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A Systems Approach to Mechanical Construction

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This article provides proven and practical tips to improve quality and productivity during pharmaceutical construction. Many downstream problems can be avoided by following an organized program of inspections, testing and documentation. Start planning system turnovers early, preferably shortly after mobilization.

Introduction

The most complicated or technically sophisticated modern pharmaceutical facility always can be broken down into simple building blocks. This article will describe proven methods to build quality projects and organize documentation for orderly turnovers. Suggestions will be given for reducing the variability inherent in construction activities and thereby allow savings in time and cost.

Get it Right the First Time

It is costly and non-productive to go back and modify previously installed work. Unfortunately everyone involved in construction has, at one time or another, experienced the consequences of this activity. Rework is disastrous to tight schedules and budgets. Craft workers returning to make corrections and/or repairs are often forced to perform work out of sequence and therefore can damage the work of other trades. Invariably the finished product is not the same high level of quality as the original installation. The goal should be to "get it right the first time."

Many tasks involved in mechanical construction are repetitive in nature such as welding pipe joints, sealing ductwork or installing insulation. In many ways, these activities are similar to a train on a track. Once the train is moving, it is very difficult to stop or get it to change direction. The key is to get it **started** down the **right** track.

Several methods are used to get started down the right track. Contractors are required to name a construction quality representative, preferably someone in a hands-on supervisory role. Remember, however, that quality is everyone's job and it is an attitude that must be shared by craftsmen through supervision. The project must seek out those who truly demonstrate "pride in their work" and encourage this as a role model.

Prior to mobilization, a site meeting is held with the construction manager, designer, trade contractor and owner. Team members are introduced and the project construction quality program is reviewed in detail. Contractual requirements as well as "expectations" are discussed. Never underestimate the importance of the expectations of the various parties. Now is the time to get all the cards on the table. Talk about roles, responsibilities and anticipated levels of performance. In all likelihood, not everyone attending this meeting will have a thorough knowledge of the construction documents. Issues worked out at this early stage will reduce or eliminate the disputes that arise later. Seek a meeting of the minds. The procedure for getting questions answered by the architect/engineer also is explained. This meeting sets the groundwork for the partnership and trusting relationships that must exist on all successful projects, and the goal is a successful project.

An effective Quality Control (QC) program sets in place a series of checks strategically accomplished and enforced during the course of construction that identify small problems early and gets them resolved before they become big problems. A set of appropriately scheduled early inspections helps to assure the "train" is headed down the right track. The first delivery of every type of material is thoroughly inspected to assure compliance to contract documents as well as to ascertain product quality and condition. Is the material the same as the approved submittal? Is it properly labeled and packaged to avoid damage? This inspection will bring attention to obvious problems of damage due to shipping but also will allow re-

Division 1	General Requirements
Division 2	Sitework
Division 3	Concrete
Division 4	Masonry
Division 5	Metals
Division 6	Wood and Plastics
Division 7	Thermal and Moisture Protection
Division 8	Doors and Windows
Division 9	Finishes
Division 10	Specialties
Division 11	Equipment
Division 12	Furnishings
Division 13	Special Construction
Division 14	Conveying Systems
Division 15	Mechanical
Division 16	Electrical

Figure 1. CSI format.

Civil/Structural/Architectural
C-01 Level One Architectural
C-02 Level Two Architectural
C-03 Level Three Architectural
C-04 Penthouse Architectural
C-05 Roofing
C-06 Exterior Architectural Precast
C-07 Exterior Windows and Skylights
C-08 Sitework and Landscaping
C-09 Site Utilities-Domestic Water
C-10 Site Utilities-Fire Water
C-11 Site Utilities-Storm
C-12 Site Utilities-Sanitary
C-13 Elevators

Mechanical-HVAC
M-01 Chilled Water System
M-02 Condenser Water System
M-03 Heating Water System
M-04 AHU-01 and Associated Ductwork
M-05 AHU-02 and Associated Ductwork
M-06 AHU-03 and Associated Ductwork
M-07 AHU-04 and Associated Ductwork
M-08 Fan Coil Units and Associated Ductwork
M-09 Exhaust Fans and Associated Ductwork

