



MIDWEST REGIONAL CHAPTER SOCIETY OF QUALITY ASSURANCE ANNUAL MEETING

Show Me Quality

REGISTRATION BROCHURE AND PRELIMINARY PROGRAM



COURTYARD by
Marriott Columbia
Columbia, Missouri
27-28 July 2010



MEETING AND TRAINING

Join us for two days of workshops, plenary and presentations to explore hot topics and the latest regulatory interpretations in the field. Experts have been invited to give presentations and training workshops. Meeting topics, sessions and speakers have been selected by the program committee to provide a wide variety of information within GxP related fields.

WHO SHOULD ATTEND

Quality Assurance professionals who are promoting and advancing the principles and knowledge of quality assurance essential to human, animal and environmental health worldwide. Personnel working in areas advancing the discovery, development and marketing of regulated health products.

Visit www.mwsqa.org for updated information.



MWSQA ANNUAL MEETING

27-28 July 2010

GENERAL INFORMATION

MWSQA MEMBERSHIP

2010 Membership in MWSQA affords attendees reduced registration fees for the summer meeting. MWSQA is a professional membership organization dedicated to promoting and advancing the principles and knowledge of quality assurance essential to human, animal and environmental health.

Tangible benefits of MWSQA membership include:

- Membership Directory - published annually
- Newsletters
- Chapter meetings and training opportunities

If you would like to take advantage of the members-only discount, please complete a membership application and submit payment for dues with your meeting registration payment. A membership application has been included in this registration packet or may be obtained at www.mwsqa.org.

LOCAL INFORMATION

Missouri's largest city between Kansas City and St. Louis on I-70, Columbia is a great cultural destination with numerous festivals, attractions, performing arts and special events throughout the year. As home to the University of Missouri, Columbia hosts many sporting events including Tiger football, basketball, baseball, gymnastics and more. You will never go hungry in Columbia with many fantastic uniquely Columbia dining options from which to choose.

Temperature/Dress

The average high/low temperature in Columbia for July is 90°F/70°F. The dress code for the meeting is business casual. Please note the temperature in the meeting rooms may vary. Dressing in layers is recommended.

Travel

Columbia Regional Airport (COU) is the city's only airport. Two other airports, St. Louis' Lambert International (STL) and Kansas City International (MCI) both provide service to Columbia either by shuttle or by rental car. Lambert International Airport is approximately 1.5 hours from Columbia and Kansas City International Airport is approximately 2.25 hours from Columbia. MoX is the shuttle service that runs to and from both airports. To schedule a shuttle, visit www.moexpress.com.

HOTEL INFORMATION

COURTYARD by Marriott Columbia
3301 LeMone Industrial Boulevard
Columbia, Missouri 65201 USA
Tel: 573-443-8000
Reservations: 1-800-321-2211
www.marriott.com/coucy

\$82.00 per night

For reservations please call 1-800-321-2211 and tell the hotel staff that you are attending the MWSQA meeting. The Courtyard by Marriott in Columbia, Missouri, is located center state, convenient to Kansas City, St. Louis, Lake of the Ozarks, and Jefferson City. You will love the location in one of America's favorite cities, with area attractions that include Bass Pro Shop, MKT fitness trail, Katy Trail, several wineries, and the award winning Eagle Knoll golf course. The hotel features Bennigan's Grill & Tavern, Courtyard Breakfast Cafe, free wireless internet, and 6,000 square feet of flexible meeting space, all on site. It has been ranked the number one Courtyard in Missouri and in the Midwest for two years running. Come experience the award winning service that has the highest number in repeat guests in the state.

Parking

Parking is available at the hotel free of charge.





KEYNOTE PRESENTATION: LARRY W. POTTERFIELD
Malcolm Baldrige National Quality Award 2009 Award Recipient,
Small Business Category



Larry W. Potterfield, President – Larry is the Founder and CEO of MidwayUSA, a local distributor of outdoor products. In 2006, Larry challenged his organization with a goal to apply for and receive the Malcolm Baldrige National Quality Award in 2009. And in 2009, his organization achieved this goal with their first application for the award.

