

ASQ-LA QUALITY NEWS

August 2017

August 2017

ISSUE

- Introduction
- August 9th presentation Preparation, Preparation, Preparation... The Secret to Successful FDA Inspections
- Message from the Section Chair
- ASQ-LA Class Offerings
- CSUDH Class Offerings
- New Members for June
- ASQ-LA 2017 Leadership Team





Welcome to the ASQLA Monthly Newsletter for August

We are looking forward to seeing you at our August 9th Member Meeting at 2nd Floor Main Conference Room at Phenomenex 2341 West 205th St. Torrance, CA 90501.

This meeting provides an opportunity to network with other Quality Professionals, learn about quality topics and earn 0.3 Recertification Units. Registration and networking starts at 5:30 PM. The meeting runs from 6:00 to 7:30 PM. Provided, at no charge; Crackers, Cookies, Coffee, Water and other food items. If you plan to attend the meeting, YOU MUST RSVP to: Chen Low 310-334-7044, pager 310-353-8293 or e-mail ChenLow_88@hotmail.com. by Noon on Monday, August 7th , so that he can provide the list of attendees to Security. ASQ -LA is looking forward to your attendance at this month's program.

Harold Martinez ASQLA Newsletter Chair



August 9, 2017 Member Meeting PREPARATION, PREPARATION... THE SECRET TO SUCCESSFUL FDA INSPECTIONS

Presented by:
ARIE MENACHEM

Consumer Safety Officer

US Food & Drug Administration

The August program focuses on FDA-regulated companies but there will be many beneficial principles and strategies for members who are responsible for successful audit outcomes in other industries. Our speaker, Arie Menachem, is an LA Section member and is an FDA Investigator. He will be speaking from an Investigator's point of view in hopes that he can bridge some differences in expectations regarding FDA inspections. Some topics he will cover:

Tools for Preparing for an Audit: Tools that are publicly available at www.fda.gov and how to leverage these tools to build an internal audit system that mimics the inspections performed by the FDA.

What & How to Prepare: Arie will draw on his experience and observations to provide tips on things to do to make the inspection process more efficient. He understandingly says that inadequate preparation makes the audit process unnecessarily stressful on the firms being audited but also on the FDA Investigator. Also, inadequate preparation costs the firm money (why host an investigator for X days, when you can host her/him for X - 1 days?).

Post Audit: What happens after the Investigator leaves the firm? What happens to the documents you provide? Who is responsible to make the final decision regarding compliance of your firm?

Finally, the talk will end with a discussion and Q&A from the audience.

Post Audit: Finally, the talk will end with a discussion on what happens after the Investigator leaves and Q&A from the audience.

About the Speaker

ARIE MENACHEM, our speaker has both "inside" and "outside" experience in FDA regulated environments. Arie has had the privilege to protect and advance the public health as a Consumer Safety Officer/Investigator with the US Food & Drug Administration for the past 3.5 years. He started his FDA career as a Drug Specialist and is currently a member of Team Biologics.

Prior to joining the Agency, Arie worked in various Quality roles in various multinational pharmaceutical companies, focusing on internal and supplier auditing and site remediation.

ASQLA Chair's Message



August, 2017

Fellow quality professionals, greetings!

Congratulations on your career and your involvement and continual interest in ASQ and your ASQ Los Angeles section. Our dedicated team of volunteer leaders pool our time and efforts to maintain our organization and assure that our membership participation yields valuable experiences. This is our core mission and I am honored to be a part of it.

Last week, ASQLA Leadership Team members came together for our annual planning meeting, led by our Chair-Elect and 2018-19 Section Chair Ron Lombrano. Many creative and exciting ideas were brought forth, explored, and further developed. Beyond our Leadership Team, we would certainly like to continue to solicit direct input from our membership as well. We look forward to your response on upcoming surveys and in-person opportunities.

Our section website overhaul is proceeding well. As of now, our new website is up and running, accessible from the same asqla.org address. While we aimed to modernize the look-and -feel and web infrastructure to facilitate security aspects, we purposed to maintain continuity with respect to content. We hope you'll like the new site.

Stay informed, stay involved, keep voicing your feedback, and let us know if you have the passion, talent, and time to volunteer on the leadership team for our section.

