

4th International Conference and Exhibition on

Biologics & Biosimilars

October 26-28, 2015 Baltimore, USA

Molecular medicine

Prabina Kumar

Royal College of Pharmacy and Health Sciences, India

Molecular medicine is a broad field, where physical, chemical, biological and medical techniques are used to describe molecular structures and mechanisms, identify fundamental molecular and genetic errors of disease, and to develop molecular interventions to correct them. The field of molecular medicine is often referred to as “tomorrow’s medicine”. It aims to provide a molecular understanding of how normal cellular processes change, fail or are destroyed by disease. Molecular Biology has proved to be a rich source of new therapeutic agents in the last three decades. Recombinant proteins continue to be developed as successful drugs that principally target extracellular proteins such as cytokines and cell-surface receptors. Protein drugs are almost always injected. Bio-informatic data can now be used to identify new intracellular target proteins and investigate the networks of interactions that the target proteins participate in. It is becoming increasingly possible to model the surfaces of target proteins and use this information to model the interaction of low molecular weight, orally available drugs and even design drugs from scratch. The completed Human Genome Project revolutionized the ways that we can consider human diseases. Single gene defects that cause rare genetic disorders took man-centuries to discover only twenty years ago. Now, because of next generation sequencing (NGS), single, novel gene defects can sometimes be identified in individual patients with only man-weeks of effort. It will soon be economically plausible to sequence all of an individual’s genes in the clinic. Common diseases, though, are not caused by single gene defects. Many clearly involve the interaction of many susceptibility genes with the environment. An important part of the environment is the micro-biome, the collective of microorganisms that inhabit an individual human. These organisms have strong interactions, many beneficial, with the immune system of the host and are fundamental to the understanding of common inflammatory diseases. It is now relatively simply to determine the composition of a micro-biome, again by NGS. Changes that do not alter DNA sequence, known as epigenetic changes, can modulate the activity of genes too. Genes can be regulated by micro-RNA transcripts. All of these changes can increasingly be analyzed by dedicated NGS methods that will be used in clinics of the future to investigate common diseases and to identify the multiple defects that drive individual patients’ cancers. Our course aims to give you insights into all of these new developments and training in how to be a modern biomedical researcher.

Kumarprabina2012@gmail.com

2015: A decisive year for the Mexican biosimilars industry

Ricardo Ibarra-Cabrera

Instituto Tecnológico de Monterrey, Mexico

Biopharmaceuticals represent a very promising option for treating the most challenging diseases; nevertheless, there is no budget in the world that could effectively provide universal healthcare with a purely innovative drugs portfolio. Biosimilars represent a lower cost alternative for public healthcare systems. For instance, subsequent versions of recombinant erythropoietin with price reductions of up to 90% were launched in Mexico in 2006 and 82% cheaper rituximab versions entered the market later, among many others. Such products were originally registered as traditional generics in Mexico, but now that the regulatory framework for biosimilars is complete and well established by the Official Norm *NOM-257-SSA1-2014* issued in December 2014, local manufacturers face a great challenge. They need to perform some or most of the required studies for demonstrating their products’ safety, quality and bio-comparability within eight months in order to renew their sanitary registration. Unfortunately, some of them cannot be fully done in Mexico due to lack of R&D infrastructure. Therefore, the biosimilars industry is at a crucial time in the country now that the Government is eager to have low-cost medicines but at the same time has developed more strict regulations for them. This all represents many business opportunities for laboratories, distributors and biotech companies who are willing to make quality their competitive advantage, as well as the possibility for patients to have improved access to safer and more efficacious treatments.

ricardoibarra27@gmail.com