The Baldrige Award is given by the President of the United States to businesses - manufacturing and service (small and large) - and to education, health care and nonprofit organizations that apply and are judged to be outstanding in seven areas: leadership; strategic planning; customer focus; measurement, analysis, and knowledge management; workforce focus; process management; and results. Each of these areas is represented by a category within, and collectively make up, the Baldrige criteria.

The Baldrige criteria provide a framework for organizations to adopt, which results in a clear focus on performance excellence. To deploy this framework within MidwayUSA, Larry led a series of teachings on the Baldrige criteria and sent employees to serve as volunteer examiners for the state quality award. He is an avid proponent of the Baldrige criteria and has started a local Baldrige Performance Excellence group in Columbia, Missouri to help further deploy the criteria to local organizations.



PRE-CONFERENCE WORKSHOPS

Register early; workshop class size is limited!

TUESDAY, 27 JULY 2010

8:00 am - 12:00 pm Concurrent Workshops

WORKSHOP 1: Information Technology Issues and Computer System Validation

Presenters: Robert Herr, (Pfizer Animal Health, Pfizer, Inc.), and Tony Ettwein (Corporate Audit, Pfizer, Inc.)

This workshop takes a non-traditional approach to discussing information technology issues, including the validation of computer systems. While the presenters will provide information on current issues on the topic, they will also act as facilitators for participants who are encouraged to share real-world case scenarios, and to try to provide some answers to such common questions as “What does the FDA expect?” and “How much is enough?” Information presented will be based on the application of good IT, project management, and regulatory practices used to define, develop, test, deliver and maintain computer systems in a state of control. We will start by giving a brief overview of the regulatory drivers and requirements for computer systems that are used in support of business processes which are subject to regulations. The discussion will take into account the notion of a risk-based approach for IT projects and validation, and how criticality and complexity play into the process of validating computer systems. We will then open up the discussion to those of you with questions and case scenarios, and will invite participants to respond to each other in terms of what worked – and didn’t work – for your respective companies.

This workshop is intended for both the QA generalist who wants to understand the basics of validating computer systems, as well as the "seasoned" professional who wants to understand the compliance power of following good IT practices for development and support of computer systems. Please come with your own questions and examples as we try to help each other and our customers.

WORKSHOP 2: Principles of GMPs for the FDA Regulated Industries

Presenter: Howard Cooper, President, EQACT, Inc.

Workshop details to be announced.

Topics subject to change and additional topics may be added. Please visit the conference website (www.mwsqa.org) for updated information.



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TUESDAY, 27 JULY 2010 (continued)

WORKSHOP 3: Computerized Systems Used in Clinical Trials

Presenter: Chris Wubbolt, BS, MS, QACV Consulting

Computerized systems used in clinical trials to capture source documentation are subject to FDA electronic recordkeeping requirements. Meeting FDA electronic recordkeeping requirements may be problematic for many investigator sites, clinics, and hospitals, particularly if systems used at these sites are used primarily for patient care purposes. This workshop discusses current regulatory requirements and considerations regarding electronic recordkeeping in clinical environments. In addition, techniques and topics for auditing computerized systems at clinical sites will also be reviewed, including case studies and examples.

12:00 pm - 1:00 pm **Lunch**

1:00 pm - 4:00 pm **Welcome Address & MWSQA Update**

Darcie Verdon, Covance Laboratories, Inc., MWSQA President

Keynote Presentation:

Larry Potterfield, President/CEO of MidWay USA

SQA Update

Debbie Green, RQAP-GLP, Owner, QA Consultant, Advantage Quality Services LLC

Regulatory Topic (details TBA)

Daniel M. Myers, Chemist, Laboratory Data Integrity Branch, Office of Compliance, Environmental Protection Agency

6:00 pm - 10:00 pm **Evening Event:**

Shuttles will depart from the Courtyard around 5:30 pm with return shuttles beginning to depart Les Bourgeois around 10:00 pm (see Page 6 for additional details).

