

THE PEOPLE COMPUTER INTERFACE IN A  
CAPSULE MOLDING OPERATION

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ABSTRACT

The effect of computer installation on operators involved in capsule manufacture is described. It is shown that worker morale can be considerably improved by the assistance provided by a computer.

INTRODUCTION

In 1954 Smith Kline Corp. installed its first hard gelatin capsule manufacturing machine. During the next 13 years the facility was expanded to its current size, and the company now operates 12 machines in a 24 hour, 7 day a week effort. Production capability is approximately 2.5 billion capsules annually. Of this total the lion's share is absorbed by SK&F Labs and other Smith Kline Corp. subsidiaries with the remainder being sold to other pharmaceutical manufacturers. There are currently 31 people directly involved in the operation of the 12 capsule machines and auxiliary equipment. They include 20 machine operators, 2 mechanics, 3 trainees, 5 supervisors and 1 gelatin chemist. Directly managing the overall operation is a chemical engineer.

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#### BACKGROUND

For many years the making of hard gelatin capsules was thought of more as an art than a definable scientific process. In 1968 Smith Kline's management instituted a program to study the process in sufficient detail that the cogent variables could be identified. The justification for this venture was an anticipated production yield increase and a consistently more uniform end product. This latter aspect was the more important since capsules of inconsistent quality and physical characteristics are considerably more expensive to inspect and can create havoc when being filled with a drug product in high speed filling equipment.

A project team was formed and an IBM 1800 DATA ACQUISITION AND CONTROL SYSTEM was leased to attach to a "pilot" capsule manufacturing machine. After the selection of "critical" process variables and installation of the necessary instrumentation to interface with the computer "on line" analysis began in December of 1968.

#### OBJECTIVES

- (1) Minimize product visual defects.
- (2) Manufacture capsules with consistent dimensional characteristics
- (3) Maximize output by minimizing machine down time.
- (4) Simplify the operators' duties.

#### APPROACH

The project began by monitoring the process variables and storing the results on the 1800's magnetic discs. The capsule

## PEOPLE-COMPUTER INTERFACE

machine operator was instructed by the computer to enter corresponding quality information at the same time via a specially designed console unit. Statistical analysis of this data then led to the emphasis of certain process variables and de-emphasis of others. The most critical variables such as temperatures and viscosity were put under the control of the computer. Further analysis defined finite process specifications which were then used to "direct" the capsule machine. This was done by a combination of computer "direct digital" control and "operator guide" control, i.e., the computer telling the operator how to set the variables. Operating data vis-a-vis improvement were then obtained using this system.

Variables monitored or controlled during this data acquisition period were:

- (1) Gelatin temperature during melt.
- (2) Vacuum during melt.
- (3) Concentration of solids during water dilution.
- (4) Gelatin temperature and viscosity at the point where the capsule is formed.
- (5) Amount and temperature of air at different points in the drying cycle.
- (6) Relative humidity of the drying air.
- (7) Capsule dome and wall thickness.
- (8) Number and type of visual defects found by the operator.
- (9) Capsule counting.

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### EFFECTS ON PERSONNEL

#### Initial Period

Most of the people involved in capsule manufacturing at the time this control project was initiated were "seasoned" personnel with up to 14 years experience in capsule making. As the project developed, however, it became apparent that there were sufficient problems to convince everyone that we all had a lot to learn about making hard gelatin capsules.

For example, the operators did not really understand how the capsule making process worked; what effected or affected the variables nor exactly how the final product's characteristics were dependant upon those variables. To put it quite candidly not even the supervisors totally understood the manufacturing process. It was clearly a situation where trial and error was the principle method of resolution and the lack of complete process knowledge compounded the problem. A run of good product was often hard to duplicate because the combination of variables was transient. In this type of situation the people involved will often polarize into two main groups. One group will say, "Since this is the best we have ever made it must be the best that can be made," and the other group will say, "This is acceptable but let's change something, change anything, and see if it gets better."

The logical rebuttal to these positions is first, that other sources (companies) are making a similar product with essentially the same molding equipment and second, that these same other sources have an apparently uniform product which probably implies a minimum of processing changes.

## PEOPLE-COMPUTER INTERFACE

The purpose of the control computer was to help the operators recall and assimilate the diverse information necessary to the process, perform the required calculations and indicate the need to make the changes necessary to quickly bring the process back to an optimum state.

It is not surprising that a quantum jump in the technology of an established process should cause some apprehension in the minds of those who are familiar with an old system. The group who considered current output to be good enough perceived a subjective menace in the potential of the new system. This fear is difficult to describe but seemed to relate to the possibility that accepted technology would be proven wrong and therefore an adverse reflection would be cast on their previous best efforts. The other group saw the computer as a device intended to do the work which they thought was their primary function, i.e., making changes in the process variables to get an improved product. Consequently they saw their jobs in jeopardy.

One of the initial objectives of the new enterprise was to educate the operators in the real purpose of the computer installation and its expected benefits. The educational program was started via lectures followed by question and answer sessions. The longer term goal was to keep everyone advised of the progress of the installation and periodically update the group on the data acquisition results from the pilot machine operation. This latter period lasted for about a year. Two significant developments during that time were the successful completion of the pilot program leading to the

## MARTYN

decision to extend computer control to all 12 machines and the general acceptance of the computer and its potentials by both the operators and their supervisors.