Mechanical-Plumbing
M-10 Storm Drain System
M-11 Sanitary Waste and Vent System
M-12 Domestic Hot and Cold Water Systems
M-13 Natural Gas System

Mechanical-Fire Protection
M-14 Sprinkler System

Electrical
E-01 Electrical Distribution Equipment System
E-02 Level One Lighting and Power
E-03 Level Two Lighting and Power
E-04 Level Three Lighting and Power
E-05 Penthouse Lighting and Power

E-06 Fire Alarm and Public Address System
E-07 Lightning Protection System
E-08 Security System
E-09 Communication System
E-10 Audio Visual System
E-11 UPS System

Instrumentation and Controls
I-01 I&C-HVAC

Process
P-01 AHU-05 and Associated Ductwork
P-02 Exhaust System
P-03 Nitrogen System
P-04 Process Water System
P-05 Neutralization System
P-06 Process Waste and Vent System
P-07 Coolant System
P-08 Scrubber System
P-09 Vacuum System
P-10 Steam and Condensate System
P-11 Breathing Air System
P-12 Compressed Air System
P-13 Process Electrical Supply
P-14 Process Electrical Distribution
P-15 Control Panel No. 1
P-16 Control Panel No. 2
P-17 Control Panel No. 3
P-18 Control Panel No. 4
P-19 Reactor Bay No. 1
P-20 Reactor Bay No. 2
P-21 Centrifuge
P-22 Dryer

Figure 2. System turnover list.

moval from the jobsite of inferior materials **before** they are installed. It will avoid forcing the compromising decision later of accepting installed work of inferior products because schedule and/or cost prohibits rework. Inspections of this type are performed by the trade contractor, construction manager and owner supervisory personnel, and are documented. Future deliveries often require spot checking only. Don't forget source inspections at the place of manufacture. They should be used early and often on specialized equipment to both monitor progress and prevent shipping problems to the job.

The first installed piece of equipment of every type also is routinely inspected. The first pump/air handling unit (AHU) set or the first variable air volume (VAV) box hung is reviewed for level, plumb, support, position etc. Construction documents may not show sufficient detail required to properly support large pieces of equipment. Now is the time to sort out the details and get them right before repetitive mistakes are made with remaining identical equipment.

Mockups have always been used to demonstrate the finished architectural product. In mechanical construction, benchmarks are used. First a typical entire assembly is completed, for example the piping configuration at a cooling coil. All valves and instruments are installed. The assembly is inspected for fit-up, clearances, accessibility, dimensional requirements, workmanship etc. Adjustments/corrections are made as necessary. Photographs and signed approvals by the trade contractor, construction manager, engineer and owner document the installation. As a result, the level of acceptance is determined early before multiple installations are complete. The benchmark serves as a reference for all future work of this type.

Pharmaceutical construction often requires a high skill level of craftsman that may not be available in a particular area of the country. Benchmarking may reveal severe skill deficiencies. It may be necessary to bring in a vendor to "teach school" for specialized activities. The few hours spent in specialized instruction are well worth the investment in avoiding an inferior work product.

Issuance of Non-Conformance Reports or long punchlists often indicates that the work has not been done right the first time and that a thoughtful quality program as outlined above has not been properly executed in the field. Remember that avoidance of costly repetitive mistakes is a goal the project is striving to achieve.

Systems/Boundaries and Turnovers

Architect/Engineers design projects and construction managers buy projects according to the Construction Standards Institute (CSI) format, i.e. Division 1 through Division 16. (Figure 1) However, this division of the work is not always the most practical for the owner who will operate and maintain the facility. What is more useful to the owner is to organize the facility as a series of systems, for example the chilled water system, the USP water system or the AHU xxx and Associated Ductwork system. Systems are by nature multi-disciplined. They are made up of all the components that make them functional including mechanical, electrical, controls etc. If the owner is to run the facility on a system basis, but it was designed, built and documented on a CSI format, the problems are obvious. At some time early in the construction sequence the conversion to a systems approach has to be made.