WEDNESDAY, 28 JULY 2010

7:30 am - 8:00 am **MWSQA Business Meeting - All attendees are welcome**

8:00 am - 11:30 pm **Sessions** (See session listings on Page 7)

11:30 pm - 12:30 pm **Lunch**

12:30 am - 4:30 pm **Sessions** (See session listings on Page 7)

Topics subject to change and additional topics may be added. Please visit the conference website (www.mwsqa.org) for updated information.



MWSQA ANNUAL MEETING 27-28 JULY 2010

WINE TASTING AND DINNER AT LES BOURGEOIS WINERY

Renowned for its spectacular bluff-top view of the Missouri River Valley, Les Bourgeois Vineyards and Winery is one of Mid-Missouri's premiere cultural and recreational attractions.

The Les Bourgeois Vineyards span 27 acres just north and south of I-70 at the Rocheport winery. These fertile vineyards yield the grapes for all award-winning wines, and include: two acres of Chambourcin, seven acres of Chardonel, three acres of Norton, 10 acres of Vidal, and five acres of Vignoles.

All grapes are cultivated on high cordon trellis systems (6' wire with shoots trained downward), except for Chardonel, which is grown with vertical shoot positioning (3' wires with shoots trained upward on six catch wires).

Today Les Bourgeois Vineyards is the third largest winery in Missouri, with more than 90,000 gallons produced and 75,000 gallons sold in 2005. Approximately 50% of this wine is sold through their own retail outlets, with the remaining sold through wholesale distribution.

Sunset over Les Bourgeois Vineyards on **July 27, 2010** will occur at: **8:25 pm**.





SESSION LISTING

(Each Session is scheduled for one hour on Wednesday, 28 July 2010, unless otherwise noted.
Times of individual sessions to be determined)

Reaching a Mutual Understanding Between IT and QA

Matt Hansen, Global Supervisor, Covance Laboratories, Inc.

Regulatory Considerations for Obtaining and Maintaining USDA Import/Transport Permits for Animal Products and By-products

Katina Frangakis, Senior Associate, Pfizer Animal Health, Pfizer Inc.

Archives: When QA Runs the Shop

Willa Bailes, Consultant, Bailes Consulting; and Deanna Talerico, Sr. Mgr., Regulatory Compliance; Charles River Laboratories

Bioanalytical 101

Don Mayer, Quality Consultant, Don Mayer Quality Consulting, Inc.

GLP Topic (details TBA)

Kathy Newland, Archives and Compliance Advisor, Pfizer Inc.

QA GMP Responsibilities for a Contract Laboratory

Darcie Verdon; QA Supervisor; Covance Laboratories, Inc.

Starting from Scratch-Designing the Perfect Quality System

Howard Cooper, President, EQACT, Inc.

SOP Management Practices and Traps to Avoid

Jon Rhodes, Director of Chemical Services, ABC Laboratories; and Chris Hughes, Manager, Quality Assurance, Chemical Services, ABC Laboratories

GMP Topic (details TBA)

Kevin Roberson, Director, cGMP Quality Assurance, Pharmaceutical Services, ABC Laboratories

Quality Metrics

Jill Nabors, RQAP-GLP, Manager, Quality Assurance, ABC Laboratories; and Jessica Dutton, RQAP-GLP, Quality Assurance Associate III Pharmaceuticals Services, ABC Laboratories

Quality: A Management Perspective

John Bucksath, Senior Vice President & General Manager, Pharmaceutical Services, ABC Laboratories

How to Introduce GLP Programs/Concepts to non-GLP Colleagues

Anne Carlson, Quality Assurance, Pioneer Hi-Bred International, Inc.; and Annette Leslie, RQAP-GLP, Pioneer Hi-Bred International, Inc.

Topics subject to change and additional topics may be added. Please visit the conference website (www.mwsqa.org) for updated information.



