



"News from the Heartland"
Mid West Society of Quality Assurance Newsletter
March 2005



Happy Spring to One and All!

With the advent of Spring comes the announcement of our **new officers**. Please welcome ...
Lea Gough – Vice President
Matthew Sliva - Secretary
Jonathan Kreuger - Director
Deanna Talerico - Director
... and give a heartfelt thanks to our outgoing officers for their hard work!

MWSQA Officers

President: Debra Green, Bayer CropScience, phone 913/433-5409; <mailto:president@mwsqa.org>
Vice President: Lea Gough, Covance, phone 608/242-7954, vicepresident@mwsqa.org
Matthew Sliva, NAMSA, phone 419/662-4331, secretary@mwsqa.org
Treasurer: Deborah Little, DLL Quality Consulting, phone 419/289-8949, treasurer@mwsqa.org
Nominations Director: Deanna Talerico, Charles River Labs, Inc. phone 419-647-4196
nomination_director@mwsqa.org
Membership Director: Sherry Garrett, Pfizer, phone 269/833-4391, membership_director@mwsqa.org
Audit Director: Jonathan Krueger, Covance, phone 608/242-2712, ext. 2503, audit_director@mwsqa.org
Communications Director: Chris Carson, Laboratory Quality Services, phone 573/445-1755,
communication_director@mwsqa.org
Past President: Bonita Weiss Ricerca, phone 440/357-3253; pastpresident@mwsqa.org
Historical Chair: Carol Thompson, Eli Lilly, phone 317/277-5233, historical@mwsqa.org
Survey Co-Chair: Debra McMillan-Ash, Compliance Resource, phone 513/777-2823, survey@mwsqa.org
Information Transfer (IT) Co-Chair: Paula Wehmeyer, Bioanalytical Systems, phone 765/497-5866,
editor@mwsqa.org
Please submit articles for the next newsletter by June 30, 2005 to editor@mwsqa.org

Mark Your Calendars for Toldedo Ohio, April 18-19, 2005!

You can bet you'll have a great time, and learn something too. See registration information at the end of the newsletter.

MWSQA Risk Series:

What's Coming Up

and

Contribute an Article!

This issue marks the first in four issues that will feature article(s) focusing on risk in regulated research. The article featured in this issue is “*21 CFR Part 11 and Risk Assessment: Adapting Fundamental Methodologies to a Current Rule*”. 21 CFR Part 11 is certainly a hot topic, and has its applications to data security and reporting accuracy beyond the FDA environment (read EPA and OECD) for those who care to install the same controls into their facilities’ operations. Next issue will include an article on “*SOPs and Other Risk mitigation Tools.*” Future articles will include additional topics who’s authors have yet to be determined... (read: your chance to contribute) Additional topics that we are interested in seeing discussed are:

- Contributing professionals or scientists, their work and reports
- Toxicology laboratories in-life phases
- Long Term Studies: Study and Data Integrity
- Field Trials
- Instrumental Analyses

If you could and would like to contribute an article addressing risk on one of the above topics, or a topic that you think would be interesting, contact Chris Carson at communication@mwsqa.org, or 573-445-1755 or Paula Wehmeyer at editor@mwsqa.org.

Sincerely,

Chris Carson

Laboratory Quality Services

21 CFR Part 11 and Risk Assessment: Adapting Fundamental Methodologies to a Current Rule

By Victoria V. Lander

Waters Technologies Corporation

Introduction

In September of 2003, the FDA issued the new 21 CFR Part 11 Scope and Applicability Final Guidance Document – partly due to concerns expressed by the industry that the breadth of applicability and the cost of Part 11 compliance have hindered the use of new technology. This guidance states that records must still be maintained in compliance to the underlying predicate rules, but that the FDA will take a “risk-based” approach to enforcing compliance to some of the technical controls for Part 11 (such as validation, audit trails, record retention, and record copying). FDA will also include Part 11 in its formal review of cGMP regulations and follow a more subjective course in taking regulatory action for compliance; the intent being to get back to its GxP, or predicate rule fundamentals for the interpretation and enforcement of Part 11. These fundamentals involve systems for generating electronic records required in support of the Agency’s regulations for “best practices” (together referred to as GxP) that encompass Good Clinical Practice (GCP), Good Laboratory Practice (GLP), and current Good Manufacturing Practice (cGMP).

