



The Parenteral Drug Association Presents:

## Denver Course Series

*Risk Management for Aseptic Processing, Integration of Risk Management into Quality Systems and What Every Biotech Startup Needs to Know about CMC Compliance*

September 30 – October 1, 2010 | Grand Hyatt Denver, Denver Colorado | [www.pdatraining.org/denver](http://www.pdatraining.org/denver)

Join us for these three great courses that will be offered in Denver, Colorado by the Parenteral Drug Association Training and Research Institute.

### Risk Management for Aseptic Processing

**Date:** September 30 - October 1, 2010

**Duration:** 1.5 Days

**Time:** September 30: 1:00 p.m. - 4:15 p.m. | October 1: 8:30 a.m. – 4:00 p.m.



Instructor: **Harold Baseman**, Principal, *ValSource, LLC*.

This interactive course will utilize *PDA Technical Report No. 44 Quality Risk Management of Aseptic Processes* methodology to identify, assess, manage and use risk to make informed decisions in aseptic processing. Instruction will include background information in quality risk management, regulatory expectations, unique aspects of risk management related to aseptic processing of sterile products, organizational culture, risk assessment methods and examples and the use of risk in process validation.

Member/Nonmembers Standard **\$1295** | Student/Academic **\$ 780** | Government **\$780**

### Integration of Risk Management into Quality Systems

September 30 – October 1, 2010

**Duration:** 1.5 Days

**Time:** September 30: 1:00 p.m. - 4:15 p.m. | October 1: 8:30 a.m. – 4:00 p.m.



Instructor: **Lisa Hornback**, Principal Consultant, *Hornback Consulting, LLC*.

Understand the methods to imbed risk management concepts into elements of your quality systems and utilize current quality data to develop a closed-loop and “living” risk management program. The workshop will include discussion of the primary risk management tools and application of risk management controls to identify, evaluate and mitigate risks. Use of risk management concepts in quality system elements such as design controls, complaints, nonconformance’s, use of trending tools and escalation into CAPA will be discussed and will include best practices to integrate these processes to obtain consistent and defensible risk-based decisions.

Member/Nonmembers Standard **\$1295** | Student/Academic **\$ 780** | Government **\$780**

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## **What Every Biotech Startup Needs to Know about CMC Compliance**

October 1, 2010

**Time:** 8:30 a.m. - 4:00 p.m.



Instructor: **John Geigert**, PhD, RAC, President,  
*BioPharmaceutical Quality Solutions.*

Strengthen your company's CMC program and avoid common pitfalls by gaining vital insight and practical guidance on developing acceptable CMC regulatory compliance strategies for your early clinical stage development (Phase 1 and Phase 2). This course will also give you suggestions on how to organize the CMC responsibilities within a biotech startup and how to develop a cost-effective, risk-managed CMC strategy.

Member/Nonmembers Standard **\$995** | Student/Academic **\$600** | Government **\$600**

### **P.S. Join PDA Today!**

PDA is a global non-profit organization of over 9,500 members. Our focus and emphasis is in the areas of **sterile product technology, biotechnology and quality and regulatory compliance concepts and systems** - become a part of our community, join PDA today!

**[www.pda.org/join](http://www.pda.org/join)**