Camp Pharma: A Novel Initiative to Generate a Pipeline of Diverse Student Talents in Pharmaceutical Manufacturing

Laurent Simon, Piero Armenante, and Rajesh Dave

Otto H. York Department of Chemical Engineering
New Jersey Institute of Technology
Newark, NJ 07102

Abstract

Camp Pharma is a new educational and outreach initiative, launched at NJIT, focusing on the preparation of a future qualified workforce of diverse talents for pharmaceutical manufacturing. This initiative is sponsored by, and organized within the framework of, the Center for Structured Organic Particulate Systems (C-SOPS), a newly created Engineering Research Center funded by the National Science Foundation, and comprising four partner universities, i.e., Rutgers University, New Jersey Institute of Technology (NJIT), Purdue University, and the University of Puerto Rico at Mayagüez.

The Camp Pharma program consists of working with both high school science teachers and students in order to (1) increase their knowledge in pharmaceutical manufacturing, with an emphasis on particulate systems, which constitute most pharmaceutical drug products (e.g., tablets), and (2) to create an interest in the pharmaceutical industry as a career option.

During the summer, the high school students attending the program will work with NJIT undergraduate and graduate students to learn basic methodologies and lab protocols related to drug manufacturing. At the same time, Camp Pharma instructors and faculty will lead a selected group of high school (HS) teachers through new training and research applications for implementation in their classrooms. HS teachers will collaborate with Camp Pharma researchers on their own classroom projects. To test their new skills in a controlled environment, they will introduce these new materials to participating students at the Camp. Through the program, both HS teachers and students will gain a better understanding of the importance of pharmaceutical research and manufacturing and the challenges that it involves. Participating HS teachers will also be encouraged to create a network consisting of other teachers attending and NJIT faculty in order to carry their new knowledge, excitement and energy into their own classrooms.

NJIT's well-established Center for Pre-College Programs will be instrumental in recruiting HS participants and monitoring the progress of the program. In order to insure diversity, the recruitment of teachers and students from underrepresented groups and local minority high schools will be a priority.

Introduction and Background

Concerns mount over the soaring price of drugs and the significant decline and delay in the introduction of new drugs into the marketplace. An often-cited impediment to drug manufacturing is the lack of a predictive framework for systematic product and process design. A number of multicomponent organic systems, prepared by pharmaceutical industries, are used every day in the forms of tablets, capsules, patches etc. It is essential that these materials meet certain preset requirements: A patch is expected to deliver active substances at a pre-determined rate, in a specific environment, and within a therapeutic range; drugs, taken orally, must be dissolved before being absorbed in the gastrointestinal tract. Drug manufacturers and clinicians routinely attempt to solve spatio-temporal control problems with minimum

information on how the particle microstruture affects the absorption and delivery rate of a medicament to a target site. The chances of this approach producing successful results are slim since the function and performance of SOPS are closely tied to their microstructure. Unless the mapping between desired outputs (e.g., transdermal flux) and inputs, such as compositions of pharmaceutical additives, is known with certainty, there is no guarantee that the final product will meet end-user specifications. Many pharmaceutical companies use a costly trial-and-error procedure that may prove successful in some cases and fail when certain conditions are not met. Several factors help explain the general propensity of researchers to settle for suboptimal solutions: 1) the intermolecular potentials and solid state physics are not well understood, 2) soft materials are shear sensitive and can not be processed at high temperatures, and 3) the behavior of the final product is the result of a complex chain reaction, the source of which spans across a hierarchy of scales.

The Center for Structured Organic Particulate Systems (C-SOPS)

To help alleviate these problems and reduce the cost associated with drug manufacturing, the Center, composed of four partner universities, i.e., Rutgers University, New Jersey Institute of Technology (NJIT), Purdue University, and the University of Puerto Rico at Mayagüez, proposes the development of a predictive framework for a methodical, efficient approach to product and process design and a system of oversight that will assure quality control and compliance with regulatory standards.

The Center's mission can be summarized as follows: i) Provide a scientific basis for the optimal design of structured organic particulate systems, ii) Design and control manufacturing processes using science and engineering-based approaches, iii) Put in place strategies to disseminate the knowledge gained from the research and transfer the technology developed and iv) Ensure that minorities and women at all levels are involved in the activities of the center.

A procedure, based on three thrusts with distinct scientific discipline components, is adopted to meet objectives i) and ii). Thrust I (Manufacturing Science) addresses technology integration efforts necessary to develop successful manufacturing processes. Thrust II (Composites Structuring and Characterization) focuses on enabling methodologies to better design, characterize, and optimize products. Thrust III (Particle Formation and Functionalization) deals with fundamental research initiatives to develop the engineered particles that go into the fabrication of such products. Goals iii) and iv) are addressed by developing strategic plans for education and outreach. These include undergraduate and graduate educational vehicles and pre-college, professional and industry-oriented activities.

