ComplianceOnline
The Largest GRC Advisory Network

2-day In-person Seminar:

SOPs for FDA-Regulated Industry: Best Practices to Withstand FDA Expectations

By: **Mukesh Kumar**, PhD, RAC, Senior Director, Regulatory Affairs, Amarex Clinical Research

Location: June 16-17, 2016 | Boston, MA

SPEAKER

Dr. Mukesh Kumar, Senior Director, Regulatory Affairs, Amarex Clinical Research

Dr. Mukesh Kumar leads the Regulatory Affairs and Quality Assurance departments at Amarex, a full service pharmaceutical product development company based in Germantown, MD (www.amarexcro.com). Mr. Kumar's key expertise is in regulatory affairs, clinical trials and multi-national project management for medicinal and diagnostic products. He has written more than 40 new INDs for FDA submission and reviewed more than 100 INDs. He has been involved in about 100 clinical trials in more than 40 countries, has made several hundred US FDA submissions, and arranged a number of meetings with the US FDA.

In addition, he has had made regulatory submission in the EU and India. He has conducted GCP, GLP, GMP and GACP audits in the US and several countries in Europe and Asia. He has conducted numerous training workshops in FDA compliance related issues. He has authored numerous articles in peer-reviewed journals. He is a well-known expert in global regulatory affairs and has been an invited speaker at several professional and academic organizations worldwide. He is a certified regulatory affairs professional by the Regulatory Affairs Professional Society, USA.

LEARNING OBJECTIVES

- Regulatory requirements for SOPs
- Legal requirements for SOP creation and maintenance
- Types of SOPs
- Formats and essential components of SOPs
- SOP driven process: process mapping
- Electronic verses paper SOPs

COURSE DESCRIPTION

Formal written Standard Operating Procedures (SOPs) are required both by the Food and Drug Administration (FDA) and European Medicines Agency (EMA). Almost every deficiency identified in FDA's 483s and Warning Letters can be traced back to deficiencies in SOPs at an organization. SOPs are often inadequate, miss important elements, do not contain important tools to increase compliance with the SOPs and many times are hard for the personnel who follow them to understand. They are frequently poorly written, communicated, monitored and enforced.

This two day In-person seminar will provide step by step instructions to create SOPs for FDA-regulated organizations.

Throughout the workshop, the instructor will discuss case studies and examples to highlight the common errors and potential solutions. Additionally, the logistics of creating, maintaining, scope, training and documentation will be reviewed. Pros and Cons of paper and electronic SOPs will also be discussed.

This workshop contains a collection of practical tips from the instructor's extensive FDA audit experience. Common questions regarding validation requirements, handling deviations, frequency of review and update, evaluating non-SOP driven processes, global SOPs, and ways to address FDA 483s regarding SOPs will be discussed using sample SOPs.

AGENDA

DAY ONE: 8:30 AM - 4:00 PM

- **Registration Process – 8:30 AM – 9:00 AM**
- **Session Start Time – 9:00 AM**
- **9:00 – 10:00 AM: SOPs for a given organization: FDA Requirements**
  - US and EU Regulations describing SOPs
  - Regulatory requirements for different organizations: sites, manufactures, labs
  - Requirements for various products: Drugs, biologics, devices, diagnostics, clinical labs
  - What processes do not need written SOPs
  - SOPs verses working practices and draft scripts
  - Legal requirements for creating and maintaining SOPs
- **10:00 – 10:15 AM: Break**
- **10:15 – 12:00 Noon: Where to Start: Developing a Strategy**
  - Listing tasks for a given organization
  - Qualifications of writing leaders and teams
  - Resource allocation and time-lines
  - Policies and procedures
  - Using Templates: Self-created and acquired
- **12:00 – 12:45 PM: Lunch**
- **12:45 – 2:15 PM: How to Get Started**
  - List of SOPs for different organizations: Clinical sites, manufacturing facilities, labs, etc
  - Process development and developing SOP on SOPs
  - Prioritizing tasks
  - Minimum requirements for SOPs
  - Risk-based approach for SOPs
  - Types of SOPs
- **2:15 – 2:30 PM: Break**
- **2:30 – 3:30 PM: Writing an SOP: 5 Steps to a Good SOP**
  - Format for an SOP
  - Essential Components of an SOP
  - Task split, distribution, and attribution
  - Documentation: Checklist, forms, and reports
  - Annotations

