Leading the Climb: Seven Essentials of GMP

Course goal
Develop your knowledge and skills so you can better interpret and apply current Good Manufacturing Practice expectations in a variety of situations.

Course description
Leading the Climb: Seven Essentials of GMP is an advanced GMP training course targeted at those who have supervisory/management responsibilities, those are working in quality, operations, compliance, training, and other staff/technical positions. It covers GMP expectations of the US, Canada, Europe, and the World Health Organization (WHO).

The course uses a unique video produced by LearningPlus that builds an analogy of mountain climbing and being a guide: role modeling, systems thinking, coaching and feedback, and satisfaction in completing a challenging task are discussed.

Activities that involve collaboration and teamwork allow participants to apply their experience and newly-gained knowledge to challenging situations as they develop answers using "GMP thinking".

The course is annually updated to reflect revised regulatory agency enforcement data, recent warning letters, and current industry/agency issues. At the end of the course, a case study is used to illustrate the business, personal, and financial impact of not meeting GMPs.

Participants use (and keep) a resource book containing a variety of regulatory reference documents, warning letters, and three selected chapters from ***GMP in Practice*** by James Vesper.

Leading the Climb is a two-day course that has been used in more than two dozen pharmaceutical companies. It has been adopted by a multinational pharmaceutical company as one of several required courses in its management curriculum; LearningPlus has trained nearly 5000 of its personnel since 1998. The course has been used and well received in the US, Canada, Singapore, Puerto Rico, Italy, and Ireland.

Objectives
- Define key words and concepts related to good manufacturing practice.
- Describe how the regulations, guidelines, best of industry practice, and other factors contribute to "Current GMP Expectations".
- Discuss how quality system elements apply your role and responsibilities.
- Discuss how quality auditors and regulatory agency inspectors evaluate conformance to current GMP expectations.
- Identify the Seven GMP Essentials and discuss current GMP expectations that are relevant to your role and responsibilities.
- Given an actual industry example, identify and discuss the regulatory, business, and personal consequences of not meeting current expectations.
- Describe the role personnel at all levels in producing drug products that meet current GMP expectations.

Time
Two days (approximately 13 instruction hours).