Enjoy the rest of summer and hope to see you in August!

Cheers!



Alan Wang, MSQA, ASQ CQA ASQ Los Angeles Chair

ASQ Section 700 Certification Preparation Courses

PREP COURSE NAME	INSTRUCTORS	COURSE STARTS	COURSE STARTS
CQA CERTIFIED QUALITY AUDITOR	Lane Parrott	October 21, 2017	April 2018
CQE CERTIFIED QUALITY ENGINEER	Dr. Cathy Martin Dr. Joe DeSimone	October 21, 2017	April 2018
CSQP CERTIFIED SUPPLIER QUALITY PROFESSIONAL	Dr. Joe DeSimone	September 9, 2017	September 8, 201 8
CMQ/OE CERTIFIED MANAGER OF QUALITY/ORGANIZATIONAL EXCELLENCE	Lane Parrott	September 9, 2017	September 8, 201 8
	ASQ EXAM	M SCHEDULE	
CQA, CQE, CQIA, CSQI CCT, CP			, CQI, CRE, CBA, CHA, BB, SSYB
TESTING WINDOW	APPLICATION DEADLINE:	TESTING WINDOW	APPLICATION DEAD- LINE:
October 6 - 22, 2017	September 8, 2017	September 1 - 17, 2017	August 4, 2017
December 1 – 17, 2017	November 3, 2017	November 3 – 19, 2017	October 6, 2017
N/A	N/A	N/A	N/A

Courses will be conducted on Six (6) Saturdays from 8 a.m. to 1:30 PM at the Phenomenex Training Facility, located at 2341 West 205th Street, Torrance, CA 90501. Each course will be 33 hours in length and a certificate for 3.3 (RU) Recertification Units will be awarded.

COURSE FEES: Non-Member: \$500, ASQ Member: \$350 & Unemployed Member: \$200. Unemployed ASQ Members must provide evidence of unemployment status, prior to first class.

Tuition Checks must be received before the second (2nd) class. Make checks payable to ASQ LA Section 0700. Currently, credit cards are not accepted

Each course will be taught using a Primer, which can be brought into the exam. Primers cost (\$60 - \$80) and are available from the Quality Council of Indiana at www.quaitycouncil.com.

Students are responsible for registering for the ASQ Exam prior to the Application Deadlines listed above. ASQ Exam Registration Fees are in addition to the class fess and are paid directly to ASQ.

REGISTRATION: Provide cell phone and ASQ Member Number to Lanep@phenomenex.com

NOTE: Courses without five (5) students one week before the course starts will be cancelled.



CEIE HOME CEIE PROGRAMS & SCHEDULES

REGISTRATION SERVICES

CONTACT US

ဗိ

Welcome to College of Extended & International Education class schedule search.

Semester: Fall 2017

Major: Quality Assurance

Program: Quality Assurance Master of Science

* C = Class Cancelled *

Click on column title Start Date, End Date, or CRN in order to sort by that column.

Start Date	End Date	CRN	Dept	Sec	Course Title	Units	Days Hours	Hours	Bldg/Rm	Fee	Instructor
09/05/2017	12/05/2017	43384	QAS 510	41	Adv Probability/Statistic	3.0		,	INT NET	\$915	S Schuelka
09/05/2017	12/05/2017	43385	QAS 511	41	Quality Function Mgt. & TQM	3.0			INT NET	\$915	P Dunahay
09/05/2017	12/05/2017	C43386	QAS 511	42	Quality Function Mgt. & TQM	3.0		-,		\$915	Staff
09/05/2017	12/05/2017	43389	QAS 512	41	Reliability	3.0		,	INT NET	\$915	D Dunahay
09/05/2017	12/05/2017	43391	QAS 515	41	Human Factors In QAS	3.0			INT NET	\$915	J Clauson
09/05/2017	12/05/2017	43393	QAS 516	41	Measure & Test Techniques	3.0			INT NET	\$915	E Hazarian
09/05/2017	12/05/2017	43394	QAS 518	41	Quality Project Mgmt. & Prod.	3.0		,	INT NET	\$915	R Spencer
09/05/2017	12/05/2017	43398	QAS 523	41	Software Reliability	3.0		,	INT NET	\$915	C French
09/05/2017	12/05/2017	43396	QAS 525	41	ISO 9000 & The Audit Function	3.0		,	INT NET	\$915	R Spencer
09/05/2017	12/05/2017	43397	QAS 530	41	Sqc For Service Prof	3.0		,	INT NET	\$915	C Carpenter
09/05/2017	12/05/2017	43399	QAS 531	41	Cust Satisfaction And QAS	3.0		-	INT NET	\$915	J Capawana
09/05/2017	12/05/2017	43400	QAS 532	41	Qa Service Delivery Process	3.0			INT NET	\$915	K Fulton
09/05/2017	12/05/2017	43402	QAS 598	41	Directed Research	3.0			INT NET	\$915	M Krivokuca
09/05/2017	12/05/2017	43403	QAS 599	41	Project	3.0			INT NET	\$915	M Krivokuca
09/05/2017	12/05/2017	43404	QAS 600	41	Grad Continuation Course	1.0			INT NET	\$150	M Krivokuca
09/05/2017	12/05/2017	43404							INT NET		

