
The regulated nature of the biotech industry requires that certain aspects of its facilities and systems are heavily scrutinized and documented, with Quality oversight, in order to ensure the highest degree of patient safety and product quality. However, somewhere along the way, the focus on regulations has eclipsed the focus on Good Engineering Practice. While it is not our intent to diminish the emphasis on regulations and, therefore, patient safety and product quality, at times our method of achieving those goals is not efficient. By refocusing our efforts on Good Engineering Practice within the Engineering Lifecycle, in conjunction with the Regulatory requirements, we can provide a better product.

This program will provide a venue to discuss the GEP elements of the Engineering Lifecycle, their relationship to the Regulatory requirements associated with manufacturing within our industry, and the definition of roles and responsibilities for these elements.

## Stating the Obvious…

- Companies are in business to make money.
- Companies have to ensure that their operations and products meet regulatory compliance.
- Companies stay in business by providing safe, high-quality products in an efficient and cost-effective manner.

## Quality Needs To Be Everyone's Responsibility

Quality Assurance is a critical role in the development and maintenance of principles and practices that assure compliance within any biotech/pharma company. All employees must adhere to these principles and practices to ensure that products are safe for patients.

## Compliance Take-Over of Business Operations

- In many biotech/pharma companies, the business operations (including engineering) are held hostage to the onerous application of Quality Assurance.
  - Quality approval of technical documents
  - Quality Change Control starting at commissioning
  - commissioning and qualification executed by Validation (Quality)

## Build quality into Engineering Programs through Implementation of Good Engineering Practice

*Good Engineering Practice: Established engineering methods and standards that are applied throughout a project's lifecycle to deliver appropriate cost-effective solutions.*

## Genzyme's Engineering Quality Program

- Genzyme is implementing an Engineering quality program to ensure that from an Engineering perspective, we are operating in a "quality" manner by following defined, standardized processes and procedures to produce expected outcome reliably.
- The program is built through a collaborative effort between Global Engineering, Site Engineering and Quality.

## Foundational Elements of an Engineering Quality Program

- clearly defined and understood roles and responsibilities
- front-loaded Engineering processes
- robust documentation management system
- robust change management program
- continuous improvement and auditing

## Clearly Defined and Understood Roles and Responsibilities

- Which roles:
  - Asset / System Owner
  - Engineering
  - Validation
  - Quality Assurance
  - Maintenance and Metrology
  - Health, Safety and Environmental
- What does handover between these roles look like?
- What are the relationships between these roles?

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## Front-Loaded Engineering Processes

- Engineering processes: the methods used to identify and achieve engineering goals
- front-loaded Engineering processes: methodology through which the issues and expectations are defined early in the project, resulting in smoother execution and benefit realization
  - project objectives
  - user requirements
  - C&Q plans

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## Robust Documentation Management System

- Identify what needs to be stored and the purpose of storing it.
  - living documents
  - historical documents
- Identify the approval requirements and method for approval of documents.
- Identify the means for storage.
- Define a method for document identification, to be used for filing.
- Ensure a method for document retrieval.
- Define a document retention period.

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## Change Management – Not Just Change Control!

- Change Control is required to ensure continued compliance, resulting in consistent product quality and assurance of patient safety.
- Engineering Change Management is required to ensure control of our facilities and equipment, safety of the workers, efficiency of the business.
- Functional Equivalence is used when replacing components in terms of manufacturer, make, model number, etc., when the replacement part is functionally equivalent to the original.
- Project Change Control is used to manage and document changes to project scope, cost and schedule.

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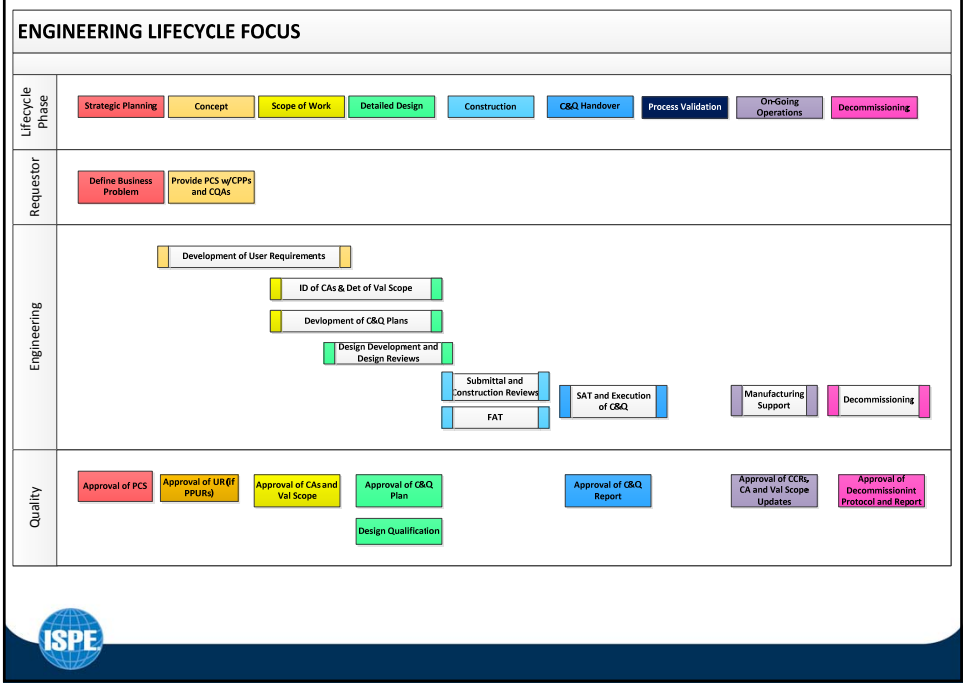
## Continuous Improvement and Audit

- Every program we create should have continuous improvement and audit components to ensure efficacy and efficiency.
- Audit can be used to inform continuous improvement.
- Communities of Practice can be used as a method of communication of program goals and requirements, and discussion with sites as to the challenges and successes of program implementation.



## Closing Comments

- Quality Assurance is critical to the success of any biotech company and their efforts should be focused on those elements that impact product quality and patient safety.
- Quality in Engineering should be used to ensure that facilities, equipment and systems are “fit for their intended use,” supporting the manufacture of high-quality products.

Thank you!

## Contact Information

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