

FULL DAY EVENT

MDSAP

MEDICAL DEVICE
SINGLE AUDIT
PROGRAM

TRAINING

TUESDAY, JUNE 11TH, 2019

Oriel STAT A MATRIX

"PREPARING FOR A SUCCESSFUL TRANSITION"

REGISTRATION BEGINNING AT 7:30 AM
SESSIONS BEGINNING AT 8:00 AM
BREAKFAST & LUNCH PROVIDED
SESSIONS ENDING AT 4:00 PM

HOSTED BY PHASE 3 REAL ESTATE PARTNERS
GENESIS - CAMPUS POINT AT 4242, SAN DIEGO, CA 92121

REGISTER ONLINE AT WWW.ATDEVENTS.NET

ADMISSION INCLUDED WITH THE ISPE SAN DIEGO CHAPTER'S ALL ACCESS PASS 2019

Medical Device Single Audit Program (MDSAP) Preparing For A Successful Transition

Tuesday, June 11, 2019
7:30am - 5:00pm

Sponsored By:

Oriel STAT A MATRIX

Hosted by:

PHASE3
— REAL ESTATE PARTNERS —

Sponsorships Available

- Location:** Genesis Campus Point, 4242 Campus Point Dr., San Diego, CA 92121
- Program Managers:** Nathan Manczarek, Senior Director of Quality, Inovio Pharmaceuticals Inc.
Eddie Luchs, Director, Facilities, Omniome Inc.
Rodney Bruce, Project Mgr, Real Estate Development & Construction, Intersect Management, LLC
- Speaker:** Bobby McVay, Director of Quality Consulting, Oriel STAT A MATRIX

Synopsis:

On Tuesday, June 11th, the ISPE San Diego Chapter will be hosting our full day MDSAP Training event at Genesis Campus Point courtesy of Phase 3 Real Estate Partners, Inc.

This exclusive training titled "Preparing For A Successful Transition" presented by Bobby McVay from Oriel STAT A MATRIX will help you learn the elements of the Medical Device Single Audit Program (MDSAP), what is included in an MDSAP audit, the use of the nonconformity grading matrix, and how to prepare for MDSAP participation.

The value this training is for anyone from the medical device industry with responsibility for one or more elements of the organization's quality management system, including auditing. Also, this is ideal for medical device manufacturers who desire an overview of MDSAP and might plan on taking advantage of this program to streamline their drug and device approval process in 2019 and beyond.

Thank you To Our Annual Sponsors

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Tuesday, June 11, 2019
7:30am - 5:00pm

COURSE DESIGN DOCUMENT & AGENDA

Medical Device Single Audit Program (MDSAP) Training

Preparing for a Successful Transition

1 DAY • SAF1D

Purpose

Learn about the elements of the Medical Device Single Audit Program (MDSAP), what is included in an MDSAP audit, the use of the nonconformity grading matrix, and how to prepare for MDSAP participation.

Target Audience

Anyone from the medical device industry with responsibility for one or more elements of the organization's quality management system, including auditing. Also ideal for medical device manufacturers who desire an overview of MDSAP and its potential benefits.

Learning Objectives

At the end of this course, participants will be able to:

1. Present an overview of the MDSAP.
2. Describe the MDSAP audit model and how it is used, including objectives, the evidence sought, audit tasks, process linkages, and the emphasis on risk management.
3. Identify the characteristics of a process-based approach to auditing, as used in MDSAP.
4. Explain how MDSAP auditors use the nonconformity grading matrix.
5. Identify the necessary MDSAP preparation steps, including performing a gap assessment and planning the transition.