Ideally, following contract buyout and shortly after mobilization the project team will analyze the project and break it up into a series of logical system turnovers. Flow diagrams and P&IDs are useful in identifying the boundaries of each system. The systems list is reviewed and approved. Figure 2 is a typical list. It's not too early to start planning for the eventual completion and turnover of the facility to the owner on a system by system basis. "Turnover packages" will contain all the documentation required to show the facility has been built per the construction documents in a high quality manner. A typical Table of Contents is shown in Figure 3. From this point on, all project documentation required to support the turnover package is filed by turnover to allow ready access to this material in the future. Sequential numbering of inspections or tests is very helpful.

Inspections/Procedures and Documentation

The "nuts and bolts" of getting it right the first time require a program of early inspections of installations. Approval of benchmarks is followed by static pressure testing of piping and ductwork. Mechanical systems are then subjected to start-up, commissioning and full functional testing. Figure 4 illustrates several testing, cleaning and startup procedures/checklists that are commonly used. Sophisticated owners may have developed procedures to cover each one of these activities. In such a case, the owner's procedures are incorporated into the construction documents by the architect/engineer. Experience has shown this to be the preferred method because the owner's requirements come as no surprise to the construction manager and trade contractor. Procedures and documentation are then uniform from project to project and the owner has the benefit of this consistency. The construction quality control (QC) documents become the foundation on which the facility's validation effort is built. When they are integrated with installation qualifications (IQs) and operational qualifications (OQs) the validation program can start earlier and progress concurrently with construction, thereby saving time. All construction disciplines must follow a progressive and systematic approach to demonstrating the acceptability of an installation. When this is done, there are far fewer problems encountered during the final acceptance (or full functional) test. At that point, all components (mechanical, electrical, controls etc.) are required to work together to prove a system's performance.

However, in many cases the owner's organization must rely on the architect/engineer, construction manager and outside consultants to provide these means and methods procedures. Often the procedures are covered in general terms in the project specifications and the generation, review and approval of the details are left to the construction phase of the project. This can be both disruptive and expensive to the project when key personnel are tied up developing procedures instead of overseeing the actual installation of the work. If the details are left up to the trade contractor to submit for approval, there often is a great deal of time and energy spent in review. This also introduces a tremendous amount of variability into the process and likely will cause difficulties for an owner trying to maintain consistency across various facilities.

Not enough can be said about the need for good documentation during construction of a pharmaceutical facility. Standardized sign-off forms for inspections and tests are normal practice (Figure 5). Final closure inspections for walls and ceilings also have proved useful in identifying problems before they get "covered up".

A Word About Materials Management

Conventional practice regarding mechanical construction materials has been to order in bulk quantities (for obvious economy), deliver and store in bulk at the jobsite. This requires on-site warehousing which in turn necessitates security and distribution management. Large costs are associated with maintaining this inventory on-site. The contract may not permit progress payments to the trade contractor until the material is actually installed, or may permit payment for a reduced percentage value of the onsite inventory. Obviously, to reduce the contractor's dollars that are tied up in inventory, it is advantageous to have contract language that permits owner progress payments for materials stored in a secure/bonded offsite warehouse. The contractor will have to document that title to the materials rests with the owner and that the materials are properly protected and insured.

An efficient approach is to do initial material quantity takeoffs on a system by system basis, keyed to either drawing number or building area. Material can still be ordered in bulk; however, the supplier is relied upon for storage and packaging of future releases to the jobsite. The supplier's additional charges for warehousing and multiple deliveries will be more than offset by savings in jobsite losses and material handling.

Using this "just in time" approach, field supervision releases material for delivery as it is needed. The supplier will label and palletize as needed. Material is delivered directly to the area where it is to be installed. A minimal number of secure storage "bins" are provided in the work area as well as simple moving equipment that can transport material directly to where it will be used.

There are several other benefits to this type of materials management. Material quantities/costs are known on a system and area basis. Installation labor costs also can be tracked. Thus unit costs of labor and productivity can be monitored and controlled. Comparisons to original budgets can be made. Problems can be identified early and corrective action can be taken. Obviously this level of control requires manpower and a degree of sophistication to implement properly, but as competition increases it becomes a necessity of doing business. The ability to accurately track production rates opens up opportunities for "continuous improvement."