What is Risk?

Prominently included in a firm’s Part 11 remediation plans should now be a risk analysis that would account for how various systems that generate regulated electronic records could

potentially affect the safety of the consumer. Although there are many definitions of “risk” depending on your industry and perspective, a useful one is comes from the ISO/IEC Guide 51:1999 “a combination of the probability of occurrence of harm, and the severity of that harm.” Whether applied to Part 11 or to other safety-related aspects of FDA-regulated products, the regulatory perspective for risk should focus on risk to product quality and/or public safety. Such products obviously would include foods and cosmetics, blood products and drugs, medical devices, and any other regulated products that are ingested, consumed by, or applied to a living creature (human or animal). When a system generates electronic records that can greatly impact product safety and quality, or the integrity of regulated records, it is considered a “high-risk” system, and the technical controls of Part 11 that protect electronic record integrity would still apply. Otherwise, the system is considered to be “low-risk” and the Agency will simply enforce the GxP requirements for protecting record integrity instead of the more stringent Part 11 controls.

For manufacturers of drugs and medical devices, a risk-based approach to protecting product quality and public safety stems logically from the fact that Part 11 was predicated on the GxPs. For example, the FDA expects a firm that is subject to GxP to develop a risk evaluation of its product, and to then mitigate the identified risks. Identified risks may be addressed by technical fixes that effectively eliminate the risks, or reduce likelihood of occurrence or severity of consequences to acceptable levels. Risks for which there are no technical fixes may be addressed by including warnings in the accompanying product labeling. Other residual risks following mitigation may remain so minimal as to intrinsically be left at acceptable levels.

The following chart lists some of the high vs. low risk systems that generate GxP records according to the recent ISPE White Paper submitted to the FDA, which addresses the risk-based approach to 21 CFR Part11 compliance (for details visit <http://www.ispe.org>).

ISPE White Paper

● High Risk

- Quality decisions
- Batch records
- Lab test results
- Clinical results
- Device history file

● Low Risk

- Environ monitoring sys
- Operator training records
- Instrument qualification records
- Word processing for SOPs
- Instrument Calibration records

Part 11 Controls

**Validation
Change Control
Configuration Management
Security
Procedural Controls**

In fact, applying a risk-based approach on Part 11 compliance should be nothing new for regulated firms. A similar approach outlined in the Quality System Regulation (QSR) requires a firm to perform a risk analysis of the various record generating and record-keeping systems maintaining electronic records and/or implementing electronic signatures. Such an analysis would also address a system's interactions with other interconnected systems. The result of this analysis would allow the company to determine which records have high-impact consumer safety issues. The firm would then evaluate the effects of the identified risks and rank them according to their criticality.

Examples of Applying Risk to Part 11-triggering Systems:

A practical example of applying risk analysis to Part 11 remediation would be the use of quality data from a Part 11 compliant database for inclusion in a Corrective and Preventative Action (CAPA) report. A spreadsheet program typically generates this report, and while the spreadsheet formula should still be validated according to GxP, the overall relative risk to public safety is low. Therefore, the typical Part 11 technical controls (e.g. audit trails) would not be required to protect the integrity of the spreadsheet. The spreadsheet itself, however, must be maintained and utilized in a current, validated state and be GxP compliant.

On the other hand, adverse event reporting and clinical trial data that fall under GCP regulation can have a potentially high impact on public safety and the quality of a regulated product. Programs that analyze and visualize clinical data subsequently have an impact on record integrity. Such systems would be considered high risk, and therefore should continue to incorporate the technical controls for Part 11 compliance as well as maintain predicate rule compliance.

In summary, Part 11 remediation has not changed for high-risk, GCP-related systems such as: adverse event and CRF data management systems; SAS analysis software; web trial systems; electronic patient diaries; patient randomization; and trial supply labeling systems. Both GCP and Part 11 definitely apply to these high-risk systems. In addition, the FDA's Guidance to Industry for Computerized Systems Used in Clinical Trials remains in effect and applies to these systems as well.

