From the producers of the Proactive GCP Compliance Conferences and Clinical Quality Oversight Forums…

May 21 - May 22, 2019
Hyatt Regency San Francisco Airport
Burlingame, CA

Clinical Trial Risk Management SEMINAR

Evaluate Processes and Develop Strategies to Identify, Assess and Manage Risk in Clinical Research

Each day features two interactive sessions, followed by a panel of industry experts sharing their own related experiences.

Tuesday May 21, 2019

MORNING SESSION

THE IMPACT OF ICH E6 R2

Break Down the Critical Elements of ICH E6 R2 and Their Impact on Clinical Operations

Facilitated by

Pam Dellea-Giltner, B.D., MBA, CCRA, *President,* **PDG CLINICAL CONSULTING, LLC**

AFTERNOON SESSION

CLINICAL RISK MANAGEMENT

Unlock the Secrets of a Successful Clinical Risk Management Process

Facilitated by

Todd Johnson, *Principal Consultant, Organizational Solutions,* **HALLORAN CONSULTING GROUP**

Sheila Gwizdak, *Principal Consultant, Quality,* **HALLORAN CONSULTING GROUP**

Wednesday May 22, 2019

MORNING SESSION

CRO OVERSIGHT

Understand the Impact of ICH E6 R2 on the Requirements for Sponsors and CROs Related to Oversight

Facilitated by

Liz Wool, *President,* **WOOL CONSULTING GROUP, INC.**

AFTERNOON SESSION

CLINICAL INSPECTION READINESS

Create a Preparation Plan That Guides All Stakeholders to Achieve a Constant and Confident State of Inspection Readiness

Facilitated by

Michele Weitz, *Senior Director, GCP Compliance Operations,* **CLOVIS ONCOLOGY**

#CTRMSeminar **Proactive GCP Compliance**

Event Sponsor

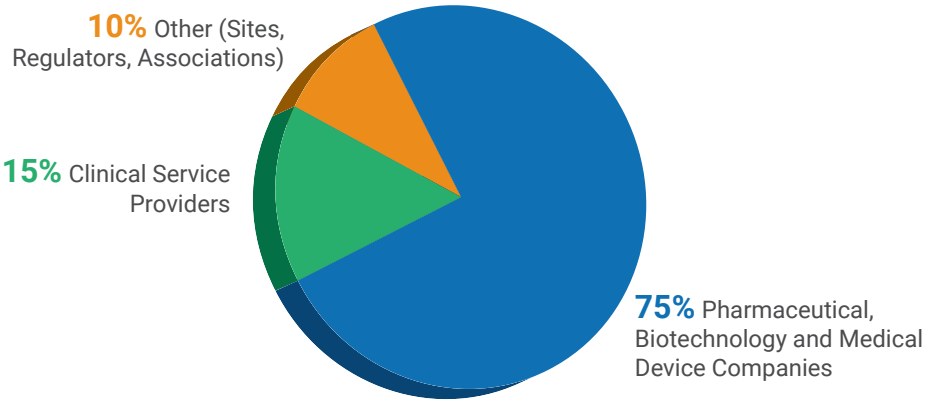
Halloran

TO REGISTER, CALL 201-871-0474 OR Click Here

Who Will You Meet?

Demographics From Our Related Clinical Quality Events

Company Type



Who Should Attend?

VP-, Director-, Manager-, and C-Level executives from the following departments at Pharma/Biotech/Medical Device companies, CROs, and other clinical trial service providers:

- Good Clinical Practice/GCP
- Clinical Quality Assurance/CQA
- Clinical Quality Control/CQC
- Clinical Operations/Management
- Audits/Inspections
- Quality Management/Global Quality Management
- Compliance/Global Compliance
- Data Management/Systems Operations
- Clinical Monitoring
- Regulatory Affairs
- Safety and Risk Management/ Operations

This conference is also relevant to clinical QA, compliance and operations professionals from:

- Quality Service Providers and Consulting Companies
- CROs
- Central, Imaging, and ECG Labs
- Investigative Sites
- IRBs
- Data Management and Software Vendors
- Safety Reporting Vendors

Dear Colleague,

ExL has extended its well-known and established clinical quality series of events to the West Coast. Responding to the many requests by our loyal audience, we have developed a Clinical Trial Risk Management Seminar, featuring two days of interactive sessions and panels. This Seminar provides a comprehensive education on clinical risk management and the tools to assess, maintain, and mitigate risk to ensure compliance. Join us on May 21–22 in San Francisco for this exciting gathering of clinical quality, compliance, and operations executives from the leading biopharma companies, service providers, and sites.