Prefabrication

Another aspect of mechanical construction that lends itself very well to improving the quality of the finished product is to prefabricate as much as possible. Seek out prefab opportunities in repetitious tasks such as piping hook up assemblies to pumps, AHUs, VAV boxes or process piping jobs where dimensioned isometric drawings are available. Obvious productivity gains are made by fabricating on the ground in a controlled shop environment rather than performing this work in position in the field. Prefabrication helps tight schedules because shop and field activities can progress in parallel simultaneously. Quality improvements also are evidenced when every assembly is the same, made in "mass production" fashion, rather than each being unique. The sophisticated contractor will use a control system that can identify and track material orders, receipt, fabrication progress, labor costs and delivery status. Usually higher wage scale field construction manhours can be reduced. Approaching the project on a system by system basis naturally lends itself to prefabricating similar components.

Learning from the O&M Experience

Typically, those involved with the construction of a facility move on to another project shortly after turnover. They never have the benefit of witnessing the completed facility in operation or debugging its systems so mistakes are repeated on the next job. Likewise when construction personnel leave at completion, operation and maintenance personnel lose a very important historical information source. On numerous occasions operational problems show up when a system is first started up during construction. Modifications may be made that temporarily correct or mask the problem. However, six months later it reoccurs and this time its correction is much more significant in terms of cost and time as the facility is now occupied by the owner.

A. Cover Page and Approval Signatures
B. System Description
C. Punchlist
D. Quality Control Documents
E. Testing/Inspection Documents
F. Start-up/Commissioning Documents
G. Training Documents
H. Signed Off Final Punchlist/Approved Final Acceptance Document
I. Other

Figure 3. Turnover package table of contents.

The Project Management Team (PMT) is usually very anxious to have the owner's maintenance personnel administer warranty claims. It is important to have key PMT personnel involved with these problems because they usually are familiar with the responsible parties and can often expedite the process. Likewise it is an invaluable experience for a construction engineer to be a part of the day to day operation of a completed facility if only for a short time. In doing so, the company is investing in preventing future errors thereby improving future facilities.

Variability - The Virus of Systems

Consider the following example which illustrates how variability can "infect" a system. The "symptom" is a mechanical failure, but the cause is a variability "virus" that "infected" production at the source supplier. A company purchases castings from a foundry and passes these castings through a sequence of machining processes. The materials purchased by the foundry are not perfectly uniform. There is always some variability in the composition and treatment of the materials. The processes in the foundry itself are not always the same. It could be said that the processes are infected with variability. They yield castings which vary in composition, dimension, hardness and porosity. The variations occur not only from casting to casting, but even within one casting. Hardness and porosity vary from point to point and part to part.

When these castings arrive at a machine tool to be scraped and cut by various tools, their variability infects the machine tools. The variation in hardness causes non-uniform tool wear. It also makes it difficult for the machinist to know at what speeds and feeds to set the controls. The tool wear is not

A. Testing/Cleaning Procedures

1. Hydrostatic Test Procedure
2. Pneumatic Test Procedure
3. Gravity Test Procedure
4. Duct Air Leakage Test Procedure
5. Water Flushing Procedure
6. Air Flushing Procedure
7. Steam Flushing Procedure
8. Chemical Cleaning Procedure
9. Disinfecting Procedure
10. DOP Test Procedure
11. Vibration Test Procedure
12. Air and Water Balance Test Procedure

B. Startup Checklists

1. Rotating Equipment Alignment Checklist
2. Motor Checklist
3. Fan and Blower Checklist
4. AHU Checklist
5. Centrifugal Pump Checklist
6. Air Compressor Checklist
7. Vessel Internals Checklist

Figure 4. Testing and start-up.

CONSTRUCTION QUALITY CONTROL MANUAL

FORM P-CQ-7.8

WATER FLUSHING REPORT	
BUILDING/PROJECT NAME:	REPORT LOG NUMBER:
BUILDING NUMBER:	TURNOVER PACKAGE NUMBER:
TRADE CONTRACTOR:	SYSTEM:
DATE OF PROCEDURE:	TIME OF PROCEDURE:
BOUNDARY DESCRIPTION: (ATTACH MARKED UP DRAWINGS)	APPLICABLE FLUSHING SPECIFICATIONS:
FLUSHING MEDIUM:	
SPECIAL CONDITIONS:	
FLUSHING DATA:	
1. START/END TIME	
2. ALL STRAINERS CLEANED	
TEST RESULTS: (EXPLAIN ANY REJECTS)	

