

836 North Street, Building 300, Suite 3201 Tewksbury, MA 01876 (866) 773-2364 sales@spec-eng.com -- www.spec-eng.com Process Engineering
Facility Design
Construction

# SPEC Process Engineering & Construction, Inc.

- Company Overview
- Primary Services
- Individual Services
- Project Approach
- Project Management Approach
- Process Automation Approach



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#### INTRODUCTION

The simplest way to describe SPEC Process Engineering and Construction (SPEC) is that we are "engineers who build." For most of our clients, we handle the entire project, from preliminary budgeting and project planning through construction. For many projects we are also able to assist with project financing. Our unique approach to design/build has the benefits of keeping project costs down while keeping project efficiency and quality high. Our company is sharply focused on manufacturing and product development related facilities for fine chemical and pharmaceutical companies. Our entire team is specifically oriented to the delivery of this type of project from the specification of process equipment to the navigation of regulatory hurdles imposed by the FDA, environmental agencies and local authorities. We also like to offer options for our clients. At the client's request we can supply an individual project component such as process engineering, project management or cGMP consulting. But even when we only supply a component of a project, the client gains from our construction oriented approach. With SPEC, you get realistic, practical service based on engineering knowledge combined with street-wise construction experience. But what makes our approach different? There are several points:

We are truly an integrated firm. All of our design engineers, process engineers, construction/project managers and controls staff are under the same roof.

The person managing the construction will be an engineer with construction experience - not just a construction person. For most technically and regulatory driven projects, this can make a tremendous positive difference in the quality of the final project.

We guarantee what it will cost up-front. Our goal is to lock a budget in, before detailed design begins. We can typically achieve this with only 2% to 5% of the project budget expended.

We take the risk. We not only guarantee the price, but we are responsible for all aspects of the project right down to the ordering of the equipment.

Our focus is to undertake modestly sized projects. Our projects rarely exceed \$25 million in total project cost, with a more common range being \$100,000 to \$15 million.

To really understand SPEC, you need to understand our approach to projects. The best way we have found to insure a successful project is to have a well thought out approach to the project, the project management and validation.



# DESIGN/BUILD MANUFACTURING

#### **Turnkey Delivery**

Whether you are constructing a new facility or renovating an existing one, SPEC can perform all the necessary services to design and construct your new plant. As a design/builder, we maintain a staff of skilled engineers in the critical disciplines of process, mechanical, electrical and controls engineering as well as manufacturing oriented architects. To complete your project, SPEC also employs construction project managers and our own field superintendents. Your project will be executed from site selection, through design and construction, to the final punch out.



#### **Upgrades and Maintenance**

If you need less comprehensive upgrade or maintenance services, SPEC can supply the same level of expertise and management to your project. We are skilled at conducting projects with minimal interference to existing operations. We can supply our tested turnkey methods to safety upgrades, maintenance operations, new equipment installations, controls upgrades and code compliance work.

#### **Process Scale Up**

Taking a product out of development and into manufacturing is a difficult process that involves numerous decisions and trials. Similarly, increasing the efficiencies or improving an existing manufacturing process offers some of the same challenges, with the added problem of continuing to fulfill regulatory and customer requirements. SPEC can help in both of these circumstances. We have experience in working with your scientists and technical staff to help them work out the problems as your manufacturing process develops or changes. SPEC can then apply practical solutions that get you up and running quickly with minimal trial and error and the smallest possible budget.

# **DESIGN/BUILD LABORATORY**

#### **Turnkey Delivery**

When a product is in development, it is advisable to build a laboratory that will allow full flexibility to take that product through a commercial launch. Careful attention must be paid to workspaces, utilities and expansion possibilities. SPEC is experienced in developing a laboratory strategy that will provide the most efficiency and flexibility when you are in a product development cycle. We are fully knowledgeable about the problems you will face during process development and scale up and can help your company set the stage to minimize those issues.

