

# The Benchmark

THE OFFICIAL PUBLICATION OF THE MINNESOTA SECTION AMERICAN SOCIETY FOR QUALITY

AUGUST 2004

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## Section Mission

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The Mission of the Minnesota Section is to enhance the quality of products and services by advancing the use of quality principles, concepts, and technology and by promoting personal and professional development of members and non-members.

## Section Vision

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The Vision of the Minnesota Section is to be recognized throughout our area and the nation as a Section of unmatched benefit and value to our members, our Society, our places of employment, our communities, and our profession.

For more information visit [www.mnasq.org](http://www.mnasq.org)



# AUGUST 2004

## UPCOMING EVENTS

### SECTION PROGRAM MEETINGS

September, 14, 2004

**Product Liability**

October 12, 2004

**Quality Tours of Mercy Hospital Heart Center and Memorial Blood Bank**

November 9, 2004

**Personal and Professional Development**

December 7, 2004 (Date change)

**Twin City Software Quality. Topics will be on Software Quality and Uses.**

January, 11, 2005

**Quality Planning/ISO & Baldrige Criteria and Tools**

February 8, 2005

**Best and Worst Quality Examples**

March 8, 2005

**Lean Sigma**

April 12, 2005

**Customer Management/Customer**

**Satisfaction**

May 10, 2005

**Chair's Night & Volunteer Recognition**

### PROFESSIONAL MEETINGS

August 12, 2004

**Are you correctly measuring, communicating, and getting all the results you want?**

Offered by Manufacturers Alliance and co-sponsored by University of St. Thomas - Division of Executive and Professional Development

**Time:** 7:30 to 9:30 am

**Place:** Dunwoody College of Technology, Auditorium, 818 Dunwoody Blvd., Minneapolis. Free Parking (For directions check our website at [www.mfrall.com](http://www.mfrall.com) and go to Events Tab.)

**Reservations:** Please call (763) 533-8239, register online at [www.mfrall.com](http://www.mfrall.com) or send email to [ma@mfrall.com](mailto:ma@mfrall.com) by Tuesday, August 10, 2004.

**Cost:** \$30

September 9, 2004

**Lean Accounting** Offered by Manufacturers Alliance and co-sponsored by University of

St Thomas - Division of Executive and Professional Development

**Time:** 7:30 to 9:30 am

**Place:** Hennepin Technical College, Auditorium, 9000 Brooklyn Blvd., Brooklyn Park (Hwy 169 & Brooklyn Blvd. Exit east). Use student lots only. (For directions check our website at [www.mfrall.com](http://www.mfrall.com) and go to Events Tab.)

**Reservations:** Please call (763) 533-8239, register online at [www.mfrall.com](http://www.mfrall.com) or send email to [ma@mfrall.com](mailto:ma@mfrall.com) by Tuesday, September 7, 2004.

**Cost:** \$30

### CONFERENCES

October 4 & 5, 2004

**51ST MINNESOTA QUALITY CONFERENCE**

For information contact Jim McLinn at (763) 498-8814 or [jmrel2@aol.com](mailto:jmrel2@aol.com).

## Performance Improvement Solutions

ISO 9001:2000 | ISO 14001 | ISO 13485 | TS 16949 | OHSAS 18001 | AS9100

### September Classes in Minneapolis/St. Paul

**ISO 9001:2000 36-hour Lead Auditor** **R&B**  
September 13-17 \$1595

**ISO 14001 36-hour Certified Lead Auditor** **R&B**  
September 13-17 \$1595

**ISO 9001:2000 3-day Internal Auditor** **R&B**  
September 15-17 \$995

**ISO 9001:2000 Lead Auditor with Medical Device Focus (ISO 13485)** **R&B**  
September 13-17 \$1695

**The Process Approach**  
September 27 \$395

**Risk Assessment**  
September 28 \$395

#### New Class Offerings!

**OHSAS 18001 Lead Auditor (Health and Safety)**  
September 13-17 ~~\$1595~~ \$995\*

**ISO 9001:2000 Blended Lead Auditor Training**  
September 20-21 ~~\$1295~~ \$894\*

**EMS Bridge Training for QMS Auditors**  
September 20-22  
~~\$995~~ \$695\*

[\* No other discounts apply]