NEW MEMBERS FOR JUNE

Pierre J. Servan

Kirilov G. Boyko

Anthony Parrille

Guihua Liu

Heather L Shay

Joseph S. Bell

Nathaniel Sutton

Richard Solis

Karen Sasaki

Karen Minassians

Christine Cantong

Phillip Skillman

Nguyen

Reem Alqaisy

Huyen Phan

Lily Sieu

Elnura Hashimova Sr

Jimmy Todorov

Flavio De Jesus

Nicholas Parker

Yun Tae Cha

Stephanie Mills

Eva George

Sandra Dancy

Patrick Hovsepian

Andrew Palomares

Quinton Pham

Chunyu Chien

Phillip Gossman

ASQLA LEADERSHIP TEAM

MEETING SCHEDULE

Time: 5:30P - 6:00P Networking & Dinner 6:00P - 8:00P Meeting

Location: CSUDH Extended Education Bldg. 1300 Room EE-1210 1000 Victoria St.—Carson, CA 90745

Contact: Alan Wang, Chair

(310) 383-2393 — awang@spectrumchemical.com

Date: August 2, 2017

2017 Officers & Committee Chairs of ASQ Los Angeles Section 700 www.asqla.org

ELECTED OFFICERS 2017

CHAIR: Alan Wang, 310-383-2393, awang@spectrumchemical.com

CHAIR-Elect: Ron Lombano, 310-864-2898, Ronald_A_Lombrano@raytheon.com

SECRETARY: Elizabeth Rowshan, 805-405-4795 ElizabethHires@gmail.com

TREASURER: Jim Morrison, 310-541-1417, jamamorr@aol.com

COMMITTEE CHAIRS 2017

Arrangements: Chen Low, 310-334-7044, chenlow_88@hotmail.com

Awards and Recognition: Jim Morrison, 310-541-1417, jamamorr@aol.com

Certification/ Re-certification: Joe DeSimone, 424-772-6371, jrdesimone@msn.com

CSUDH Liaison: Alan Wang, 310-383-2393, awang@spectrumchemical.com

Education: Lane Parrott, 310-489-9018, lanep@phenomenex.com

Financial Audit: Michael Schaffer, 310-895-0802, michaels@psychemedics.com

Job Listing: Armen Yeghoian, 818-912-9272, Armen2049@yahoo.com

Membership: Catherine Martin, 310-616-0936, Catherine_Martin@raytheon.com

Newsletter Editor: Harold Martinez, 310-214-1606, martinez2004@verizon.net

Nominating Chair: Catherine Martin, 310-616-0936, Catherine Martin@raytheon.com

Performance Awards and Recognition (PAR): Ron Lombano, 310-864-2898, Ronald_A_Lombrano@raytheon.com

Publicity & Advertising Chair: Alan Wang, 310-383-2393, awang@spectrumchemical.com

Simon Collier Quality Award: Jim Morrison, 310-541-1417, jamamorr@aol.com

Social Media: Open

Voice of the Customer: Chen Low, 310-334-7044, chenlow 88@hotmail.com

Website Chair: Alan Wang, 310-383-2393, awang@spectrumchemical.com

Programs Chair: Muriel Sasaki, 562-221-0168, Muriel@aims-online.com