I look forward to greeting you in May! Don't hesitate to reach out with any questions.

Sincerely,

Kristen Hunter

Do You Want to Reach the Audience at This Event?

Do you want to spread the word about your organization's solutions for potential clients and prospects in attendance? Take advantage of the opportunity to exhibit, present an educational session, share your expertise on a panel discussion, host a networking event, and/ or distribute promotional materials at this conference. ExL works closely with our sponsors to create customized opportunities to fulfill your conference objectives.

Venue Information

Hyatt Regency San Francisco Airport
1333 Bayshore Highway / Burlingame, CA 94010

To make reservations, guests can call 650-347-1234 or 877-803-7534 and reference **ExL's Clinical Risk Management Seminar**. You may also visit **https://bit.ly/2HSBFvl** to make reservations online.

The group rate is available until **April 30th, 2019**. Please book your room early, as rooms available at this rate are limited.

**ExL Events is not affiliated with Exhibition Housing Management (EHM)/Exhibitors Housing Services (EHS) or any third-party booking agencies, housing bureaus or travel companies. ExL Events is affiliated with event company Questex, LLC. In the event that an outside party contacts you for any type of hotel or travel arrangements, please disregard these solicitations and kindly email us at info@exlevents.com. ExL has not authorized these companies to contact you and we do not verify the legitimacy of the services or rates offered. Please book your guest rooms through ExL's reserved guest room block using the details provided.*

TO REGISTER, CALL 201-871-0474 OR Click Here

Day One – **Tuesday, May 21, 2019**

7:45 Registration and Continental Breakfast for Day One Participants

8:30 **THE IMPACT OF ICH E6 R2**

Break Down the Critical Elements of ICH E6 R2 and Their Impact on Clinical Operations

Pam Dellea-Giltner, B.D., MBA, CCRA, *President,* **PDG CLINICAL CONSULTING, LLC**

- Identify the aspects of ICH E6 that impact clinical operations
  - Define the portions that relate to GCP
  - Understand the elements that have changed as a result of R2
  - Evaluate regional variations and different possible interpretations
- Examine the areas of clinical operations that are most heavily impacted by ICH E6 R2
  - Conceptualize risk identification, tolerance, and mitigation approaches
  - Demonstrate necessary changes to monitoring and oversight
  - Understand where the challenges lie in achieving compliance

10:30 30-Minute Networking Break

11:00 **EXPERT PANEL: THE RESPONSE TO ICH E6 R2**

PANEL

Discuss Changes to Clinical Operations That Companies Have Implemented Responding to ICH E6 R2

- Examine current operations to assess where changes must be made to remain compliant
  - Conduct a gap analysis of processes
  - Develop an action plan to remain compliant
  - Construct a methodological approach to achieve full compliance
- Execute the necessary changes

12:00 Lunch

1:00 **CLINICAL RISK MANAGEMENT**

Unlock the Secrets of a Successful Clinical Risk Management Process

Todd Johnson, *Principal Consultant, Organizational Solutions,* **HALLORAN CONSULTING GROUP**

Sheila Gwizdak, *Principal Consultant, Quality,* **HALLORAN CONSULTING GROUP**

- Uncover the elements of a successful clinical risk management process to achieve optimal results with limited resources
- Outline the factors of ICH E6 R2 that have changed the industry's approach to risk management and vendor oversight
- Develop an achievable implementation plan that leverages available resources
- Leverage the risk management processes to predict clinical risk areas and achieve overall confidence in compliance

