

# Pharmaceutical automation project management



## FAST FORWARD

- In pharmaceutical automation projects, define and fix your requirements.
- Have a robust plan, obtain management support, and maintain the discipline to execute the plan.
- Too little testing during the development process will result in missed mistakes during application coding.

By Dave Adler

**D**id you ever wonder why it is so difficult to have a successful pharmaceutical automation project? My definition of success is measured by achieving the schedule milestones, meeting the cost estimate, satisfying the system automation requirements, having the automation system work from day one, and satisfying the facility's business leaders. To satisfy all of these measures is almost impossible. Pharmaceutical automation is tough, but when successful, it is very rewarding.

Numerous studies of software projects have found success rates of less than 20%, where success was defined as achieving schedule, meeting cost estimates, and satisfying requirements. Automation professionals who find project success challenging have lots of company. There are many ways to do

automation projects poorly, but just a few ways to do them correctly.

I recently conducted research on pharmaceutical automation technology, costs, and benefits for 24 facilities of 16 member companies of the Pharmaceutical Automation Roundtable (PAR). This study analyzed the relative automation cost per input and output device (I/O). The costs per I/O varied greater than a factor of three from the least expensive to the most expensive automation system. The wide variance in automation cost per I/O in the study indicates the opportunity exists to optimize the business processes to manage automation projects.

Pharmaceutical companies have developed a rigorous methodology for automation systems. The industry uses a life-cycle model known as computer

# Automation is a risky endeavor—improve your odds with planning, requirements, testing, and documentation

system validation to ensure the automation system does what it is supposed to do and can be expected to continue doing so in the future. Before I lose my non-pharmaceutical industry readers, this is just a fancy way of saying automation professionals need to:

1. Do upfront planning.
2. Define requirements for the automation system.
3. Test the automation system.
4. Document the technical content.

I hope every automation professional does each of these activities on every project, but of course not to the level of the pharmaceutical industry.

The pharmaceutical industry is regulated by the U.S. Food and Drug Administration (FDA) and the international Ministry of Health. These regulations apply to the manufacturing of drugs and medical devices including the use of computers to manufacture these products. In 1983, the FDA published its first guide to computer system validation. Since then, the industry's automation professionals have developed the business processes to support a cradle to grave life-cycle approach to automation. The industry has had a lot of opportunity over the years to use business processes to support the delivery of automation. An industry trade group, International Society of Pharmaceutical Engineers has produced a reference guide to Good Automation Manufacturing Practice that highlights one approach widely adopted.

I have been involved with more than 20 major pharmaceutical automation projects in my career, so I have had the opportunity to be on many critical and even a few troubled automation projects. I have learned many painful lessons and now have many stories to tell. These lessons are applicable to an automation professional in any industry. Your chances of having a successful automation project can be greatly increased by using appropriate planning, requirements, coding, testing, and documentation practices.

## Planning can be guide to success

Step one in improving your odds of a successful automation project is developing a plan and getting all the key stakeholders to buy into your approach. I hope by now I have convinced you how difficult it is to have a successful automation project. A structured approach, starting with a plan, can increase your odds of success.

An automation plan at a high level defines: the project drivers, the scope of work, the automation system's desired functionality, the operational strategy, the safety expectations, the maintenance strategy, the schedule, and the cost estimate. In the pharmaceutical industry, there is a regulatory requirement to have a validation master plan. An automation validation master plan defines at a high level the expectations for quality, requirements, testing, documentation, review, and approval. It would also cover expectations for security, change control, contingency planning, and periodic reviews.

There are a number of guides available to help organize a plan. Business processes are available for project managers such as those documented by the Project Management Institute that have been used by automation professionals for our discipline. Guides are available for scoping and estimating automation projects from the author.

During the initial planning of a proposed automation upgrade project, controlling cost was identified as the number one issue with getting approval. The initial proposal by the facility planning group was rejected by the management team based on the cost of other recent upgrade projects. The automation team was asked to significantly reduce the estimated cost for the proposed project. The planning effort required the automation team to think outside the box. None of the existing automation business processes were immune from review. The planning process took several months. A plan was developed that reduced the proposed automation estimate by 25%. This cost reduction was

due to changes in the business process and not the overall scope of the work (e.g., fewer control loops). Highlights of the planning process were to:

1. Choose experienced handpicked automation professionals.
2. Dedicate automation staff with no other responsibilities.
3. Co-locate all automation staff in one room.
4. Ensure tech service, process engineers, and operations personnel availability when needed.
5. Define roles and responsibilities.
6. Develop a prototype for the entire software development process.
7. Replicate from previous projects.
8. Have well-defined scope and fixed requirements.
9. Create a "just say no" list of cost enhancers.

