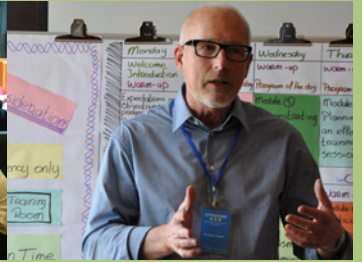


What did LearningPlus accomplish in 2012?



What Are The Risk of Proj Panda becoming a Success?

Hazard Desc	Cause	Effect	Scoring
Reliance on 7 yr mktg. report	lack of updated mktg data not collected	Miscalculate mkt demand	7 7
optimistic review of regulatory opinion	lack of subst. info of communication w/ the industry	unexpectedly proj. rejection	7 7
Not getting exec committee approval	assuming budget is below the amt	short fall associate comm is not pleased	5 5
unknown impact the change would have	insufficient information	No product more costly to make	7 5



Here are some of the interesting learning and performance projects we've been working on!



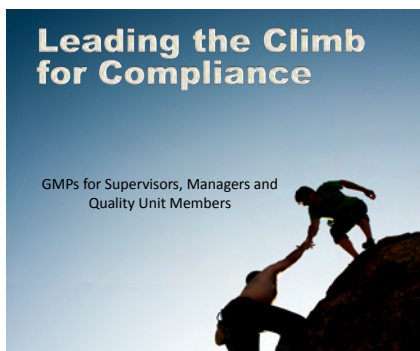
Training for Chinese SFDA

LearningPlus was invited to be part of a capacity-building project to

support the Chinese SFDA develop its capabilities in performing Good Clinical Practice (GCP) inspections. English-speaking inspectors participated in a special facilitation skills course that helped them effectively adapt and then teach a GCP learning course for their Chinese-speaking colleagues.

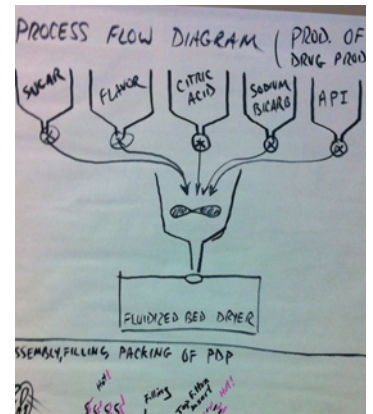
Remediation effort

As part of its commitment to the US FDA, a multinational firm requested that LearningPlus adapt its two-day *Leading the Climb* course and present it to 500 of its supervisors, managers, and directors in 2012. The course will be continued in 2013 as more people join the firm's leadership ranks.



Root cause investigation and report writing

One of the courses that LearningPlus was asked to present most frequently in 2012 has been a two-day course to develop skills in performing root cause investigations and then writing investigation reports. The workshop, given in Denmark, Canada, and US examines different accident models to help learners tell the story of the unwanted event. The course also includes opportunities to write and review investigation reports.



Contamination Control – needs analysis & course design

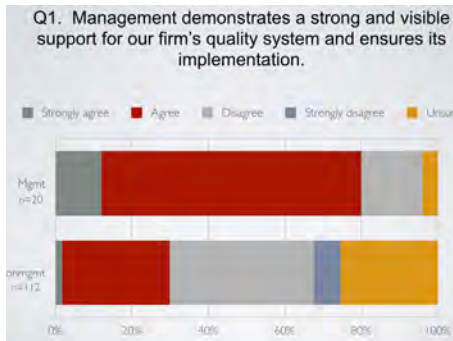
To enhance its training efforts on contamination control, a client asked LearningPlus to perform a needs analysis and then present recommendations and designs for an advanced workshop and hands-on practical skills training on contamination control. The design includes some novel uses of technology to get participants to “see the invisible”.



Since 1992, LearningPlus has worked with leading pharmaceutical, vaccine, biopharmaceutical, and blood products firms around the world.

What can we do for you this coming year?

Workshop on management responsibilities



For its 2012 annual GMP program for management, LearningPlus developed a survey to better understand how management and operations personnel each viewed management's commitment to the ICH Q10 view of quality. The questions were based on specific Q10 statements. The results, along with possible reasons and ways to better communicate management's quality vision were discussed by the participants. Other aspects of the workshop looked at current cases of noncompliance, highlighting the impacts on the finances and reputation of the organization.

LearningPlus designs, develops, and implements learning and performance solutions for pharma and biopharma firms 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 acquire, use, and apply the information and skills 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.

TALKSPOT keynote on Quality Risk Management



As it began a unique learning opportunity called TALKSPOT, Global Learning Opportunities (GLO) at the World Health Organization (WHO) invited James Vesper to be its first presenter. The short presentation entitled, *Diphtheria: Dog sleds, serum run, and saved lives*, illustrated how informal techniques of risk management were used in 1925 as Nome, Alaska was on the brink of a diphtheria epidemic. In telling this illustrated story, he showed how basic questions of Risk Management were applied. The talk was an innovative way to introduce an important topic.

Quality Risk Management - use in product development

Risk Question: What are the risks with design of PDP?

Process step or parameter	Failure Mode	Failure effect	Failure Mechanism	O	S	D	P
Plastic Packaging	Difficult to open	No drug	Wrong material	1	3	1	
			Wrong adhesive to small dimension	1	3	1	
			Bad design	1	3	1	
Labelling	Difficult to read	Wrong dose wrong use	Wrong use	4	5	5	
Ergonomic	Drop it break it	No medicine	Hard to handle	2	5	1	
			Hard to stop	2	5	1	
Control	Blocked						

Quality Risk Management (QRM) continues to be a topic of high interest as firms are looking for ways to implement risk-based thinking and standard their terminology and practices. In 2011 and 2012, LearningPlus provided on-site learning programs at a number of firms, including several that wanted their development people to have a common language and a defined set of tools. LearningPlus helped create cases and scenarios that were client-specific, incorporating relevant examples and situations.

LearningPlus founder and president James Vesper has had more than 30 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 the coming year? 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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