Keep in mind that while Part 11 is an enforceable law, an FDA guidance document is not a law. Guidance documents present the FDA's current thinking on a subject and are only a recommendation on how to proceed in addressing a law's requirements. Guidance documents are not binding on either the industry or the Agency.

Risk Assessment Methodologies

There are many risk assessment protocols or methodologies available originating from various industries (automotive, aerospace, defense, food, etc.). It behooves regulated manufacturers to build risk analysis into their quality processes from the start. FDA-regulated firms have commonly utilized several of these methodologies over the years. What follows is a discussion of the most common risk analysis methodologies, which is by no means all-inclusive.

Fault Tree Analysis:

A fault tree analysis (FTA) is a deductive, top-down method of analyzing system design and performance. It involves specifying a "top event" to analyze, followed by identifying all of the associated elements in that system that could cause that top event to occur. Fault trees provide a convenient symbolic representation of the combination of events resulting in the occurrence of the top event. Events and gates in fault tree analysis are represented by graphic symbols such as AND / OR gates. Sometimes certain elements, or basic events may need to occur together in order for that top event to occur. In this case, these events would be arranged under an AND gate, meaning that all of the basic events would need to occur to trigger the top event. If the basic events alone would trigger the top event, then they would be grouped together under an

OR gate. The entire system, as well as human interactions, would be analyzed when performing a fault tree analysis.

FMEA and FMECA:

Failure Mode Effects and Criticality Analysis (FMECA):

FMECA originated in the 1950's in the military and aerospace industries. The basic concept is to categorize and rank potential process failures, or critical issues, and then to target the prevention of those critical issues. It is important to prioritize the potential failures according to their risks and then implement actions to eliminate or reduce the likelihood of their occurrence.

Failure Modes and Effects Analysis (FMEA):

FMEA originated in the 1960's and 1970's and was first used by reliability engineers. FMEA involves the evaluation of documentation of potential failures of a product or process. Actions are then identified which could eliminate or reduce the potential failures. It is a system of various group activities provided through documentation of potential failure modes of products and/or processes and their effect on product performance. FMEA is a tool that should identify product and process failures before they occur, identify appropriate risk mitigation measures to prevent or otherwise control the failure, and ultimately improve product and process design. An assumption is made that all product and process failures (and the actions required to control these failures) are predictable and preventable. Surprisingly, organizations still frequently experience predictable and preventable failures with costly consequences. These failures can lead to product recalls, death or injury, poor quality, and unanticipated cost. Although the aerospace and defense industry have used FMEA for decades, FMEA has recently been making significant inroads into the biomedical device industry.

HACCP:

A common methodology embraced by the FDA is Hazard Analysis and Critical Control Points (HACCP). HACCP received its start in the food arena and was initially developed in the 1960's by the Pillsbury Co., NASA and Natick Labs for the space program in order to reduce the need to test the finished packaged product. Pillsbury made a commitment to improve on existing "good quality programs" by using techniques developed to supply food to NASA's astronauts. In 1996, the US Food Safety and Inspection Services Task Force (FSIS) developed a HACCP-based regulatory proposal that became the Pathogen Reduction/Hazard Analysis and Critical Control Point Systems (HACCP) Rule. In this rule, FSIS determined that its food safety goal was to reduce the risk of food borne illnesses associated with the consumption of meat and poultry products to the maximum extent possible. This involved ensuring that appropriate and feasible measures were taken at each step in the food-production process where hazards can enter, and where procedures and technologies exist or can be developed to prevent the hazards, or reduce the likelihood they will occur.

HACCP is made up of seven basic principles (see Figure 2) that enable the production of safe products. This is determined through the analysis of production processes, followed by the identification of all hazards that are likely to occur. Then identification is made of critical points in the process at which these hazards may be introduced into the product, and therefore should be controlled. Next is the establishment of critical limits for control at those points, followed by the verification of these prescribed steps, and finally establishment of the methods by which the firm and the regulatory authority can monitor how well process control through the HACCP plan is working. Overall, risks are minimized by proper implementation of HACCP. It is understood that implementation of HACCP does not mean the absolute elimination of risks, but rather, one can prevent and reduce hazards to a degree that substantially reduces the risk to an acceptable level.