MARKETING OPPORTUNITIES

ATTENDEE PROFILE

Meeting attendees will include professionals working in pharmaceutical, agricultural, industrial, chemical, and contract testing organizations, as well as those in academic and regulatory organizations, and consultants. SQA and MWSQA foster interaction, communication and professional competence through their extensive development programs of meetings, lectures and information exchanges. Because the quality assurance profession typically involves interactions with all levels of management, scientific and support staff, our Meeting Exhibitor and Meeting Sponsor Programs serve as conduits for sharing information on technological advances and services available to industries that must continually improve to remain competitive.

EXHIBITORS

Exhibit Days: 27-28 July 2010

Market your organization to approximately 80 expected attendees! Exhibitors may promote their products or services by hosting exhibits at the meeting. Exhibit days are Tuesday through Wednesday, 27-28 July 2010. Exhibitors are placed in the center of high traffic events that offer great visibility to meeting attendees. Exhibitors will be listed on the Meeting Website, in the Meeting Program, and on signage at the meeting. The Registration Fee for Exhibitors is \$250. To register as an exhibitor, please contact Deanna Talerico at 419-647-4196 ext. 332.

CONSULTANT MEMBER TABLE

This option is open to the independent MWSQA member consultants who wish to display marketing materials at the meeting. Consultants will have table space in the exhibit area to display marketing materials and will be listed in the Meeting Program. This opportunity is available to meeting attendees and MWSQA members in good standing. The cost of registration is \$50. To register, please contact Deanna Talerico at 419-647-4196 ext. 332.

CALL FOR POSTERS

Share your knowledge with your QA colleagues and submit a poster for the MWSQA Meeting! Posters will be displayed in the center of high traffic events that offer great visibility to meeting attendees. Each poster will qualify for one unit towards RQAP-GLP re-registration and they can be published in the QA Journal! To register for a poster, please contact Deanna Talerico at 419-647-4196 ext. 332.

MEETING SPONSORS

MWSQA Meeting Sponsors help underwrite some of the meeting expenses in exchange for recognition in the Meeting Program, on signage at the meeting, in MWSQA Newsletters, and on the MWSQA Website. Titanium, Platinum, Gold and Vendor (Exhibitors) contribution levels are available. More information is available at www.mwsqa.org. To register as a meeting sponsor, please contact Deanna Talerico at 419-647-4196 ext. 332.

GIFT SPONSORS

This is a unique opportunity to showcase your company or organization by providing a gift to all meeting attendees! You are invited to provide a gift displaying your corporate logo to meeting attendees. These gifts will be distributed to all attendees. Example gifts are: pens, highlighters, letter openers, lavalier badge holders, mints, mini stress balls, calendars, sticky note pads, page flags, magnets, etc. Do not miss this opportunity to showcase your company or organization. To register, please contact Deanna Talerico at 419-647-4196 ext. 332.

JOB POSTINGS

MWSQA will sponsor an employment opportunities board at the Conference. This opportunity is being offered free of charge to anyone who would like to advertise employment opportunities at the Meeting. You must be a Meeting attendee to utilize this service. Ads should not exceed one page in length and should be formatted in the manner in which you would like the posting to appear. If you are interested in posting an ad, please visit the registration desk at the Meeting. Job postings will not be accepted prior to the meeting.



MWSQA ANNUAL MEETING

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MEETING INFORMATION

CONFERENCE CONTACTS

MWSQA Program Information

- Deanna Talerico
deanna.talerico@crl.com
- Darcie Verdon
darcie.verdon@covance.com

Exhibitor/Sponsor/Consultant Members Table Information

- Deanna Talerico
deanna.talerico@crl.com

Poster Information

- Deanna Talerico
deanna.talerico@crl.com

REGISTRATION DESK

Please visit the registration desk upon your arrival at the meeting to receive your admission badge and registration materials. Hours of operation:

7:00 am - 4:00 pm Tuesday, 27 July 2010
8:00 am - Noon Wednesday, 28 July 2010

MWSQA SUMMER BUSINESS MEETING

The MWSQA Summer Business Meeting of Members will be held Wednesday, 28 July 2010, 7:30 - 8:00 am. Please make plans to attend this meeting and learn about the activities of your Chapter! All attendees are welcome.

