

AGENDA

Day 1

8:00 a.m. – 8:30 a.m.

Registration and Continental Breakfast

8:30 a.m. – 12:30 p.m.

Introduction

- **ACTIVITY:** Connections between mountain climbing and pharma/biopharma manufacturing
- **VIDEO/DISCUSSION:** Characteristics of a guide
- Key concepts important to regulators and the industry
- **ACTIVITY:** Terms of compliance
- **GMP Expectations:** What they are and where they come from.
- **ACTIVITY:** Identifying expectations for training and learning
- **Quality Systems:** GMPs as an example of a quality system.
- **ACTIVITY:** GMP systems and your role
- **VIDEO/DISCUSSION:** Characteristics of systems

12:30 p.m. – 1:30 p.m.

Lunch

12:30 p.m. – 4:15 p.m.

- The Seven Essentials of GMP
- **Essential 1:** Protect the product from contamination
- **ACTIVITY:** Sources of contamination and ways to prevent it
- **Essential 2:** Prevent mix-ups
- **ACTIVITY:** Minute mix-up mysteries
- **VIDEO/DISCUSSION:** Climbing Essentials

4:15 p.m.

Summary and Wrap-up

Day 2

8:00 a.m. – 8:30 a.m.

Continental Breakfast

8:30 a.m. – 12:30 p.m.

- **ACTIVITY:** Review of Day 1
- **VIDEO/DISCUSSION:** The real goal
- GMP Essentials - continued
- Essential 3: Know why, how, and what you are doing before you do it
- Essential 4: Document all activities
- **ACTIVITY:** 10 Characteristics of a well-prepared document
- **ACTIVITY:** Dear Professor GMP
- Essential 5: Strive for consistency and control – qualification, validation and change management

12:30 p.m. – 1:30 p.m.

Lunch

1:30 p.m. – 4:00 p.m.

- GMP Essentials - continued
- Essential 6: Have management that supports an independent group that makes final decisions on documents, product release and quality issues
- **ACTIVITY:** Management responsibilities –and Q10
- Essential 7: Learn from mistakes, solve problems; monitor and continually improve
- Case Study: An examination of GMP compliance issues in an organization
- How I can apply this back in my job

4:00 p.m.

Summary and VIDEO/DISCUSSION: On being a guide to others