DOCUMENT RESUME

ED 363 388 JC 930 530

AUTHOR	Lindeman, Lynn William; Boerner, Hank
TITLE	The Development of a Generic Pharmaceutical Training Institute.
PUB DATE	21 Oct 93
NOTE	13p.; Paper presented at the Annual Conference of the National Council for Occupational Education (19th, Atlanta, GA, October 21-23, 1993).
PUB TYPE	Reports - Descriptive (141) -- Speeches/Conference Papers (150)
EDRS PRICE	MF01/PC01 Plus Postage.
DESCRIPTORS	*Career Education; Community Colleges; Cooperative Programs; Corporate Support; Education Work Relationship; Government School Relationship; *Personnel Needs; Personnel Selection; *Pharmaceutical Education; Recruitment; *School Business Relationship; Small Businesses; Staff Development; Technical Institutes; Two Year Colleges; *Vocational Education
IDENTIFIERS	Generic Pharmaceutical Training Institute NY

ABSTRACT

The manufacture of generic drugs is a growing industry, generally composed of small companies that are more dependent than brand-name companies on hiring entry-level workers. To provide standardized training for employees in the generic drug manufacturing field, the Generic Pharmaceutical Training Institute (GPTI) was established by a partnership between Rockland Community College (RCC), in New York, private industry, and government agencies. The GPTI was designed to assist the development of a close working relationship between the New York-based generic drug manufacturing industry and RCC, recruiting employees to be trained for immediate entry into the industry and providing instruction for the upgrading of skills of experienced industry technicians. The GPTI curriculum features 11 units, each of which contains measurable learning objectives and mastery levels, developed in-house and shared with the Federal Drug Administration for recommendations. Three training cycles per year are expected, with each cycle involving about 30 participants who will earn a stipend of $190 per week. The GPTI is administered by a team of RCC and industry partners who meet on a monthly basis to evaluate progress toward goals and objectives. Challenges encountered have included delays in the acquisition of laboratory equipment, budget issues due to industry professionals donating their time as teachers, and the need for close communication among the partners. (MAB)

The Development of a

Generic Pharmaceutical Training Institute

Lynn William Lindeman
Assistant Dean of Instructional and Community Services
Rockland Community College

Hank Boerner
Senior Vice President
Rowan & Blewitt, Inc.

Paper presented at the Nineteenth Annual Conference of the National Council for Occupational Education, Atlanta, Georgia, October 21-23, 1993.

THE DEVELOPMENT OF A GENERIC PHARMACEUTICAL TRAINING INSTITUTE

by

Lynn William Lindeman
Assistant Dean of Instructional and Community Services
ROCKLAND COMMUNITY COLLEGE

and

Hank Boerner
Senior Vice President
ROWAN & BLEWITT, INCORPORATED

I. INDUSTRY DESCRIPTION

The manufacture of generic drugs is an emerging, growth industry. There are more than 8,000 generic drugs now being marketed in the United States. This amounts to between 30 and 45 percent of all prescriptions purchased by consumers at an estimated 30 to 50 percent below the price of the equivalent brand-name drugs.

Landmark federal legislation - the Drug Price Competition and Patent Term Restoration Act of 1984, called "The Waxman-Hatch Bill" - ended a long history of state, federal and professional obstacles to making drugs more readily available to consumers at lower prices through full competition between the producers of generic and brand-name drugs and among generic manufacturers. Under the Waxman-Hatch Bill, generic drug replacement or substitution for brand-name drugs is possible after the patent protection expires on the branded product.

After 1984, Wall Street investors embraced publicly-traded generic drug producers and capital became available for new generic drug companies to expand and grow. According to American Druggist (10/90), generic drug manufacturing went from "almost a zero base" in the early 1980s to a $5.5 billion industry in 1992 and an estimated $15 billion industry by 1995. The industry estimates that only 55% of the drugs are manufactured by brand-name companies. The remainder are produced by smaller entrepreneurial companies, a number of them established and now headquartered in New York State. One of the major national trade associations, the Generic Pharmaceutical Industry Association, is also headquartered in New York State. Between 1992 and 1996, $8 billion in brand-name drugs come off patent protection; it is projected that 25% to 40% of this market will be replaced by generics. In the next five years, (1993-1998) $14 billion (sales) of brand-name drugs will no longer be protected by patents. Loss of patent protection creates multiple sources for drugs; more choice has meant reduced prices for consumers.