Many Thanks to the MWSQA Meeting Sponsors

TITANIUM SPONSOR AND MEETING HOST

ABC Laboratories

GOLD SPONSORS

Monsanto
Pfizer, Inc.
WIL Research Laboratories, LLC

SILVER SPONSORS

Charles River Laboratories, Inc.
Leifheit & Company, Inc.

These generous contributions provide for the venue, networking events, lunches and breaks which make this event possible.
THANK YOU!



REGISTRATION INFORMATION

REGISTRATION

Reservations need to be made early to ensure group rate, as well as availability! All meeting registration fees include training workshops, plenary and sessions, all scheduled lunches and breaks as outlined in the program, and dinner and wine tasting at Les Bourgeois on Tuesday evening. Meeting registration will be accepted to **16 July 2010**. Hotel reservation rooms will no longer be eligible for the reduced rate after **16 July 2010**.

Important Payment Note: The registration form must be accompanied by your credit card information or check in full payment of registration fees and events. Checks should be made payable to the Midwest Society of Quality Assurance (MWSQA). All non-U.S. members will be charged the U.S. dollar equivalent at the time the charge is processed, unless otherwise indicated. **Registrations must be faxed or postmarked by 16 July 2010.**

Please fax or mail your registration form to:

MWSQA Headquarters, 154 Hansen Rd. Suite 201, Charlottesville, VA 22911 USA
Telephone: 434-297-4772, Facsimile: 434-977-1856

Rates: Attendees must be current members of MWSQA to qualify for the member rate. Attendees who have not paid MWSQA membership dues before or at the time of registration will be charged the nonmember rate as appropriate.

Refund Policy: Refund requests must be made in writing to MWSQA Headquarters. A refund of the full registration fees, minus a \$50 processing charge, will be made for cancellations on or prior to **16 July 2010**. No refunds will be made for requests received after **16 June 2010**.

Substitution Policy: If you find that you are unable to attend the Meeting, you may send a substitute in your place. Each registration substitution will be charged a \$50 processing fee.

Returned Check Policy: Remittance must be made in U.S. dollars. A surcharge may be assessed to cover any collection fees.

Emergency Illness or Death of Registrant or Immediate Family Member: Attendees who are unable to attend the Meeting based on a serious illness or death may receive a refund (amount paid minus a \$50 processing charge) in the following instances:

- Personal illness of the attendee; or
- Illness or death in the immediate family of the attendee

HOTEL INFORMATION

MWSQA has rooms reserved at the conference hotel. Please make your reservation by **16 July 2010**.

Courtyard by Marriott Columbia
3301 Lemone Industrial Boulevard, Columbia, MO 65201
Tel: 573-443-8000
\$82.00 per night

For reservations please call 1-800-321-2211 and tell the hotel staff that you are attending the MWSQA meeting

Check-in time is 3:00 pm and check out time is 12:00 noon.

Midwest Regional Chapter
Society of Quality Assurance

**PRINT COMPLETED FORM AND
RETURN WITH FULL PAYMENT TO:**



MWSQA
154 Hansen Rd. Suite 201
Charlottesville, VA 22911 USA
Tel: 434-297-4772
Fax: 434-977-1856

MEMBERSHIP REGISTRATION FORM
(The 2010 membership fee is \$20.00)

**Important: Include this registration form with the meeting registration form
to obtain discounted member registration fee.**