Figure 2.

The Seven Basic Principles of HACCP:

1. Conduct a Hazard Analysis:
 - Define Terms of Reference
 - Select the HACCP team
 - Describe the product
 - Identify intended use
 - Construct a flow diagram
 - Onsite verification of flow diagram
 - List all hazards and control measures
2. Determine the Critical Control Points (where hazards must be eliminated or minimized) using a decision tree.
3. Establish Critical Limits that must be met to ensure CCPs are under control.
4. Establish a system for monitoring the control at the CCPs.
5. Establish the corrective actions to be taken when monitoring indicates that a particular CCP is not under control.
6. Establish procedures for verification to confirm that the HACCP system is working correctly.
7. Establish documentation for all procedures and records.

Where to Start

Risk-based compliance can analyze computer systems and information handling processes to assess not only risk, but also the cost of converting paper based information to an electronic format. A good place to start is by performing a system assessment, then plotting your various systems and processes on a simple X-Y matrix that measures, from low to high, the risk to security of the data (X-axis) and the cost of remediating (Y-axis). Then prioritize those systems and processes needing upgrades or replacement, based on where they fall in the matrix. Computer systems, for example, that fall in the "high data security risk, low conversion cost" area of the matrix could be targeted first for compliance validation.

Because they had to address Y2K issues, many organizations had already generated an inventory of all their computer systems, and then hopefully evaluated them to determine the potential risk in the event of a computer error or failure. Companies with cost considerations and many noncompliant computer systems must, of course, prioritize which ones to remediate first. In order to sanely tackle this problem, one must estimate the data security risk for each system and the cost of Part 11 validation – then plot that system on a matrix. Systems and processes falling into the high risk category should get top remediation priority.

The following is a typical criticality assessment (high to low) for non-clinical laboratory systems (Source: Clarkston Consulting, 2003):

Systems for quality processes and standard operating procedures
Lab spreadsheets and databases for data collection
Systems for other R&D data
Central database for inventory management
Systems for liquids processes
Systems for company financials
Systems for customer relationship management
Systems for packaging
Systems being decommissioned

Conclusions

21 CFR Part 11 is not going away – the FDA intends to enforce it. What has recently changed is the adoption of a narrower scope for the Rule, a new understanding of Agency enforcement discretion and the application of a risk-based approach to compliance. The important thing to remember about choosing a risk assessment protocol or methodology for Part 11 remediation is to use basic common sense. All of the methodologies mentioned in this article have a basic premise in common that is founded on pure common sense. That is, to analyze your processes, identify where in your processes you have the greatest potential for risk (to product quality and ultimately to public safety), to subsequently put in place ways to mitigate those risks and document the entire endeavor. Whether you choose to adopt a standard risk assessment methodology like FEMA or HACCP, or you develop your own, the important thing to remember that the FDA will show enforcement discretion if you have a well-documented plan in place and are making true progress against it.

Thank You, MWSQA!

By Heather Howard Bloom
Northern Biomedical Research

I am the fortunate recipient of the MWSQA \$1,000 scholarship for the 21st Society of Quality Assurance Annual Meeting and Pre-conference Training. This was the 1st Global QA Conference, and what a conference it was! It was empowering to be part of such a committed group of quality assurance professionals from across the world!

For the past two years, I have been working as the Quality Assurance Officer for Northern Biomedical Research (NBR), a small, pre-clinical, pharmaceutical lab, specializing in providing access to the central nervous system for drug delivery (intrathecal, intraparenchymal, epidural, intracerebroventricular, and CSF sampling). Twenty years ago, I first started working in the industry, right out of Albion College, at Ross Labs/Abbott Pharmaceuticals in Sturgis, Michigan. I changed fields, married and eventually took a leave from the workforce to raise children. I never dreamed I would be working in quality assurance later in life. After receiving the position at NBR, I knew I needed more training. The conference was just what I needed!