Camp Pharma

Camp Pharma was created in partial fulfillment of goals iii) and iv) and is the first step in the C-SOPS's goal of developing diverse and competent human resources including minorities and women at all levels (K-12, pre-graduate, graduate, post graduate, faculty) to help overcome challenges faced by the pharmaceutical industry.

A complete bottom-up strategy that focuses on educating the public, recruiting high school, college and university teachers, and training K-12, undergraduate and graduate students is necessary so that a talented pool of investigators is well-trained and ready to participate in research on drug manufacturing. Unequivocal inclusion of minorities at all levels is paramount to the success of the program.

Recruiting HS Science Teachers and Students for Camp Pharma

With the help of the NJIT's Center for Pre-College Programs (CPCP), aggressive recruiting of HS teachers and students from schools in local urban districts with high minority populations will be

achieved. The CPCP has a 30-year history of partnering with students, teachers, school administrators, and parents from New Jersey's inner cities. For the past several years, professional enrichment workshops for HS science teachers and science department chairs[1,2] have been made available through the CPCP.

High school teachers who participate in other professional development activities at NJIT will also be made aware of this unique opportunity. The Center sponsors a one-day seminar, which includes interactive presentations, laboratory experiments, demonstrations, and lecture modules at the New Jersey Institute of Technology. This year, the topic is *Learn about Pharmaceutical Techniques*. The knowledge, ideas, notes, and teaching material for activities acquired by teachers in attendance should be easily implemented in the classroom.

Camp Pharma participants may also be recruited from the RET (Research Experience for Teachers) site for high school science teachers. The main objective of this site is to provide an authentic research experience for high school science and technology teachers within the Center. Through a summer research experience, teachers will develop the skills and knowledge in materials and composites that will allow them to integrate this cutting-edge science and engineering into the development of standards-based classroom lessons and modules.

There are many other opportunities for recruitment at NJIT. The Otto H. York Department of Chemical Engineering at NJIT has been involved in "One Day Workshop for High-School Teachers on Engineering Topics" programs. Each year, over 30 teachers discuss topics that have included *pharmaceutical engineering* and *nanotechnology*. This year, the seminar features *Future Energy Sources for High School Science Teachers*. For students, the NJIT's Center for Pre-College Programs also offers a series of summer programs from post-fourth to post-eleventh grades to include "Introduction to the Chemical Industry for Minorities in Engineering Programs", "Pre-Engineering Program", and the "Women in Engineering & Technology Initiatives FEMME Program". The Camp Pharma goal for student recruitment is 15 to 20.

Camp Pharma for High School Teachers

The program is a five-day educational engineering summer camp for middle/high school science and math teachers. To cover incidental expenses and transportation costs, a modest stipend is provided to the twelve teachers expected to participate in this event. A number of activities are planned for this camp, including lectures by NJIT faculty and speakers from the pharmaceutical industry, laboratory tours, laboratory hands-on activities including pharmaceutical related experiments (e.g., dissolution testing, microscopy, particulate and fluid flow) and visits to nearby pharmaceutical facilities. The effectiveness of the program is assessed by monitoring the participant's progress in the classroom. Supplemental materials are provided, when necessary. This program is coordinated by NJIT Chemical Engineering Professor, Dr. Laurent Simon, in collaboration with the C-SOPS Education Director for NJIT, Dr. Piero Armenante and personnel from the Center for Pre-College Programs (CPCP) at NJIT, including Dr. Howard Kimmel and Ms Rosa Cano, CPCP Associate Director. This activity is build on, and benefit from, continual initiatives organized by the CPCP. The preparation for this program, including the development of the material and the organization of the experiments, is an ongoing endeavor during the academic year with the help of a TA from the Chemical Engineering Department.

The HS instructors receive teaching and lesson material that will, not only be used in their classrooms, but may be incorporated into the technological literacy component of the New Jersey Core Curriculum Content Standards. They also work on developing experiments that will be motivating, and exciting to their students. Lasting relationships and partnerships are created within a network of educators who, by using real-world applications in their classrooms, will be able to show their students how their

involvement in pharmaceutical research can have a great impact on the quality of healthcare in our society. Upon completion of the program, The HS teachers earn 30 professional development hours.

Camp Pharma for High School Students

Camp Pharma for High School Students is a one-of-kind opportunity designed to encourage students to pursue and successfully complete education degrees in science, mathematics, engineering and technological fields. NJIT faculty and CPCP staff will organize and facilitate these activities. The curriculum will be similar to Camp Pharma for high school teachers, but appropriately modified in scope to benefit high school students.

