Curriculum Vitae for

James L. Vesper, PhD, MPH

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Professional Experience

2009 – present Consultant to World Health Organization (WHO) Global Learning Organization on Vaccine Quality

The Global Learning Opportunities on Vaccine Quality's (GLO/VQ) objective is to improve practices related to vaccine quality and especially on vaccine regulation and production through a series of training courses offered by selected training centers and defined follow-up procedures.

Projects that Mr. Vesper has been involved with as part of the GLO/|VQ include:

- *Design and development of two-week workshop for inspectors inspecting vaccine manufacturing sites on behalf of WHO.* Course outline completed December 2012.
- *TalkSpot presenter* – "Dogsleds, Serum Run, and Saved Lives: A case of risk assessment". WHO Headquarters, Geneva, September 2012.
- *Facilitator – Facilitation Skills Course for Chinese SFDA inspectors (China's national authority).* Taizhou City, China, March 2012.
- *Design and development of a web-based e-learning solution, covering the handling of time-temperature sensitive pharmaceutical products.* (This project is in conjunction with a PhD program at Murdoch University, Perth, Australia.)
- *Collaboration on design/development consulting for new GLO/VQ course, "Design and Development of Training Materials."* July–Oct 2009; was co-instructor for course given in Antalya, Turkey, Nov 2009 and Sep 2010.
- *Planning, presentations, facilitation, and evaluation of the GLO/VQ Consultative Group and Regional Consultation meeting*, Antalya, Turkey, Feb 2009.
- *Design/development consulting for new GLO/VQ course, "Evaluation of Clinical Data for Registration of Vaccines",* Geneva, May 2009.
- *Preparation, mentorship to participants, observation, evaluation, and analysis of WHO "Pharmaceutical Cold Chain Management on Wheels" course*, Turkey, June 2009, 2010, 2012, and 2013. Outcomes will include collaborating on articles for publication and developing a comparable, technology-based learning experience.

1991 – present LearningPlus, Inc: President

Mr. Vesper and his colleagues provide training and performance-related consulting services and on-site training courses on GMP (Good Manufacturing Practice) topics to pharmaceutical, biologicals, and blood-products organizations.

Projects that have directly involved Mr. Vesper include:

- *Quality Risk Management system review:* A global pharma firm based in Europe requested that LearningPlus review its policy and draft procedures for applying QRM in its product development activities in light of best-of-industry practices. LearningPlus provided a report and recommendations to strengthen

the firm's QRM activities.

- *Advanced Deviation Investigation Courses*: As part of a plan to improve its investigations and meet a regulatory commitment, a large generics manufacturing firm requested that LearningPlus design an advanced investigation course covering the use of investigation tools and incident models. An additional short course for management was also requested in order to better implement and sustain the investigation efforts.
- *GMP Update E-learning Course*: To accomplish its periodic GMP training requirement using e-learning, LearningPlus was asked to design and develop the content covering inspection trends–both within the pharma industry and within the specific organization–and changes in GMP expectations.
- *Baseline GMP/QSR training*: To forestall a significant regulatory action, LearningPlus was asked to create a 3-4 hour "baseline" course covering drug GMPs and the medical device QSRs for a multi-national organization. The content will be presented using instructors. Capability for local adaptation (for products and specific regulatory concerns was a key feature of the design. The course will seen by over 35,000 personnel world-wide.
- *GMP/Quality Systems for OTC Product Development:* A large international developer and manufacturer of over-the-counter (OTC) products asked LearningPlus to conduct one and two-day sessions for its leadership and management teams related to GMPs and how they apply to developing OTC products.
- *Quarterly GMP Presentation.* A large pharma/biological manufacturer asked LearningPlus, for the third time in four years, to give a one-hour long presentation on a GMP topic to nearly 2500 of its personnel. 20 sessions were conducted in a 9-day period, including two that were attended by senior management from the site. To make it more interactive, an audience response system was integrated into the presentation.
- *Risk Assessment and Quality/Compliance Auditing*: LearningPlus was asked to develop and present a two-day workshop for a firm's GMP and GCP auditing team.
- *Compliance/GMP Remediation Project:* As part of a much larger GMP remediation plan submitted to the US FDA, LearningPlus is providing multiple sessions of a two-day learning course for supervisors and managers.
- *Contamination Control and Vaccine Technology course instruction/ facilitation:* to support a vaccine manufacturer's internal training efforts, Mr. Vesper was asked to join the firm's cadre of instructors to co-teach a number of sessions and provide a broader industry perspective on current practices. Courses have been conducted at several US sites and in Ireland, Belgium, France, Mexico, and Japan.
- *Needs analysis and program design:* A manufacturer of sterile injectable products asked LearningPlus to conduct a detailed needs analysis and high-level design document for a knowledge course on contamination control and a follow-up "hands-on" practical course for those working in aseptic areas. This project was part of a US FDA Warning Letter remediation commitment.
- *Pre-approval inspection preparation*: A biotech firm, preparing for their first FDA pre-approval inspection, wanted an outside consultant to review their training efforts, procedure system, quality system, and use of risk assessment. LearningPlus spent several days on-site examining policies, procedures, and records, identifying immediate and longer-term opportunities for improvement.
- *Investigation Report Writing Workshops*: As part of its enhancement of its quality systems, a biologics firm needed to improve the quality of its incident

