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# Understanding Validation

## ***Purpose***

To understand how we arrived at the current validation approach, the current regulatory requirements, and how that actually translates into a practical approach to validation.

## **Objectives**

At the completion of the class, employees will be able to describe the background and method of validating processes.

## ***Prerequisite***

Those viewing this program should have at least an introductory level of GMP or QSR knowledge.

## ***Who should attend this course?***

This class is appropriate for all employees of drug, biologic, or medical device manufacturing will be involved in validating processes.

## ***Intent of the class***

This course is intended for training purposes only and is not a substitute for technical recommendations, regulatory or legal advice. These materials are intended to raise compliance issues for further discussion at your company. It is recommended that you consult appropriate authorities for specific recommendations and advice.

***Class Length:*** This time includes testing time.

*2.5 Hours in 5 segments*

## ***On-site Options***

This class can be taught with a live instructor at your company. Call for details.

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## *Topics Covered*

### **Introduction**

1. History of validation
2. Benefits
3. Definitions
4. Regulations and guidance
5. 483 Observations
6. Validation strategies

### **Qualification and Validation**

1. Design qualification
2. Installation Qualification
3. Operation qualification
4. Performance qualification
5. Assessing validation needs
6. Continual verification

### **Documentation**

1. Master plan
2. Protocols
3. Qualification report
4. Validation study report
5. Validation certification
6. Documentation retention