



Five Pillars of Effective BioPharm Training

Why Traditional Compliance Training Doesn't Work and What to Do About It

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The Problem

A recent article from the Harvard Business Review about the ineffectiveness of company training programs¹ stated that about 75% of managers surveyed felt that their training programs were ineffective. The article cited areas where Learning & Development (L&D) teams have fallen short in producing an effective program, and made several valid points. In a recent conversation with a senior leader at a prominent biotech company, he said he didn't know if he'd ever worked at a company with an effective training program.

This sentiment is not unique or surprising. In my 30 years of biopharma Manufacturing, Quality, and L&D experience, most companies

subscribe to a very traditional, even antiquated, compliance-based training paradigm with heavy reliance on Read-and-Understand (R&U) "training." The problem is that this paradigm sets up its employees for ineffectiveness. In other words, it sets them up for deviations, rework, and firefighting.

Contributing Factors

Check-the-Box Training: My experience at many companies, as an employee or consultant, has been consistent. New hires are inundated with SOPs they must read, usually in 30 days or less. For many operations employees, this means hundreds of procedures, usually long and wordy, written in

paragraphs of black and white text. Many companies impose a limit on how many documents a new hire can read in a given day, which the FDA often looks for when they inspect companies. To avoid cognitive overload, the limit is often 10, but I've seen it as low as five. Manufacturing, Engineering, or Quality Unit employees are often assigned 200 – 300 documents on their first day. If they read 10 per day, they can't get them done in the usual 30-day due date, and are out of compliance. The 10-documents-per-day is a band aid, and not a good one at that.

It is a fallacy to expect this approach to yield a high-performing, risk-aware workforce with a low error rate. We know from basic learning theory that adults only retain a fraction of what they read over time. If they don't use the information right away, and/or are overloaded with volume, knowledge retention decreases even more.² New hires don't use many of the documents they read for weeks or months, if ever. Having been in the new hire's shoes many times, I know that not only could I not remember the content, I couldn't remember which documents I had "trained on" at all.

However, this remains a prevalent approach in biopharm in 2023. With or without documents/day limits, reading hundreds of documents in any 30-day period qualifies as cognitive overload, especially for employees with little or no biopharm experience, and especially when combined with all of the new people, logistics, access and security, company culture, new teams and routines, facility/room locations, eLearnings, on-the-job training, instructor-led training, company policies, benefits, and myriad other information a new employee must learn in the first weeks of hire.

Interestingly, the vast majority of employees I've spoken to over the years at all levels agree with me. They see the shortcomings of such an approach. Yet if you try to take away even some R&U, most leaders, managers, and QA balk. They are highly reluctant to do so out of compliance concerns. I'll address this in the solutions section.

Organizational Structure: Most biotech leaders have discovered the criticality of effective training, and understand that they need a true L&D function. About 15 years ago, many companies had a Training Manager as its highest-level training employee, often with little to no background in L&D. Now, many if not most biotech companies have L&D Directors, Senior Leaders, or even Chief Learning Officers. Most of these individuals have strong backgrounds, sometimes even PhD's, in L&D, Instructional Design, Performance Consulting, and/or Learning Technology.

However, these employees have a mountain to climb to flip the R&U paradigm. It seems like many companies aren't quite sure what to do with L&D leaders once they have them. Sometimes they report to HR. Sometimes Quality, sometimes Manufacturing. And sometimes, though less often, they are their own function, with a seat at the leadership table.

Regardless of whom they report to, they are tasked with developing a Learning Strategy, garnering support from leadership in all major GMP functions, drawing up elaborate project plans, and asking for subject matter expert (SME) resources to support the plan. At many companies, this is all to help them "clean up" a sea of outdated requirements, and untangle the quagmire, born of decades of

traditional thinking about the need for “compliance” training (i.e. R&U).

Leadership Support: That said, the premise that the industry must work to improve this training paradigm, for performance improvement, stronger compliance, and for the patients we serve, makes sense. Convincing leaders and managers that their training program is ineffective is usually not difficult. Showing them what good looks like – an approach to training based more on skills and competencies than reading documents - is also relatively straightforward. Getting verbal agreement from leadership for a new strategy, with its projects, milestones, and even resources – also not a major problem.