DAY TWO: 8:30 AM - 3:30 PM

- **8:30 – 10:00 AM: Essentials of a SOP Driven Process**
  - What is Process Mapping and how can it be best used?
  - Categorization and organization of SOPs
  - Rules for electronic SOPs in the cGMP, GLP and GCP environment
  - Maintaining SOPs
  - Best practices for access control and distribution
  - Archiving, retiring, and audit trails for SOPs
- **10:00 – 10:15 AM: Break**
- **10:15 – 12:00 Noon: Effective Writing Strategies**
  - Writing Exercise for SOP
  - Style, tone, and content arrangement
  - Best practices for SOP approval process
  - Electronic verses paper SOPs
- **12:00 – 12:45 PM: Lunch**
- **12:45 – 2:15 PM: Education and Training on an SOP**
  - Best practices for training and documenting
  - Periodic reviews
  - Tools for SOP tracking and training validation
  - Train the trainer programs
  - Adapting Generic, Institution, or Sponsor SOPs for your Needs
  - SOP updates
  - Dealing with deviations
- **2:15 – 2:30 PM: Break**
- **2:30 – 3:30 PM: Getting Ready for FDA Audits of SOPs**
  - Common FDA 483s and Warning Letters regarding SOPs
  - Logistics of an FDA audit
  - Best practices for coordinating FDA review of SOPs
  - Addressing FDA findings
  - Responding to an FDA 483
  - Dos and Don'ts of an FDA audit

WHO WILL BENEFIT

This workshop will be beneficial for the following personnel in all FDA-regulated organizations such as clinical trials, manufacturing, advertisement, marketing, regulatory affairs, auditing, and laboratory testing:

- Directors
- Managers
- Supervisors, and lead workers in Regulatory Affairs
- Quality Assurance and Quality Control personnel
- Auditors
- Clinical investigators, site management and contracting personnel
- Clinical trial specialists
- Project managers
- People investing in FDA-regulated product development projects

Registration Form

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.
- Call +1-888-717-2436 or Fax your PO: 650-963-2556.
- 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

GROUP REGISTRATIONS

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

2 Attendees	-	Get 10% off
3 to 6 Attendees	-	Get 20% off
7 to 10 Attendees	-	Get 25% off
10+ Attendees	-	Get 30% off

Call Toll Free +1-888-717-2436
if you have any queries.

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.

Seminar Topic: SOPs for FDA-Regulated Industry: Best Practices to Withstand FDA Expectations

Date & Location: .....

Attendee Details:

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

	Name	Title	Email
Attendee 1			
Attendee 2			
Attendee 3			
Attendee 4			

Email address (so you can receive order acknowledgements, updated news, product information and special offers)

Company Information

Organization .....

.....

Address .....

.....

City .....

State ..... Zip.....

Country .....

Phone ..... Fax .....

Payment Options

☐ Check enclosed, payable in U.S. funds to ComplianceOnline (MetricStream, Inc.)

☐ Charge to: ☐ Visa ☐ MasterCard ☐ American Express

Credit card no. .....

Expiration date .....

Total amount $ .....

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

Print name.....

☐ Bill me/my company $ .....

Purchase order # .....
(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

ComplianceOnline
The Largest GRC Advisory Network
www.complianceonline.com
2600 E. Bayshore Road Palo Alto, CA 94303
Ph: +1-888-717-2436 | Fax: 650-963-2556