As the introduction of new brand-name drugs has slowed, the generic manufacturers have created an economic boom within the drug

manufacturing industry and in New York. From 1984 to 1991, the Food and Drug Administration (FDA) received 6,635 applications for Abbreviated New Drug Applications (ANDAs) from hopeful manufacturers. Of these, 3,672 applications were approved and these generic drugs are being marketed. Abbreviated supplemental applications which modify existing and FDA-approved generic drugs (e.g., by increasing strength, dosage form, manufacturing methods) totaled 5,487. About 200 new generic drugs are approved annually.

1993 will be a watershed year for the generic manufacturers. A profound shift could take place in the retail drug marketplace. At the same time that brand-name drugs are losing patent protection (and therefore, marketing exclusivity), pharmacists are increasingly filling prescriptions with generic drugs -- from less than 15% about ten years ago to more than 40% today of all druggists are filling prescriptions with generics *(Hearst Business Publishing Research)*.

As this shift occurs, the 65-plus age population is increasing dramatically; these seniors consume drugs at 3 times the rate of the general population and are presently 30 percent of the U.S. drug market. Only half of the drug costs are covered by third-parties, including Medicare, which puts pressure on retail pharmacists to reduce costs. Increasingly, they are satisfying customers' demands through generic substitution. About 90% of state laws encourage such substitution; virtually all states allow some type of substitution. Nat West Investment Banking Group has charted this phenomenal growth and predicts a $20 billion generic drug market by 1996, as $500 million to $1.5 billion worth of brand-name drugs come off patent each year and generic drug sales increase by 19% annually.

Generic drug manufacturers are small and entrepreneurial companies. New York State's generic drug industry, in particular, is characterized by the entrepreneurial nature of the companies resident here. Many are a decade old, or younger. Because of the nature of generic drug manufacturing, the critical "entry level" size for a company is between 100 and 400 employees, including laboratories, manufacturing, inspection and distribution functions. This size is somewhat larger than the N.Y.S. Department of Economic Development's profile for small businesses, but is quite characteristic of the generic drug industry.

There are no accurate data available to project the dollar value of generic drugs manufactured in New York State. Some estimates by the industry assert that up to 40% of all entrepreneurial generic drug companies are headquartered in New York State. Generic manufacturers may be in a better position to compete in the expanding generics marketplace than the major brand-name drug companies now entering the generics industry. Existing generic companies are familiar with the generics market and structured marketing mechanisms (especially, extensive wholesaler networks).

In short, New York State could become the nation's major generic drug manufacturing center. One key to this positioning would be the formal training of pharmaceutical manufacturing technicians

available in New York State as companies seek to expand or relocate.

II. WORKFORCE DEVELOPMENT AND EXPANSION

The generic pharmaceutical manufacturing industry faces exacting and uncompromising regulatory standards that require a significant outlay for the training of employees. Generic pharmaceutical companies operate with a payroll and with training expenses that are second only to the costs of raw materials. These training requirements are mandated by every firm's need to comply with the dictates of the Food and Drug Administration's Good Manufacturing Practices (GMPs). The industry requires a workforce that is not only cognizant of the rigorous federal and state licensing and operating procedures, but also aware of the implications of failure to meet those performance standards. Employees are in essence required to perform their tasks based on a broader base of knowledge than those of their counterparts employed by the brand-name pharmaceutical companies. The brand-name companies, because of their larger size, have several advantages:

- They can attract the most highly skilled and experienced workers with the immediate enticement of higher pay.
- They operate long runs on machinery devoted solely to a single product, requiring less cross-training for various processes and machines.
- They tend to specialize the task responsibilities of their work force.

Generic manufacturers, on the other hand, are more dependent on hiring employees who are typically newer entrants to the industry. They must train all new employees and retrain old employees on the operating procedures of equipment that must be used to produce several distinct products, responding quickly to shifts in marketplace demand. On-the-job training, without a pre-employment training program, means high turnover; high turnover causes manufacturing errors which can make the difference between a company being profitable or not.