SUBMITTED BY:				
	COMPANY	PRINT NAME	SIGNATURE	DATE
INSPECTOR				
ACCEPTED BY:				
REPRESENTATIVE	COMPANY	PRINT NAME	SIGNATURE	DATE
TRADE CONTRACTOR				
CM/ GC				
OWNER				

Figure 5. Typical sign-off form.

predictable. Machine maintenance is not predictable either. Thus the infection spreads to the tool room where a larger inventory is carried than would be needed if the life of tools could be predicted accurately. Inventories are now subject to wider variations. The ability to predict the requirements for maintenance increases the number of people who need to be hired for maintenance and complicates the maintenance process.[1] The net result is the price of the product is forced up and its reliability is reduced.

What happens when this casting, in this case an inline process strainer, finally arrives at the construction-site? Its arrival was delayed because it had to be backordered due to inventory problems at the distributor. Because of this delay, it could not be shipped with the rest of the order, but had to be sent separately at an extra charge. In arriving late to the job, it required special handling to be installed. Late arrival of the strainer caused delay to the hydrotest and cleaning of the system. Three months after being placed in service, the strainer developed a leak due to porosity in the casting. Its replacement caused a system shutdown and the loss of several thousand dollars in product. Overtime wages had to be paid to workers and the production schedule was devastated. The mechanical contractor received a warranty claim from the owner and numerous meetings involving dozens of people were held on and off-site to resolve the costs involved with the failure.

The point is that variability can "infect" a system and cause problems just the same way that germs can infect a person and cause disease. The project is at the mercy of its suppliers to provide quality goods. The carry over effects of installing defective materials can be extremely costly. Early in the chain of events had the material supplier to the foundry and the foundry itself endeavored to "get it right the first time," many problems would have been avoided. The key is early prevention and intervention. The aforementioned onsite quality programs of periodic inspection and testing go a long way to identify and correct the majority of construction related problems before they become critical after occupancy.

TQM

Many of the topics that have been discussed for improving quality and productivity fall under the umbrella of total quality management (TQM). TQM is probably one of the best understood change mechanisms and one of the best options to confront the competitiveness challenge for the engineering and construction industry. A fundamental principle of TQM is "continuous improvement." Continuous improvement involves focusing on processes within a system to ascertain how they can be changed to be more efficient. The change, to be verifiable, must be measurable. This is accomplished by the use of "metrics," measurable outcomes that indicate degree of success in achieving some TQM objective. To determine the degree of success, however, the measured level of success must be compared to something. The procedure of determining the value of metrics that process measurements are compared against is known as benchmarking. This idea is similar to the previously described practice of early inspection of completed typical assemblies.

Internal benchmarking involves measuring similar work processes across the company and determining which practices within the organization perform the best. External benchmarking requires examination of processes outside the company and can be broken into two subcategories: noncompetitive and competitive. Noncompetitive benchmarking refers to comparing the work processes of companies in an entirely different industry. Competitive benchmarking entails measuring oneself against one's toughest direct competitors.

There currently is a lack of benchmarking standards for the construction industry in general (and pharmaceutical construction in particular). The Houston Business Roundtable has started to collect data which indicates a tendency within the construction industry to overestimate total costs by 8 percent and underestimate schedule by 8 percent, while change orders average $\pm$11 percent.[2] Needless to say there are large opportunities available for collecting data and determining trends in the pharmaceutical mechanical construction field.

Likewise it is difficult to analyze the cost and schedule impact of any construction quality improvement program. Construction projects are by their nature unique and do not lend themselves to easy comparisons. The framework and methodology for data collection often takes the form of a questionnaire distributed at the end of a project. With judgment, small projects can simplify and incorporate key quality programs that are successfully utilized on larger jobs.

Conclusion

Many important elements must come together for a project to be successful. Because of its complex nature, pharmaceutical construction is especially challenging. Approaching the project on a system by system basis has proven to be an effective method of organizing construction and turnover activities. The onsite quality program must inspect and approve installations early and thereby prevent repetitive mistakes. A sequential record of quality inspections and tests, categorized by system, will document construction activities for those who follow. Continuously improving practices through attention to detail, better materials management, prefabrication, user feedback and focusing on reducing variability will allow future savings in time and cost.

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