Good Laboratory Practice Compliance Monitoring
SUMMIT
January 21-22, 2016 | Sheraton Pentagon City | Arlington, Virginia

Best Practices for Regulatory Adherence, Technology Implementation and Data Management in Order to Remain GLP Compliant

Chairperson and Moderator

- **RANEE HENRY**
  President
  MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE (MARSQA)

Featured Speakers and Sessions

- **CASE STUDY: The Establishment of a GLP-Compliant Quality Assurance Program for Medical Device Research and Development**
  THOMAS SCHAER, VMD
  Director Preclinical Research Services (GLP)
  UNIVERSITY OF PENNSYLVANIA SCHOOL OF VETERINARY MEDICINE

- **Explore the Relationship Between Quality Process Development and Quality Audits**
  TRISHA PRYCE
  Senior Manager Research Quality Assurance
  ALEXION PHARMACEUTICALS

- **Best Practices for CRO and Vendor Oversight**
  SHIRLEY WARE
  Head of Research Compliance & Quality
  SHIRE PHARMACEUTICALS

- **Risk-Based Approach in GLP and Non-Regulated Audits**
  DAVID MALWITZ, M.S.
  Senior Specialist, Bioresearch Quality Assurance
  JANSSEN

The **inaugural event** dedicated to Good Laboratory Practice (GLP) and quality assurance during preclinical studies

**Compliance Master Class: Prepare Your Laboratory for a GLP Audit from the FDA**
- Streamline standard operating procedures
- Prepare internal teams for interviews
- Liaise with federal regulators
- Ensure data and record keeping compliance

**Master Class Leader**
Christina D. Hamm, B.A., RQAP-GLP
Director, Global Regulatory Affairs and Quality Assurance,
CELLULAR TECHNOLOGY LIMITED

Sponsor:

To Register Call 866-207-6528 or Visit Us at www.exlevents.com/GLP
Good Laboratory Practice standards were put into place not only to prevent the falsification of records, but also to ensure the uniformity and reproducibility of nonclinical safety testing. Those working in the pharmaceutical and biotechnology industries must constantly examine and improve quality processes in order to adhere to FDA guidelines.

The GLP Compliance Monitoring Summit is the most specialized venue available for quality professionals working in nonclinical studies to exchange strategies, techniques and best practices for maintaining GLP standards. Issues such as overseeing vendors, preparing for an FDA audit, outsourcing GLP work and identifying risk prior to developing an audit plan are just some of the topics we’ll examine in depth at this two-day event.

This summit features an expert speaking faculty that will guide attendees through the regulatory process, provide insight into steering clear of violations and help your organization remain compliant in its nonclinical activities.

We welcome you to join us for this collaborative, intensive learning experience!

Sincerely,

Derek O’Connor
Conference Production Director
ExL Events
doconnor@exlevents.com

Dear Colleague,

Good Laboratory Practice Compliance Monitoring Summit

This conference is designed for representatives from laboratories as well as pharmaceutical and biotechnology companies with responsibilities in the following areas:

- Good Laboratory Practice (GLP)
- Quality Assurance/Quality Management
- Lab Safety
- Regulatory/Compliance
- Audits
- Laboratory Management
- Government Oversight
- Preclinical Development
- Preclinical Trials
- Research and Development
- Global Regulatory Affairs
- Product Development
- Research Labs

This conference is also of interest to:
- Preclinical Lab Services
- CROs/CMOs
- Quality/Compliance Service Providers
- GLP Consultants

SPONSORSHIP AND EXHIBITION OPPORTUNITIES

Do you want to spread the word about your organization’s solutions and services to potential clients who attend this event? Take advantage of the opportunity to exhibit, present an educational session, host a networking event or distribute promotional items to attendees. ExL works closely with you to customize a package that suits all of your needs.

To learn more about these opportunities, contact David Borrok, Senior Business Development Manager, at 212-400-6234 or dborrok@exlevents.com to learn more.

