



MIDWEST REGIONAL CHAPTER SOCIETY OF QUALITY ASSURANCE SUMMER MEETING

A Taste of Quality

REGISTRATION BROCHURE AND PRELIMINARY PROGRAM

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.



**Radisson Plaza Hotel & Suites
Kalamazoo, MI
17-18 July 2007**

Visit www.mwsqa.org for updated information.



MWSQA SUMMER MEETING 17-18 JULY 2007

GENERAL INFORMATION

MWSQA MEMBERSHIP

2007 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 - publishes 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.

KEYNOTE PRESENTATION

WILLIAM HARRISON

MPI Research



Tuesday, 17 July 2007
Opening Plenary

QA: Yesterday's Experience, Today's Issues and Tomorrow's Challenges

While the GLP regulations themselves have essentially remained unchanged in the almost thirty years from their inception, the interpretation and application of the GLPs has changed. The Quality Assurance Professional (QAP) has had to adapt continually to assure compliance with the GLPs. It is the fundamental understanding of the purpose of the GLPs and the role of the QAU that allows the QAP to use past experiences to apply the GLPs to various current issues such as multi-site studies, computer validation, and new study types required to be conducted according to GLPs. Tomorrow's challenges eventually become today's issues. Some of today's issues will continue to be tomorrow's challenges as they become more prevalent.

LOCAL INFORMATION

Kalamazoo is a city rich in history, which includes participation in the underground railway and a diverse economy during the 20th century. Located in southwest Michigan, less than one hour east of Lake Michigan, Kalamazoo is home to Western Michigan University, Kalamazoo College, and Kalamazoo Valley Community College. The city offers many cultural attractions including theatre, art galleries, museums and planetarium. The area has many fine golf courses, lakes for fishing and boating, wineries and beer distilleries. For more information, visit <http://www.kalamazoomi.com/>

Temperature/Dress

The average high/low temperature in Kalamazoo for July is 85/62. 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

Kalamazoo is centrally located within the MWSQA chapter area, which may make traveling by car an attractive option. Flights are available to the Kalamazoo/Battle Creek International Airport.

HOTEL INFORMATION

Radisson Plaza Hotel at Kalamazoo Center

100 West Michigan Avenue

Kalamazoo, MI 49007, USA

Tel: 269-343-3333; Fax: 269-381-1560

www.radisson.com/kalamazoomi

\$124.00 per night

For reservations please call **269-343-3333** or **888-201-1718** and tell the hotel staff that you are attending the MWSQA meeting.

In the heart of downtown Kalamazoo, the Radisson is only minutes from Western Michigan University and the Kalamazoo/Battle Creek International Airport, and within walking distance to shops, restaurants, art, museums, and entertainment. A world of hospitality awaits your arrival at this four diamond award winning hotel. Relax in a whirlpool or sauna, or work out at the Athletic Club (a comprehensive gym, 20 meter swimming pool, and workout facility). Choose your dining style from several distinctive in-house restaurants. What a great place to meet with over 44,000 sq. ft. of meeting space. New Jacuzzi Suites available.



MWSQA SUMMER MEETING

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PRE-CONFERENCE WORKSHOPS

TUESDAY, 17 JULY 2007

8:00 am - 12:00 pm Concurrent Workshops

**MWSQA Meeting Registration includes admittance to Pre-Conference Workshop 1, 2 or 3.
Register early; workshop class size is limited!**

WORKSHOP 1: Regulatory Pathways for Drugs, Devices and Biotechnology Products

Presenter: Martha Feldman, RAC, (Drug and Device Development Company, Inc.)

This workshop will cover the typical process for navigating the different regulatory pathways for (1) drugs and therapeutic biotechnology-derived products, (2) medical devices, (3) in vitro diagnostic devices, (4) biologics, and (5) a brief overview for combination products. This workshop will cover the regulatory strategies throughout and products' lifecycles, i.e., from pre-market strategy development, through the testing phases, to pre-market submissions, through ongoing maintenance of the submission.

WORKSHOP 2: Differences - US and OECD GLPs and Managing Multi-Site Studies

Presenter: Deborah Garvin, MS, RQAP-GLP (WCQTI/Pacific Rim Consulting, Inc.)

There are numerous philosophical and regulatory differences between the OECD and US GLPs. Many people get these confused and lack understanding of what are actually regulatory requirements and what is optional. The first part of this session will focus on the differences between the US and OECD GLPs. Currently there is no guidance or regulation in the US detailing the various nuances of multi-site studies, so we often default to the OECD GLPs and consensus documents to provide direction when addressing complex issues. The second portion of the session discusses items to consider when conducting multi-site studies, utilizing the various OECD documents coupled with applicable portions of the US Good Laboratory Practices.

WORKSHOP 3: GXP: Good, eXtreme Practice for Validation of Computer Systems

Presenter: Robert Herr, (Pfizer Animal Health, Pfizer Inc.)

