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Practical Series Seminars and Workshops

Understanding California State Inspections, Regulatory Requirements, and Quality Systems for Pharmaceuticals and Medical Devices

Who should attend: Quality Assurance, Quality Control, Process Development and Management Personnel

This one day presentation and discussion will outline the expectations of California State Food and Drug Branch requirements for licensure, regulatory aspects of manufacturing drugs and devices, and quality systems requirements for passing California State Inspections. The speakers include ex-CA State Food and Drug Investigator and Regulatory and Quality Experts. There will be panel discussions to address attendee questions

Benefits

Hear how California State FDA requirements are becoming rigorous

Learn what State Investigators will look for?

What quality system requirements are scrutinized during State Inspection Visits?

Learn when to apply for State Licensure and what inspection readiness means for State Inspections

Finally learn how to establish cost effective and compliant quality systems for State Licensure Inspections and avoid overkill

27 September 2010

Understanding CA State Licensure Requirements

This overview presentation is intended to provide a general introduction to regulatory requirements for the development of drugs and devices. The attendee will get a high-level view of the key items involved in the process of complying with the regulations.

Devices

- ◆ Device definition and classification
- ◆ Types of device submissions
- ◆ QSR GMP compliance
- ◆ Overview of Agency interactions
- ◆ Review and approval process
- ◆ Post-marketing requirements

Drugs

- ◆ Drug development process – Phases
- ◆ Types of submissions at the different Phases
- ◆ cGMP compliance
- ◆ Overview of Agency interactions
- ◆ Review and approval process
- ◆ Post-marketing requirements

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Understanding CA State Licensure Requirements

This presentation will help start-up companies understand state licensure requirements, how to apply, and what to expect during inspection.

- ◆ Understand the relationship between FDA and the State
- ◆ What do State investigators do when on site
- ◆ Learn about processes State Investigators use when on-site inspections
- ◆ An insight into the state powers and authorities
- ◆ What are the actions State Investigators take if the company is deficient
- ◆ How can you get them to accept your compliance plans
- ◆ What are the consequences of delaying or not even applying for licensure
- ◆ What happens if you move?

Establishing and Implementing Quality Systems for CA State Licensure

Industry and FDA Perspectives on the Pharmaceutical/Medical Device Quality System

Quality philosophy-Quality by design-build quality into the product

Overview of Quality Systems for Pharmaceuticals and Medical Devices-Similarities and Differences

Quality System Attributes

- ◆ Implement a modern, comprehensive and robust quality system, consistent with CGMPs that, defines a state of control to facilitate:
 - the consistent production of high quality, safe and efficacious product
 - change control - continuous improvement
 - quality by design - building in quality to process and product
 - adoption of risk management
 - harmonization with other quality systems

Quality Systems Model

- ◆ Management Responsibilities
- ◆ Resources
- ◆ Manufacturing
- ◆ Evaluation Activities-Continual Improvement

Example of Quality System

- ◆ Quality Personnel
- ◆ Quality Processes
- ◆ Documents and Records Controls
- ◆ Design/Development Controls
- ◆ Acceptance Activities
- ◆ Production and Process Controls

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ABOUT THE PRESENTERS

Dennis M Moore is currently Chief Technical Expert and CEO of Auk Technical Services LTD, Beverly Hills, CA. Mr. Moore has 27 years of experience in medical device design, quality systems training, pharmaceutical manufacturing and 21 CFR 210,211 quality systems. Mr. Moore also has extensive experience helping firms achieve compliance to FDA regulation and International Standards regulations. Mr. Moore additionally has drug and device auditing experience as an FDA Investigator; was a California Medical Device Senior Investigator and Sworn Government-POST Certified Criminal Investigator; is a Lead Trainer; was a Compliance Officer and is now a company Chief Technical Expert and CEO. Mr. Moore has given numerous web seminars on GMP issues; has traveled the world putting out FDA compliance related fires and authored many documents on quality system inspection, FDA/CA narrative report compilation, drug quality systems and software auditing techniques. Mr. Moore is a member of RAPS, AAMI and is a former official with the State of California Medical Device Team. Mr. Moore also has RAB certification to the ISO 13485:2003 standard. Mr. Moore holds a BA degree in Zoology, with Graduate work in Toxicology and a POST certified Government Criminal Investigator peace officer badge <retired>

Dr. Pravin Soni is president of PharmaCRO, LLC, a company that provides consulting services in the areas of medical device, drugs and combination medical products development. He has twenty-nine (29) years of industrial experience, including fifteen years in medical products development. He has successfully led development of drugs, devices and combination products from early stage to launch. His approach incorporates a strategic perspective that integrates design, manufacturing, regulatory, clinical, toxicology, and marketing requirements to identify the least burdensome and most efficient route to commercialization of safe and reliable medical products. Dr. Soni is co-inventor on fifty-seven (57) US and foreign granted patents.