VENUE INFORMATION

Sheraton Pentagon City | 900 S. Orme St. | Arlington, VA 22204

Room Reservations: If you require overnight accommodations, please contact the hotel to book your room. ExL Events has reserved a block of rooms at a group rate for conference participants. To make reservations guests can call 1-800-325-3535 and request the group rate for ExL’s January Meetings. We encourage participants to make reservations by January 6, 2016 in order to be eligible for the group rate. Please make your reservations early as rooms available at this rate are limited.

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### Day One  
**Thursday, January 21, 2016**

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<tr>
<td>8:15</td>
<td>Registration and Continental Breakfast</td>
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<tr>
<td>9:00</td>
<td>Chairperson’s Welcome and Opening Remarks</td>
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</tbody>
</table>
| 9:15   | **COMPLIANCE MASTER CLASS:** Prepare Your Laboratory for an FDA Audit of GLP Compliance  
  - Establish what regulatory inspectors look for to determine compliance  
  - Hear about how internal auditors prepare their quality teams  
  - Identify common errors and trends that lead to failing an audit  
  - Examine case examples of audits and create appropriate strategies to mitigate an audit  
  - Implement best practices to equip and train your compliance team  
  - Promote interview techniques and data collection strategies that appropriately meet FDA standards  
  Christina D. Hamm, B.A., RGAP-GLP, Director, Global Regulatory Affairs and Quality Assurance, CELLULAR TECHNOLOGY LIMITED  
  Bonnie Pappacena, Vice President, Head of Quality, TURING PHARMACEUTICALS  
  This Master Class will include a 30-minute networking break. |
| 10:00  | Luncheon                                                               |
| 10:15  | **CASE STUDY:** Implementation of GLP in an Academic/Research Setting  
  - Understand the financial and resource limitations of maintaining GLP compliance  
  - Recognize partnership benefits and opportunities between industry and academia/research on preclinical testing  
  - Discover who assumes the quality oversight role in a non-industry environment  
  Chartley Bondurant, Associate Director, Quality Improvement Office, INDIANA UNIVERSITY |
| 12:15  | Luncheon                                                               |
| 2:00   | Best Practices for CRO and Vendor Oversight  
  - Review techniques for identifying GLP compliance and non-compliance within a contract research organization (CRO)  
  - Determine the role of the quality assurance of record from a CRO and its responsibilities in laboratory quality  
  - Observe methods for monitoring CRO activities  
  Shirley Ware, Head of Research Compliance & Quality, SHIRE PHARMACEUTICALS |
| 2:45   | Networking Break                                                      |
| 3:15   | **Quality Operations vs. Quality Compliance (Audit)**  
  - Address conflicts that internal quality departments face in the creation of SOPs and the need for auditing  
  - Learn which aspects of quality particular departments are responsible for and how to keep them separate  
  - Discover common compliance issues internal customers face in the absence of SOPs  
  Trisha Pryce, Senior Manager Research Quality Assurance, ALEXION PHARMACEUTICALS |
| 4:00   | **CASE STUDY:** The Establishment of a GLP-Compliant Quality Assurance Program for Medical Device Research and Development  
  - Understand the difficulties of establishing quality programs in a cost-prohibitive nonprofit environment where GXP is not common  
  - Hear about the ambiguity regarding guidance from CDRH on medical device regulations prior to 2013  
  - Pinpoint cost hindrances of test metrics and how to compliantly outsource to collaborators  
  Thomas Schaer, VMD, Director Preclinical Research Services (GLP), UNIVERSITY OF PENNSYLVANIA SCHOOL OF VETERINARY MEDICINE |
| 5:00   | Day One Concludes                                                     |