The challenge starts with the ask for resources, namely SME time and availability, and management taking a vested interest in their departments’ training, which is their regulatory responsibility. Most SMEs and Managers want to help, but too often can’t. They’re often stretched paper thin - in meetings, on the production floor, or in the lab. Streamlining curricula and developing effective training will always, understandably, take a back seat to production, when staffing, time, and budgets wear thin.

Regulatory guidance documents are clear about leadership’s and management’s essential responsibilities in an effective training program. If they don’t support it, not only verbally, but in terms of their actions, goals, resources, and governance, then like most other initiatives, it is doomed from the outset.

L&D professionals are typically not SMEs in Manufacturing, or Quality Control, Materials Management, Engineering, or other functions.

They are experts in Adult Learning, Training, Instructional Design, and performance improvement. They know how to design learning solutions that change behavior and drive results. They use (hopefully simple – more on this later) analytical tools to recognize when training is not the answer to a performance problem. They are not experts in the functional areas they serve, and cannot decide which employees need what training. Again, regulatory guidance documents recognize this.

However, it’s a challenging endeavor to be sure. Many biopharma leaders don’t fully recognize L&D as its own field of expertise. They hire or assign technical experts to build and deliver training, especially in response to performance concerns. If you’ve ever worked at a company that repeatedly performs retraining on Good Documentation or Aseptic Practices in response to deviations, often with little or no effect, then you understand what I mean. As I’ll discuss in the solutions section, effective training and curriculum development relies on collaboration between area management, area SMEs, and L&D.

Reactive Retraining. Let’s dial in on the retraining point mentioned above. As an L&D leader at one firm, I became involved in a major deviation investigation. The Quality investigator was trying to determine the root cause of a trend of documentation errors in Production – over 40 deviations in fact - in under a year. For many of those deviations, the root cause found was ‘operator error’ or ‘did not follow the SOP.’ In fact, the firm had provided retraining for essentially the same audience approximately 20 times in one year. Reactive, mass retraining like this is incredibly expensive, often doesn’t involve L&D, and rarely works to reduce deviations in any sustainable manner.

I interviewed Production supervisors and operators. I spoke to their management and QA, compiled and summarized the results, and then presented them to leadership. The reasons for the constant documentation errors had nothing to do with a lack of knowledge. The SMEs doing the work every day pointed to myriad other factors – lack of approved buffers and materials when needed, lack of trained operators to execute the work (i.e. actual operations, not documentation), short staffing, lack of available equipment (e.g. calibration standards), cluttered work areas, rushing, distractions, multi-tasking, hard-to-follow or inaccurate instructions, and more. In this environment, I found it impressive that they were able to produce batches that passed release testing at all. They did it using heroism as opposed to robust systems and strong on-the-job technical training. The documentation errors were simply a symptom of poor systems, scheduling, management, and processes. Since they were well aware of how to document operations, no amount of documentation practices retraining would have fixed the documentation issues.

“ . . . reasons for the constant documentation errors had nothing to do with a lack of knowledge . . . ”

The Solution

So how do we fix it? I won't lie. Fixing these issues is not easy or free, but it can be entirely manageable. It takes recognition and a willingness to invest a little bit of time, resources, goals, and governance. Specifically, there are five primary elements that must be in place to have a truly effective training program:

1. Tangible leadership support

2. Appropriate organizational structure
3. SME resources and performance goals
4. Project governance and visibility
5. Streamline L&D model and playbook.

Let's look at each of the five pillars in more detail.

1. Tangible Leadership Support

This one is most important, and a pre-requisite for all of the other 'pillars.' Yes, it includes leadership requiring a learning strategy from L&D, reviewing it, and nodding verbal approval. However, the support must then be manifested in the form of leadership including training program development initiatives in functional area and L&D performance goals. If the expectation is that area leadership, management, and SMEs support any significant training initiative, but it's not part of their goals, then L&D must ask them to do so in between the 'cracks' of their day jobs and fulfilling their priorities. Training development must itself be a priority or it is ill-fated from the start.