It is generally agreed within the pharmaceuticals industry in New York State that there is a shortage of qualified and trained pharmaceutical personnel. In recent years pharmaceutical companies have utilized both traditional and innovative methods of recruiting. However, efforts have not yet created a <u>new</u> pool of talent. The usual result of recruiting has been the hiring of qualified candidates trained by *other* pharmaceutical companies, thereby impacting on other companies within the industry. Such a hiring pattern does not <u>expand</u> the industry workforce or increase employment opportunities for the state's unemployed or underemployed, especially for bright young people who have all of the qualifications and motivation to succeed but little or no formal training. Although many American colleges and universities offer pharmaceutical-related training -- for example, through New York State's four schools of pharmacy -- these institutions of higher

learning produce the *highly educated* pharmacist, not the highly-trained technicians or the other support or manufacturing personnel. In sum, no training program has addressed the critical needs of the state's pharmaceuticals manufacturing industry.
There is a need today for primary education and training for the majority of technician positions that are found in pharmaceutical companies. The first formal program to address this critical need is that of Rockland Community College of the State University of New York. In cooperation with the generic pharmaceutical manufacturing industry and the State of New York, Rockland has created the Generic Pharmaceutical Training Institute.

The partnership companies, **Par Pharmaceuticals, Rugby Darby,** and **Schein,** will provide immediate opportunities for course graduates. Over 120 current job openings are available among the three companies. Just as important, the industry offers a clearly defined and achievable career ladder for its employees.

III. DESCRIPTION OF THE GENERIC PHARMACEUTICAL TRAINING INSTITUTE PARTNERSHIP.

The Generic Pharmaceutical Training Institute is a reality because of the cooperation and partnership of College, industry, and government. The idea of the Institute emerged from discussions among personnel from Rockland Community College's Business and Industrial Development Office and Small Business Development Center and representatives from Pharmaceutical Resource, Inc., a local generic drug manufacturer. The Rockland Economic Development Corporation and the New York State Department of Economic Development joined the College and industry and developed a grant proposal for state funding of the Generic Pharmaceutical Training Institute. The preparation of the grant proposal allowed key partners to work together in the formative stages to define the idea of the Generic Institute. Through the grant-writing process, the College, industry, and government representatives who would have to turn the idea into a reality came to respect each other's abilities. A state grant in the amount of $322,000 was secured to start the Institute.

The current group of partners from the pharmaceutical industry consists of:

a. Pharmaceutical Resources, Inc.
One Ram Ridge Road
Spring Valley, NY 10977

b. Schein Pharmaceutical, Inc.
(Danbury Parmacal, Inc.)
12 Stoneleigh Avenue
Carmel, NY 10512

c. Rugby Darby Group Companies, Inc.
100 Banks Avenue
Rockville Center, NY 11570

As the training institute progresses, this industry group will be expanded to include generic pharmaceutical manufacturers located throughout the Mid-Hudson, New York City and Long Island Regions. The participating companies believe that the Institute can ultimately service the generic drug manufacturing industry statewide.

Each partner of the Pharmaceutical Training Institute plays an important role in the working of the Institute. The specific roles are as follows:

Partners/Companies	. Assist Rockland Community College with curriculum development, teacher recruitment, and student recruitment
Rockland Community College	. Recruit students . Provide project management and contract compliance as principal grant recipient . Provide instruction
Rockland Economic Development Corporation (REDC)	. Promote an advanced technology bioscience park . Encourage other pharmaceutical manufacturers to locate and expand in Rockland County and/or the Hudson Valley . Engage in legislative activities to support pharmaceutical job retention and expansion
Small Business Development Center (SBDC)	. Assist Rockland Community College with program implementation, contract requirements/reports . Identify/recruit professionals to support instruction
Department of Labor Job Service (DOL)	. Participate with companies and Rockland Community College to recruit and select students for new hires . Where applicable, certify students for DOL/PIC sponsored services (i.e., OJT and TJTC)
Department of Economic Development	. Help with program promotion, advocacy of Training Institute and Generic Pharmaceutical Manufacturing Industry . Contract compliance, site reviews . Funding

IV. INSTITUTE OBJECTIVE AND GOALS

The goal of the Generic Pharmaceutical Training Institute is to provide standardized training for critically-needed positions within the expanding generic drug manufacturing industry. Two initial training courses will be offered, Pharmaceutical Operator and Quality Assurance Technician. Later stages will expand the Institute by adding courses for Packaging Operators, Pharmaceutical Mechanics, Quality Control Technician, and Research and Development Technicians. In order to accomplish this goal, the following objectives were established:

First, the development of a close working relationship between the New York-based generic drug manufacturing industry and Rockland Community College.