investigations and investigation reports. After an abbreviated needs analysis, LearningPlus adapted a 1.5 day-long workshop on investigation report writing for the firm. The learning event included an assignment for teams to write an investigation report and present it to the larger group for comments.

- *Learning Event for Quality Leadership Team:* One of the largest manufacturers of cosmetics and healthcare products and devices wanted a facilitated discussion regarding GMP/Quality trends. LearningPlus developed and facilitated a day-long workshop with key discussion points for the firm's global senior quality leader team.
- *Instruction and Qualification Program for Medical Device Repair Technicians:* An international medical device firm wanted to create additional factory-authorized repair centers in 3 countries beyond the US. The challenge was to create an integrated learning and qualification strategy and materials to support detailed procedures and hands-on training. LearningPlus created a series of on-line training modules and an assessment strategy that could be used internationally.
- *Designing Risk Management Strategy:* An international biotech firm requested assistance with the design and implementation of a risk management strategy that would integrate with their quality and business efforts. LearningPlus is working with all levels of the organization in developing a system optimized for their particular needs.
- *Transforming into a "Learning Organization":* One of the leading pharma firms that was changing its focus from "training" to "learning" requested that LearningPlus provide a 90 minute interactive presentation to its 2000 personnel and executives. Using current industry trends and analogies, LearningPlus developed the session and presented 26 sessions over a 3 week period.
- *Refresher training courses:* LearningPlus has worked with a number of firms to create meaningful, targeted GMP "refresher" training for their executive, operations, quality, and technical personnel.
- *Assisting with FDA commitments:* Two different firms received serious observations from FDA and committed to providing specific training to supervisors, management, and those writing/reviewing investigation reports. LearningPlus was asked to provide the content and on-site training.
- *Featured speaker and facilitator, Global Quality Conference:* A pharmaceutical firm wanted an independent expert to share information on global pressures affecting the pharma industry and the regulatory/industry responses to those pressures. As part of the project, LearningPlus facilitated a SWOT analysis with data that helped shape the quality unit's goals for the coming year.
- *Investigations and report writing:* A biopharma firm wanted to improve its skills in conducting deviation investigations and writing solid investigation reports. They also wanted to develop the competency to deliver this instruction on an ongoing basis. LearningPlus examined their entire investigation process, identified system/organizational issues that needed strengthening and created instructional materials that could be delivered by their own qualified trainers.
- *Quality system training design:* A non-US-based biologicals products organization was trying to develop quality systems training relevant to a wide variety of learners in different roles and organizational units. LearningPlus created an integrated conceptual sketch of both the quality systems and its various operations; this sketch became the basis of an extensive training effort.
- *Inspection readiness:* To help prepare for FDA inspections, LearningPlus developed a set of courses and interviews with past regulatory agency

inspectors. Feedback was given to the participants to help them improve the effectiveness of their interactions with regulatory officials. A similar workshop was developed for another organization with an emphasis on helping product development staff present to regulatory officials a clear, concise picture of a complicated biotech process.

