# A Governance Model for Learning & Compliance Processes

## BEST PRACTICES FOR TRANSITIONING TO FULL-SCALE PRODUCTION

In our previous Knowledge Brief, we shared the six elements of a learning and compliance infrastructure.

In this brief, we focus on the Governance element. As Life Sciences companies transition from trials to commercialization, they often seek to build consistency and standardization into all aspects of manufacturing, operations and distribution. In a similar way, companies can develop the rules around learning and compliance processes, commonly referred to as a governance model.

While a governance model serves as the "playbook" for managing learning, development and compliance, it does more than simply add procedural control: it also ensures operational efficiencies. As the benefits below point out, a governance model lets all employees know who owns administrative control of the process, who manages training roles and learner roles, and how new training activities are initiated.

Without a governance model, the company faces several risks. One risk is that process knowledge will be lost when key owners move to other positions. For the commercializing company, perhaps the more pressing risk is that without a model in place, explosive short-term growth forces individual departments to generate their own learning and qualification processes, making it very difficult for senior management to gain visibility into the company's overall learning and compliance status.

## Benefits of a Learning & Compliance Governance Model

There are several business benefits to defining a governance model for learning and compliance:

- Establishes a clear and scalable enterprise vision for how learning gets managed, from senior executives to training managers to learners;

- Drives regulatory compliance and/or business efficiency;

- Enables a team to quickly resolve troubleshooting issues and find common ground;

- Recognizes and encourages the entrepreneurial culture by acting as a business partner via collaboration with learning communities;

- Promotes harmonization, standardization, continuous improvement and knowledge management across the wider organization.

## The "Brain" of the Governance Model: The Training Policy

While there are five core policies that should make up the governance model (listed on the right), the training policy is the "brain" of the model.

That's because it establishes the training requirements for your entire organization, describes the process for establishing job-specific training curricula, and also walks through the required methods for documenting completion of training.

Here are just a few key items that a training policy should include:

1. **Personnel Requirements:** the policy demands that personnel have the education, training, and experience (or any combination) to enable each role to perform his or her assigned functions.

2. **Continuous Process:** the policy states that training must be conducted on a continuing basis with sufficient frequency to assure that employees remain familiar with regulatory and job-specific requirements.

3. **Training Process:** the policy explains the process that qualified individuals must use when conducting training; and it explains the steps needed to conduct training effectiveness verification.

4. **Record Keeping:** the policy outlines how activities are properly documented and maintained (e.g. date, content of training, trainer, length of training, etc).

5. **Training Content:** the policy explains how training content is developed and named or coded, so trainers can focus on company-specific topics and targeted employee or third-party roles.

## Core Procedures within a Governance Model:

### Training Policy
This policy outlines the scope, training responsibilities, procedures for GxP training and non - GxP area personnel, training curricula, training documentation, Annual GxP Training, and contractor or third party training.

### Use and Operation Procedures
These are general use and operations instructions for administrators and end users. While the operational procedures explain Learning Management System functionality, companies should also have these procedures when learning management systems are not in place, and training is conducted via spreadsheets and classroom sign-in sheets.

### System Administration Procedures
These procedures are only necessary when a learning management system is in use; these procedures define security roles, system administrative roles and responsibilities, maintenance (including system releases), configuration changes requiring change control, and related system usage.

### Computer System Change Control
These procedures focus on learning management system configuration changes, addition of new functionality, how new functionality is released and validated, and so on.

### Electronic Signature Policy
This policy discusses the type of training or compliance activities (SOPs, Work Instructions) that require an "electronic signature" versus other records in which the learner can simply type "I acknowledge" -- some systems provide these options.