At the conference, I took advantage of the pre-conference training sessions, “Basic Training – GLPs” and “GLPs-Building on the Basics.” Both sessions were interesting and knowledge-based. In the first session, I was able to clarify issues and understand that the company I work for, NBR, is following GLPs with their best intention. That knowledge is most rewarding. In the second session, I was able to expand on my basic understanding of GLPs and learn more detail. Another highlight for me was being welcomed in many languages at the Opening Plenary and Ceremony. Bertrand Piccard, M.D., scientist and adventurer, was the insightful keynote speaker. He explained his philosophy of life with his world-record breaking balloon flight around the world. From this, I learned that it is sometimes it is easier to go with the wind rather than fight it and that changing altitudes can take you in a different direction.

My only regret was that I could not stay longer! I am privileged to have had the opportunity to be with and trained by a dedicated and knowledgeable group of quality assurance professionals from across the world--with Mickey Mouse right outside, no less!

New Chapter President Speaks Against Gambling

Wow! Time is really flying! We have nearly completed the first quarter of the year. The board and planning committee have been working very hard to provide a quality meeting in April in Toledo. The program will have informative sessions for both those in Quality Assurance and for Study Directors. Information and registration packet are included in this newsletter.

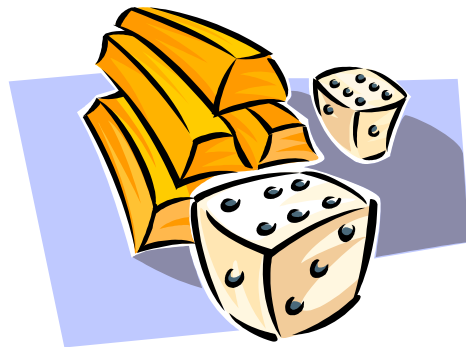
We are making plans for our fall meeting. This year, for the first time, we will be trying something new. The meeting is being planned in conjunction with the SQA fall training. If this is successful, SQA fall trainings may rotate through other regional chapters and be held in conjunction with their meetings. There is still plenty of time to join the planning committee to help make this meeting a huge success!

We are also working on plans for our 2006 meeting. Since it is our 15th anniversary as a chapter, in 2006 we will have one meeting, with three full days of sessions. It promises to include something for everyone!

In addition to planning and preparing for the upcoming meetings, the board is reviewing chapter procedures and position descriptions, which are posted on our web site as they are completed. If you have any interest in volunteering for a position in the chapter, the website at www.mwsqa.org is the place to get all the information you need. Of course, you can also contact the board members directly as well.

All board and committee positions with the Midwest SQA are filled by volunteers. But if you would rather not commit as much time, and still would like to volunteer, there are lots of other opportunities. For example, you can volunteer to work at the registration desk at one of our meetings. It is the perfect opportunity to get to meet and network with other members of the chapter.

The success of the Midwest Chapter of SQA depends on the members who make it happen. I look forward to working with all of you, and I hope to see you in Toledo in April! Remember, "Don't Gamble on Quality!"



Who's Who?

Our 'mystery guest' last issue was Brian Mitchell and our first correct guess came from Jonathan Krueger. Jon has won a year's free membership in MWSQA. Congratulations, and 'thank you' both! If you would like to win a free membership be the first correct guess to submit your answer to P. Wehmeyer via e-mail to 'editor@mwsqa.org' (or use your MWSQA directory to contact P. Wehmeyer). The subject of "Who's Who" is not eligible to win.

