Pharmaceutical MANUFACTURING

Vertical Slicing for Customer Acceptance Tests

USING A "VERTICAL" APPROACH TO COMPLEX CAT PROJECTS ENSURES FEWER HEADACHES WITH A HIGHER DEGREE OF CERTAINTY.

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THIS ARTICLE describes an approach for executing a process automation project during the customer acceptance stage, where the automation supplier faces the challenge of delivering a system that not only meets the contractual requirements of a project, but also the expectations of the customer.

Virtual organizations are a fact of today's drug industry. In the automation world, it's not unusual to have multiple engineering teams or even different world areas working on a large project—there might be 50 engineers in India, 50 in Scotland, and a team in the Philippines. Unfortunately, there may be "creativity" and inconsistency among those groups which must be addressed. Oftentimes, especially for Life Science projects, there's a rush to execute a project, which may cause automation vendors and/or integrators to bring more people on board, exacerbating the problem.

For such projects, it's best to use ISA88 (aka S88) as the standard so everyone involved is using the same terminology, and is organized to act in concert. ISA88 provides an overlay to break the project into chunks. Having a single standard as opposed to overall vague standards helps the project team execute the rest of the units faster. While it's not intuitive to take this approach, it makes sense, especially given diverse and different engineering groups, and different world areas. There must be clear communication among those groups and clear expectations for the customer, the drug manufacturer.

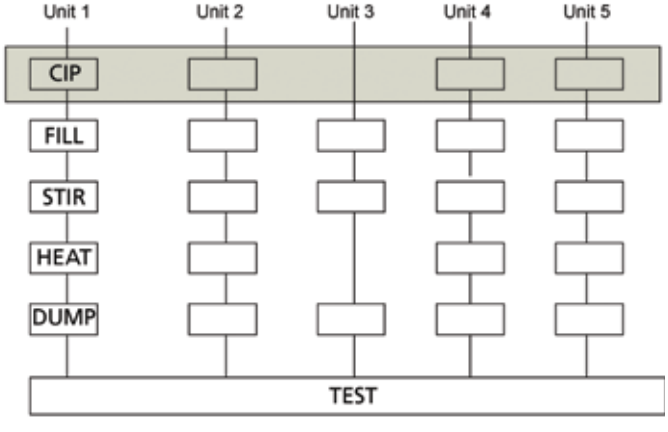

Figure 1. A typical bioreactor setup. With traditional Customer Acceptance Testing, the testing would run parallel and down through the various stages. If there is an error or redo in one level, it has to be redone in every phase of that same level.

CASE STUDY: BIOREACTORS

Let's look at an example of how a major CAT project might be traditionally executed, before discussing how we recently undertook a different approach. Let's say that the manufacturer has a collection of bioreactors, as well as a clean-in-place (CIP), a fill, a stir, a heat, and a dump. This is the case for unit one, unit two, unit three, unit four, and so on (Figure 1). Each one of these areas contains a complicated amount of code.

For Customer Acceptance Testing in a large Life Sciences project, you might have a separate document for each one of these units—detailed design specifications that go out to the various customer contacts that have responsibilities for those units. The project team will start marching down all these units simultaneously—all the CIP, then the fills, the stirs, and so on. There is parallel activity going on, but engineer A, B and C may not conduct their work in exactly the same way.

In this horizontal, parallel approach, there is inconsistency regardless of how well-intentioned the engineers are. Performing the CAT in this manner might be efficient in the fill stage if a particular protocol, like blending or adding the ingredients in a certain order with certain times, was used. However, if inconsistencies between units develops here, they will only get worse as testing continues, and the problems created would have to be fixed across the board.

VERTICAL SLICING

There's a better way to conduct large CAT projects such as this, one that takes a more vertical approach (Figure 2) and is based on a project I recently participated in. In this situation, our two world-area teams were divided into two different scopes of work. Both teams were doing as they were directed, but the project wasn't coming together

like it was supposed to. The way it was originally divided, one site was going to write the standard control module blocks, and the other site was supposed to do the rest of the configuration and implementation.

