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Automation of Aqueous Film Coating

Jean Yves Le Floc'h

Thomas Engineering Inc., 575 West Central Road, Hoffman Estates, IL 60195

ABSTRACT

Among the major manufacturing segments of a pharmaceutical dry products department, coating—to a much larger extent than granulating and tableting—has been at the forefront of the quest for productivity, and hence, the earliest target for automation. Among the reasons for this situation, the following factors can be cited: Coating is a repetitive, labor-intensive, batch process; it is an "inexact" process, to be formalized and disciplined; it is easy to computerize, as it is slow; its control strategies are simple and well understood.

As the "per-pan" automation and computerization of a coating operation is gaining maturity and commercial acceptance, it is virtually certain that the modernization of pharmaceutical coating will follow the general path traced by modern industrial automation and will conform to the following pattern: Once single-pan automation proves itself, several automated pans will be grouped into a control hierarchy that will allow supervisors and managers to centralize the monitoring, archiving, and alarming functions of their coating department; the coating hierarchy will then be integrated in a higher-level manufacturing unit (Dry Products, Pharmaceutical Production), thus becoming part of a computer-integrated manufacturing system allowing its integration into higher functions such as planning, scheduling, quality control, MRP, etc.

The following analysis, with reference to Figure 1, will briefly examine the current state of automated coating and will then anticipate the upcoming phases of its evolution. Finally, automated coating will be placed in the general perspective of modern industrial automation, and conclusions will be drawn from this analysis.

PROCESS AUTOMATION

Single-Pan Configuration

The first step in the coating automation project deals with the machine level and attempts to automate the process on a single pan. This involves the instrumentation, control, and monitoring of four subunits: the coating pan, the spray system, the air handling unit, and the coating environment.

The parameters to be monitored and/or controlled in the first three subunits vary from application to application and implement the basic coating process. The

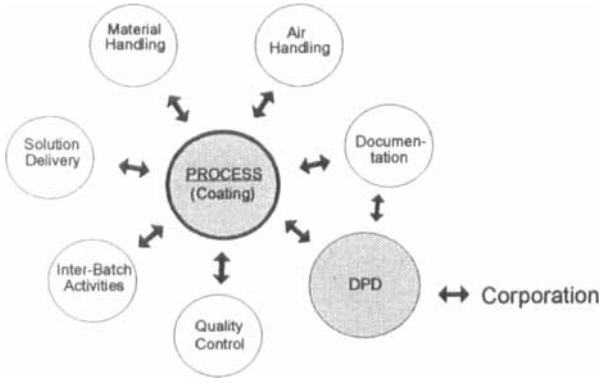

Figure 1. Coating processes and their related activities (DPD = Dry Products Department).

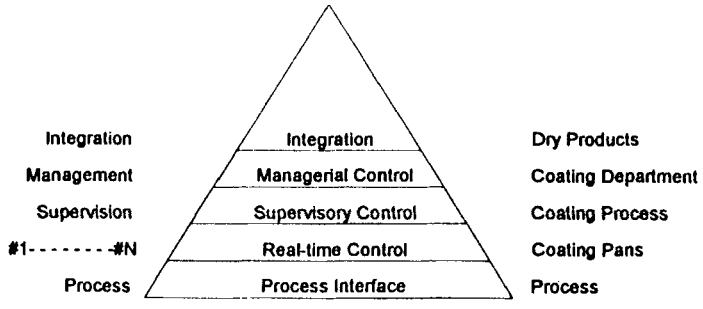

Figure 2. Control hierarchy pyramid of coating automation.

environment refers to air treatment units that may be located upstream or downstream from the coating pan/air handler entity, and can include some of the following: air pretreatment, solvent recovery, and centralized dust collection. The environment could also include a centralized HVAC (heating, ventilating, and air conditioning) control into which the pan and its air handler must be integrated.

Control Aspects of the Single-Pan System

The single-pan system is a process-level application of production automation, and consequently, is geared toward devices of control and monitoring: control of coating, air handling, and spraying equipment (motors, dampers, actuators); regulatory control of the primary parameters (pan speed, airflow and temperature, solution delivery, etc.); monitoring of the secondary parameters (dew point, differential pressure, etc.); and sequencing of the coating stages to a predetermined endpoint to conform to a recipe.

Secondary functions of the single-pan system include system setup, configuration, alarming, and logging.

SYSTEM AUTOMATION

Multipan Configurations

Once the process has been successfully automated on a single-pan basis, the next step will require the integration of several processes into a vertical hierarchy that will bring the benefits of automation into higher levels of the manufacturing entity. The specific layout of the control hierarchy will depend on the number of coating pans, the structure of the coating department, and how it is integrated in the dry products organization. The literature and trade magazines are replete with control pyramids that summarize control hierarchies and can be adapted to coating automation as shown in Figure 2. Table 1 lists control functions of the multipan hierarchy.