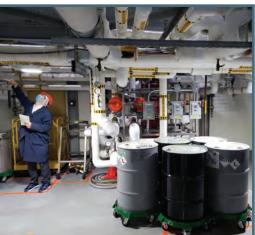




# In addition to our primary services, SPEC offers development and manufacturing companies a wide variety of support services on a smaller scale. These services include:

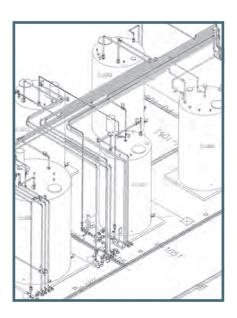
- As-built Documentation
- Facilities Piping
- Hazard Analysis
- P&ID and PFD Development
- Process and Utility Piping
- Process Development, Control, and Improvement
- Mass and Energy Balance
- Particulate Control Systems
- Instrument Selection/Procurement/Calibration/Installation
- Electrical Classification
- UPS/Generator Engineering & Installation
- Electrical Fault Studies
- Intrinsically Safe Instrumentation System Design
- Instrument Network Design & Installation (profibus, ethernet, modbus, foundation fieldbus, ASI)
- HVAC System Analysis, Design and Upgrades
- Boiler Analysis, Design and Upgrades
- Correction of Chronic HVAC Problems
- Building Automation/Energy Management System Analysis, Upgrade or Replacement
- Energy Cost Reduction, Analysis and Implementation
- HVAC System Master Planning
- Owner's Representative in Contracting with Energy Service Contractors (ESCO)
- Due Diligence Reports
- Peer Review/Second Opinion
- Hazardous Area Classification
- Hazardous Chemical Storage Regulations











The SPEC approach follows a design/build model, with some modifications to overcome the deficiencies in a typical design/build project as practiced by others in the construction industry. The following is an overview of our approach to a typical manufacturing project for a process-based company.

#### OBTAINING A DESIGN/BUILD PROPOSAL

The first step in any design/build project for SPEC is the development of a design/build proposal for the entire project. This is done by developing the scope of work in conjunction with the owner and using that preliminary design with selected sub-contractors to develop a preliminary document set and budget.

During this initial phase, SPEC works to understand the client's standards and if applicable, the existing facility. Complete knowledge of standards and existing conditions expedites the design of similar systems, and highlights shortcomings, if any, of the existing installation. Once the scope is fully developed, a schedule is compiled and all information is reviewed with the client.

The client's standards and the project scope become the design basis for the project. This design basis is key to defining the detailed engineering scope including the list of drawings and specifications which will be completed during detailed design.

## **DETAILED ENGINEERING**

After a design/build contract has been negotiated, the detailed design effort begins. SPEC typically divides projects into two "tracks", with one group focused on the development of P&ID's and the process equipment and the second group completing engineering of the mechanical, electrical and architectural details. Design documents are only completed to a level of detail required to facilitate the bidding process.

During the bidding process, it is very possible that potential subcontractors will suggest improvements in the design that will reduce cost or enhance the quality of the project. The drawings are then brought to a further level of detail incorporating these suggestions from the subcontractors where appropriate. This results in a project that is well designed, efficient and constructable.

SPEC is standardized on AutoCAD. SPEC believes strongly in CAD, and we require all our engineers to work in the CAD environment. Additional design programs for piping, instrumentation, and electrical design are also utilized, based on the level of design documentation required.



#### BUYING OUT THE PROJECT

Most projects will require a variety of construction trades such as:

- Mechanical (process piping, HVAC, plumbing & fire protection)
- Electrical (power and instrumentation)
- Steel (decking and equipment supports)
- Concrete foundations and housekeeping pads etc.
- Architectural (exterior & interior trades)
- Controls & instrumentation

Using the design documents, a written scope of work and specifications for different aspects of the project, each of the above trades are bid and the results presented to the client for review. Each bid will be compared to the original budget for the project, and final selection of subcontractors made in consultation with the client. SPEC will hold all contracts for the client, but the client will always fully participate in the selection process.

SPEC will prepare specifications for all equipment involved in the project, and where appropriate, will obtain competitive bids for this equipment. Bid information would also be presented to the client to allow a coordinated selection of the best equipment suppliers. SPEC will prepare all purchase orders for equipment and manage the expediting process as part of the overall contract.

In addition to purchasing major process equipment, SPEC believes that the process automation component of the project is crucial to a successful startup. Therefore, SPEC has developed their own automation group to provide the detailed design, programming, and startup services directly. Because the automation engineers are intimately involved with the client right from the scope definition phase of the project, instead of just starting at the end of the buy-out phase, the time for startup is significantly reduced.

## CONSTRUCTION

The key to successful construction is the coordination of the subcontractors on the site. SPEC's project manager also performs the construction management role during this portion of the project. Day to day site management is typically handled by a Site Superintendent who will work hand in hand with the project manager for the duration of the project. Larger projects may sometimes require multiple Site Superintendents to focus on different aspects of the construction.

This professional team will also be responsible for orchestrating the many meetings that help keep a construction project on track - from the daily meetings with the subcontractors to weekly meetings with the owner for updates on budget and schedule.



