutical plant named Ispahani Alliance Pharmaceuticals Limited (IAPL). They have already hired several experienced professionals to make this company a successful one. IAPL

focuses predominantly on the export market including highly regulated US and EU market.

To design the plant, IAPL has appointed a renowned European engineering consulting firm. IAPL expects to come into production by 2<sup>nd</sup> Quarter of 2016.

### Aspirin: The Miracle Drug Now Establishes Anticancer Effects

Aspirin has already been known for its anti-inflammatory and analgesic properties for years. Currently it has also claimed its place in the list of cardiotoxic drugs. The most recent update of this miracle drug in the field of healthcare sector is its newly discovered ability to prevent cancer development, especially colorectal cancer with its prolonged use. Research data obtained from UK and Australia and National Health and Medical Research Council (NHMRC) Guidelines support the use of low dose aspirin (75mg) to prevent the growth of adenoma in people with history of prior adenoma in family or themselves. Along with prevention of cancer development, aspirin seems to prevent spreading of cancer in diagnosed patients, further enhancing its anticancer activity and reducing death risks by nearly 40%. Aspirin is also found to be effective in decreasing risk of bowel and



ovarian cancer associated with Lynch Syndrome but not against other cancers that are not associated with this syndrome. However, considerations must be made before prescribing aspirin for achieving prophylaxis against cancer as long term aspirin intake can cause serious side-effects like internal bleeding.

Researchers believe that aspirin may work against cancer, at least in part, by blocking the activity of COX-1 and COX-2 enzymes in the body's inflammatory response. Inflammation is a normal response to tissue injury or infection that helps the injured tissue to heal or to clear the infection. In chronic inflammation, the inflammatory process does not end when it should. Over time, chronic inflammation can cause changes, such as the formation of new blood vessels and DNA mutations, which can promote tumor development and growth. Research is being carried out in search of answers to test whether aspirin reduces the risk of cancer incidence, death due to cancer, or both. [Source: <http://www.forbes.com>]

### Novartis' Signifor Gains FDA Approval

The Swiss drug-maker Novartis Pharmaceuticals Corporation received the Food and Drug Administration (FDA) approval for the drug Signifor® on the 16<sup>th</sup> of December 2014. It is a long-acting-release (LAR) Pasireotide for the treatment of a rare endocrine disorder, acromegaly.



The next generation Somatostatin Analog (SSA), Signifor LAR, has been approved by FDA based on two Phase III studies– the result of which proved medically effective to the naive patients. It exerts its pharmacological activity via binding onto somatostatin receptors (SSTRs) that stimulates both SSTR2 and SSTR5 subtype receptors, resulting in inhibition of GH and IGF-1 secretion.

Signifor LAR is an injectable suspension administered once-a-month intramuscularly for the treatment of adult patients with acromegaly who either have shown inadequate response or are ineligible for surgery. It received an orphan drug designation for acromegaly in the US. In countries outside of US or the EU, safety and the efficacy profile of Signifor LAR has not yet been established in patients with acromegaly; thus, little is the guarantee of the commercially availability of Signifor LAR elsewhere in the world.

-Zainab S. Ahmed [Source: <http://www.novartis.com.bd>]

### Why Women Are More Prone to Rheumatoid Arthritis?

Surprising information was found about rheumatoid arthritis, in a study by the epidemiologists with the Mayo Clinic in Rochester that, the incidence of rheumatoid arthritis in women was increased by nearly 50 percent from 1995 through 2004, while the incidence in men remained largely unchanged. Now the rising question is "why the rate of this disease is rising among women?" Rheumatoid Arthritis (RA) is an autoimmune disease that

affects the joints. Lifestyle and environmental factors such as smoking, diet, pregnancy and infection are believed to play an important role for the development of rheumatoid arthritis in women, but genes also influence their risk for this disease. Researchers say that genes specific to the X chromosome are among the newly identified genes linked to rheumatoid arthritis and could help explain why women are more likely than men to develop the disease.



Women have two X chromosomes while men have an X and a Y chromosome. The X-chromosome-specific genes are among 14 newly identified genes in both women and men that can lead to rheumatoid arthritis, adding to the 32 genes previously pinpointed by the researchers at the Arthritis Research U.K. Epidemiology Unit at the University of Manchester. It is believed that these 46 genes account for the vast majority of genes associated with rheumatoid arthritis. This finding provides a useful clue in helping us to understand why rheumatoid arthritis is three times more likely to occur in women. Moreover it can also help the researchers to find out the new techniques to treat this disease. -Tanisha Momtaz [Source: <http://health.usnews.com>]

### Novo Nordisk Gets Positive Opinion on Tresiba For Children in Europe

Insulin degludec (Tresiba®, Novo Nordisk A/S) is a new-generation basal insulin with a distinct absorption mechanism that results in an ultra-long duration of action. Upon subcutaneous injection, insulin degludec forms long chains of multi-hexamers, resulting in a soluble depot in the subcutaneous tissue from which insulin degludec monomers gradually separate. This results in slow and continuous absorption of insulin degludec into the circulation. It has a flat and stable glucose-lowering effect, with a four-times lower within-subject variability in glucose-lowering effect [area under the curve (AUC) values] than insulin glargine. These properties of insulin degludec lead to a decreased risk of hypoglycemia compared with insulin glargine.



Insulin degludec, Tresiba, is suitable for use in treating patients of ages 18 years and older with type 1 or type 2 diabetes but may not be suitable for people who experience reactions to glycerol, metacresol, phenol or zinc sulphate.

Drug maker Novo Nordisk said the European Committee for Medicinal Products for Human Use (CHMP) has issued a positive opinion on the use of its diabetes drug Tresiba for the treatment of children and adolescents, meaning physicians in the European Union will be able to prescribe Tresiba to children with type-1 and type-2 diabetes. According to the International Diabetes Federation, an estimated 497,100 children are living globally with type 1 diabetes and rates of type 2 diabetes among children are also on the rise. [Source: December 2014 (Reuters)]