The Monitoring Hierarchy

The First Level

Functionally, the coating segment of pharmaceutical production reduces itself to three levels: the real-time control (process level, Figure 3); the supervisory control (supervision level, Figure 4); the managerial control (management level, Figure 5). Somewhere in the last two levels a connection must be provided for the integration of the coating segment in a higher level.

The process level has been described earlier and involves the single-pan automation. This level deals mostly with machines and instruments in real-time and provides minimal human interaction.

The Second Level

The second level supports several functions that provide the supervisor with immediate access to global or detailed status of several coating pans. It also allows the control of recipe loading and scheduling of daily production. Detailed batch documentation is also logged for archiving.

Typical functions of the second level are as follows:

Data acquisition: Collect all process data from several pans for analysis, display, and logging.

Status display: Display functional status (multipans) and detailed status (pan-by-pan).

Table 1

Control Functions of the Multipan Hierarchy

Function	Process Level (ACU)	Supervision Level (CSU)	Management Level (PMU & Above)
Process interface	✓		
Discrete control	✓		
Regulatory control	✓		
Process monitoring	✓		
Time and event sequencing	✓		
Manual backup and bumpless transfer	✓		
Alarms handling	✓		
Alarms summary and prioritization		✓	✓
Status display, single pan	✓	✓	
Status display, multipan		✓	✓
System configuration	✓		
Batch logging (minute-by-minute)	✓		
Orderly shutdown	✓		
Recipe management	✓	✓	
Identification (operator, product)	✓		
Operator interface	✓		
Data acquisition and reduction		✓	
Database management		✓	
Archiving		✓	
Batch documentation		✓	
Security management	✓	✓	
Supervisor interface		✓	
Trending		✓	
Gateway to dry products		✓	
Maintenance/calibration		✓	
Production tracking			✓
Management reports			✓
Scheduling			✓

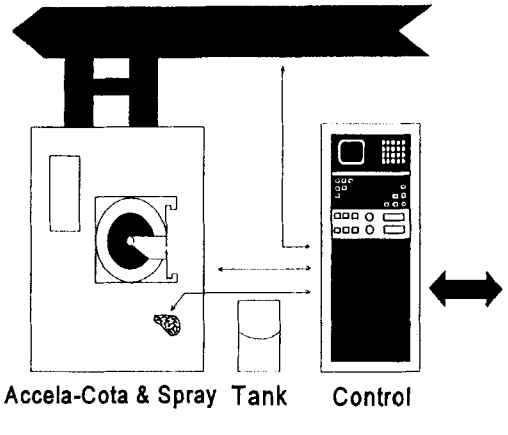

Figure 3. Process level (coating pan, spray, air handler, environment).

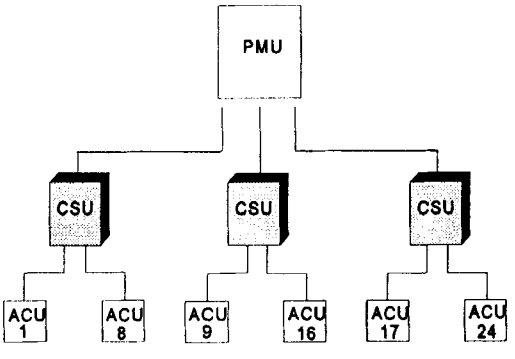

Figure 4. Supervision level (coating supervision unit).

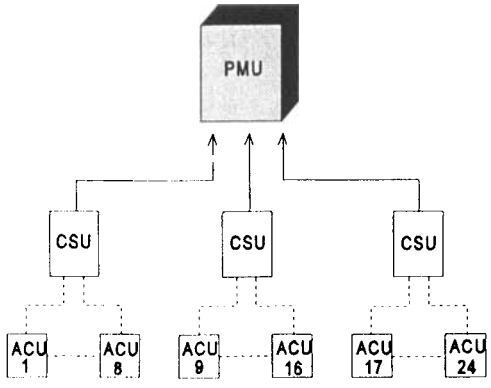

Figure 5. Management level (production monitoring unit).

Alarms: Collect and display process alarms from pans, air handling, and spraying systems.
Recipe entry: Supervisor-controlled selection of recipes for downloading to any of several pans.
Communications: Processing and formatting of operation data for transfer to Production Monitoring Unit or access by plant mainframe or local area network (LAN).
Batch documentation: Extensive customized batch documentation, minute-by-minute/phase-by-phase, on permanent storage media.

Communications between the first and second levels are mostly upward, as the supervisor gathers information for several coating processes. Downward communications take place to load recipes in a coating pan or to control the scheduling of batch cycles.