3:00 30-Minute Networking Break

3:30 **EXPERT PANEL: CLINICAL RISK MANAGEMENT LEADING PRACTICES**

PANEL

Translate Experiences and Lessons Learned Into Leading Practices for Optimizing Clinical Risk Management

- Discuss how clinical risk management has changed at your company following ICH E6 R2
- Understand how successful vendor qualification and oversight practices improve your clinical risk management practices
- Outline effective strategies for developing and implementing clinical risk management approaches when working with limited resources
- Share advice and guidance for companies looking to implement or optimize their clinical risk management approach

4:30 Day One Concludes

7:45 Registration and Continental Breakfast for Day Two Participants

8:30 **CRO OVERSIGHT**

Understand the Impact of ICH E6 R2 on the Requirements for Sponsors and CROs Related to Oversight

Liz Wool, *President,* **WOOL CONSULTING GROUP, INC.**

- Examine the portions of ICH E6 R2 that address CRO oversight
- Discuss regulatory authority communications and inspection findings related to CRO oversight
- Describe leading practices for CRO oversight and CRO Oversight Plans
  - Evaluate if your current strategy and approach are keeping up with the changing times and practices
- Identify what a CRO needs to do when they use a subcontractor and how this impacts the sponsor's oversight of the CRO

10:30 30-Minute Networking Break

11:00 **EXPERT PANEL: CRO-SPONSOR RELATIONSHIP OPTIMIZATION**

PANEL

Promote a Culture of Quality, Transparency, and Compliance With Your CRO Partner

- Discuss regulatory authority inspection trends and the focus on sponsors for CRO oversight
- Determine what makes a successful partnership with your CRO
- Discuss different outsourcing and oversight models
- Identify common oversight challenges and how they were overcome

12:00 Lunch

1:00 **CLINICAL INSPECTION READINESS**

Create a Preparation Plan That Guides All Stakeholders to Achieve a Constant and Confident State of Inspection Readiness

Michele Weitz, *Senior Director, GCP Compliance Operations,* **CLOVIS ONCOLOGY**

- Recognize the need for a coordinated inspection readiness strategy
- Develop a risk-based inspection readiness plan that is achievable and resource-friendly
- Foster a corporate environment to achieve this inspection-ready state
- Manage the quality expectations of the clinical team to ensure consistency and compliance
- Recognize the importance of continual risk assessments
  - Understand the value of the mock inspection
- Measure the effectiveness of the plan and adjust when needed based on risk areas

3:00 30-Minute Networking Break

3:30 **EXPERT PANEL: LEARN FROM INSPECTION EXPERIENCES**

PANEL

Discuss Observations and Lessons Learned From Panelists' Inspection Experiences and Providing Guidance to Optimize Preparation Efforts

Panelist

Rhonda Pisk, M.S., ACRP-CP, ACRP-PM, *Clinical Program Director,* **STANFORD UNIVERSITY SCHOOL OF MEDICINE**

- Evaluate recent inspection experiences and observed trends
- Assess how inspections have changed regarding what inspectors expect and require
- Identify common obstacles and challenges during an inspection and strategies for overcoming them
- Outline best practices for managing expectations and preparation strategies

4:30 Seminar Concludes

Five Ways to Register

Phone: 201-871-0474

Fax: 253 663 7224

Online: Click Here

Email: register@pmaconference.com

Mail: PMA Conference Management POB 2303 Falls Church VA 22042

Pricing Information for the Clinical Trial Risk Management Seminar

	TWO-DAY RATE	ONE-DAY RATE
EARLY BIRD PRICING *Register by April 12, 2019*	$1,895	$1,195
STANDARD PRICING	$2,095	$1,295
ONSITE PRICING	$2,295	$1,395

**Includes Sales Tax and Service Fees*

Group Discount Programs

Offers may not be combined. Early Bird rates do not apply.

SAVE 25%

For every three simultaneous registrations from your company, you will receive a fourth complimentary registration to the program (must register four). This is a savings of 25% per person.