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1989 - 2004

[www.aqsperformance.com](http://www.aqsperformance.com)

For more information or for additional offerings...Call 1-800-633-2588 or email: [ben@aqspperformance.com](mailto:ben@aqspperformance.com)

# CHAIR'S MESSAGE

## A NEW YEAR

by Gary Townsend  
2004-2005 Section Chair

The new ASQ year is upon us. In the previous year, the Section accomplished its operational objectives as planned, thanks to the insight and leadership of Marilyn Pehl (Chair 2003-2004), Ralph Arnott (Senior Director 2003-2004), the Executive Board, and Committee volunteers. My hat's off to all who helped. I hope to do just as well because we are focused on satisfying the customer, you, and the community at large.



In April, I held leadership training for incoming officers. Looking for appropriate terms to share my perspective for leading our quality efforts, I found quotes to share with the group. I appreciate humor. And so, one quote, which I shared and has stayed with me, is as follows: "Leaders are visionaries with a poorly developed sense of fear and no concept of the odds against them." — *Robert Jarvik*. In all that we wish to do for you and given the representatives you elected for this year, you have a fervent group of leaders who are committed to maintaining and improving your experience in the quality movement. I've detected no fear from the new Board members, only excitement for continuing the work at hand.

**"Leaders are visionaries with a poorly developed sense of fear and no concept of the odds against them." — *Robert Jarvik***

In the past months, I had the opportunity to meet a lot of new folks both involved and interested in growing in the arena of quality. One of my greatest qualms is that quality has become so ingrained in daily life, its value is forgotten or taken for granted. We need to remember and remind ourselves that each contribution an individual makes to maintain and improve quality adds value to the outcome of every effort. For those who are just getting involved, and for those "mature practitioners," I salute you for your commitment to maintaining and improving all we touch.


Our new Chair Elect, Dick Alberg, just completed his term as Vice-Chair of Conferences. Thanks to him, our newly formed Biomedical Focus Task Group, in cooperation with Medical Alley, we were able to participate and share information with the biomedical/medical

community through the MedEdge Conference in June. The attendance for the Quality Track(s) we presented was extremely well attended. We are looking forward to additional cooperative efforts in the future where Quality is fundamental for success. 00347209

In addition to regular educational events, we have the start of a video library. With permission from presenters at our last combined conference, we filmed presentations of CAPA and Project Management, which are available on CD or DVD. This is valuable to promote understanding and growth in specific areas of Quality where there is

significant interest. Feedback from test audiences was extremely positive. "I can view this whenever I wish." "I can play this on my CD video player or computer." "This is valuable information on quality." These are just a few of the feedback comments. For those of you who are into digital media, we have opportunities for volunteers to help with the process of building and maintaining our library.

Section ASQ Members, we need you! Our Membership Committee oversees operations including the website. Our Outreach and Public Relations Committee interacts with the community. Our Conferences Committees plan and organize conferences. Our Education Committee oversees and provides training, educational programs, and certification exams. Our Program Committee oversees Section monthly membership meetings. Our new Task Groups are looking for people to be involved in promoting topic or industry specific objectives. Contact me or the Section office to let us know where you would like to be involved and find out how you can help.

One last comment. I am looking for one individual to recommend a person to be honored for their commitment to quality. That individual should be a peer, a manager, a director, or an administrative leader who is willing to recognize a person within their operation. The individual nominating this person should be able to quantify this person's contribution by some factor such as percentage improvement or value. The individual nominating this person should also not be shy. My expectation is to pay tribute to the accepted nominee and to the organization who accepts the challenge to honor its ASQ contributor for the value returned to the organization. I am looking forward to you contacting me to discuss details. 

# SEPTEMBER SECTION MEETING

## PRODUCT LIABILITY

**SEPTEMBER 14, 2004**

**LOCATION:**

St. Thomas University  
2115 Summit Avenue  
St. Paul, MN 55105  
(651) 962-5000

Speakers will be at the O'Shaughnessy Education Center Auditorium. Dinner will be held at the Murray-Herrick Campus Center, Rogge/Leyden Room. Visit [www.stthomas.edu/campusmaps/](http://www.stthomas.edu/campusmaps/) for campus maps and directions.