### Day Two  
**Friday, January 22, 2016**

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<tr>
<th>Time</th>
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<tbody>
<tr>
<td>8:15</td>
<td>Continental Breakfast</td>
</tr>
<tr>
<td>9:00</td>
<td>Chairperson’s Recap of Day One</td>
</tr>
</tbody>
</table>
| 9:15   | **The Benefits of Using GLP Standards in Non-GLP Studies**  
  - Learn GLP-mandated processes and metrics that are transferable to GCP studies  
  - Review examples of how GLP compliance has resulted in more successful FDA approvals  
  - Develop a program to train non-GLP quality and lab teams in GLP compliance  
  Linda Hook-Dinnocenzo, Director, GCP Compliance, FORUM PHARMACEUTICALS |
| 10:00  | The Transition from In-House to Outsourced GLP Studies  
  - Hear a transitioning organization’s perspective on how this change affects studies in progress  
  - Explore the benefits, from both a quality and cost perspective, to having studies conducted by a third party specializing in GLP  
  - Determine how to properly source a third party and audit their compliance  
  Irma Annehmenacho, Senior Quality Assurance Manager, SYNTA PHARMACEUTICALS |
| 10:45  | Networking Break                                                      |
| 11:15  | **Risk-Based Approach in GLP and Non-Regulated Audits**  
  - Use risk assessment data/tools to develop an audit plan  
  - Mitigate risk by targeting common compliance and audit issues  
  - Examine fit-for-purpose strategies for a non-regulated quality system  
  Christiana Velez, B.S., RGAP-GLP, Program Manager/Bioresearch Quality, JANSSEN  
  David Malwitz, M.S., Senior Specialist, Bioresearch Quality Assurance, JANSSEN |
| 12:15  | Luncheon                                                               |
| 2:00   | **Understanding Basic Concepts of Study Reconstruction; What GLP Compliance Should be Accomplishing**  
  - Receive regulatory guidance on maintaining compliance throughout preclinical work  
  - Hear perspective on GLP challenges from a federal perspective  
  - Update internal GLP standards to meet regulatory guidelines  
  Vernon D. Toelle, PhD, Supervisory Team Leader, Pre-Market Compliance and Administrative Actions Team, Division of Compliance, Office of Surveillance and Compliance, Center for Veterinary Medicine, FOOD AND DRUG ADMINISTRATION (FDA)  
  Debi Garvin, GLP/GCP Specialist, Center for Veterinary Medicine, FOOD AND DRUG ADMINISTRATION (FDA) |
| 2:45   | Networking Break                                                      |
| 3:00   | **PANEL SESSION:** Guidance for Compliant Submission of Preclinical Data  
  - Decipher global differences in requirements for documenting acceptance criteria  
  - Ponder the potential of a global quality standard for acceptance criteria  
  - Compare examples of international regulatory bodies’ interpretations of GLP as they relate to bioanalysis  
  Stephanie Farmer, Senior Director, Business Development, ACCUTEST LABORATORIES |
| 3:45   | Chairperson’s Closing Remarks                                         |
| 4:00   | Summit Concludes                                                      |
5 Ways to Register

Phone: 866-207-6528
Fax: 888-221-6750
Email: registration@exlevents.com
Online: www.exlevents.com/GLP

Phone: 212-400-6240.*

More on how you can take advantage of these group discounts, please call

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QUESTIONS? COMMENTS?

Do you have a question or comment that you would like to be addressed at this event? Would you like to get involved as a speaker or discussion leader?

Please email Conference Production Director Derek O’Connor at doconnor@exlevents.com.

To receive a refund or voucher, please email cancel@exlevents.com or fax your

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- Less than four weeks: A voucher to another ExL event valid for 12 months from the voucher issue date.
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The fee includes the conference, all program materials, and designated continental breakfasts, lunches and refreshments.

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GROUP DISCOUNT PROGRAMS

*Offers may not be combined. Early Bird rates do not apply. To find out more on how you can take advantage of these group discounts, please call 212-400-6240.*

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 15%

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

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