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PHARMACEUTICAL PROFESSIONALISM - BRIDGING THE GAP TO HIGH TECH

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Introduction

Technological retraining is a concept that has only recently been introduced to American industry. This buzzword describes the massive educational effort that will be necessary to provide industrial workers with the new skills needed to compete in the high tech society of the future. In some cases, high tech will completely eliminate currently existing jobs, but in most companies jobs will be modified gradually as old machines are replaced with new automated or computer-controlled equipment. American industry is in the beginning stages of this evolutionary process and the bulk of the retraining phase is still several years in the future. But there are concrete steps that can, and must, be taken now to prepare for this inevitable educational task. Industry must insure a solid base of transferable skills and knowledge of current systems that can be subsequently amplified and enhanced as new technology is implemented. The production environment of the pharmaceutical industry is not immune to the high tech revolution. Computer-controlled robots, microprocessor-guided equipment, CAD/CAM systems and so forth are reality in state-of-the-art manufacturing facilities today. How are our training programs coping with this wave of technology?

To answer this question, we need to examine what type of pharmaceutical production training has been done traditionally in the industry. Primarily it falls into two basic categories: GMP or theoretical-type training and skills training. GMP training, mandated by federal GMP Regulations, is general by nature and merely provides broad guidelines for manufacturing personnel. GMP training programs cover "what" is to be done, but only in very nonspecific terms. On the other end of the spectrum is skills training. This has traditionally been conducted on the shop floor by means of the buddy system, that is, pairing a new operator trainee with an experienced operator and having the trainee observe the experienced operator at work. This type of training covers very specific action steps in order to perform a particular task. Skills training covers "what" is to be done in very specific terms. Both of these methods have been successful, to a greater or lesser extent, in answering the questions "what?" or "how to?". This experience, however, has been gained primarily by rote and many times operators are not aware of the reasons behind the actions they perform and are equally unaware of the impact that their operations have on the ultimate bioavailability and uses of the drug product by the patient. What is missing in current training programs are the answers to "why" actions are to be performed and guidelines are to be followed. The answers to the "why"

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questions provide the broad base of knowledge and skills needed as a foundation on which expertise in newly evolving high technology systems can be built. The training programs that provide these answers are also the precursors to future technological retraining.

Program Philosophy

At Schering-Plough Corporation, the Pharmaceutical Professionalism series has been developed to meet these needs and bridge the gap between current training practices and future technological retraining programs. Pharmaceutical Professionalism is a series of training programs designed to go beyond the "whats" and answer the "whys" of pharmaceutical production. Originally conceived to enhance operator compliance with manufacturing directions, the purpose and benefits of the system have grown considerably since the program was first proposed. Philosophically we felt that if an operator had a general understanding of basic pharmaceutics principles, he would be more likely to follow the batch instructions, less likely to take shortcuts and try new methods, and also experience a greater pride in his work. These benefits are reason enough to justify the program. Additionally however, we now see the series as a kick-off for enhanced and intensified shop-floor skills training designed to prepare both operators and supervisors for new high tech systems. It should be stressed, however, that pharmaceutical professionalism is not merely a theoretical training program. Each module is carefully designed to present the theoretical principles but also to directly relate those principles to actual operating steps on the shop floor. This series was never intended to be "nice to know" information. Instead it is designed to be a integral part of and enhancement to skills training presently being conducted and a springboard for future skills expansion.

Program Development

Although the idea for the Pharmaceutical Professionalism series came from the Manufacturing Education and Training Department, the development of specific module topics quickly became a joint effort between Manufacturing Education & Training and the operating departments. A key factor of this project was that production management "bought into" the program from the start. By actively participating in topic selection and by becoming "technical content experts", production supervision not only insured the relevance of the topics but also increased their own knowledge of the chosen subjects. This team approach also effectively guaranteed the acceptance of the program.

Program Content

The initial program in the series is an overview/introduction designed to lay the groundwork for future modules. It is presented to all departments participating in the program. Subsequently specific programs have been designed/planned for each operating unit to address specific operating conditions within that area. For our purposes we broke the manufacturing areas into four groups: 1) Liquids, Ointments and Creams; 2) Sterile Products; 3) Tablet Granulation and Compression; and 4) Tablet Coating. Although each of these areas can be broken down into further subdivisions, we felt that the operators in these groupings would benefit from hearing presentations directed to their overall area.

Overview: Two major themes are covered in this first program. Since we manufacture a wide variety of dosage forms at Schering, drug product formulation is one of the topics of the overview. Defining different types of drug product formulations - for example, compressed tablets, coated tablets, liquids, ointments, creams, sterile products - is covered, as well as the reasons for choosing a particular dosage form for a particular product. In covering this area some general pharmaceutics principles are outlined including how the various dosage forms are used in the body.