Ziva Abraham has over 25 years of academic, research, clinical and industrial experience in Microbiology, and Quality Assurance. She has trained personnel from various industries in microbiology techniques and methods. Ziva has received her Master's Degree in Microbiology and has conducted research on developing Microbial Insecticides during her graduate studies working mainly with fungi. She has established clinical laboratory systems in Israel, and Microrite, Inc. a consulting company based in San Jose, CA that helps Pharmaceutical, Medical Device, and Biotechnology Companies. Microrite focuses on helping companies with contamination control, microbiological quality control for sterile and non-sterile manufacturing, and Quality Assurance. Ziva has also developed "BACTISPELL" a microbiology spellchecker to spell check genus and species names of microbes and other microbiology related terms. She is a member of PDA, ISPE, AAMI, and PMF and is an active mentor for graduate students at Stanford University working through the American Woman in Science Organization (AWIS). She is involved in Expanding Your Horizons a program through the Math and Scientific Network to educate young girls about careers in science. Ziva served on the editorial board of Pharmaceutical Microbiology Forum (PMF) Newsletter.

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SCHEDULE AND VENUE

27 September 2010

Microrite Training Center
2338B Walsh Avenue
Santa Clara, 95051

PROGRAM

Registration and Light Breakfast	8.00 AM to 8.30 AM
Regulatory Requirements for Drugs and Devices	8.30 AM to 10.30 AM
Regulatory Requirements for Drugs and Devices	10.30 AM to 10.45 AM
Question & Answer	10.45 AM to 11.00 PM
Understanding the CA State Licensure Process	11.00 AM to 12.00 PM
Luncheon (Lunch provided by Microrite)	12.00 PM to 1.00 PM
Understanding the CA State Licensure Process	1.00 PM to 2.00 PM
Question & Answer	2.00 PM to 2.15 PM
Establishing and Implementing Quality Systems for CA State Licensure	2.15 PM to 3.15 PM
Break	3.15 PM to 3.30 PM
Establishing and Implementing Quality Systems for CA State Licensure	3.30 PM to 4.30 PM
Panel Discussion	4.30 AM to 5.00 PM

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REGISTRATION FORM

Personal Information of One Registrant

Last Name: Mr. Ms. Dr. First Name: _____

Title: _____ Organization: _____

Mailing Address: _____

Telephone: (Area Code) _____ Facsimile: (Area Code) _____

Email: _____

Fees: \$900.00 per attendee

Additional Attendees:

Additional Attendees:					
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	
Last Name:		First Name:		Title:	

Method of Payment: Check, Credit Card or Purchase Order
Fax : 408-445-1236

Checks payable to Microrite, Inc.
5019, New Trier Avenue
San Jose, CA 95136

Confirmation of registration will be sent via email if payment is made by check or PO. For credit card payment on website, a payment receipt will be considered as confirmation of registration. For credit card information faxed to Microrite an email confirmation will be sent with a copy of payment receipt. Please call 408-445-0507 in due time if confirmation is not received after payment.

Cancellation Policy: Your notice of cancellation must be received in writing via facsimile or email 10 working days prior to the seminar date.

Fax: 408-445-1236

Email: sales@microrite.com or info@microrite.com.

A 10% cancellation fee is applicable for all credit card payments

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Closest Airport

Norman Y. Mineta San Jose International Airport (SJC)

1732 N 1st St # 600

San Jose, CA 95112

Distance from Microrite Training Center

Estimated Driving Time: 9 minutes Estimated Distance: 4.77 miles

Accommodations

Biltmore Hotel and Suites

2151 Laurelwood Road

Santa Clara, CA 95054

408-988-8411

0.96 miles away from Microrite Training Center

Microrite's discounted rates will apply to this hotel.

Standard Garden Room: Rate \$109.00 per night, KING or QQ

Tower Suite: Rate \$129.00 per night, QUEEN w/ sofa Sleeper

Executive Tower Suite: Rate \$ 149.00 per night, QUEEN w/ sofa

Hotel services will include pick-up and drop off, to and from San Jose International Airport and Microrite's Training Center and Shopping within 5 miles of radius from Hotel.

Breakfast and internet access is free of cost at the hotel. Mention "MICRORITE" when reserving room to receive the discounted rate.

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Business name: _____

CREDIT CARD INFORMATION

Credit Card Payment may be made on the Micro rite's website-
<http://www.microrite.com>

Or this form may be faxed to 408-445-1236

Choose one:

VISA

Master Card

American Express

Card Holder's Name _____

Address of Card Holder

Please note Company Address if it is a Corporate Card and
Personal Address if Personal Card

Street _____

City _____

Zip Code _____

Country _____

Contact Phone Number _____

Card Number: _____

Expiration(Month/Year): _____

Name on Card: _____

Email: _____

Amount (US Dollars): _____

Signature: _____

Name of Attendee(s) _____

City and Date of Seminar

Understanding California State Inspections, Regulatory Requirements, and
Quality Systems for Pharmaceuticals and Medical Devices, Santa Clara, CA, 27
Sep. 2010

Comments or
Instructions _____