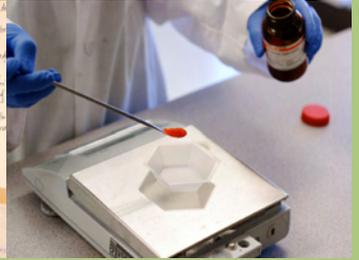


What did LearningPlus accomplish in 2008?



What can we do for you in 2009?

Since 1992, LearningPlus has worked with leading pharmaceutical, biopharma, medical device, and blood products firms around the world. We'd like to give you an idea of some of the interesting learning and performance projects that we've recently completed.

Improving Technical Reports

Client Need: An east-coast biopharma firm realized that their technical reports – which would be included in their first

New Drug Application (NDA) submission – were inconsistently written, incomplete, and lacking complete rationales. The firm was concerned this deficiency would delay their approval. **LearningPlus Solution:** After reviewing numerous examples and helping the firm define what it wanted in its technical reports, LearningPlus designed and delivered a customized workshop so participants could distinguish between adequate and inadequate reports, identify specific ways to improve the reports, and write reports that would have a better probability of being “first time right”.

Risks in Outsourcing & Partnering

Client Need: Several firms contacted LearningPlus wanting a better, more systematic way to determine potential risks and how to



control the risks as they partnered or had relationships with other pharma organizations. **LearningPlus Solution:** A training course that applied Quality Risk Management to outsourcing and partnering was created and adapted to the particular needs of each client. Participants in the courses – senior management, procurement, technical services, and quality professionals – identified risks that they faced and went away with an integrated control and mitigation strategy that they could begin to apply.

Training of suppliers

Client Need: Two pharma firms were concerned that their key vendors didn't have a clear understanding of Good Manufacturing



Practices (GMPs) and quality systems. The pharma clients wanted a third party to provide a “neutral”, best-of-industry point of view to the vendors. **LearningPlus Solution:** After gaining a better understanding of the specific issues that had been noted during quality audits, LearningPlus worked with the vendor firms to define who would attend the course, what they already knew about GMPs and quality thinking, and what would help them better meet their customer needs. These topics were incorporated into several different training events presented in the US and Canada.



LearningPlus designs, develops, and implements learning and performance solutions to the healthcare manufacturing industry on topics related to Good

Manufacturing Practice (GMP) requirements. Our industry experience, technical knowledge, and skills in training course design allow us to produce unique leader-led, technology-based, and “blended” courses. Our learning solutions actively involve the learners so they can learn, use, and apply the information in their jobs. We can adapt our previously developed courses to the special needs of an organization or create a highly specific and customized performance solution to address a particular area of concern.

LearningPlus is led by James Vesper who has had more than 25 years experience in the pharma and biopharma industry. As the author of five books and numerous book chapters and technical articles, he and LearningPlus’ training consultants have had an impact on GMP training affecting literally tens of thousands of people world-wide.

What can LearningPlus do for you in 2009? We would enjoy talking with you about your specific needs or how risk management, human error reduction, and new tools for learning can give your firm a performance advantage. Call, email, or visit our website!

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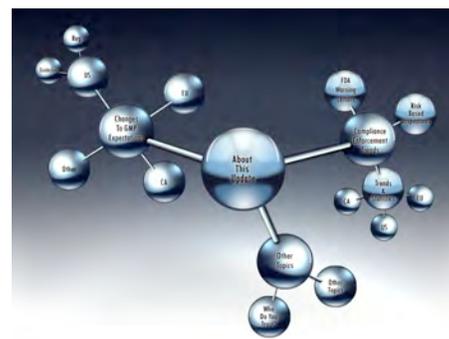
Training for 6000 people, please

Client Need: A global pharma firm wanted a course on applying and interpreting GMPs as part of their basic curriculum for all supervisors, managers, and directors. To provide a true industry perspective, they wanted an experienced outside organization to present the sessions. **LearningPlus Solution:** A two-day course, *GMPs for Supervisors and Quality Unit Personnel* was developed using a unique video, *Leading the Climb*, that examines the similarities between mountain climbing guides and supervisors. The updated course, still being presented 10 years after its start, has included 6000 participants world-wide. Different versions of this course have been adapted and used with other pharma and biopharma firms.



Investigation report writing: taking investigations to a new level

Client Need: A biologicals firm wanted a significantly expanded course on investigation report writing that their internal trainers and subject matter experts could teach. **LearningPlus Solution:** Based on experiences that we have had throughout the industry, LearningPlus recommended a comprehensive, integrated workshop solution to strengthen investigation skills, identify direct and contributing causes, and find more effective and comprehensive corrective and preventive actions (CAPAs). The project, to be completed in 2009, will include training materials and train-the-trainer sessions that will enable the firm’s staff to carry on the training without relying on an outside provider.



A web-based GMP Update course

Client Need: How can you provide a useful, relevant, cost-effective “GMP Refresher” course to management and staff personnel located throughout the world? **LearningPlus Solution:** For more than 10 years, LearningPlus has presented a leader-led *GMP Update* course at firms in the US, Canada, and Europe. In 2008, we created a web-based version of the course. Firms can adapt the “Flash”-based program by including their own video and audio segments. Learning assessments (tests) can be given in electronic or paper formats. The *GMP Update* can be integrated into a firm’s learning management system (LMS).

Sign up for a free, full demo at www.gmpupdate.com