The Nature of Camp Pharma Activities

The experiments/activities that will be conducted at Camp Pharma will focus on the pharmaceutical industry. For example, the dissolution of drugs[3] will be explored. Topics, such as heat, temperature and state of matters, currently being taught in high schools, are foundations for an understanding of the dissolution of materials. It is important to design experiments that illustrate, to the students, the relationship between concepts covered in their classrooms and day-to-day pharmaceutical applications.

Because of the importance of active participation and the emphasis on learning through laboratory experiments, significant effort is devoted to designing a set of activities that specifically target HS teachers and tasks that solely focus on HS students. This approach will help enrich the Camp Pharma experience and maximize benefits to the participants.

Sample Experiments for Teachers

- ***Rate of dissolution of a tablet***

In the pharmaceutical industry, special dissolution apparatus is used to test the dissolution of tablets. The process depends on several interactions and is facilitated by agitation and mixing. "The dissolution of a lollypop in an agitated vessel" is an experiment that can be implemented to explain the rate of dissolution[4-6]. An equation can be derived that relates the dissolution rate of a lollypop (spherical or cylindrical) to the diameter of the lollypop. The apparatus, to successfully conduct the experiment, basically involves a beaker, lollypops, magnetic stirrer, hot plate and magnet, a ruler and a thermometer. The teachers can learn several concepts that are easily used in the classroom.

- ***Fluid dynamics of a mixer***

A complete course in fluid dynamics is necessary to appreciate several processes encountered in the pharmaceutical industry. For instance, the type of flow in an agitated vessel is a very complex phenomenon that is influenced by factors, such as, the diameter of the impeller and the fluid density. Although a basic knowledge of transport phenomena is required to adequately design and optimize these processes, simple experiments consisting of a vessel equipped with baffles help clarify and illustrate some underlying principles[7].

Sample Experiments for Students

- ***Relative solubility of solvents***

A drug's solubility is one indication of its absorption potential. A poorly soluble compound may result in a slow absorption and therefore elicit a minimal response for a given dosage[3]. To illustrate the concept of solubility to HS students, simple experiments, using a range of *solvents* (e.g., water, oil, rubbing alcohol) and *solutes* (e.g., salt, sugar and cornstarch), may be used to help define terms commonly employed in preformulation studies and to explain considerable differences in solubility among various drugs.

- ***Partition coefficient***

A drug molecule must cross biological membranes to reach a specific target. The partition coefficient measures the affinity of the drug for a lipophilic or hydrophilic phase. In theory, the partitioning behavior of a compound is influenced by several factors such as the system pH and temperature. In addition, studies have shown that protein partitioning, in a two-phase system, can be controlled by manipulating the environmental conditions. Experiments, conducted by the HS students, using a biphasic system, graduated tubes and a temperature bath may help them to understand the distribution of molecules in a lipophilic-hydrophilic phase system.

Presentations

Through presentations by NJIT faculty members and guest speakers, participants will have a better understanding of how pharmaceutical applications affect daily lives and the importance of integrating related topics into the classroom.

- ***Dissolution test in the Pharmaceutical Industry***

Oral solid dosage forms (e.g., tablet, capsule, powder and pills) represent the most convenient ways for drug administration. Dissolution tests, mandated by the FDA (Food and Drug Administration) and specified by the USP (United States Pharmacopoeia), are critical components of pharmaceutical development and manufacturing. The purposes of dissolution testing are to guide the development of new formulation, assess lot-to-lot quality of drug products, ensure continuing product quality and performance after certain changes and serve as a surrogate for drug bioavailability through *in vitro-in vivo* correlation. This presentation, among others, will help the participants, both teachers and students, to see the relevance of certain topics, such as dissolution of a tablet, to the classroom experience.

- ***Optimization of drug release from transdermal patches***

Transdermal patches are used as a non-invasive method of drug delivery. They increase patient compliance and facilitate a precise and accurate delivery of the drug. However, several questions concerning the type of membranes and solvent properties necessary to meet a particular objective (i.e. drug-release rate) remain unanswered[8]. This presentation outlines some of the methodologies that can help to address these issues and shows how the type and thickness of a patch and the solvent concentration influence the permeation rate. The participants have the opportunity to relate concepts, illustrated in typical drug-release experiments, to pharmaceutical applications.

Summary

The primary goal of Camp Pharma is to develop a diverse and well-educated workforce of HS science teachers, eager to transfer their laboratory and research experience to the next generation of scientists. The program also intends to train HS students while offering exiting career opportunities in pharmaceutical engineering. The teachers involved in the Camp will be able to devise experiments and incorporate, in their classroom, concepts focusing on the development and manufacture of drugs. As participating teachers bring their experiences and educational materials into their own classrooms, the effort will ultimately reach thousands of students in addition to the ones who participate in Camp Pharma. This exposure has the potential to increase the number of students enrolling in chemical and pharmaceutical engineering.

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