

**The New Jersey and North Jersey Sections of the American  
Institute of Chemical Engineers present their**

**Annual Spring Symposium:**

**Advances in Chemical-Synthesis Methods for  
Manufacturing Biologically Active Compounds**

**(or: the real nuts and bolts behind synthesizing drugs, and  
what chemists and chemical engineers can teach each other  
about the art and science of synthesis)**

**Friday, March 28, 2003**

**New Jersey Institute of Technology**

**3<sup>rd</sup> Floor, Guttenburg Information Technologies Center**

**9:00 AM – 4:00 PM**

**Registration starts at 8:00 AM**

**Networking hour starts at 4:00 PM**

## **Technical Program**

### **Pharmaceutical Engineering at NJIT: Education and Research Opportunities for New Jersey's Pharmaceutical Industry and its Engineering Workforce - An Introduction to NJIT's New Degree Program for Engineers and Scientists**

**Piero M. Armenante, Ph.D.**

Distinguished Professor of Chemical Engineering  
New Jersey Institute of Technology

The objective of this presentation is to illustrate the new educational and research opportunity available through the Master of Science Degree Program in Pharmaceutical Engineering — a new program developed at the New Jersey Institute of Technology (NJIT) to educate the future engineering workforce for the pharmaceutical industry and provide new employment opportunities for displaced engineers with significant experience in the chemical and allied industries.

The pharmaceutical/medical technology industry is the largest manufacturing industry in New Jersey. Pharmaceutical engineers play a vital role in all aspects of drug development, from the synthesis of active pharmaceutical ingredients to dosage form design and product manufacturing. In addition, engineers are responsible for the design, scale-up, and operation of pharmaceutical facilities where new drugs are developed, synthesized, and eventually manufactured under stringent conditions.

NJIT's Master program in Pharmaceutical Engineering, one of only a handful of in pharmaceutical engineering programs in the United States, is designed to prepare engineers, and scientists for technical careers and career advancements within the industry, and provide them with the foundation needed to work within the rigorous technological requirements of this highly regulated work environment.

The program is designed to provide educational opportunities in areas such as pharmaceutical processing and manufacturing, validation and regulatory issues in the pharmaceutical industry, pharmaceutical facility design, pharmaceutical packaging technology, reaction engineering for pharmaceutical production, pharmaceutical separation processes, pharmacokinetics and drug delivery, molecular modeling for drug discovery, pharmaceutical synthesis, fluid mixing in the pharmaceutical industry, instrumental analysis, and industrial quality control.

The presentation will cover all the major topics related to the program and will provide details on all the new educational and research opportunities that it offers.

## **The Role of Simulation in Process Development, Technology Transfer, and Manufacturing of Bulk Pharmaceuticals**

**Demetri Petrides**  
**INTELLIGEN, INC.**

The successful development, scale-up, design, and optimization of integrated processes for synthetic and biosynthetic pharmaceuticals is a challenging task that requires collaboration of professionals from many disciplines. Process simulators and other computer aids can facilitate this task by introducing a common language of communication among the various teams involved in process development and product commercialization. They can facilitate answers to the following questions: What is the impact of product titer increase (through media change) on the capacity load of the downstream section, the overall throughput of a plant, and the total manufacturing cost? Can the cost of expensive chromatography steps be reduced through changes in preceding concentration steps? What is the impact of changes in scheduling and cycles times on the demand for resources (e.g., labor, utilities, raw materials, etc.) and the overall throughput of a plant? Our experience in addressing the above questions will be presented using an industrial example in which we evaluated alternative technologies for producing therapeutic monoclonal antibodies.

## **ESTIMATING CAPITAL COSTS WITHOUT GENERATING EQUIPMENT DESIGN SPECIFICATIONS**

**Marvin Greene**  
AIChE Fellow

The more capital estimates one makes, the more one becomes aware of a "similarity" among certain chemicals manufacturing plants. It is this fact that forms the rational basis for what is called the engineer's experience.

The "Process Step Scoring" method is a technique popularized by Dr. John Taylor of ICI more than 25 years ago. The method was formulated for the purpose of

allowing rapid cost estimates during the early stages of process development. Such estimates are invaluable in allowing the potential cost of production of the product to be weighed along with other aspects of its evaluation, such as market price, market demand, health/safety/environmental constraints and competitiveness.

