This symposium will detail the development of drugs for public health. Drug development is composed of three divisions necessary for a drug to arrive in the consumer’s hand. The first division features scientists from academia and industry who work to create and design drugs that show promise in treating diseases. The next segment is industry’s role in development, which takes the drug with promising results through clinical trials. The last division is the government agencies that regulate and define the safety protocols for the public and the environment. The goal of this symposium is to educate about the work and deliberation that goes into the creating and testing of drugs while promoting public health. Furthermore, it is our intention to provide insight in order to bridge the gaps between academia, industry and government for the process of drug development.
the number and diversity of new chemical entities (NCEs) approved for human use has not kept pace from the 1980s to now. The pharmaceutical industry faces challenges, such as reduced efficiencies, declining innovation and the industry’s tarnished image. Pharma has embarked on a range of initiatives to address these challenges; other sectors have also responded. Academic drug discovery centers have been established to facilitate the transition of academic ideas and breakthroughs into drug discovery opportunities. The talk will highlight challenges facing the pharmaceutical industry with an emphasis on the impact of chemical sciences and academic drug discovery centers in addressing the innovation gap.

Peter R. Bernstein [9:15AM]
President and principal consultant in medicinal chemistry and drug discovery, PhaRNAB LLC
The Evolving Role of Chemistry in Small Molecule Drug Discovery
During the past several decades, the role of chemistry in small molecule drug discovery has changed dramatically. The functions that chemists fill in R&D efforts have become more diverse, complex and specialized. However, at the end of the day an effective small molecule drug is a chemical with specialized properties that allow it to be administered to people safely. This talk will illustrate how synthetic organic chemistry developed from the “core” chemical science to be one part of a complex amalgam. Now the medicinal chemist is more of a conductor/composer who integrates input from synthetic, analytical, computational, structural biological, physical and informatics chemists.

Patrick Y. S. Lam [9:55AM]
President, Lam Drug Discovery Consulting LLC
Structure-based discovery of a novel Factor Xa inhibitor, Eliquis®/Apixaban, as a new anticoagulant and the discovery of Chan-Lam Coupling Reaction
Thrombosis is a leading cause of death in developed countries and there is a need for novel antithrombotics with an improved safety profile. Factor Xa is at the junction of the intrinsic and extrinsic pathways of the coagulation cascade. Preclinical data demonstrated that blocking FXa is an effective approach for anticoagulation with improved safety profile. Using structure-based drug design tools, Bristol-Myers Squibb has discovered a novel class of potent, selective and orally bioavailable Factor Xa inhibitors culminating in Eliquis®/Apixaban. Eliquis® is being evaluated in Phase III clinical trials. During the optimization process, we have discovered the powerful Chan-Lam Coupling reaction of copper promoted C-X bond cross-coupling via boronic acids, a complementary reaction to Suzuki-Miyaura Coupling.

Steven R. Tannenbaum [10:50AM]
Univ.-Wood-Prescott Professor of Toxicology and Chemistry, MIT
The Chemistry of Inflammation and Cancer: Lessons from Inflammatory Bowel Disease
When tissues are exposed to inflammatory stimuli such as bacterial infections, inflammatory cells migrate to and invade the infected or damaged tissue. In a mouse model of inflammatory bowel disease (IBD) and colon cancer, bacterial infection leads to chronic inflammation, dysplasia and cancer, by a process that is promoted by pro-inflammatory cytokines/chemokines, oxidative and nitrosative stress and DNA/protein damage. The invading inflammatory cells produce a mixture of chemicals, including NO, H2O2, HO•, CO3−•, HOCl, and NO2•, which damage and lead to degradation of proteins, lipids and nucleic acids, inducing mutation and/or cell death. Analysis of protein and nucleic acid damage in the mouse and human validates the model. Application of the results to the discovery of serum biomarkers of the disease can monitor disease severity and activity in IBD patients.

Bonnie A. Charpentier [11:30AM]
Vice president, regulatory and quality, Metabolex Inc.
Chemistry and Regulatory in Drug Development
The process of turning a molecule into a medicine involves not only good science, but the ability to meet regulatory requirements for development and approval. Regulations and guidelines have changed over time, often as a result of public safety disasters. Chemistry is important at every step of the development of new medicines. Chemistry is involved in drug design, synthesis, isolation, formulation, manufacturing, quality testing and measurement. Training in chemistry can be helpful in guiding drug development, not only in the laboratory but in such careers as regulatory affairs. This presentation will describe some of the history of drug regulations and the current role of chemistry in the development and approval of new drugs.

Bob Maughon [1:35PM]
Lead R&D director, Dow Wolff Cellulosics
Health by Design: Dow Wolff Cellulosics Excellent Innovations for the Pharmaceutical Industry
Dow Wolff Cellulosics delivers cellulose derivatives and companion chemistry that chemists use to manufacture the food and nutrition and pharmaceutical markets. We tailor polymer chemistry, morphology and blending into solutions that enable our customers to provide consumers healthier outcomes. In modified release, our research enables formulators and manufacturing teams to address regulatory and sustainability initiatives. Focus areas include modeling the performance design space to better predict structure-property relationships; enabling enhanced quality-by-design; the development of materials that can deliver direct compression, which can cut costs; and improved technologies for osmotic delivery systems. In immediate release, developments in low viscosity HPMC polymers and their applications to improve product performance and sustainability vs. conventional methods in coatings, capsules and granulation will be discussed.

Michael Hurrey [2:15PM]
Senior scientist, Vertex Pharmaceuticals
Development of Blockbuster Drugs in the 21st Century: A Personal Journey
Turning a drug candidate into a world-class medicine takes a number of years and a number of smart people. Some pharmaceutical scientists, hampered by factors beyond their control, spend their entire careers without launching a successful drug. During my eight years at a medium-sized biotech company, I’ve had the privilege of helping launch two, both of them successful. In this talk, I’ll take you through my perspective on the key factors needed to develop a drug through clinical trials and eventually to launch it. I’ll also give you examples of the inevitable blood, sweat, tears, and luck it takes to succeed.

Nancy Lewen [3:10PM]
Principal scientist, Bristol-Myers Squibb
Forensics in the Pharmaceutical Industry
Recent headlines paint a frightening picture of the state of drug supply to the consumer. Here are just a couple of the recent headlines: “Big Haul of Fake Medicines Seized in Joint European Police Sting,” Dow Jones Newswires, March 20, 2012; “The Fatal Consequences of Counterfeit Drugs,” Smithsonian Magazine, October 2009. Counterfeit pharmaceuticals are becoming more prevalent in domestic and foreign marketplaces. With patient safety at the forefront, the pharmaceutical industry is working to prevent and detect the manufacture and distribution of counterfeit pharmaceuticals. This talk will highlight work being performed in the pharmaceutical industry to identify counterfeit products as well as their source.

Elizabeth Pollina Cormier [3:50PM]
Chemist, U.S. Food and Drug Administration’s Center for Veterinary Medicine
Chemists, Chemistry, and the FDA: Building Quality into Drug Manufacturing
Most scientists entered their fields of study with the idea that they would improve the lives of those around them. Throughout the last century, members of the FDA staff, many of them chemists, have been striving to protect and promote public health. A component of any drug application is the Chemistry, Manufacturing, and Controls (CMC) technical section. The CMC section is designed to ensure that the drugs our children take tomorrow are as safe and effective as the ones we approve today. This talk will explore the importance of quality controls and the role FDA plays in drug development.