I was asked by the project director to help put it all together, ignore the boundaries contractually between the two teams, and scope things in a way that we could execute the project successfully. The project director was an employee of the manufacturer, the customer, and was responsible for the entire project. Though he was not an automation expert, he had an automation engineer at his side. So we worked with both of them to come up with a schedule that basically said, we're not going to draw any boundaries between this team and that team.

Together, we came up with a plan that everybody felt would be successful and easy to implement. We called the approach a "vertical slice". The "vertical" term was used in reference to the ISA88 batch architecture standard. The "slice" taken was a single unit, a bioreactor, with the most number of steps. Components of the selected unit included I/O, Control Modules, Equipment Modules, Phases, Operations, Procedures and Unit Procedure.

We picked the most complex unit because we wanted to be sure that we captured all the complexities, variations of configuration, and the sequencing that may come up on the project. We built the configuration and executed the code from start to finish on this one unit, and then tested it with the customer. Then we had operators come in to look at the graphics and interact with the system. We went through the whole design and implementation of just that unit before moving on to the others.

Naturally, the customer provided input: "I really like the way you did this, but I want one extra thing. I want you to bubble some Nitrogen in here . . . and the heat, you're doing that too aggressively, so I want you to slow down the ramp rates. And then the dump, we need you to first verify all the wiring or pumping and have a manual intervention . . . " We made the adjustments as requested then and there, and in doing so we developed a sound model for the others phases.

It's a valid way to do a project. One might argue that it's not as efficient as doing the units in parallel, but we were able to determine with 15% of the scope what the remaining 85% of execution should look like. If the team has done a detailed CAT for a single, complex unit, then they have a good blueprint by which to do the other units.

READY TO PLUG AND CHUG

The reason for selecting a vertical slice was to maximize the potential for customer satisfaction, determined early in the project—before the full scope of work was implemented—and minimize the risk of rework should the slice reveal, for example, an unsatisfactory approach to coding or creating graphic displays.

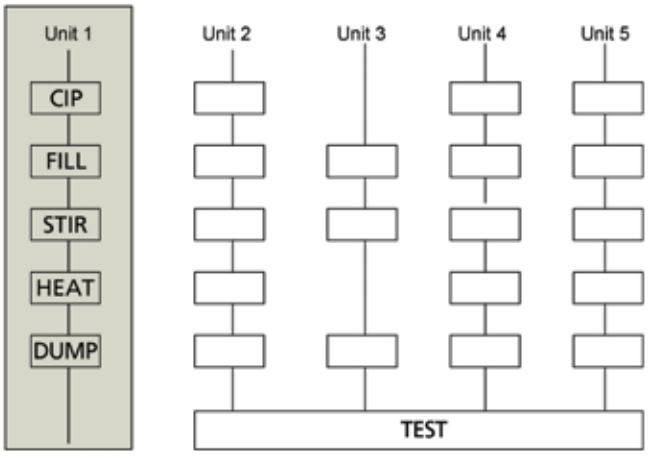

Figure 2. The vertical slice involves addressing one complete unit and all its associated control levels. Underneath are equipment modules with software blocks of code that operate equipment such as pumps and motors, agitators and such that are used in the processing of the pot. The control module is yet another lower layer of detail which handles all the various IO bits and pieces such as transmissions coming in, outputs to the control valves, and other control functions.

At the time this approach was considered, the client raised concern that there may be inefficiencies, and therefore extra costs, involved. However, we looked at it from a standpoint of risk mitigation. There are huge savings in avoiding problems and making deadlines though it's hard to put a price tag on them. Many customers have learned the hard way, which makes them much more amenable to an approach like this.

For the rest of the project, we proceeded to implement the remaining units consistent with the initial slice. With few surprises, the final CAT proved to be highly successful. The manufacturer's operations personnel and project manager were equally pleased with the results.

The vertical slice concept forces the customer and the vendor to talk earlier, agreeing to what the procedures are and what the programming should look like. This allows for efficient execution and predictability in the outcome of the product acceptance test. So once the project team starts plugging and chugging with the main bulk of resources, most problems have been avoided and all parties are communicating well. Most important, it allows for the customer to stay on its planned timeline.

About the Author

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