This workshop takes a non-traditional approach to the validation of computer systems. It is based on the application of good IT and project management practices to define, develop, test, deliver and maintain computer systems in a state of control. We will start by identifying the regulatory drivers and requirements for computer systems that are used in support of business processes that are subject to regulations. We will then turn our focus to specific methods for meeting the regulatory requirements. Several case studies will be included to see how these methods have been successfully applied, along with some projects that didn't go so well and what could have been done to prevent the problems that were encountered. Finally, we will discuss how criticality and complexity of the system play into the process of validating a computer system.

This workshop will appeal to both the QA generalist who wants to understand the basics of validating computer systems, as well as the "seasoned" computer validation professional who wants to understand the compliance power of following good IT practices for development and support of computer systems.

*Topics subject to change. Please visit the conference website
(www.mwsqa.org) for updated information.*



MWSQA SUMMER MEETING

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Tuesday, 17 July 2007, continued

- 12:00 pm - 1:00 pm Lunch
Sponsored by: Covance Inc.
- 1:00 pm - 1:15 pm Welcome Address & MWSQA Update
Brian Mitchell, MWSQA President, Eli Lilly and Company
- 1:15 pm - 1:45 pm Keynote Presentation:
William Harrison, President & COO, MPI Research Inc
- 1:45 pm - 2:00 pm SQA Update
Deb Green, Advantage Quality Services, LLC
- 2:00 pm - 3:30 pm FDA Regulatory Update, GLP/Bioanalytical Method Issues, Q & A
Jacqueline O'Shaughnessy, PhD, US FDA
- 4:00 pm Buses depart from hotel lobby to tour MPI, followed by dinner at Gilmore Car Museum.

*Topics subject to change. Please visit the conference website
(www.mwsqa.org) for updated information.*

DINNER AT GILMORE CAR MUSEUM

The Gilmore Car Museum began in 1963 as the hobby of Donald S. Gilmore when his wife, Genevieve, gave him an antique car for his birthday – a 1920 Pierce-Arrow “project car.” With the help of some friends, the auto was placed under a tent and a full restoration followed. The hobby soon grew into a collection of over 30 automobiles. Mr. Gilmore purchased 90 acres of farm property and had several historic barns dismantled piece by piece and moved to the site. It was Mr. Gilmore’s wife who suggested the idea of turning the collection into a museum where future generations could enjoy the restored cars for years to come. The Gilmores established a non-profit foundation, and opened the museum to the public for the first time on Sunday, 31 July 1966. Donald Gilmore passed away in 1979, and Mrs. Gilmore in 1990, but the legacy they began continues to grow.

Today, the site includes eight historic barns, a re-created 1930s service station, a small town train station, and nearly three miles of paved roads.

We will enjoy a Michigan summer cook out. Southwest Michigan local brewers and vintners will be on hand to ensure your summer thirst is quenched and your taste buds tantalized. Vintage cars will be available to view and take for an evening drive on the grounds.

**Dinner at the Gilmore Car Museum is included in the cost
of the meeting and fully sponsored by MPI.**





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WEDNESDAY, 18 JULY 2007

- 7:30 am - 8:00 am Summer MWSQA Business Meeting - All attendees are welcome
- 8:00 am - 9:00 am *Concurrent Sessions:*
Your Quality System, a Yugo, a Ford or a Cadillac?
Martha Feldman, RAC, Drug & Device Development Company Inc
Preclinical Testing of Drugs
Ali Said Faqi, DVM, PhD., DABT
- 9:00 am - 10:00 am *Concurrent Sessions:*
My Journey In & Out of the Cult of Computer Validation
Robert Herr, Pfizer Animal Health, Pfizer Inc.
Charting a Moral Course: Ethical Development in Human Subjects Research
Jason Eberl, PhD, Indiana University, School of Liberal Arts
- 10:00 am - 10:20 am Break
Sponsored by: Charles River Laboratories, Preclinical Services, Ohio
- 10:30 am - 11:30 am *Concurrent Sessions:*
Clones, Chimeras, and Stem Cells: Ethical Implications of Genetic Research
Jason Eberl, PhD, Indiana University, School of Liberal Arts
Study Reconstructibility - Life After GLP Study Conduct
Celeste Rose, BS, RQAP-GLP, RoseTECH Consulting, Inc.
- 11:30 am - 12:30 am Lunch
Sponsored by: Eli Lilly & Company and Pfizer, Inc.
- 12:30 am - 1:30 am An Approach to GXP Risk Assessment, Prioritization and Mitigation
Rick Huddleston, YourEncore, Inc.
- 1:30 pm - 2:30 pm Effective GLP Training for Animal Technicians
Wendy Eland & Lisa Mathews
- 2:30 pm - 3:30 pm Everything You Wanted to Know About Dose Formulation Analysis But Were Afraid to Ask
Celeste Rose, BS, RQAP-GLP, RoseTECH Consulting, Inc.

*Topics subject to change. Please visit the conference website
(www.mwsqa.org) for updated information.*



JOIN US IN KALAMAZOO!

A Taste of Quality



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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: 17-18 July 2007

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, 17-18 July 2007. 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 Barbara Stephenson at 269-833-2856.