- Q: My birthplace was Evanston, IL**
- Q: I got into Quality Assurance because the job sounded intriguing and the boss was charismatic.**
- Q: My favorite quote is "To thine own self be true".**
- Q: The first job I had was filing for a lawyer's office. (In QA, it was GLP QA for agricultural and animal health products.)**
- Q: On a cold rainy day I like to stay indoors**
- Q: My favorite food is Italian.**
- Q: The one word that best describes me is adventurous.**
- Q: One of the most memorable events in my life was swimming with wild manta rays.**
- Q: My hobbies/favorite pastimes are breathing underwater.**
- Q: I just can't resist teaching when the opportunity arises.**
- Q: The most respected occupation should be teaching (and quality assurance).**
- Q: My all time favorite movie character is Nemo in "Finding Nemo".**
- Q: My pet peeve is people who talk, but don't know what they are talking about.**
- Q: The one person I'd like to swap places with is Sylvia Earle.**
- Q: If there were one thing I'd like to be remembered for in my life it would be for being a decent, honest person.**
- Q: The person who had the most impact on my life was my dad.**
- Q: One thing that really makes me laugh is watching my cats play.**

*Midwest Regional Chapter
of the
Society of Quality Assurance
2005 Spring Meeting*

Don't Gamble on Quality



*Wyndham Hotel; Toledo, Ohio
April 18-19, 2005*

Hosted by:

NAMSA

The Midwest Regional Chapter of the Society of Quality Assurance (MWSQA) is holding their 2005 Spring Meeting on April 18-19, 2005, at The Wyndham Hotel, Two Seagate/Summit Street, Toledo, Ohio. This 1½ day meeting promises to foster interaction between professionals in industry, provide benchmarking opportunities and facilitate learning through lectures and interactive discussions.

Subjects to be covered at this meeting include topics of interest to GLP, GCP, GMP, and GXP professionals such as:

- ❖ Risk Based Part 11 Assessment
- ❖ Life After Part 11 Validation – Auditing Post Computer Validation
- ❖ Archival and Disaster Recovery
- ❖ QA as Arbiter of Ethics
- ❖ Auditor Skills Training
- ❖ Bioanalytical Method Validation\
- ❖ Multi-site Studies
- ❖ Risk Based Critical Phase Selection
- ❖ GLPs – University Challenge
- ❖ Academia & Industry – Building a Quality Relationship

To take advantage of this great opportunity to interact with QA peers and colleagues, send your meeting reservation today! Please make checks or money orders payable to MWSQA. Mail to: Beckie Kwis, NAMSA, 6750 Wales Road, Northwood, Ohio - 43619, telephone 419-666-9455 ext. 432, fax 419-662-4386, email bkwis@namsa.com for registration information.

Social Event

In conjunction with the meeting, there will be a social event on April 18th. Join us for dinner and a Casino experience.

Membership Information

Membership information for the Midwest Regional Chapter of the Society of Quality Assurance will be available at the meeting, or you may obtain this information by visiting the website at www.mwsqa.org. Membership cost has been included in the non-member registration fee. Please indicate if you would like a membership.

Message Board

A message board will be available for job openings and positions being sought.

If you need additional information or require arrangements for special needs, please contact , Beckie Kwis, NAMSA, at (419)-666-9455 ext. 432 or by e-mail at bkwis@namsa.com.

Travel Questions

Travel arrangements, if necessary, should be made through your usual travel service. Air service is available into Toledo Express airport (about 20 miles from the hotel) or Detroit Metro airport (about 60 miles). If you have any questions about hotel or travel arrangements, please contact Karen Caldwell (419-666-9455 ext. 370 or E-mail: kcaldwell@namsa.com) or Jackie Breno (419-666-9455 ext. 439 or E-Mail: jbreno@namsa.com).

Transportation Information

Toledo Express Airport is approximately 20 miles from the hotel. There is a shuttle service. Car rental agencies located at the airport are Avis, Budget, Hertz, and National.

Detroit Metropolitan Airport is approximately 60 miles from the hotel. Car rental agencies located at the airport are Alamo, Avis, Dollar, Hertz, National and Thrifty.

Directions to the Hotel – Two Seagate, Toledo, Ohio 43604

Toledo Express Airport – Exit the airport to I-80/90 turnpike east. Follow I-80/90 turnpike to I-75 North (exit 4A). Take I-75 North to exit 201B. At the light, turn left onto Erie Street. The next intersection will be Washington Street, turn right. Go three blocks to Summit Street and turn left. The hotel is approximately four blocks up on the right-hand side at the intersection of Summit and Jackson.