Second, the establishment of new industry standards for training. The new standards will be based on good manufacturing practices developed by industry and the Federal Drug Administration. The standards will be contained in the curriculum developed for each training course. This process, we hope, will lead to generally-accepted standards for industry training and eventually a certification process. The New York State Generic Drug Manufacturers will improve the quality of their workforce based on knowledge of GMPs.

Third, the recruitment of new employees to be trained for immediate entry into the generic pharmaceutical manufacturing industry. The industry will provide employment opportunities for the state's diverse workforce and provide employment opportunities for persons displaced by major changes in other industries, such as the defense industry, and by the downsizing of larger corporations.

Fourth, the recruitment and training of one hundred new prospective employees for the generic pharmaceutical industry. A pool of trained workers will improve the competitiveness and efficiency of New York-based drug industry as they enter the period of growth. The availability of a pool of new employees will reduce "raiding" by drug companies seeking new employees.

Fifth, the placement of graduates. Participating industry partners sponsor students attending the Institute. Those who graduate are to be guaranteed employment with sponsoring companies.

Sixth, providing instruction for the upgrading of skills and the advancement of experienced technicians already in the industry. This instruction will lead to the development of a ladder of career advancement based upon the upgrading of employee skills and expertise.

Through the achievement of these goals, there will be a standardized program of classroom and on-the-job training to expand the pool of

entrants into the industry and to improve the skills of existing workers, lending to career advancement within the generic drug manufacturing industry. The industry will increase its competitiveness and improve the quality of its production through a guaranteed workforce.

V. CURRICULUM DEVELOPMENT

The first curriculum to be developed was for the Pharmaceutical Operator. Curricula are currently in development for Packaging Operator and Pharmaceutical Mechanic, Quality Assurance Technician, Quality Control Technician, and Research and Development Technician. In every case the training consists of two components: classroom training and internships at the sponsoring companies. The training hours depend on the position.

The development of these curricula is a cooperative effort between the College and the industry partners. The lead comes from the industry, with its knowledge of the industry's needs and regulatory demands.

A course description and training guide have been developed for the Pharmaceutical Operator course. The units of study for the course are:

A. Overview of the pharmaceutical industry

B. Regulatory agencies

C. Production facilities

D. Hazard communication and environmental awareness

E. Tour of facilities

F. Good manufacturing practices

G. The pharmacy

H. Mixing and granulation

I. Compression

J. Encapsulation and coating

K. The Food and Drug Administration

Each of these units has measurable learning objectives and mastery levels. For example, the unit on production facilities has the following objectives for students successfully completing the unit:

A. Describe in general terms the flow of production of a drug product from the time a customer places an order until it is shipped;

B. If given a sample purchase order, identify the purchase order number, item number, component name, quantity, and manufacturer;

C. If given sample packing slips and purchase orders, match the ones which correspond;

D. Explain what the receiving department and Quality Control look for when examining incoming containers;

E. Define "quarantine;"

F. Define "assay" and describe what the laboratory's role is in receiving materials;

G. Explain the role of the pharmacy and describe "FIFO;"

H. Identify what is contained in standard operating procedures and who uses SOP's;

I. Define "cross-contamination;"

J. Identify what is contained and what is documented in a batch record during batch processing;

K. If given the necessary information, calculate gross, net, and tare weight;

L. Correctly complete a container label if given adequate information;

M. Differentiate between different types of blenders;

N. Briefly describe the processes which take place in the mixing and blending area;

O. Interpret a batch record for mixing and blending;

P. State the number of people who must witness each step during the production process and the purpose of each witness;

Q. Describe what is done whenever there is a discrepancy between the batch record and the manufacturing process;

R. Briefly describe the processes which take place in compression and encapsulation;

S. Briefly describe the processes which take place in packaging;

T. Describe the importance of the yield calculation;

U. If given adequate information, calculate the yield at any point of in-process production; and,

V. State the purpose of the current good manufacturing practices as they relate to the manufacture of pharmaceutical products.