- *Risk Management applied to project management.* A large research center affiliated with a university asked for a course on risk management that emphasized project management of complex research projects. LearningPlus conducted the workshop using cases developed for their needs.
- *Risks of working with out-sourcing sites:* A pharma firm that was increasing its use of contract manufacturing sites requested LearningPlus to develop a training course on risk management of outsourced operations for its own staff. LearningPlus was also recommended to and engaged by the contracting site for GMP training assistance.
- *Learning management system selection:* LearningPlus was engaged to help a mid-size pharmaceutical firm develop its requirements and create a "short list" of LMS vendors that the firm would then interview and select from.
- *Quality Risk Management:* A review of a large plant site (>3000 people) on the site's risk assessment tools and efforts; a report with recommendations covering tool use, training, and integration was developed for site management. Competencies needed for those involved in risk management were identified and an integrated training program was developed that the firm could implement. Meetings with key leaders were facilitated to achieve consensus on risk scales and evaluation criteria as well as documentation of the risk process. Training was conducted for executives, managers, and those leading risk assessment efforts.
- *Failure/deviation investigations:* An integrated corporate strategy, policy, and training program were developed for a large, multinational firm as part of the firm's remediation of an FDA consent decree.
- *Supervisors training course*: A two-day workshop was designed, developed, and implemented with the goal of training supervisors (line supervisors through managing directors) to interpret GMPs consistent with current industry and regulatory expectations. The course includes a 30 minute video on mountain climbing. Mr. Vesper is one of three instructors who have trained over 5,000 personnel.
- *Training program analysis and recommendations*: The training program of a UK-based pharmaceutical manufacturer was reviewed and recommendations provided so the firm could meet EU and US regulatory expectations as well as the firm's business/technical needs.
- *Executive management training*: Training sessions were provided to the executive staff and also the board of directors of a major blood organization covering GMP concepts and their corporate and individual legal responsibilities.
- *Program development and roll-out*: Since 1995, training programs (1-2 per year) have been developed for a major multinational drug firm as updates and reinforcements for GMP training. The courses are designed for the firm's instructors to adapt and deliver at their sites world-wide.
- *Consent decree remediation*: Unique training-related programs, courses, and performance solutions have been created and implemented to help five pharmaceutical and blood organizations accomplish their consent decree commitments.

1997 – 2006 LearnWright, Inc: Executive Producer, Pharma Programs

LearnWright (and its predecessor firm) created web-based e-learning courses for pharmaceutical, active pharmaceutical ingredient (API), and blood/plasma products organizations. Mr. Vesper's work as executive producer included:

- Providing conceptual design and subject matter expertise in the design and development of basic and intermediate-level GMP training courses that total over 150 hours of training.
- Providing design and analysis for a series of courses on Good Clinical Practices
- Collaborating with instructional designers, production specialists, and computer engineers in the design and development of a series of 25 one-hour e-learning modules on various laboratory techniques, instrumental, and microbiological methods. (Project is continuing through 2004.)
- Directing on-location still photo and digital video shoots in US and Switzerland for use in Learnwright's intermediate-level training courses.

1989 – 1991 Eli Lilly and Company, Project Leader – GMP Education and Instruction

Mr. Vesper established the eight-member group and its mission as Lilly responded to an FDA-imposed "voluntary agreement" (a compliance device that preceded the agency's use of consent decrees.) His responsibilities and actions included:

- Designing, developing, and implementing a corporate-wide curriculum of basic, intermediate, and advanced GMP training courses.
- Developing a tool for providing consistent training of corporate quality/GMP procedures.
- Managing a staff of eight people.
  Managing and contributing to the timely meeting of the corporate-wide training commitments.