Major Topics Covered

- MDSAP objectives
- The MDSAP audit model and audit process
- The nonconformity grading matrix
- Preparing for the MDSAP

Highlighted Takeaways

- MDSAP Organizational Readiness Tool
- MDSAP Audit Model
- MDSAP Audit Checklist
- MDSAP FAQ
- Transition Quality Plan Template: Prepare for MDSAP Participation

Tuesday, June 11, 2019
7:30am - 5:00pm

Module	Topics	Methods	Time
Welcome and Course Overview	<ul style="list-style-type: none"> • Introductions • Course purpose and objectives 	Presentation, discussion	8:00-8:30 a.m.
Overview of MDSAP and the Audit Model	<ul style="list-style-type: none"> • Define MDSAP goals, timelines, resources, and intended outcomes • Identify roles, responsibilities, and relationships among participating authorities • Evaluate impact on medical device manufacturers • Introduce the seven MDSAP processes, outcomes, and tasks • Organizational readiness assessment • Takeaway: MDSAP Audit Model • Exercise: Analyze MDSAP linkages • Takeaway: Organizational readiness 	Presentation, discussion, exercises, readiness tool	8:30-10:30 a.m.
Nonconformity Grading	<ul style="list-style-type: none"> • Explain how nonconformities are graded in the MDSAP • Review the NC tool used by MDSAP auditors • Exercise: Assign nonconformity grades 	Presentation, discussion, exercise	10:30 a.m.-12:00 p.m.
LUNCH			12:00-1:00 p.m.
Process Approach and Risk	<ul style="list-style-type: none"> • Explain the MDSAP process approach to auditing and integration of risk-based thinking • Review tools and terminology for understanding processes • Discussion: Communicating processes 	Presentation, discussion	1:00-3:00 p.m.
MDSAP Audits	<ul style="list-style-type: none"> • Describe the process for certification • Describe the audit criteria associated tools • Audit duration and the audit report • Explore the OSAM-MDSAP audit checklist • Review case study of organization experiences • Takeaway: FAQ • Takeaway: MDSAP Audit Checklist 	Presentation, discussion, exercise	3:00-4:00 p.m.
Next Steps	<ul style="list-style-type: none"> • Discuss aligning the internal auditing program to the MDSAP model • Describe MDSAP trends and status • Identify next steps for your organization • Takeaway: Transition Quality Plan 	Presentation, discussion, audit checklist	4:00-4:50 p.m.
Wrap-Up	<ul style="list-style-type: none"> • Program evaluation 	Discussion, Q&A	4:50-5:00 p.m.



Medical Device Single Audit Program (MDSAP) Preparing For A Successful Transition Tuesday, June 11, 2019

About the Speaker Bobby McVay, Director of Quality Consulting, Oriel STAT A MATRIX

Bobby has more than 20 years of medical device experience spanning the entire product life cycle, including applied research, device design, submission, launch, operations, auditing, quality system development, and continuous improvement.

He leverages his diverse background and real-world experiences to ensure that customers obtain both a transparent audit evaluation and consultative engagement. He has experience developing and standardizing key quality system processes and applies a proactive risk-based approach to process improvements. Because of Bobby's involvement with a broad range of product designs and QMS processes, he is quickly able to use a relevant real-world example to help illustrate a topic.

He spent nearly 11 years at Medtronic Spine & Biologics. His previous position was Continuous Improvement Program Manager. He previously held various engineering positions including Global Quality Engineering Manager. Prior to Medtronic, he was the Senior Design Engineer/Project Manager at Enteroptyx, Inc.

Bobby holds a BS in Mechanical Engineering, an MS in Mechanical Engineering, Biomedical Systems from The University of Memphis, and an MBA from The University of Memphis. He has received several certifications including CQE from ASQ and is a Lean Sigma Blackbelt.

Oriel STAT A MATRIX has provided regulatory training and consulting to life sciences organizations since 1977. Services: FDA strategic planning, 510(k), PMA and other regulatory submissions, FDA 483 review and Warning Letter response, QSR /cGMP and ISO 13485 quality system implementation, transition support for ISO 13485:2016, MDSAP, and EU medical device regulations, mock audits, process/software validation and Lean Six Sigma.

Medical Device Single Audit Program MDSAP

The International Medical Device Regulators Forum (IMDRF) recognizes that a global approach to auditing and monitoring the manufacturing of medical devices could improve their safety and oversight on an international scale. At its inaugural meeting in Singapore in 2012, the IMDRF identified a work group to develop specific documents for advancing a Medical Device Single Audit Program (MDSAP).

The Medical Device Single Audit Program allows an MDSAP recognized Auditing Organization to conduct a single regulatory audit of a medical device manufacturer that satisfies the relevant requirements of the regulatory authorities participating in the program.