SAVE 25%

SAVE 15%

Can only send three? You can still save 15% off of every registration.

To f nd out more on how you can take advantage of these group discounts, please call 201 871 0474.

SAVE 15%

Media Partners

MEDtube sharing medical knowledge™

pharmaphorum bringing healthcare together

PharmaVOICE

pharmaLEADERS News. Resources. Community.

PM360 THE ESSENTIAL RESOURCE FOR PHARMA MARKETERS

www.PharmCast.com – Pharmaceutical Internet –

TECHNOLOGY NETWORKS

TERMS AND CONDITIONS:
By registering for an ExL Events ("ExL") event, you agree to the following set of terms and conditions listed below:

REGISTRATION FEE:
The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

PAYMENT:
Make checks payable to ExL Events and write 783819 on your check. You may also use Visa, MasterCard, Discover or American Express. Payments must be received in full by the conference date. Any discount applied cannot be combined with any other offer and must be paid in full at the time of order. Parties must be employed by the same organization and register simultaneously to realize group discount pricing options.

Please Note: There will be an administrative charge of $300 to substitute, exchange and/or replace attendance badges with a colleague within five business days of any ExL conference.

CANCELLATION AND REFUND POLICY:
If you cancel your registration for an upcoming ExL event, the following policies apply, derived from the Start Date of the event:

- Four weeks or more: A full refund (minus a $295 processing fee) or a voucher to another ExL event valid for 12 months from the voucher issue date.
- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
- Five days or less: A voucher (minus a $395 processing and documentation fee) to another ExL event valid for 12 months from the voucher issue date.

To receive a refund or voucher, please email cancel@exlevents.com or fax your request to 888-221-6750.

CREDIT VOUCHERS:
Credit vouchers are valid for 12 months from date of issue. Credit vouchers are valid toward one (1) ExL event of equal or lesser value. If the full amount of said voucher is not used at time of registration, any remaining balance is not applicable now or in the future. Once a credit voucher has been applied toward a future event, changes cannot be made. In the event of cancellation on the attendees' behalf, the credit voucher will no longer be valid.

ExL Events does not and is not obligated to provide a credit voucher to registered attendee(s) who do not attend the event they registered for unless written notice of intent to cancel is received and confirmed prior to the commencement of the event.

SUBSTITUTION CHARGES:
There will be an administrative charge of $300 to substitute, exchange and/or replace attendee badges with a colleague occurring within five business days of the conference.

ExL Events reserves the right to cancel any conference it deems necessary and will not be responsible for airfare, hotel or any other expenses incurred by registrants.

ExL Events' liability is limited to the conference registration fee in the event of a cancellation and does not include changes in program date, content, speakers and/or venue.

*The opinions of ExL's conference speakers do not necessarily reflect those of the companies they represent, nor ExL Events.

Please Note: Speakers and agenda are subject to change without notice. In the event of a speaker cancellation, significant effort to find a suitable replacement will be made. The content in ExL slide presentations, including news, data, advertisements and other information, is provided by ExL's designated speakers and is designed for informational purposes for its attendees. It is NOT INTENDED for purposes of copywriting or redistribution to other outlets without the express written permission of ExL's designated speaking parties. Neither ExL nor its content providers and/or speakers and attendees shall be liable for any errors, inaccuracies or delays in content, or for any actions taken in reliance thereon. EXL EVENTS EXPRESSLY DISCLAIMS ALL WARRANTIES, EXPRESSED OR IMPLIED, AS TO THE ACCURACY OF ANY CONTENT PROVIDED, OR AS TO THE FITNESS OF THE INFORMATION FOR ANY PURPOSE. Although ExL makes reasonable efforts to obtain reliable content from third parties, ExL does not guarantee the accuracy of, or endorse the views or opinions given by any third-party content provider. ExL presentations may point to other websites that may be of interest to you, however ExL does not endorse or take responsibility for the content on such other sites.

TO REGISTER, CALL 201-871-0474 OR Click Here