From the south, follow I-75 North to exit 201B. At the light, turn left onto Erie Street. The next intersection will be Washington Street, turn right. Go three blocks to Summit Street and turn left. The hotel is approximately four blocks up on the right-hand side at the intersection of Summit and Jackson.

From the east, follow I-80/90 turnpike west to Exit 5. Take I-280 North into Toledo. Take exit 10A. The exit will turn into Summit Street and will be headed towards Downtown Toledo. Stay on Summit Street for approximately one mile. The hotel is located on the left hand side at the intersection of Summit and Jackson.

From the west, follow I-80/90 turnpike east to Exit 4A. Take I-75 North to exit 201B. At the light, turn left onto Erie Street. The next intersection will be Washington Street, turn right. Go three blocks to Summit Street and turn left. The hotel is approximately four blocks up on the right-hand side at the intersection of Summit and Jackson.

From Detroit Metro Airport, north on Merriman road to I-94 West towards Chicago. Take I-275 exit (number 194) toward Toledo/Flint. Take the I-275 South exit on the left towards Toledo – keep right at the fork in the ramp. Merge onto I-275 South. Take I-75 South ramp towards Toledo. Merge onto I-75 south. Take the I-280 exit, exit number 208 on the left towards (I-80)/(I-90)/Turnpike. Merge onto I-280 South ramp. Merge onto I-280 south. Take the OH-675/Summit Street exit (exit number 10A) towards Downtown. This exit will turn into Summit Street and will be headed towards downtown Toledo. Stay on Summit Street for approximately one mile. The hotel is located on the left hand side at the intersection of Summit and Jackson.

Valet parking is available at the hotel. There is a parking garage across the street, which has a connecting walkway with the hotel.



Hotel Information

The Wyndham Hotel has an indoor pool, whirlpool and exercise room. The room rate for the Midwest SQA (MWSQA) meeting is \$89 per night (plus taxes). A block of rooms has been reserved and will be held until April 3, 2005. Please make your hotel arrangements directly with the Wyndham Hotel, (419) 241-1411. Be sure to mention that you are with the Midwest SQA (MWSQA) meeting.

The Radisson Hotel may be used as an alternate hotel in the event the Wyndham has no vacancies. It is located two blocks from the Wyndham. The Radisson is located at 101 North Summit Street, Toledo, Ohio – 43604; phone (419) 241-3000.

Points of Interest & Area Attractions

Toledo Mud Hens (baseball team)
Toledo Museum of Art
Toledo Zoo
Tony Packo's Restaurant of M.A.S.H. fame

REGISTRATION FORM

Midwest Regional Chapter of the Society of Quality Assurance's Summer Meeting

April 18-19, 2005, at the Wyndham, Toledo, Ohio (419) 241-1411

Name: _____

"Name Badge": _____

GXP Specialty _____ *GLP* _____ *GCP* _____ *GMP*

Title: _____

Company: _____

Address: _____

City, State, Zip: _____

Phone: _____ Fax: _____ E-Mail: _____

Meeting Registration Fee: Midwest SQA Member: \$150 (_____ Yes, I am a member of MWSQA)

*Non-Member: \$170 (_____ I would like to become a member of the
Midwest Regional Chapter of the Society of Quality Assurance)*

Note: Registration Fee includes seminar, meals and evening event.

Please make check or money order payable to Midwest Society of Quality Assurance

CANCELLATION POLICY

Notification of cancellation must be received in writing by April 1, 2005 in order to receive a refund. Correspondence should be mailed to Beckie Kwis, NAMSA, 6750 Wales Road, Northwood, Ohio - 43619 or by e-mail at bkwis@namsa.com. Meeting registration may be transferred to another individual with written notification.

PLEASE RETURN REGISTRATION FORM WITH FULL PAYMENT BY April 7, 2005 TO:

**Beckie Kwis
NAMSA
6750 Wales Road
Northwood, Ohio - 43619**

**NOTE: Deadline for hotel reservations in the reserved block is April 3, 2005.
Please make arrangements directly with the Wyndham (419) 241-1411.**