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 18 x 24 inches of table space in the exhibit area to display marketing materials and will be listed in the Meeting Program. This opportunity is available to MWSQA members in good standing. The cost of registration is \$50. To register, please contact Barbara Stephenson at 269-833-2856.

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 Barbara Stephenson at 269-833-2856.

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 Barbara Stephenson at 269-833-2856.

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 Barbara Stephenson at 269-833-2856.

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.



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MEETING INFORMATION

CONFERENCE CONTACTS

MWSQA Program Information

- Steve Drzick
Steve.drzick@mpiresearch.com
- Barbara Stephenson
barbara.a.stephenson@pfizer.com

Exhibitor/Sponsor/Consultant Members Table Information

- Barbara Stephenson
barbara.a.stephenson@pfizer.com

Poster Information

- Barbara Stephenson
barbara.a.stephenson@pfizer.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, 17 July 2007

8:00 am - Noon Wednesday, 18 July 2007

MWSQA SUMMER BUSINESS MEETING

The MWSQA Summer Business Meeting of Members will be held Wednesday, 18 July 2007, 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

MPI Research

PLATINUM SPONSORS

Covance Inc.
Pfizer Inc.

GOLD SPONSORS

Charles River Laboratories, Preclinical Services, Ohio
Eli Lilly and Company

VENDOR SPONSORS

Covance Inc.
YourEncore Inc.



MWSQA SUMMER MEETING

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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 at the Gilmore Car Museum on Tuesday evening. Meeting registration will be accepted to **6 July 2007**. Hotel reservation group rate is guaranteed only until **25 June 2007**.

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 6 July 2007.**

Please fax or mail your registration form to:

MWSQA Headquarters, 2365 Hunters Way, 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 **25 June 2007**. No refunds will be made for requests received after 25 June 2007.

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 **25 June 2007** and request the group rate for MWSQA. The conference room rate is not guaranteed after this date.

Radisson Plaza Hotel at Kalamazoo Center
100 West Michigan Avenue, Kalamazoo, MI 49007 USA
Tel: 269-343-3333; Fax: 269-381-1560
\$124.00 per night

For reservations, call 888-201-1718 or 269-343-3333 and tell the hotel staff that you are attending the MWSQA meeting.

Check-in time is 4:00 pm and check-out time is prior to 12:00 noon. If guests arrive prior to check-in time, the Guest Services desk will hold their luggage until their room is available. Shuttle service is available from the airport.

MWSQA encourages participants to book their overnight accommodations at the conference headquarters hotel. MWSQA makes every effort to secure the best possible rate for overnight accommodations. This rate for overnight accommodations is part of a negotiated overall program package that incorporates meeting room rental, meals and breaks, as well as other services associated with conducting these meetings.



MWSQA
2365 Hunters Way
Charlottesville, VA 22911 USA
Tel: 434-297-4772
Fax: 434-977-1856

MEMBERSHIP REGISTRATION FORM
(The 2007 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"/>	Veterinary GCP	<input type="checkbox"/>	Pharmaceutical GMP
<input type="checkbox"/>	EPA GLP	<input type="checkbox"/>	Human GCP	<input type="checkbox"/>	Medical Device GMP
My occupation is oriented towards (Check all that apply):					
<input type="checkbox"/>	Human drugs, vaccines or devices			<input type="checkbox"/>	Educational Research Organization
<input type="checkbox"/>	Animal drugs, vaccines or devices			<input type="checkbox"/>	Innovator pharmaceutical, vaccine or device firm
<input type="checkbox"/>	Agricultural products (including pesticides)			<input type="checkbox"/>	Generic pharmaceutical, vaccine or device firm
<input type="checkbox"/>	Contract Research Organization			<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"/>	Meeting Presenter - List Topic(s)				
<input type="checkbox"/>	Elected Officer (preference?)				
<input type="checkbox"/>	Committee Member (preference?)				



MWSQA SUMMER MEETING

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MWSQA SUMMER 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, 17-18 July 2007

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

Select One: MWSQA Member Meeting Speaker Nonmember

MWSQA Member Rate \$150
Attendees must be 2007 members of MWSQA to qualify for Member Rates.

Reduced Rate for Nonmembers applying for membership in MWSQA \$170
Attendees must submit the 2007 membership form along with this registration.

Nonmember Rate \$200

Speaker Registration Complimentary

Pre-Conference Workshop Registration (please select one) Complimentary

1 - Regulatory Pathways for Drugs, Devices & Bio products

2 - Differences - US and OECD GLPs and Managing Multi-Site Studies

3 - GXP: Good eXtreme Practice for Computer Validation

Dinner at Gilmore Car Museum (Tuesday, 17 July 2007) Complimentary

Guest Ticket(s) for Dinner at Gilmore Car Museum \$25 x No.: _____ = \$ _____

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, 2365 Hunters Way, Charlottesville, VA 22911) or fax (434-977-1856) registration form (and MWSQA membership form, if applicable) no later than 6 July 2007
Questions? Phone 269-833-2856 or 434-297-4772***