The facilities business leaders agreed and bought into this plan because they wanted the lower cost. The automation upgrade project was approved. I will skip forward several months as this project was recently completed. The automation project actually pleased the facility's business leaders. The software and hardware worked flawlessly during start-up, the project was completed on schedule, and the final automation project cost was 20% less than the revised project plan estimate. If you have a robust plan, obtain management support, and maintain the discipline to execute the plan, you can achieve your targets.

## Define, fix your requirements

You must accurately define your automation project requirements with the help of the users of the automation system. The requirements should be measurable and testable. They need to identify the business, equipment, and process needs. Define the requirements before you start the design, and get the key stakeholders to agree to them. Communicate broadly these requirements. You need to keep the requirements fixed during the course of the project design,

implementation, and through start-up. If you can minimize scope creep, you have removed a major hurdle to automation project success. Scope creep can result in changes and additions to requirements that can greatly lengthen and increase the cost of the project.

One of my early failures was a major pharmaceutical plant upgrade in the early 1990s that was a fast track project. It looked like we would not make enough material to launch this projected blockbuster product. The project manager and manufacturing executives wanted automation to get started and get off the critical path of the overall project. The automation team felt a lot of pressure to get started. We started ordering instruments without piping and instrument drawings. We started writing automation application code without agreed to valid

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requirements. In fact, we were still arguing about requirements during start-up. Not surprisingly, this project went poorly, and start-up did not go well. Cost estimates were missed, and schedule milestones were not met. Product was not made on time. This story does not have a happy ending. Even though it was not a good experience for me, I learned some valuable lessons.

Later in my career, in the mid 2000s, I was again assigned to a fast-track pharmaceutical upgrade project. The business drivers mandated a compressed schedule. The project manager and manufacturing executives wanted automation to get started and get off the critical path of the overall project. The automation team felt a lot of pressure to get started. However, we refused to write code and order instruments until we had requirements and piping and instrument drawings. Of course, I was getting worried looks and phone calls from everyone in management. We took two months to define requirements and locked in the piping and instrument drawings before we started writing code and ordering instruments. I will make a long and grueling story short and jump to the end of the story: Automation was

done on schedule and on budget, and it worked well. We had a successful start-up, and within six months, automation facilitated some dramatic improvements in the operations of the facility. It does pay to plan your project and get the requirements right before you start your work.

### Testing reduces start-up issues

If a developer does too little testing during the development process, there will be mistakes in the process control application code. The software will then have to be debugged later in the development process or during start-up of the manufacturing equipment in the facility. It is significantly more costly to debug software during start-up than during the development process. The sooner a developer catches a mistake, the cheaper it

is to fix. Appropriate testing can reduce overall project cost and minimize rework during start-up. Of course, inappropriate testing will increase cost and lengthen the development time.

Testing determines if the automation system meets the previously defined requirements. The success of testing depends, in part, on good requirements. If a process automation professional has solid and fixed requirements, it is much easier testing.

The development process consists of testing the software at each stage of the process. The testing starts with the individual software module, and then the units should be individually tested. This module and unit testing uses “test scripts” that test small portions of the whole system software. It is important to define test scripts so the observed results are clear and concise. This testing is frequently conducted in an off-line or development system.

Once all the individual units have been tested, the overall system is tested as a whole. A portion of this may be achieved as a Factory Acceptance Test, or FAT. Final testing in the pharmaceutical industry is often defined as on-site acceptance testing and includes installation qualifica-

tion, operation qualification, and performance qualification.

During a recent retrofit project, it was critical to minimize the time the facility was down. The facility was producing a life-saving medicine. The needed production output would not allow for an extended downtime. This retrofit required software and hardware changes to replace an existing obsolete automation system, including its I/O with a new automation system. This led to significant off-line testing of the automation software. In addition, a plan was developed to optimize hardware changeover. Off-line testing of the hardware was desired. An I/O room was built of plywood and plastic sheets to simulate the hardware changeover process. This room was a full-scale mock-up of the actual I/O room including the elevated floors. It allowed training of the electricians and trial runs of wiring efforts. The electricians practiced disassembly of the old I/O system and reassembly of the new I/O system. It allowed optimization of the number and activities of the electricians, pre-labeling terminations, fabrication of panels, and even allowed some pre-cut wire to be made up to exact lengths. This reduced the wiring effort during construction by over 75%. The actual hardware change-out took days rather than the normal weeks to change out a large I/O system. The most surprising outcome was the project actually was less expensive than planned because start-up went so well with almost no hardware and software issues. Even with the extra testing expense, this project was less expensive overall than other retrofit projects being done at the same time.