1985 – 1989 Eli Lilly and Company, Corporate Quality Assurance – QA Representative

Mr. Vesper was the primary contact between the Corporate QA organization and the US facilities and international sites that produced sterile small volume injectable products. His responsibilities and actions included:

- Facilitating resolution of quality and compliance issues of injectable products.
- Conducting GMP/quality audits of Lilly's aseptic manufacturing facilities in the US, Puerto Rico, France, and all Lilly facilities/contract sites in Central and South America.
- Escorting/hosting inspectors from FDA and other regulatory agencies during inspections at US and European sites.
- Coordinating on-site corrective actions in response to a failed FDA pre-approval inspection at Lilly's French affiliate; FDA approval of the site was achieved upon the following inspection.
- Providing multi-month, on-site QA/technical expertise and training to a Lilly licensee in India that was producing lyophilized antibiotics.

1980 – 1985 **Eli Lilly and Company, Industrial Health and Safety – Corporate Industrial Hygienist**

Industrial Hygiene is a multi-disciplinary profession that protects workers from chemical and biological agents that could present acute or chronic risks. His responsibilities and actions included:

- Providing onsite technical assistance and information to Lilly R&D, Development, and Insulin manufacturing management and personnel related to protecting worker health.
- Member of the extended design team for the world's first r-DNA manufacturing facility to produce r-DNA derived human insulin, addressing worker health/safety issues.
- Interpreting toxicology results on research and isolated products and intermediates *vis a vis* engineering controls and personal protective equipment.

1979 **Eli Lilly and Company, Industrial Health and Safety – Industrial Hygienist Intern**

Affiliations and Memberships

Advisory boards

- *DHI/PDA Publications*
- *PDA-Training Biannual Training Conference 2006, 2008, 2010, and 2012 Planning Committees*

Professional memberships

- PDA (Parenteral Drug Association)
- ISPE (International Society of Pharmaceutical Engineers)
- ASTD (American Society of Training and Development)
- SRA (Society for Risk Analysis)
- ASIS&T (Association for Information Science and Technology) [emphasis on knowledge management]

Awards and Scholarships

2001 *James P. Agallaco Award for Excellence in Education*, PDA (Parenteral Drug Association) Training and Research Institute.

1978, 1979 NIOSH (National Institute of Occupational Safety and Health) Trainee Grant.

Academic Background

2010 – 2014 Murdoch University, Perth, WA, Australia. PhD (Education), working under Professor Jan Harrington. Research project entitled: *Developing Expertise of those Handling Temperature-Sensitive Pharmaceutical Products Using E-Learning: A Design Research Study*. Dissertation is available online at: **http://researchrepository.murdoch.edu.au/24443/**

1978 – 1980 University of Michigan, School of Public Health, Department of Environmental and Industrial Health: MPH (Industrial Hygiene with a toxicology emphasis).

1976 – 1978 Wheaton (IL) College: B.S. (Biology with a biochemistry emphasis).

1974 – 1976 Grand Rapids (MI) Junior College: A.S.

Publications

Books, author

Risk Assessment and Risk Management for the Pharmaceutical Industry: Clear and Simple. Bethesda, MD: PDA/DHI, 2006.

GMP in Practice: Regulatory Expectations for the Pharmaceutical Industry. Bethesda, MD: PDA/DHI, 2002. (4th Edition published in September 2011.)

Documentation Systems: Clear and Simple. Buffalo Grove, IL: Interpharm Press (now CRC Press), 1997.

Quality and GMP Auditing: Clear and Simple. Buffalo Grove, IL: Interpharm Press (now CRC Press), 1997.

Training for the Healthcare Manufacturing Industries: Tools and Techniques to Improve Performance. Buffalo Grove, IL: Interpharm Press (now CRC Press), 1993.

Contributing author

"The Special Training Needs for Personnel Making Sterile Drug Products." *Microbiology in Pharmaceutical Manufacturing, Second Edition* Richard Prince, Editor. Bethesda, MD: PDA/DHI, 2008.

"Training and Learning: Critical Contributors to Quality" In *Quality in Pharmaceutical Manufacturing.* Richard Prince, Editor. Bethesda, MD: PDA/DHI, 2004.