## VALIDATION AND TESTING

Even though validation is after construction on this list, the validation effort actually begins when the project begins. During the design phase, SPEC will work with the owner and their third party validation consultant to identify all crucial areas of validation and determine with the client what systems and equipment need to be validated and what level of documentation will be developed. Please see the validation section that follows for further information on validation procedures.

#### SAFETY

The safety and well-being of SPEC Process Engineering & Construction's employees, subcontractors and clients has always been our highest priority. We have experienced an excellent safety record throughout our history and have a consistently favorable Experience Modification Rating (EMR). Our commitment to safety is reinforced by our Vice President of Construction who is a certified OSHA instructor that makes regular visits to all of our job sites to ensure that SPEC's strict safety policies and procedures are being enforced. In addition, all of our field personnel have completed OSHA 30-hour training.

SPEC has a comprehensive, ISN approved safety program in place to ensure compliance throughout the company and we continue to grow our safety culture. This program includes:

- Conducting Site-Specific Job Safety Analysis Tracked to Ensure Compliance.
- Regularly Held Tool Box Talks.
- Jobsite Visits and Inspections by our Vice President of Construction and Project Managers.
- 100% Personal Protective Equipment (PPE) Requirement on All Jobsites for All SPEC Personnel and Subcontractors That Includes: Hard Hats, Safety Glasses, Cut-Resistant Gloves, Steel-Toe Boots, Hearing Protection and Proper Clothing.
- Continual Safety Training for All SPEC Personnel.







A well-planned project approach needs strong project management to actually make it work. Without experienced project management and solid project management tools, the many issues and decisions that are presented during a project can simply not be handled in the appropriate way. Good project management has its highest impact on the project in two areas: scheduling and cost control.

#### PROJECT MANAGEMENT - SCHEDULING

For manufacturing facilities, scheduling revolves around three key aspects of the project:

- Design
- Process equipment
- Contract packages

As a true design/build firm, SPEC starts each project by defining the project's goals with the owner from a cost and schedule point of view. This allows us to formulate a milestone schedule working backward from the required facility completion date. Some of the expected schedule items for a typical project include:

- Client process validation
- Client engineering runs
- Completion of OQ's and PQ's
- Completion of punch list
- Contractor submittals
- · Contract package release, bid and award
- Design from concept to approval to release for bids

During the milestone scheduling review, key scheduling impacts are identified and examined for their effect on design. In the design/build method which SPEC utilizes, these impacts are explored up front and a design basis is selected to meet the overall project goals of schedule, cost, and functionality. In this way, SPEC, in conjunction with the owner, is able to flag key decisions very early and address them to avoid redesign and scheduling impacts later in the project.

Weekly in-house project coordination meetings are held with the owner and all involved design disciplines. This meeting functions as a clearing house for the latest design developments as well as a project management tool for identifying and resolving design issues and conflicts.

Every issue identified is assigned a meeting number, which is carried in the meeting minutes, until the issue is resolved. Design drawing progress is tracked via a drawing control index which monitors design progress versus the schedule of release for bids.

Within the SPEC design schedule exists a parallel effort regarding all process equipment. Key facility equipment items are tracked from the initial data sheet through approval, bid, award, submittals, inspection, and receipt at the job site. SPEC tracks this data on our equipment



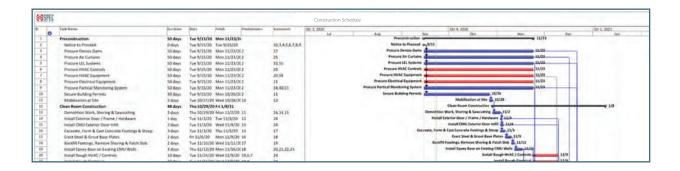
control index, which indicates both the scheduled and actual dates for each phase for every single piece of equipment. This project management tool is critical in identifying items for expediting or special attention at the weekly coordination meeting. On fast track projects, the schedule frequently drives the design process as well as equipment selection, both of which are best served by a design/build approach to project delivery. Examples include:

- Early foundation release to avoid winter construction
- Exterior construction selected to support building enclosure prior to winter
- Selection of packaged HVAC units versus separate sections (indirect gas fired heating, air handling, and cooling)
- Selective use of used equipment
- Single sourcing for early award on selected equipment
- Start automation program prior to final design completion

Prior to completion of design, SPEC's project manager in conjunction with the construction superintendent, formulate the scope of work for each construction contract package. This is reviewed with the design disciplines for completeness, as well as exceptions and issues, which must be clarified to the bidders. In this way, SPEC ensures the quality of the bid package prior to release, thereby avoiding confusion, delays, and additional costs in the bid cycle.