**COST:**

\$20.00 ASQ Members  
\$25.00 Non-members  
\$5.00 Students with Full-time Student ID  
Please make checks payable to Minnesota ASQ prior to registering.

**TIME:**

5:00 pm Registration and Networking  
6:00 pm Pre-dinner Presentation  
7:00 pm Dinner  
8:00 pm After-dinner Presentation

**DINNER MENU:**

Grand Buffett includes: Chicken Marsala, London Broil with sherry mushroom sauce, Gem Elli Pasta with peas and garlic, Alfredo sauce, Spinach salad, Relish tray, Fresh fruit, Lemon mousse

**CALL THE SECTION OFFICE AT (651) 779-9820 NO LATER THAN 5:00 pm THURSDAY, SEPTEMBER 9th** with the names of members and guests wishing to join us for dinner (spell the names). **If you call to register after 5:00 pm on Thursday, you will be placed on a waiting list and seats will be given if cancellations come in.** Include your company name and membership status when calling in your reservation. Specify special dietary needs. **If you have made a dinner reservation and cannot attend, you must cancel your reservation by noon on Thursday, September 9th or you will be invoiced for the dinner fees.**

## PRE-DINNER PRESENTATION

METALLURGICAL FAILURE ANALYSIS - SOME CASE STUDIES  
PRESENTED BY LESTER B. ENGEL, ENGEL METALLURGICAL

The use of metallurgical failure analyses to determine the failure modes and root causes of a number of selected failures will be reviewed. The failures include a hypodermic needle, gas turbine part, truck fire, pole barn nail, and copper water pipe. The evaluation, methodology and results for each failure will be discussed.


Lester B. Engel has a Bachelor of Science, Metallurgical Engineering, 1963, and a Master of Science, Metallurgical Engineering, 1969, from the University of Cincinnati. He has worked for the General Electric Company in their Nuclear Systems Program and Aircraft Engine Group and Brown Boveri Turbomachinery. He then founded Engel Metallurgical in 1983. He has over 30 years experience in performing failure analyses and has presented numerous talks on metallurgical issues and failure analysis to a wide variety of organizations. He is a registered Professional Engineer in the states of Minnesota and Ohio.

## AFTER-DINNER PRESENTATION

THE IMPACT OF PRODUCT LIABILITY LITIGATION ON THE DESIGN PROCESS  
PRESENTED BY DIONNE PEART, BLACKWELL IBANUGO P.A.

The growing number of product liability suits has propelled the role of quality control in the design process to the forefront. This presentation will address the need for companies to focus on the potential impact of litigation on the design process and how companies address the liability factor before, or after, a product enters the marketplace.

Dionne Peart is an Associate with Blackwell Igbanugo P.A. practicing in the areas of entertainment and civil litigation. Ms. Peart's experience covers a variety of intellectual property issues on the Internet including the identification of infringers on the Internet, taking action against online service providers that host or connect to websites with infringing content, and bringing suit against repeat infringers. Ms. Peart recently spent eight weeks on loan to a major media corporation's law department working on various matters including independent contractor agreements, contract drafting and negotiation, licensing agreements, intellectual property agreements, freedom of information act issues, and pre-publication review. Prior to joining the firm, Ms. Peart served as a judicial extern for the Honorable Michael J. Davis of the U.S. District Court for the District of Minnesota. 00108472

Ms. Peart graduated from the University of Manitoba, Canada with a Bachelor of Arts in Criminology. She received her law degree at Hamline University School of Law where she was on the Dean's List, the Frederick Douglass Moot Court Team, and was the 2001 recipient of the Michael J. Davis Scholarship for academic excellence and community service. Ms. Peart also served on the Midwest Black Law Students Association's Regional Board. Ms. Peart is a member of the Minnesota State Bar Association and the U.S. District Court of Minnesota. 

