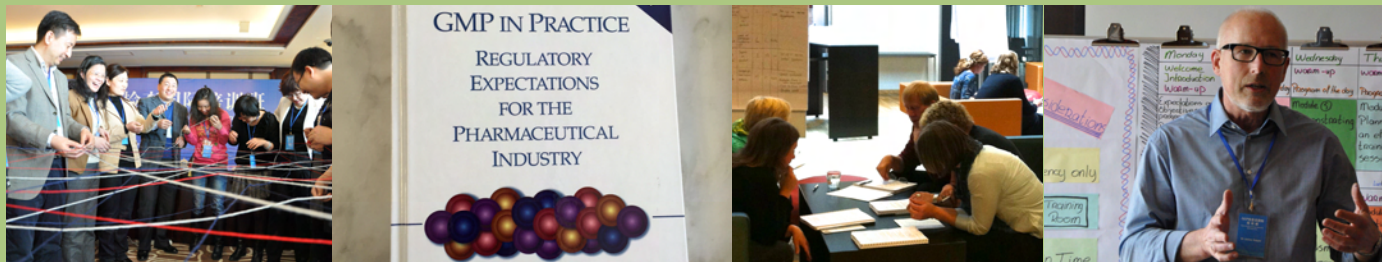


# What has *LearningPlus* accomplished recently?



How can we help you achieve your compliance, learning, and performance goals?

**Quality Metrics, 2**

Here are some options being discussed. Click on each one to learn more.

- Right-first-time
- Batch failure rate
- OOS/lab result failure rates
- Recalls – number, severity
- Process capability
- Trend data

On 12 February 2013, FDA published a notice in the Federal Register to let the industry know it wanted to identify quality metrics. To read that notice, click here.

To visit the website and the 131 comments submitted, click here.

Whatever metrics are selected, FDA wants metrics from firms so they can (1) compare sites and products to one another and (2) more efficiently evaluate systems on inspections.

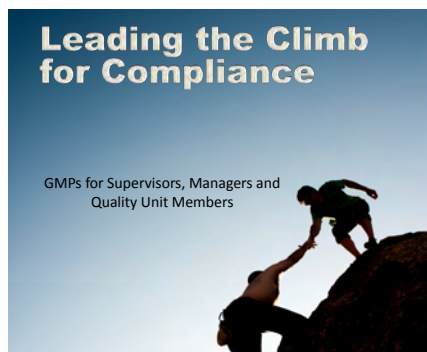
## Online GMP Update

A major pharma/vaccine producer asked LearningPlus

to design and write the content for a **GMP Update** course that examined what was new at FDA and also what FDA was finding in their inspections throughout the industry. The course also shared what regulatory inspections were finding at the company's sites and included a call to action and a short quiz. Using the design and content from LearningPlus, the firm created the final e-learning course using Articulate.

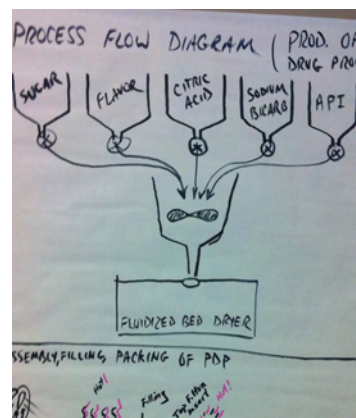
## Developing GMP thinking in supervisors & managers

LearningPlus has continued to present its **Leading the Climb** course to biological, pharma, and consumer health products companies in North America. The two-day course examines sources of GMP expectations, quality systems, Seven Essentials of GMP, activities and a case study.



## Quality Risk Management

Several different firms in the US and Europe asked LearningPlus to review their current QRM activities and also provide training for their QRM team members. The two-day workshop covers basics of risk-based thinking, the QRM process, and a variety of tools used in risk assessment.



## Baseline GMP and QSR course

As part of a "level setting" project covering drug and device GMP requirements, a global manufacturer invited LearningPlus to develop two similar courses covering the history, concepts, and requirements of the 21 CFR Parts 210-211 – Good Manufacturing Practice – and Part 820 – Medical Device

Quality System Regulation. Course materials were prepared and a train-the-trainer course was presented that qualified their instructors to facilitate the course at their sites around the world.

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

**What can we do for you this year?**

## A continuing best seller

### Top 5 Best Sellers

1. **GMP In Practice Regulatory Expectations for the Pharmaceutical Industry, Fourth Edition, Revised & Expanded**  
by: James Vesper
2. **PDA Technical Report No. 29, Revised 2012 (TR 29) Points to Consider for Cleaning Validation (single user digital version)**
3. **PDA Technical Report No. 29, Revised 2012 (TR 29) Points to Consider for Cleaning Validation (single user digital version)**

*GMP in Practice*, is in its 4th Edition and continues to be one of the top selling books in the PDA bookstore ([www.pda.org](http://www.pda.org)). Thirty-three quality system elements are examined in this 600-page book with expectations and citations from the US FDA, EU-EMA, WHO, and ICH.



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.

## Public workshops in US, Sweden, and Denmark



LearningPlus continues to work with Key2Compliance in northern Europe and FDANews in the US who sponsor public workshops on GMP topics. In 2015, public workshops will also be sponsored by the Canadian Pharmaceutical Sciences Group (PSG) and the PDA.

Topics in these workshops include **Knowledge Management & Learning, Quality Risk Management, Advanced Root Cause and CAPA Investigations, and GMPs for Supervisors.**

LearningPlus designs, develops, and implements learning and performance solutions for pharma and biopharma firms on topics related to Good

## Design-based research on WHO e-learning course



Begun in 2010, James Vesper completed an extensive design-based research project (and his PhD in Education) for an e-learning course, “e-Pharmaceutical Cold Chain Management” for the World Health Organization’s Global Learning Opportunities unit. The work involved multiple iterations of evaluation by experts, mentors, and learners, all of whom provided important input to strengthen the course’s unique design. Information on the course can be found at [www.epela.net](http://www.epela.net).

LearningPlus founder and president James Vesper, PhD, MPH, 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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