### CURRENT STATUS

#### System

As currently installed, the system senses the process variables, makes changes if required, accepts operator input and displays information via the following sensor points and terminals:

- 24 gelatin temperature points
- 24 water jacket points
- 12 air temperature points
- 24 gelatin viscosity points and feedwater valves
- 12 drying air relative humidity points
- 1 electronic scale (kg.)
- 2 solenoid water valves for gelatin preparation
- 1 IBM electric typewriter/printer

#### Effects

It was proven that the data processor could effectively and efficiently handle many of the duties which previously had been the exclusive province of the operator. The system monitored and controlled the gelatin viscosity in the dip pot by reacting to changes in the gelatin temperature and providing automatic water addition. This resulted in a consistency of capsule wall thickness which was several orders of magnitude better than when the operators controlled the viscosity manually. This uniformity in

## PEOPLE-COMPUTER INTERFACE

gelatin thickness has resulted in greatly improved capsule stripping and trimming functions by the machine. This viscosity control has then improved the quality of the capsules while reducing the operator's direct manual effort in an important area of capsule quality control.

A second effect noted is the part the computer plays in the melting and mixing of the raw material gelatin before it is delivered to the capsule making machines. Under current procedures the operator takes one manual viscosity check (Pipette method) of the gelatin solution as it is being drawn from the vacuum melting tanks into transfer cans. This viscosity reading (in centipoise units) becomes one factor which in conjunction with the gelatin temperature and weight of solution in the transfer cans is entered into a stored equation in the central processing unit. The computer then determines the amount of water which must be added to bring this gelatin to a predetermined viscosity at the operating temperature of the machine dip pot. This quantity of water is added automatically via an electronic scale and solenoid operated feed water valves. Thus the operator is essentially relieved of the computation and manual water addition previously required. Again more of the operators working time is available for checking other parameters of the capsules being produced. As an added plus the computer is far more accurate, consistent and much faster than the operators in making the water additions and viscosity adjustments.

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### RESULTS

Primarily, computer control has created a situation where the operators are free to spend the major part of their work day in direct quality observation and adjustment of non-controlled functions. As a consequence, the output of acceptable capsules at the molding stage has increased by more than 38% since the inception of the program. The operators are very aware of this improvement and are very proud of it. In the "old days" the quality of the capsules was a relatively consistent source of complaints from the Inspection, Filling and Packaging areas. The current situation, however, is that complaints have declined dramatically and the capsules have contributed to record production levels in these areas. The capsule operators now share in the praise for those achievements.

A second and more subjective result of the computer installation has been that the operators stand secure in the knowledge that they are capable of maintaining an effective conversational relationship with a digital computer. They can ask questions and get answers. They can, by observation of the monitor printout, anticipate problem situations.

The installation has, in a very real sense, enriched their jobs. They see improved output; they experience a reduction in routine effort, and they are responsible for the operation of the computer.

The consistency and reliability of computer control has enabled the men to take better advantage of holidays and vacation periods. Before its installation, the procedure for shutdown and then re-starting the department was almost an exercise in frustration. All



## PEOPLE-COMPUTER INTERFACE

machines had to be stopped, residual gelatin removed from dip and storage pots and machines cleaned. This took approximately two full days before the operators left for a holiday period. The start up time was about twice as long and on occasion as much as 14 days elapsed before acceptable capsules were produced. Under these conditions, the only regularly scheduled "down" time was the annual two week plant shutdown and the three or four days at Christmas. The Christmas shutdown and start up often took three or four times longer than the holiday period itself. The problems here in terms of scheduling and operator frustration do not require any elaboration.

Since the computer installation the department has been able to shutdown for every holiday period scheduled by management. These varied from one to four days in length. We were even able to effect a two shift stop on New Year's Eve. The most remarkable aspect of this capability is that the preparation for a shutdown is now about three hours and the start up time less than one shift. As an example, the total non-productive time associated with the New Year's Eve shutdown was less than six hours.

The impact of this on the operators has been dramatic. They no longer dread the problems of restarting; they look forward to and thoroughly enjoy their holidays, and they react to these conditions with a reduced absence rate. In 1972, for example, the rate was improved over 1971 by approximately one equivalent man/year.

## MARTYN

This capacity of being able to shutdown for short holiday periods presented an interesting situation. When the capability was first discussed, many operators felt that this was a move designed to maneuver them out of their overtime pay for holiday periods. This attitude changed, however, with experience and within the first year of computer controlled operations, holidays were as cheerfully greeted by the Capsule Making Group as any other group in the plant. Perhaps even more so because it was a new experience for all involved.

An example which further illustrates our confidence in employee acceptance of the process controller is as follows: A well established hard capsule manufacturer build a new facility within 80 miles of SK&F. They advertised their need for experienced operators in the local newspapers. To our knowledge only one of our employees investigated the opportunity. We feel this is a strong indication of job satisfaction and confidence in the continuing security and progress of their positions.

However, there are two sides to every coin and one of the drawbacks to the use of the computer is in the area of viscosity control where the machine has had the effect of becoming a crutch. In the infrequent instances (less than 4 times per year) where electrical or component failure has forced the operation to go off line, there has been an initial period of extreme disorganization while both operators and supervisors attempt to recall and re-establish the manual methods to maintain the machine output of proper quality. In certain instances this attempt has not been successful

## PEOPLE-COMPUTER INTERFACE

and good capsules were not produced in significant quantities until the computer was put back on line. It is logical that the longer the computer handles the problems, the longer it will take for the operators to relearn how to work without it.

### SUMMARY

The primary effects of the computer installation on the operators have been:

- (1) Confidence in their ability to produce high quality capsules.
- (2) Simplified results-oriented duties with no reduction in responsibilities.
- (3) Ability to plan and use holiday periods more effectively.
- (4) Reduced absenteeism and improved employee morale.
- (5) Certain manual skills have deteriorated.

In general, the computer project was well conceived and has been effectively implemented. Its results have been beneficial to both employer and employee.