2. Organizational Structure

Another form of tangible leadership support is to install an independent L&D function that does not report to QA, Manufacturing, or other functions, and is led by an L&D professional with the appropriate education and experience for the role. If the person came up from a technical function, then received the appropriate training, education, and experience in L&D, even better.

This role should report to an executive level of leadership and be part of the leadership team, or at least have regular, standing contact with it. This is required in order to gain and maintain support, and explain to leadership risks and challenges, and to get real time

constructive or positive feedback they are hearing from their functional area management and staffs. It must be a partnership, not a structure of 'us' and 'them' silos.

3. SME Resources and Performance Goals

Tangible support means leadership requires area management to allocate sufficient SME resources to support training program development. L&D plays a key role here. They must work to minimize the amount of SME time and resources required, and area management must in turn carve out time to provide support – to inform what skills and knowledge are needed by their teams for various roles, which documents and training materials (existing or not) are needed to meet those requirements, and to provide content to develop, and to review and approve, training materials. Again, L&D must understand this is not a blank check. Their processes must be developed to minimize SME contact time to the extent possible.

L&D must understand that SME resources are not a blank check.

4. Project Governance and Visibility

Tangible leadership support also means enabling proper governance around training development. In my experience, many training efforts fail because they simply aren't on management's radar. They're not discussed at daily tiered management meetings (or huddle boards). They're an afterthought at the end of Quality Management Review meetings. If training metrics, which often measure % on-time compliance only, are not met, often the blame game begins, and training development is further hampered.

Developing an effective training program, especially any significant curriculum cleanup, streamlining, or restructuring efforts, writing OJTs, or developing training materials for critical processes, means having an approved project with a plan, due dates, action owners, and metrics, and a forum for reporting progress, risks, and challenges, like any other project. Without this, the likelihood of developing an effective program that streamlines onboarding and improves performance, is greatly reduced.

This can still mean starting small, or right-sizing the project. It could be a pilot scale project in one department or subdepartment, or with one aspect of the operation or one training subject. The goal is to complete that one pilot, measure its effectiveness, and report it publicly. If successful, the initiative can be expanded to other groups the following year. But leadership must hold both area management and L&D accountable to complete it, and area managers must hold SMEs accountable to support it with their input and expertise, or it won't work.

Sometimes projects fail because there simply isn't enough time and resources to support them all. Strong project governance that selects a manageable number of high-priority projects aligned to corporate strategy, and then provides a visible, well-attended leadership forum where appropriate metrics, risks, challenges, and accomplishments are presented, is critical to the success of any training project.

5. Streamlined L&D model and playbook

When provided adequate support and governance, L&D must work hard to develop a playbook that is aligned with the speed of the business. This means having a simple

framework that can be described to any leader, manager, or SME in 10 minutes or less such that they clearly understand it, and its benefits and value.

Once a clear, simple competency-based framework is in place, building content to populate its curricula must be performed as a collaboration between L&D and SMEs. This partnership is cradle-to-grave – as soon as a training need is identified, SMEs should be able to submit a simple training design request to L&D, and the two should work together, following agile, rapid instructional design methodology, to build the solution, and then, measure its effectiveness.

Measuring effectiveness is another aspect of training that is too often cast aside, but is critical for building credibility and support for the training model.

The framework must also be scientifically sound from an adult learning theory standpoint. This means competency-based training that targets performance improvement above compliance. That is not to say that compliance should be abandoned. In fact, by targeting performance improvement and skills, rather than reading volumes of documents, the firm’s compliance profile will soar as a byproduct. The FDA’s Janet Woodcock, as Head of CDER in 2013, said, “FDA will shift their inspection focus to performance and away from compliance.” She added that “. . . 100% trained reports and SOP quizzes will not be enough to satisfy . . . training effectiveness. Industry needs to document how they qualify their employees;” And that “during final performance demonstration, Qualified Trainers observe performance and determine if the employee is qualified or needs more time to practice.