This curriculum will provide standardized training and internship experience for the pharmaceutical industry. The training guide and lessons are shared with the Federal Drug Administration for their recommendations. Thus, there has been an opportunity for industry to work with the FDA to advance the quality of the generic drug industry workforce. Improved product safety and improved quality for generic drug customers are a direct result of this curriculum and this cooperation.

VI. RECRUITMENT, SCREENING AND PLACEMENT OF TRAINEES

The Institute anticipates training 100 candidates in its first year. The first cycle will involve 30 candidates. It is expected that three training cycles will be completed each year. Certificates of completion will be awarded. While in training, students receive a stipend of $190 per week.

Sources for the recruitment of trainees include:

A. Job applicants in the files of participating companies.

B. Graduates and current students at Rockland Community College and other educational institutions.

C. New York State Department of Labor.

D. Large-size companies in the Lower Hudson Valley which are downsizing their work force (e.g., GM, IBM).

E. New York State and Local County Departments of Social Services.

F. Defense Industry Companies losing DOD contracts.

The screening committee identified five criteria for accepting applicants to the training program:

A. No drug or arrest record (FDA and DIA Regulations)

B. Cleanliness

C. Ability to follow direction in completing a complicated application

D. Ability to communicate (interview, written assessment)

E. Willingness to work

Recruitment into the Institute for pre-job training protects the industry partners from unemployment claims and other liabilities for unsuccessful trainees. Those who successfully complete the program are guaranteed employment at their sponsoring company.

VII. ADMINISTRATION AND EVALUATION

The Institute is administered by a team of Rockland Community College and industry partners who meet on a monthly basis to evaluate progress toward the Institute goals and objectives. The College team is composed of an Assistant Dean of Instructional and Community Services, a grants administration officer from our Business Office, the Director of Business and Industrial Development, the Senior Director of Quality Assurance at Par Pharmaceutical, and the Vice President of Quality Operations at Schein Pharmaceutical, Inc. A part-time Institute Director was employed to provide day-to-day supervision and management of the Institute.

The first cycle of students is completing their training next week. Four students withdrew during training. The remaining students will be entering their new positions upon completion of the training. Our industry partners have had a chance to evaluate their new employees prior to their being hired and have expressed satisfaction with the training and abilities of the graduates. Student evaluations of the program have rated instruction as excellent.

VIII. CHALLENGES ENCOUNTERED

Three challenges have emerged so far.

First, the acquisition of manufacturing equipment for the Institute classroom laboratory was delayed and held up the start of training.

Second, teachers are industry-based professionals who teach for a day or two in their area of expertise. Rather than filling out the College-required payroll forms, some instructors are donating their time. This generosity forces us to revise our budget and funding arrangements.

Third, communication between partners of the Institute requires close attention. A change in Institute activities requires communication and agreement by all partners.

IX. CONCLUSION

By blending the resources of education, business and government the Generic Pharmaceutical Institute has become a reality. The long-term picture could be very bright.

After the first cycle of graduates has been successfully placed in industry, the program will be expanded to include applicants from all part of the state of New York. The program is intended to become a permanent state institute for the training of pharmaceutical company personnel.

The generic drug manufacturing industry will have the financial resources to continue funding the Institute. The industry has

demonstrated its commitment to the concept by assisting state and local government and the college in the structuring of the program and making available internship training positions for participants.

The industry is suggesting that the Institute lead the way in pioneering the concept of certifying trained employees in the pharmaceutical industry. New York State could be one of the first states in the nation with such a forward-looking program. The availability of the training program -- and the resulting expansion of the pool of qualified job applicants -- could help attract domestic and foreign drug manufacturers to New York State in the years ahead, as the American generic drug industry experiences geometric growth.

The Institute could develop a standard curriculum for the U.S. generic drug industry, with candidates drawn to New York State's program from other locales. The curriculum would be made available to others on a profit-making basis in order to offset the costs of the Institute. The Institute would also serve as a nexus for greater cooperation between the regulators and the industry.

Eventually New York State's training program could become the *sine qua non* for the American generic drug manufacturing industry located in the state, having an effect similar to the location and encouragement of the electronics industry in Silicon Valley.