SBE Update

Vaccine Production

The topic of vaccines seems to be controversial at times, with concerns ranging from the safety and efficacy of new vaccines to whether traditional pediatric vaccines are linked to autism. This SBE Supplement will not delve into these debates, but instead is intended to give you a better understanding of vaccine technology and how chemical and biological engineers are involved in vaccines, from development to manufacturing.

This discussion is especially timely — with the flu season right around the corner, many of us are geting the flu shot. And, as this issue was about to go to press, the *New England Journal of Medicine* published the first results of a large-scale Phase III trial of a malaria vaccine candidate (RTS,S) that reduced by half the risk of malaria in children.

The global vaccine market is estimated at over $28 billion and growing, and is dominated by five major competitors: Merck & Co., GlaxoSmithKline, Novartis, Pfizer, and Sanofi Pasteur. All of these companies employ chemical and biological engineers. With their understanding of cell culture, systems biology, thermodynamics, kinetics, separations, bioprocessing, and scale-up, these engineers play a key role in the production of vaccines.

Vaccination and vaccines are important to immunity. Innate immunity is the defense system with which we are born. It is the immune system's first line of defense and is nonspecific, providing protection against all antigens. It involves primarily barriers (chemical or cellular) that prevent harmful materials from entering the body. Adaptive immunity, the body's second line of defense, develops after exposure to various antigens (foreign substances). The exposure triggers the immune system to build a defense to that specific antigen and generate a stronger immune response upon subsequent exposure.

Vaccination is the administration of an antigenic material (a substance or molecule) that triggers the immune system to produce antibodies, which help to kill or neutralize the antigen. Vaccines are examples of these antigenic materials, and are intended to prevent or ameliorate the effects of infection by stimulating the immune system to develop adaptive immunity (eliminating or inhibiting pathogenic growth) — thereby preventing infectious disease.

Last month, Bruce Beutler, Jules Hoffmann, and Ralph Steinman won the Nobel Prize in Medicine for their research on immunity. Their discoveries enabled the development of improved vaccines against infectious diseases, and in the long term could lead to ways of preventing a wide range of diseases and conditions.

Buetler and Hoffman were honored for their discoveries of proteins that can recognize microorganisms as they enter the body and activate the first line of defense in the immune system (innate immunity). Steinman, on the other hand, was recognized for his discovery of the dendritic cells that help to regulate the body's second line of defense (adaptive immunity). Dendritic cells activate infection-fighting T cells, and they develop a memory that helps the immune system mobilize its defenses the next time it is under attack by a similar antigen; this is referred to as building immunity.

In the first article of this supplement, SBE's Derek Lapiska provides an introduction to immunity and vaccines.

In the second article, John G. Aunins, Michael Laska, Bret R. Phillips, and José M. Otero of Merck give an overview of vaccine development and production, discuss the technical and manufacturing hurdles in bringing vaccines to market, and explore some of the challenges and opportunities in vaccine technology. Throughout the article, they discuss the roles of chemical and biological engineers in each step of vaccine development and manufacturing.

SBE is helping to improve pharmaceutical manufacturing efficiency through its upcoming conference on Sustainability in (Bio)Pharmaceuticals. Co-chaired by Conchita Jimenez-Gonzalez (GlaxoSmithKline) and Gene Schaefer (Johnson & Johnson), it will bring together experts from industry, academia, and government to address material selection and efficiency, multiuse vs. single-use process decisions, greening manufacturing processes, and sustainable approaches to product delivery. The conference will be held in San Juan, Puerto Rico, Feb. 19–22, 2012. For more information, please visit www.sustainabilityinbiopharma.com.

In addition, SBE and the International Society for Stem Cell Research are partnering to co-organize the 3rd International Conference on Stem Cell Engineering (ICSCE), which will take place from April 29 to May 2, 2012, in Seattle, WA. ICSCE's objective is to advance our understanding of biology and tissue regeneration, and eventually lead to the development of new cell-based therapies. The event will be co-chaired by Chuck Murry (Univ. of Washington) and Sean Palecek (Univ. of Wisconsin). For a full list of topics and speakers, go to http://stemcell.aiche.org.

If you have any ideas that you think would benefit SBE members, please share them with us at bio@aiche.org. We welcome your feedback and value your involvement in helping SBE to stay relevant in a field that is constantly advancing. If you are not a member of SBE, please visit http://bio.aiche.org and join our community today!

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