International partners that are participating in the MDSAP include:

- Therapeutic Goods Administration of Australia
- Brazil's Agência Nacional de Vigilância Sanitária
- Health Canada
- Japan's Ministry of Health, Labour and Welfare, and the Japanese Pharmaceuticals and Medical Devices Agency
- The World Health Organization (WHO) Prequalification of In Vitro Diagnostics (IVDs) Programme and the European Union (EU) are Official Observers

From 01 January 2014 to 31 December 2016, FDA, alongside its international partners, participated in a Medical Device Single Audit Program Pilot. On 29 June 2017, a report was generated summarizing the outcomes of prospective "proof-of-concept" criteria established to confirm the viability of the Medical Device Single Audit Program. The outcomes documented in the Final MDSAP Pilot Report are based on data generated during the three (3) year pilot.

Based on its evaluation of the MDSAP Final Pilot Report, the MDSAP Regulatory Authority Council (the international MDSAP governing body) determined that the MDSAP Pilot had satisfactorily demonstrated the viability of the Medical Device Single Audit Program.

FDA will continue to accept MDSAP audit reports as a substitute for routine Agency inspections. Firms with activities related to the Electronic Product Radiation Control (EPRC) provisions of the Act will continue to be subject to FDA inspections for the EPRC activities.

Source: U.S. Food & Drug Administration website



REGISTRATION INSTRUCTIONS

Medical Device Single Audit Program (MDSAP) Preparing For A Successful Transition

Tuesday, June 11, 2019

Sponsorships Available

To Register and Receive an immediate receipt, use our on-line registration: <http://atdevents.net/register.php>

ISPE LA, SD, SF Members:

If you are an ISPE Member in California, please do not set up a new account, you should already be in our system. Please email Rob Fleming for assistance with your username and/or password.

ISPE Members of other Chapters:

You will not be in our system unless you have previously set up an account. Please follow instructions for Non Members below. To update your account to a Member account, please forward your confirmation email from ISPE or ISPE Membership Card to Rob Fleming. We need your Chapter name, your ISPE Member number and expiration date. You can get your Membership card once logged onto the ISPE website (see bottom left side of the screen).

Non Members:

If you do not have an account on our system, you can set one up on the site using letters (not numbers) as your username.

****Students:**

The Student Rate is for individuals who are enrolled full time in a related academic program at an accredited institution. The Student Rate does not apply to working professionals taking one or two courses on the side. To verify your status as a student, we may ask you to supply your student ID and copy of current class schedule. Final eligibility determined by ISPE SD.

Registrations can also be faxed. Complete the form and fax to 949-266-8461.

If paying by check, please mail your check made payable to:
ISPE San Diego Chapter, 5319 University Dr., Suite 641, Irvine, CA 92612. Tel: 949-387-9046. Tax ID#33-0551783.

Registration Fee Includes continental breakfast, lunch and free parking

Note: If you are between jobs or your company does not support your registration fees, please contact Kimberly Syre (ksyre@cox.net) for reduced fee options or sponsorship opportunities.

Registration or Online Questions? Contact Rob Fleming: rob.fleming@yahoo.com
Name Badges will be given at the event.

Cancellations must be received via email to: rob.fleming@yahoo.com by June 3, 2019 for refund. After the cancellation date if you have reserved a space but do not attend, your payment MUST be remitted, however, an alternate person may attend in your place. If the alternate is not a member, they will need to pay the additional amount for non-members. Name badges will be given at the on-site registration desk.



ISPE®

San Diego
Chapter

Registration Form
Medical Device Single Audit Program (MDSAP)
Preparing For A Successful Transition

Tuesday, June 11, 2019

REGISTRATION RATES

- _____ \$250 **ISPE Members**
- _____ \$315 **Non-Members**
- _____ Free ***Free for First 10 Phase 3 Employees**
- _____ \$50 ***Phase 3 Employees (after first 10)**
- _____ \$100 **ISPE YP (Young Professional) Members**
- _____ \$50 **Students Student Members**
- _____ \$500 **Sponsors (includes a table top at the meeting and one attendee)**
Additional attendees can attend at the ISPE Member rate

Please list the name of your attendee: _____

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