Secondly, the methods of how the various drug product formulations are made are also reviewed, in addition to how the different components and raw materials affect end usage in the body and the ultimate bioavailability of the active ingredient. The purpose of this program is to show that the overall processes of drug product formulation and the development of manufacturing instructions are carefully thought out and based on solid scientific principles. This knowledge logically reinforces the GMP-type requirements of following batch instructions and completing batch documentation.

After the overview programs was completed, we next moved into each operating area to address specific manufacturing issues in each department.

Liquids/Ointments/Creams: In the liquids, ointments, and creams subdivision we plan to begin by giving more detailed definitions of the product formulations. What is a liquid? What is a cream? What is an ointment? How do they differ? We will next address the raw materials that go into these products - active, coloring, flavoring, preservatives, base, etc. What is the purpose of these raw materials and how do they affect the usage of the drug product? In each case we will cover how the product is manufactured, always relating the theory to the operator's influence over the end result. Subsequent sessions will cover equipment types and processing steps in greater detail.

Sterile Products: For the sterile products department, there is a large amount of pure theory to cover before addressing specifics of batch production. For example, general aseptic technique alone could be the subject of several modules. The procedures of component preparation and the need for this process, various methods of sterilization and why one would be chosen over another in a particular case, specific aseptic technique in the compounding and filling operations and the need for inspection are other examples of general topics to be handled. Again production methods for the different sterile product formulations - injections, ophthalmic solutions, otic solutions, sterile powders and pellets, etc. - are also planned for future sessions as well as particular production techniques such as filtration and stoppering. Since technique plays such a critical role in the successful manufacture of a quality parenteral product, a greater amount of emphasis will be placed on these topics for the sterile products department than for the other production departments.

Tablet Granulation and Compression: In the tablet granulation and compression area basic definitions will be covered first: What is a granulation? Why is mixing necessary? Why is overmixing bad? Why is lubricant added? Specific processing techniques will also be reviewed and the reasons behind choosing one process over another will be discussed. (For example, the differences between a fluid bed granulation/drying technique and a spray drying technique will be explained.) We will also cover how the quality of the granulation directly affects the compressibility of the tablet. Since the tablet granulation and compressing departments are so interrelated, these two areas have been grouped together for presentation purpose in order to foster a greater sense of teamwork.

Tablet Coating: In tablet coating we will also begin with basic definitions: Why is a tablet coated? What are the different types of coated tablets? Next we will discuss the purpose of each type of coat (acacia coats, gross coats, active coats, sugar coats, color coats, barrier coats, etc.) and cover basic coating technique, not just "how to" but also "why". Future sessions will cover Quality Control test methods such as disintegration and dissolution, for understanding the purpose of these tests and the way in which the test results are reported can provide valuable feedback for the operator to sharpen his techniques. Similar to the parenteral sessions, the "art of coating" requires not only an explanation of the physical raw materials and dosage forms, but also extensive coverage of the techniques of tablet coating as well.

The preceding paragraphs have discussed general examples of topics covered by the Pharmaceutical Professionalism series. This list is certainly not all inclusive. The key to each session is the relation of theory and principle to practice. Each session covers some form of operating technique, practice, or requirement and also covers the reasons behind the requirement or the instruction. It is this combination of theory and practice that allows this series to span the gap between the "whats" and the "whys" in pharmaceutical production.

Benefits

As the name implies, Pharmaceutical Professionalism provides a greater feeling of professionalism among our pharmaceutical operators. There are, however, a variety of other benefits to be derived from this program. As said before, Pharmaceutical Professionalism bridges the gap between GMP-type training, theoretical type training, and the "nuts and bolts" skills training being done by the buddy system on the shop floor. By explaining the reasons behind requirements, Pharmaceutical Professionalism training lessens the likelihood of shortcuts or modifications of procedures. It also insures that one consistent method is taught to each trainee, thereby eliminating the problem of varying interpretations by different "trainers" which has historically been one of the major drawbacks of the "buddy system". In situations where operator judgment is called for, such judgment is now likely to be better informed and more consistently applied. And looking to the future, Pharmaceutical Professionalism can be regarded as a precursor to technological retraining that will become more and more necessary as automation and computerization increase. When a process is automatic, there will be an even greater need for informed operator judgment and knowledge in monitoring such a process.

Pharmaceutical Professionalism represents a significant trend in pharmaceutical industry training programs. It takes traditional skills training programs one step further, providing job enrichment and resulting in better, more well-informed operator compliance with the GMP Regulations and company requirements. It also represents the wave of the future - the first step toward greater employee knowledge and technological retraining.

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