Name: _____

Title: _____

Company: _____

Address: _____

City, State, Zip: _____

Phone: _____ FAX: _____ E-mail: _____

Please send me email updates regarding chapter events

My regulatory interests are (Check all that apply):		
<input type="checkbox"/>	FDA GLP	<input type="checkbox"/>
<input type="checkbox"/>	EPA GLP	<input type="checkbox"/>
<input type="checkbox"/>	Veterinary GCP	<input type="checkbox"/>
<input type="checkbox"/>	Human GCP	<input type="checkbox"/>
<input type="checkbox"/>	Pharmaceutical GMP	<input type="checkbox"/>
<input type="checkbox"/>	Medical Device GMP	<input type="checkbox"/>
My occupation is oriented towards (Check all that apply):		
<input type="checkbox"/>	Human drugs, vaccines or devices	<input type="checkbox"/>
<input type="checkbox"/>	Animal drugs, vaccines or devices	<input type="checkbox"/>
<input type="checkbox"/>	Agricultural products (including pesticides)	<input type="checkbox"/>
<input type="checkbox"/>	Contract Research Organization	<input type="checkbox"/>
<input type="checkbox"/>	Educational Research Organization	<input type="checkbox"/>
<input type="checkbox"/>	Innovator pharmaceutical, vaccine or device firm	<input type="checkbox"/>
<input type="checkbox"/>	Generic pharmaceutical, vaccine or device firm	<input type="checkbox"/>
Professional Affiliations (Please list)		
I would consider future participation in the MWSQA as a (check all that apply)		
<input type="checkbox"/>	Meeting Attendee	<input type="checkbox"/>
<input type="checkbox"/>	Meeting Presenter - List Topic(s)	<input type="checkbox"/>
<input type="checkbox"/>	Elected Officer (preference?)	<input type="checkbox"/>
<input type="checkbox"/>	Committee Member (preference?)	<input type="checkbox"/>



MWSQA SUMMER MEETING

27-28 JULY 2010

MWSQA ANNUAL MEETING REGISTRATION FORM

Please use this form to register for the MWSQA Meeting and Training Workshops

Name: Mr. Ms. Dr. (circle one): _____
(First) (Middle) (Last) (Suffix)

Badge Name: _____
(First Name or Nickname)

Title: _____

Organization: _____

Address: _____

City and State: _____ Zip/Postal Code: _____ Country: _____

Phone: _____ FAX: _____ E-mail: _____

How did you hear about the meetings? _____

Special Food Requests: Vegetarian Meals Food Allergies, please list: _____

Emergency Contact: _____ Phone: _____

REGISTRATION FEES

MWSQA Pre-Conference Workshops and Meeting Sessions Registration Tuesday - Wednesday, 27-28 July 2010

(includes all pre-conference workshops, meeting sessions, lunches, and networking events)

- Select One: MWSQA Member Meeting Speaker Non-member
- MWSQA Member Rate (through 16 July 2010). Attendees must be 2010 members of MWSQA to qualify for Member Rates **\$200**
 - Reduced Rate for Nonmembers applying for membership in MWSQA **\$220**
Attendees must submit the 2010 membership form along with this registration.
 - Nonmember Rate **\$275**
 - Speaker Registration **Complimentary**
 - Pre-Conference Workshop Registration (please select one) **Complimentary**
 - 1 - Information Technology Issues and Computer System Validation
 - 2 - Principles of GMPs for the FDA Regulated Industries
 - 3 - Computerized Systems Used in Clinical Trials
 - Dinner & Admission for the *Les Bourgeois* winery (Tuesday July 27, 2010) **Complimentary**
 - Guest Dinner & Admission for the *Les Bourgeois* winery: Number of guests _____ **\$25 per guest**

Total MWSQA Meeting Fees: \$ _____

METHOD OF PAYMENT FOR MWSQA MEETING FEES (Please circle one)

- Enclosed is my check payable to Midwest Society of Quality Assurance Check number: _____
 - Charge to one of the following credit cards (check one): MasterCard VISA American Express
- Card Number: _____ Expiration Date: _____ Security Code: _____
 Cardholder Printed Name: _____ Signature: _____
 Credit Card Billing Address: _____

Please mail (MWSQA Headquarters, 154 Hansen Rd. Suite 201, Charlottesville, VA 22911) or fax (434-977-1856) registration form (and MWSQA membership form, if applicable) no later than 16 July 2010
Questions? Phone 434-297-4772 or 608-242-2712 ext. 7314