One and Half-day In-person Seminar:

**FDA Compliant GLP for Nonclinical Studies - For Pharmaceutical and Medical Device Industries**

Thursday, July 26, 9 AM to 4 PM EDT and Friday, July 27, 8 AM to 12 Noon EDT, Orlando Airport Marriott, FL

*RAPS pre-approved. Earn up to 10 RAC credits*

Location:
Orlando Airport Marriott
7499 Augusta National Drive,
Orlando, FL 32822
(407) 851-9000

Course “FDA Compliant GLP for Nonclinical Studies - For Pharmaceutical and Medical Device Industries” has been pre-approved by RAPS as eligible for up to 10 credits towards a participant’s RAC recertification upon full completion.

Speaker:

**Dr. David Lim**
Ph.D., RAC, ASQ-CAQ

Dr. Lim obtained his Ph.D. in biological sciences at the University of Missouri-Columbia and published his thesis research in the prestigious journal “Science.” Since then, Dr. Lim has held various positions at Duke, US National Laboratories, Intrexon Corporation, Terumo, US FDA/CDRH, and EraGen Biosciences, Inc., A Luminex Company. In 2009, Dr. Lim served as a panel member during the FDA’s Transparency Public Meeting. Prior to founding his own consulting firm (www.RegulatoryDoctor.com/davidlim), Dr. Lim was Senior Vice President of Scientific and Regulatory Affairs at Aquavit Pharmaceuticals, Inc. in New York, wherein Dr. Lim provided inspiring and actionable solutions for sustainable business operation. Dr. Lim as Regulatory Doctor provides practical, actionable and strategic solutions integrated with emotional intelligence (EQ) skills for all aspects of global regulatory, quality, clinical and compliance matters. Read more...

Course Description:

Understanding GLP regulations and requirement and achieving GLP compliance can significantly expedite the regulatory processes, bringing innovative medical products to the market faster and saving enormous amount of your unnecessary time, efforts and investment.

During this interactive workshop, Dr. David Lim (Regulatory Doctor) will walk you through the relevant and applicable US regulations, regulatory requirements and guidance necessary for good laboratory practice (GLP) and GLP compliance. This workshop is intended to provide guidance on GLPs for conducting nonclinical laboratory studies that support or are intended to support applications for research or marketing permits for pharmaceutical and medical device products for human use regulated by the United States Food and Drug Administration (US FDA). During this workshop (2nd day), group discussions on implementing GLPs will be engaged.
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Agenda:

### Schedule for Day 1 (GLP Seminar)

<table>
<thead>
<tr>
<th>Day 1</th>
<th>9:00 AM – 4:00 PM</th>
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| Morning | 9:00 AM – 10:30 AM | US FDA GLP regulations and requirements  
Good laboratory practices: scope, objectives and definitions  
Organization and personnel: personnel, management, study director and quality assurance unit |
| 10:30 AM – 10:40 AM | Short Break |
| 10:40 AM – 12:00 Noon | Facilities and equipment  
Testing facilities operation: standard operating procedures (SOPs)  
Test and control articles |
| Day 1: Lunch from 12:00 Noon – 1:00 PM |
| Afternoon | 1:00 PM – 2:30 PM | Protocol and conduct of a GLP study  
Records and reports  
Implementing GLPs |
| 2:30 PM – 2:40 PM | Short Break |
| 2:40 PM – 4:00 PM | Preparing for GLP inspection  
Numerous case studies for deficiencies and for improvement |

### Schedule for Day 2 (GLP Workshop)

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<th>Day 2</th>
<th>8:00 AM – 12 Noon</th>
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| Morning | 8:00 AM – 9:30 AM | Agenda for group discussion  
Intra-group discussion  
GLP implementation and checklist |
| 9:30 AM – 9:40 AM | Short Break |
| 09:40 AM – 12:00 Noon | Inter-group presentation  
Speaker moderation and discussion |
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Areas Covered:

Who will benefit:

The following areas will be discussed during this workshop:

- US FDA GLP regulations and requirements
- Good laboratory practices: scope, objectives and definitions
- Organization and personnel: personnel, management, study director and quality assurance unit
- Facilities and equipment
- Testing facilities operation: standard operating procedures (SOPs)
- Test and control articles
- Protocol and conduct of a GLP study
- Records and reports
- Implementing GLPs
- Preparing for GLP inspection
- Numerous case studies for deficiencies and for improvement
- GLP workshop for GLP implementation

- Research and development (associates, scientists, managers, directors and VPs)
- Product and development (associates, scientists, managers, directors and VPs)
- Regulatory affairs (associates, specialists, managers, and directors)
- Quality assurance, quality control, and quality systems (associates, specialists, engineers, managers, directors and VPs)
- Contract research organization (associates, scientists, managers, directors and VPs)
- Site managers, and consultants
- Senior and executive management (VPs, SVPs, Presidents and CEOs)
- Contractors and subcontractors

Group Registrations
Send Your Team for Maximum Benefit Get your team up to speed!

Significant tuition discounts are available for teams of two or more from the same company. You must register at the same time and provide a single payment to take advantage of the discount.

The discount will be calculated automatically.

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<thead>
<tr>
<th>Number of Attendees</th>
<th>Discount</th>
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<tbody>
<tr>
<td>2</td>
<td>Get 10% off</td>
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<tr>
<td>3 to 6</td>
<td>Get 20% off</td>
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<tr>
<td>7 to 10</td>
<td>Get 25% off</td>
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<tr>
<td>10+</td>
<td>Get 30% off</td>
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Call Toll Free
+1-888-717-2436 if you have any queries.
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Registration Information:

- Register Online. Use your American Express, Visa or MasterCard.
- Get your group to attend the seminar at a discounted price call +1-888-717-2436.
- Pay your check to (payee name) "MetricStream Inc" our parent company and Mail the check to: ComplianceOnline (MetricStream, Inc), 2600 E. Bayshore Road, Palo Alto, CA 94303.
- Please fill this form with attendee details and payment details and fax it to 650-963-2556.

Terms & Conditions

Your Registration for the seminar is subject to following terms and conditions. If you need any clarification before registering for this seminar please call us @ +1-888-717-2436 or email us @ editor@complianceonline.com.

Cancellations and Substitutions

Written cancellations through fax or email (from the person who has registered for this conference) received at least 10 calendar days prior to the start date of the event will receive a refund — less a $200 administration fee. No cancellations will be accepted — nor refunds issued — within 10 calendar days from the start date of the event.

On request by email or fax (before the seminar) a credit for the amount paid minus administration fees ($200) will be transferred to any future ComplianceOnline event and a credit note will be issued. Substitutions may be made at any time. No-shows will be charged the full amount. We discourage onsite registrations, however if you wish to register onsite payment to happen through credit card immediately or check to be submitted onsite. Conference material will be given on the spot if it is available after distributing to other attendees. In case it is not available we will send the material after the conference is over. In the event ComplianceOnline cancels the seminar, ComplianceOnline is not responsible for any airfare, hotel, other costs or losses incurred by registrants. Some topics and speakers may be subject to change without notice.

Registration Form

I want to attend FDA Compliant GLP for Nonclinical Studies - For Pharmaceutical and Medical Device Industries on Thursday, July 26, 9 AM to 4 PM EDT and Friday, July 27, 8 AM to 12 Noon EDT, Orlando, FL. I understand the fee includes all seminar materials, tea/coffee in the morning and evening, and lunch on July 26, breakfast and tea/coffee in the morning on July 27th.

Register for 3 and 4th person gets a free pass.

Attendee 1 : Name ............................................................ Title ............................................................ Email ............................................................
Attendee 2 : Name ............................................................ Title ............................................................ Email ............................................................
Attendee 3 : Name ............................................................ Title ............................................................ Email ............................................................
Attendee 4 : Name ............................................................ Title ............................................................ Email ............................................................

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(Signature required on credit card and bill-me orders.)

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Bill me/my company $ ............................................................
(Payment is required by the date of the conference.)

Please fill this form with attendee details and payment details and fax it to 650-963-2556.

Price: $849

Click here for more info