Scheduling compliance is insured via weekly construction coordination meetings. After award of the various bid packages, the project manager tracks each contractor's submittals, deliveries, and installation progress against the master project schedule. Expediting of submittals, inspection of equipment at the factory, and vendor shop visits are utilized as means of insuring on-time delivery as well as adherence to project specifications.

Involvement of the appropriate design engineer is maximized in order to expedite the receipt and approval of submittals, as well as to clarify issues which arise during construction. The expeditious return of submittals and fast response on contractor questions (RFI's - Request for Information) is assured by SPEC's design/build approach. All our personnel are committed to the final project result and are not tied solely to design, construction or controls.





## PROJECT MANAGEMENT - COST CONTROL

Cost control is most effective when it is focused on three critical areas:

- Assuring that the original design represents the least possible expenditure to meet the owner's operational and quality goals.
- Eliminating "scope creep" so that the project scope does not expand beyond it's agreed upon intent during the construction phase.
- Eliminating inefficiencies and excess overheads commonly found in technically and regulatory driven projects.

All of SPEC's clients have fixed budgets for their projects, and most budgets these days are tight. The SPEC approach is to work very hard to design and build a facility that meets the budget but also meets our client's expectations while meeting regulatory requirements. While we have not discovered a "scientific method" for doing this, we feel that we have developed an organization that thinks and acts this way.

Many of our staff are from the owner's side of the table and have had hands-on operating experience. Our people care directly about the budget and are not tied to standard engineering solutions.

Eliminating "scope creep" during construction can be a little more scientific because various control mechanisms are put in place. SPEC uses recognized change order procedures and weekly job cost reporting so that the owner and the project team are always aware of current project costs as well as where they are heading.

However, we have found that we have to go beyond these standard management tools to effectively control project scope. One way we do this is to involve the trades (Mechanical, Piping, Electrical, etc.) early in the design process. By involving these professionals, current market prices are made available to the design team allowing them to avoid costly designdecisions.

We also find that requiring our engineers to have regular involvement on the site helps eliminate scope growth. When a request for additional work comes from someone on the owner's team, there is someone on site who can quickly assess the request, estimate a budget for it, and many times find alternative means of meeting the request.

The last area of cost control for SPEC is one that is built into our very structure. By having a vertically integrated team we can avoid two common cost drivers - overhead and inefficiency. Many of our people perform double duty. For example, site superintendents will commonly assist in commissioning & turnover. Secondly, since many of our engineers will not only design but also be responsible for building a project, there is very little time (i.e. money) lost in translating the project design to the people actually doing the construction work.



Typical examples of the project tools, which SPEC uses to control costs, are listed below:

- The design/build contract budget indicates the contract budgets by account line, which are then tracked from bid to placement to contract completion.
- The bid tabulation, which evaluates the technical offering as well as the vendors/subcontrac tors schedule and budget compliance. Client sign-off is required by SPEC on all bid tabula tions.
- The contract change order which is used to document scope additions as well as all shifts of money from the contingency account. Again SPEC requires client sign-off on all change orders.











## PRELIMINARY DESIGN PHASE

SPEC automation engineers get involved in the project during the initial design and scope definition phase. How the plant is supposed to operate is as important as how it is constructed, so preliminary functional specifications for plant automation are developed in the preliminary design phase of the project. The I/O count, instrumentation standards, operator interface requirements, and the recipe and data collection philosophy are defined up front so a qualified price estimate can be developed. This is in contrast to the traditional engineering/bid methods of construction which leave the real fixed costs of the process automation budget to the later bidding phase.

# **DETAILED DESIGN PHASE**

During the design phase, the control panels are designed and detailed program functional specifications are developed. Due to the fast track of SPEC projects, automation programs are developed in house as soon as the specifications are completed and approved. SPEC has a team of experienced engineers to program a variety of automation platforms, PLC, DCS, and computer based control systems.

#### **CONSTRUCTION PHASE**

During the construction phase, SPEC automation engineers purchase instruments and automated valves. They are inspected individually by the purchasing engineer prior to release of the item to the installing contractor. SPEC's automation engineers then provide field supervision, answer RFI's and provide general assistance to the overall SPEC field superintendent as well as the instrument installers, electricians, and calibration technicians.

# **S**TARTUP

After mechanical completion, SPEC automation engineers work closely with the process engineers to start up each automated process and execute detailed site acceptance testing procedures.

# LONG-TERM SUPPORT

Through on-site assistance and use of remote access communications, SPEC can provide services for system upgrades, troubleshooting, and periodic backup of control system computers.