Qualification Events are . . . when effectiveness of training can actually be verified. This is the true measure of SOP training effectiveness.”³

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-Dr. Janet Woodcock

This framework is effective because it relies on more effective methods of training, such as eLearning, ILT, and SOJT, and less on reading. It also breaks the training into smaller, more digestible chunks of learning, delivered just in time, instead of just in case.

Best Practices

Part of L&D’s agile playbook must include the actual design of content for eLearning, ILT, and SOJT in a rapid yet effective manner. This is another area where firms tend to struggle. I’ve seen firms try to solve this challenge in different ways. Some allow department SMEs to develop all of their own training. Some use internal or external instructional designers to design the training, and work with SMEs to gather appropriate content. Some use a hybrid approach.

The problem with SMEs designing their own training – they know the content to be sure, but most are not learning professionals who understand how to design effective training that actually improves performance. This method discounts decades of research and vast literature about how adults learn best, and often leads to redundant, ineffective training with paragraphs of text on slides, or informal or ad hoc hands-on training, neither of which is particularly effective in helping adults retain and apply the information.

The problem with L&D designing the training is that although they understand instructional design models and adult learning theory, many of the methods used to design effective training are often too time and resource consuming to work in a fast-paced GMP manufacturing environment. And in my experience, many of the turnaround times for eLearning and ILT don't match the needs or timelines of the business.

It's critical for L&D to develop, gain approval and support for, clearly and concisely document, and relentlessly communicate, the firm's training model. The model summarizes at a high level the roles, responsibilities, and process for the partnership approach. It explains how L&D and area SMEs/managers will work together following a simple, streamlined process to build training following industry best practices and tools for instructional design, to meet identified business needs

This is where L&D must be laser focused, and align their processes with the speed of the business. For example, facilitating a kaizen-style workshop following a basic template to build competency-based curricula minimizes the SME time needed to define competencies in their respective function. This enables relatively rapid establishment of streamlined, effective curricula. Using simplified needs analysis templates that can be completed in a one-hour meeting with SMEs to understand the need and agree on desired performance objectives for the training reduces delays, email volleys, and jump starts training development. However, SME time and area management engagement and support can't be zero under any scenario. I've found this

method particularly helpful, and feedback from area managers and SMEs has indicated almost universally that the process was efficient, productive, and helpful in ensuring the training hits the right scope for the need. It also often uncovers process and knowledge discrepancies that SMEs can fix prior to training to ensure greater consistency in performance.

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Another best practice is to employ the willing – pilot new training approaches with small groups who need help, recognize the benefit, and are willing to offer a few limited resources to support them. Then demonstrate and publicize the value relentlessly. I've experienced success with this practice at different firms.

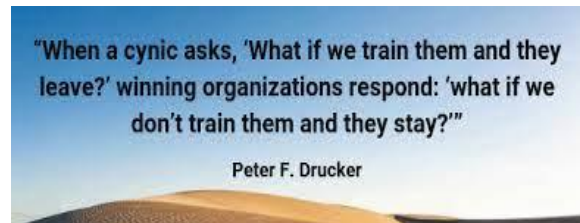
Conclusion

Sounds simple, right? As stated above, only with appropriate leadership support, area management engagement, and a limited time allocation of SME resources, including governance and goals, can this, or any training model, be effective. It helps immensely if L&D is recognized as an individual function, not reporting to QA or Manufacturing, etc., with a leader represented at the leadership table at the Director, Senior Director or above level. They need constant access to the leadership team and input into the site or division strategy in order to build and maintain support for an effective training program, and to highlight risks, challenges, and demonstrated value.

Firms that don't invest in this or a similar model are likely going to be saddled with excessive

R&U training, long times-to-proficiency for new hires, ineffective ILT and OJT, and inconsistent performance. This leads to further issues, such as a vicious cycle of high turnover, recurring deviations, and rework, then lower morale, more turnover, and so on.

If this model is applied using a risk-based approach, as all quality systems should be, it can be manageable and very effective, and actually improve performance, reduce deviations and firefighting, reduce 'door-to-floor' and onboarding times for new hires, and eliminate non-value-added work in the form of reading volumes of SOPs that employees don't need. It also provides competitive advantage in recruiting new hires, retaining talent, employee development, and getting more business. ■



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