The Third Level

This is the management level, the highest layer in the multipan hierarchy, and consists of a Production Monitoring Unit (PMU) which, depending on the size of the coating operation, monitors several Coating Supervision Units.

The PMU oversees the total coating operation from a single location, providing the production manager with timely and detailed information. The PMU tracks coating operations by pan or by coating room and will monitor productivity and batch performance on a daily, weekly, or monthly basis.

Communication flows mostly upward between the supervision level and the management level. Downward communications may take place for scheduling functions.

NETWORKING AND INTEGRATION OF AN AUTOMATED COATING SYSTEM

Definitions and Background

During the planning of a multipan coating system, two fundamental issues must be addressed: how to physically connect and establish communications between the various levels of the hierarchy; how to integrate the coating hierarchy into a higher-level information system that will gracefully incorporate the coating operations into the Dry Products Department and the higher levels of the production entity.

Both questions can be answered by the deployment of a communication network. Some background and definitions pertaining to this emerging technology are summarized in Table 2.

Implementation of the Multipan Hierarchy

In a fully decentralized approach, each pan controller communicates bidirectionally with a Coating Supervision Unit (i.e., two to eight pans per CSU) and the CSUs communicate to a third-level unit (PMU: production management unit). Horizontal communications (peer-to-peer) are not required at the process level or the supervision level. Several options are then available:

If the control unit is based on a PLC, the hierarchy can be implemented by using the proprietary communication scheme for the PLC supplier selected.
If the control unit is based on an industrial PC, a microcomputer, or a proprietary controller, communication can be established by implementing a LAN such as Ethernet, Stalan, Token-Ring, etc.
If the coating operation is automated by a commercial, minicomputer-based process control system, the supplier's data communication schemes have to be implemented.
When a MAP network is implemented in the Dry Products Department, then the ACU/CSU/PMU hierarchy can be treated as a baseband network in which the CSU acts as a coating cell controller.

Integration of the Coating Operations

After having connected the three levels of the multipan coating system into some sort of a computer network, the last challenge consists of integrating the coat-

Table 2

Historical Perspective of Automated Chemical Processes

Milestones, Computers	Year	Automation, Industrial	Automation, Coating
Mainframes	1960	First automated chemical process (Texaco)	
Batch Processing	1965	Introduction of minicomputers	
	1970	First programmable logic controller	
Minicomputers	1976	First computerized pharmaceutical plant (Merck, U.K.)	Automated coating (columns)
	1977	Aldomet tableting (Merck, U.S.)	Automated sugar coating (Ayerst, Sandoz)
	1980	MAP task forces	
	1982	Automated antacid production (Ayerst, U.S.)	
Personal computers	1983		Introduction of commercial computerized system
"Connectivity"	1984	Smart instruments	First installations (1984–85)
	1985	Corporation for open systems (COS)	
	1986	PCs reach the shop floor (1985–86)	Introduction of first commercial coating network
	1988		Installation of multipan networks
Networking	1994	Smart field instruments	
"Integration"	1996	Integration of computerized coating	
Smart devices	1998	Computer-integrated manufacturing (CIM)	

ing hierarchy into the Dry Products Department's data communication system, thus avoiding its isolation, and incorporating it into a computer-integrated manufacturing system, which ultimately will cover granulating, tableting, coating, and packaging.

If a computer system (or a computerized process control system) is already in place in the Dry Products Department, a data access should be provided between the coating supervision unit (CSU) and the higher-level system. The extent of the integration afforded by such a scheme depends on the compatibility, features, power, and communication abilities of the host system.

If the planning of the coating automation project can be coordinated with the computerization of the Dry Products Department, the best solution is to implement a department-wide LAN, of which coating is a subnetwork. This could be implemented using an IEEE 802.X LAN, an example of which is proposed in Figure 4.

If the coating department is automated and networked prior to the implementation of a MAP backbone (plant-wide or Dry Products–wide), the coating subnetwork (proprietary or 802.X) can be integrated by means of a "gateway" between the subnetwork and the backbone.

A HISTORICAL PERSPECTIVE

The Past

The first automated chemical process is credited to Texaco (catalytic cracking process, 1959–60). The first fully automated tablet manufacturing operation is claimed by Merck & Co. in Cramlington, England (1976), and included computerized film coating in air-suspension columns.

Pioneering automated sugar coating operations were reported by Ayerst and Sandoz in 1977; commercial, turn-key computerized coating systems have been announced since 1984 by Thomas Engineering, Glatt, Vector, and other suppliers.

The Present

Several commercial automated, single-pan, film coating systems have been commissioned since 1985 by major coating suppliers, and the single-pan automation of film coating is gaining rapid momentum as approximately a dozen Accela-Cota–based automated coating systems are commissioned every year.