This paper will discuss the basis of the technique and provide quantitative information on using the method for estimating current day equipment costs when there is insufficient time and resources available to generate more rigorous capital cost estimates. Two examples will be presented, one for a commodity chemical and one for a pharmaceutical chemical.

There will also be a brief discussion of how to translate or scale individual equipment costs from one design capacity to another.

## **Regulatory Aspects of Developing and Marketing New Low-Calorie Food Ingredients**

**Michael. H. Auerbach, Ph.D.**

Senior Science Advisor, Regulatory Affairs  
Danisco USA, Inc.

Just about all food additives and ingredients must have some sort of regulatory approval by FDA or USDA in order to be sold and consumed in food in the US. For new additives or new uses of approved additives, this usually means preparation and submission of a food additive petition (FAP) or establishment of GRAS (Generally Recognized As Safe) status via statutory procedures. The documentation must contain sufficient information to establish the safety of the material according to published FDA guidelines to the standard of "reasonable certainty of no harm for its intended use."

For low-calorie ingredients, however, establishment of safety to FDA's satisfaction is usually not sufficient to successfully market the product. Because new low-calorie ingredients usually cost more than their full calorie counterparts, the marketability of such ingredients depends on one's ability to communicate the reduced calorie content to consumers, primarily via labeling. Securing approval for such labeling usually also requires regulatory activity. For a low-calorie ingredient, this often means additional testing and submission of supporting documents to FDA.

Four examples of such low-calorie ingredients will be discussed:

1. Polydextrose (Litesse<sup>®</sup>), a 1-kcal/g carbohydrate bulking agent developed by Pfizer (an approved food additive);
2. Simplex<sup>®</sup>, a microparticulated whey protein fat substitute developed by Monsanto (an affirmed GRAS substance);
3. Olestra (Olean<sup>®</sup>), a sucrose-polyester zero-calorie fat developed by Procter & Gamble (an approved food additive); and
4. Salatrim (Benefat<sup>®</sup>), a 5-kcal/g fat developed by Nabisco and Pfizer (a GRAS substance, petition filed).

### **Making Sodium Bicarbonate for Medical Use - Interpreting FDA Regulations for a Large, Continuous, Inorganic Process**

**Andrew D. Kurtz**  
Church & Dwight Co., Inc.

When does a simple commodity chemical achieve the status of "medical device"? When the chemical is sodium bicarbonate, and when it is used in hemodialysis. This talk will discuss the special features and aspects of a chemical process in order for the product to be acceptable for use as a medical device.

### **Cold-War Production of Botulinum Toxin**

**Phil Messina**  
AIChE Fellow

Back in the late 1940's and early 1950's, the Cold War between capitalism and communism was an active reality. The USA was particularly concerned about the threat of biological warfare. Fort Detrick in Maryland was assigned the mission of studying all possible defensive and offensive aspects. A major potential deadly toxin was that produced by the clostridium botulinum bacteria. It caused botulism. Small quantities had been extensively tested on a micro scale. Fort Detrick awarded a confidential contract to U.S. Industrial Chemicals, Inc., to produce larger quantities of a less-pure grade, which could be purified at Fort Detrick and tested on a macro scale. This presentation discusses the small, unusual plant that met this objective.

## **ChemPharma—A Networking Organization for the Chemical and Pharmaceutical Industry**

### **Rich Brautigam**

ChemPharma is a networking organization dedicated to helping members pursue their career objectives in the chemical and pharmaceutical industries. The purpose of the organization is to identify advancement, career-development, and growth opportunities in the chemical, pharmaceutical, life-science, and allied industries for its members, in a way that:

- is supportive, focused, and mission-driven;
- grows each individual's network through member and alumni interaction;
- promotes growth of long-term business and personal relationships;
- shares job leads and contact names;
- attracts top industry recruiters to the talents of its members;
- keeps members apprised of industry news, events, and trends;
- educates members through expert speakers, books, articles, reports, courses, etc.; and
- supports special-interest subgroups (e.g.: buying a business, starting a consultancy, etc.).

The goals of the organization are: to grow the network so it is recognized as a key source of quality leaders, and to help its members more rapidly attain challenging and satisfying career roles.

### **Travel information**

NJIT is located in Newark, NJ, and is easily accessible from the Newark airport by rail, bus, or taxi. If you are driving in, you will have access to the campus parking deck. Directions to NJIT and a map of the campus are available on their website: [www.njit.edu](http://www.njit.edu). Local accommodations are available within walking distance of the campus.