World Health Organization GMP Requirements Part 3: Guide for Training. Geneva: WHO, 2007. Freely available at: www.who.int/vaccines-documents/DocsPDF06/799.pdf

Four Chapters: "Human Factors and Information Systems"; "Investing in Education and Training"; "Documenting Education and Training"; "Evaluation and Certification". In *Automation and Validation of Information in Pharmaceutical Processing.* Ed. Joseph deSpautz. New York: Marcel Dekker, Inc., 1997.

Articles

Vesper, J.L., Kartoğlu, Ü., Herrington, J., Reeves, R. C. (2015) *Incorporating risk assessment into the formative evaluation of an authentic e-learning program.* British Journal of Educational Technology, 2015. Published online as of 8 Jun 2015: http://onlinelibrary.wiley.com/doi/10.1111/bjet.12295/

Vesper, J. L., Herrington, J., Kartoğlu, Ü., & Reeves, T. C. (2015). Initial design principles for establishing a learning community for public health professionals through authentic e-learning. *International journal of continuing education and life-long learning*. 25:2 (pp. 241-257).

Vesper, J. L., Reeves, T. C., & Herrington, J. (2013). Using preliminary risk assessment in a formative evaluation. In J. Herrington, A. Couros & V. Irvine (Eds.), *Proceedings of World Conference on Educational Multimedia, Hypermedia and Telecommunications 2013* (pp. 407-412). Chesapeake, VA: AACE.

Vesper, J. L., & Herrington, J. (2012). Considering communities of learners when creating an e-learning course. In T. Amiel & B. Wilson (Eds.), *Proceedings of World Conference on Educational Multimedia, Hypermedia and Telecommunications 2012* (pp. 481-490). Chesapeake, VA: AACE.

Vesper, J. L., Reeves, T. C., & Herrington, J. (2011). The application of expert review as a formative evaluation strategy within an educational design research study (AACE, Trans.) *Proceedings of World Conference on E-Learning in Corporate, Government, Healthcare, and Higher Education (E-Learn) 2011* (pp. 973-978). Honolulu, HI: AACE.

Vesper, J. L., Kartoğlu, Ü., & Reeves, T. C. 2011. An Example of Experiential and Social Learning: WHO's Pharmaceutical Cold Chain Management on Wheels. *Pharm Tech Japan*. (Accepted for publication.)

Vesper, J. L., Kartoğlu, Ü., Bishara, R., & Reeves, T. C. 2010. A case study in experiential learning: Pharmaceutical cold chain management on wheels. *Journal of Continuing Education in the Heath Professions, 30*(4), 1-8.

Vesper, J. L. 2009. "Shifting the focus from Training to Learning" *Pharm Tech Japan*. November 2009.

Vesper, J. L. 2008. "Moving GMPs from Compliance Systems to Quality Systems" *Pharm Tech Japan*. July 2008.

Vesper, J. L. 2008. Published interview on Management and Training *Pharm Tech Japan*. April (vol. 24, no. 4) pp. 84-86.

Vesper, J. L. and Reeves, Thomas. 2005. "Training and the FDA Draft Guidance on Quality Systems" *BioExecutive International*. May 2006.

Vesper, J. L. and Reeves, Thomas. 2005. "Training and the FDA Draft Guidance on Quality Systems" *Pharm Tech Japan*. December (vol. 21, no. 14) pp. 2363-2369.

Vesper, J. L. 2005. "Challenges in Providing e-Learning Solutions in the Regulated Pharmaceutical Industry" *Pharm Tech Japan*. October (vol. 21, no. 11) pp. 1877-1880.

Vesper, J. L. 2005. "Risk Assessment and Risk Management in a GMP Environment" BioPharm *International*. March (vol. 18, no. 3) pp. 46-58.
Vesper, J. L. 2003. "What are GMPs Anyway?" *BioProcess International.* February (vol. 1, no.2) pp. 24-29.

Vesper, J. L. 2001. "Writing Procedures that Contribute to Performance." *BioPharm.* August (vol. 14, no. 8) pp. 22-25.