### Long-term viability

Documentation is critical to the success of an automation project. If the development team does too little, the long-term support team will have a difficult time and exert additional effort to maintain the automation system. If the development team does too much, the project could be delayed and experience cost overruns.

When I first started in process automation in the early 1980s, I learned a painful lesson. On one of my first projects, I did the minimum level of documentation. It resulted in frequent phone calls from me

to explain to my replacement what the design or software was doing. Since the new engineer could not figure out what I did, I clearly had not documented the automation system well. In future projects, I spent a lot more time and effort to document as I designed and coded the automation applications.

By the late 1980s, the pharmaceutical industry was implementing computer system validation. One of the unique features of the pharmaceutical industry is the actual medicine you take sometimes cannot be completely tested. A sampling of medicine from each batch is tested, but the testing itself often destroys the product. Obviously the pill that the patient takes cannot undergo a destructive test. This has led to a business process to ensure quality called *validation*. Quality has to be built into the process of manufacturing the product and the software to control the equipment. Quality cannot be tested into a product, but it must be built into the process for making the product. Industries' response to build quality into the manufacturing process resulted in progressively more rigorous and larger computer system validation documentation packages on pharmaceutical projects. By the early 2000s, automation projects were being implemented with only 10% of the effort on design and coding, but 90% of the effort on testing and producing documentation.

By the mid 2000s, the pharmaceutical industry was taking a look at using a more appropriate level of documentation. Numerous FDA investigators made comments that it was not the thickness of the documentation that was important, but rather the business value of the

documentation. The FDA encouraged industry to take a critical look at its business processes to ensure cost-effective drugs for its patients. Concepts such as using a "risk-based" approach to the overall validation process and the use of in-line quality measurements through Process Analytic Technology were initiated. This openness by the regulators to change resulted in the automation discipline taking a critical look at all its business processes including documentation.

Before the start of a major project in 2006, the level of documentation was identified as important to a cost-effective and on-schedule project. The area's management team set up an improvement team to study the computer system validation process. It defined the problem, measured the process, analyzed the data, improved the process, and set up a control system to manage the new process. The process completely prototyped the workflows and insured they functioned as intended. The process revised policies and procedures appropriately. Specific examples of improvements were using checklists instead of detailed narratives to aid in document assembly and preparation, smaller test scripts, minimizing the process to fix script errors, reducing the number of reviewers and approvers, shorter targeted QC reviews, moving to an electronic document management system from a paper system, and reducing the level of documents to support unit level testing with more focus on system level testing documentation. These efforts reduced the total level of effort on documentation by 50%, but more importantly, it produced more useful content for the long-term system

support and the future optimization of the manufacturing process.

### The details do matter

Contrary to a prevalent management myth that claims you do not need to worry about the details, in pharmaceutical automation projects, it is the details that really matter. If you do not worry about the details, your project will not be successful. When you work on a project you need to sweat the details including: doing upfront planning, having well defined and fixed requirements, conducting testing, and documenting the appropriate technical content.

### ABOUT THE AUTHOR

**Dave Adler** ([davidadler@comcast.net](mailto:davidadler@comcast.net)) is an automation consultant with Brillig Systems. His interests are managing automation projects and programs, developing automation strategies, developing & training automation professionals, and educating business leaders on the life-cycle cost and benefits of automation. He spent 33 years at Eli Lilly and Company in a wide variety of automation assignments. He is also currently leading ISA's workforce development efforts.

View the online version at [www.isa.org/intech/20100401](http://www.isa.org/intech/20100401).

### RESOURCES

***Automation Applications in Bio-Pharmaceuticals, ISA, 2008***

[www.isa.org/link/AABP\\_bk](http://www.isa.org/link/AABP_bk)

***A Guide to the Project Management Body of Knowledge***

[www.isa.org/link/PMBOK\\_bk](http://www.isa.org/link/PMBOK_bk)

***Bridging batch gap in pharma***

[www.isa.org/link/Standards\\_sept07](http://www.isa.org/link/Standards_sept07)

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