Vesper, J. L. 2001. "Performance: The Goal of Training (or Why Training Is Not Always the Answer…)." *BioPharm.* February (vol. 14, no. 2), pp. 44-46.

Vesper, J. L. 2000. "Defining Your GMP Program with a Training Procedure." *BioPharm.* November (vol. 13, no.11), pp.28-32.

Vesper, J. L. 1993. "Measuring the Effectiveness of Training." *Pharmaceutical Engineering*. Jan/Feb 1994 (vol. 14, no. 1), pp. 8-16.

Vesper, J. L. 1993. "Considering Users When Implementing New Pharmaceutical Technology." *Pharmaceutical Engineering*. May/June 1993 (vol. 13, no. 3), pp. 92-95.

(Note: copies of many articles are available on-line at www.learningplus.com/news.htm.)

Presentations

(selected)

Vesper, J. L, Herrington, Jan, Reeves, T. C. "Using Preliminary Risk Assessment in a Formative Evaluation". *Ed-Media Conference*, June 2013, Victoria, BC.

Vesper, J. L and Herrington, Jan. "Considering Communities of Learners When Creating an E-learning Course". *Ed-Media Conference*, June 2012, Denver.

Vesper, J. L, Reeves, T. C. and Herrington, J. "The Application of Expert Review as a Formative Evaluation Strategy within an Educational Design Research Study". *E-Learn Conference*, October 2011, Honolulu.

Vesper, J. L. "Knowledge Management and Training". Invited speaker. *GMPs by the Sea*, 9 August 2011. Tampa, FL

Vesper, J. L and Herrington, Jan. "Developing Expertise in those Handling Time/Temperature Sensitive Pharmaceutical Products: Applying the Early Phases of a Design Research Methodology". *Ed-Media Conference*, 28 June 2011, Lisbon.

Vesper, J. L. "Using Risk Management in Manufacturing Safe, Pure, and Effective Sterile Products". Invited speaker. *Proceasep2011*, 29 April 2011.

Vesper, J. L. "What Constitutes a Subject Matter Expert?" Invited speaker. *PDA Regional Conference*, 26 April 2011, Raleigh, NC.

Vesper, J. L. "Developing Expertise: It's more than carrying a nice briefcase". *PDA Annual Meeting*, 12 April 2011, San Antonio, TX

Vesper, J. L. "Experiences and applications in the pharmaceutical industry with virtual education". Invited speaker. Pharmaceutical International Congress, Istanbul, 7 Sept 2009.

Vesper, J. L. "The Path Ahead: Where might we be with pharmaceutical industry training in five years?" *Biannual PDA Training Conference*, May 2008, New Orleans.

Vesper, J. L. "Challenges in Providing e-Learning Solutions in the Regulated Pharmaceutical Industry." Invited speaker. *e-learn 2002*, November 2002, Montreal.

Vesper, J. L. "Critical Training Issues: Common Features of Industry Leaders." *FDA/PDA Joint Meeting*, September 2002, Washington.

Public Workshops

(selected) *From Training to Learning - Improving GMP Performance.* Key2Compliance workshop, Stockholm, Sweden, December 2014. To be repeated May, 2015 in Copenhagen.

Conducting Effective Incident Investigations and Writing Investigation Reports. Key2Compliance workshop, Stockholm, Sweden, December 2014.

Reportedly Trained or Truly Trained: Developing GMP Training That Works. One and one-half day workshop produced by FDANews. Workshop presented in Raleigh, NC; Boston and Chicago in 2009, 2010, 2011, 2012, and 2013.

Applying Quality Risk Management Principles: Moving ICH Q9 from Theory to Practice. Two-day workshop produced by FDANews. Workshop presented in for Chicago and Princeton, NJ and Philadelphia in 2009, 2010, 2011 and 2012.

Using Risk Management to Prepare for Inspections. Pre-conference workshop presented at 4th Annual Inspections Summit, produced by FDANews, 21 Oct 2009, Washington, DC.