# SEPTEMBER SECTION MEETING

SEPTEMBER 14, 2004 (CONTINUED)

## DRIVING DIRECTIONS

**To St. Paul Campus: East I-94 (from Minneapolis)** Take I-94 east to the Cretin/Vandalia exit. Go right (south) on Cretin Avenue and follow for approximately one mile to just before the intersection of Cretin and Summit Avenues. Turn left into Parking Lot H and follow the signs for visitor parking that lead you to Levels R2 and R3 of the Morrison Hall parking ramp. **West I-94 (from St. Paul)** Take I-94 west to the Cretin/Vandalia exit. Go left (south) on Cretin Avenue follow for approximately one mile to just before the intersection of Cretin and Summit Avenues. Turn left into Parking Lot H and follow the signs for visitor parking that lead you to Levels R2 and R3 of the Morrison Hall parking ramp.



If you would like to contribute to *The Benchmark*, contact the Minnesota ASQ office at [mnasq@aol.com](mailto:mnasq@aol.com)

**THE SEPTEMBER ISSUE DEADLINE IS  
AUGUST 15, 2004**



## ASH & ASSOCIATES

INTERNATIONAL CONSULTANTS  
IN QUALITY & COMPLIANCE  
MANAGEMENT

TRAINING ♦ AUDITS ♦ CONSULTING

*Ash & Associates provides services that support its customers' quality and compliance needs. Some of the services available are in the following areas:*

Ash & Associates has been serving customers since 1987 and is committed to providing:

- Dependable service
- Guaranteed customer satisfaction
- Experienced consultants and trainers

### Quality Systems & Standards

- ♦ World Class Quality Systems
- ♦ FDA Quality Systems Regulation (QSR)
- ♦ ISO 9000 Quality System Standards
- ♦ ISO 14000 Environmental System Standards
- ♦ QS 9000 US Automotive Quality Standards
- ♦ QSR for Drugs & Pharmaceuticals
- ♦ QSR for Medical & Diagnostic Devices

### Design Quality Assurance

- ♦ Design Quality Into Your Products
- ♦ Failure Modes & Effects Analysis (FMEA)
- ♦ ISO 9001 and QSR Design Control Requirements
- ♦ Packaging Design Assurance
- ♦ Quality Function Deployment
- ♦ Reducing Product Development Cycle Time
- ♦ Risk Analysis/Hazard Analysis
- ♦ Software Quality and Compliance
- ♦ Clinical Studies
- ♦ Reliability Analysis

### Process Quality Assurance

- ♦ Design of Experiments (DOE)
- ♦ Process Capability Studies
- ♦ Process Validation
- ♦ Statistical Methods for Quality Improvement
- ♦ Statistical Process Control (SPC)
- ♦ Software Quality Assurance
- ♦ Supplier Quality Assurance

# ASH & ASSOCIATES

Ashwani (Ash) Sahni, President  
2789 14th Street NW, Suite 101  
St. Paul, MN 55112 USA

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Phone/Fax: 651-631-8307  
Cell: 612-743-8939  
[ashquality@attbi.com](mailto:ashquality@attbi.com)



# MN ASQ EDUCATION PROGRAM

## REFRESHER CLASSES

### GENERAL INFORMATION

**Content:** Exam refreshers are review courses and not intended to be first time learning the basics. The student should have sufficient background in the certification area to efficiently answer 40-60 percent of the questions BEFORE the review. Exam refreshers provide exam advice, review some of the more difficult topics, and provide an opportunity to network with other exam takers.

**Class Size:** Each class will be limited to 40 registrants on a first-come, first-serve basis. If you register after a class is full, your name will be put on a waiting list.

**Class Materials:** You will receive your class materials when you attend the class. No materials will be mailed to anyone.

**Class Format:** The format for all refresher classes is structured using the Indiana Quality Primer and Solution text or materials from National ASQ.

**Registration Cancellation:** Registrations cannot be accepted after the deadline. Cancellations for a full refund must be received by 5:00 pm on the deadline date. Cancellations received after that date are subject to a \$60.00 cancellation charge.

**Class Registration:** Registration can be made by mail. Send registration form (on right) and check to:

Minnesota Section ASQ

P.O. Box 9370

North Saint Paul, MN 55109

Credit card registration by fax: (651) 779-0244

on-line [www.mnasq.org](http://www.mnasq.org) or email [mnasq@aol.com](mailto:mnasq@aol.com).

**Refresher Class Questions:** Call the Section office at (651) 779-9820 or email [mnasq@aol.com](mailto:mnasq@aol.com).

## REGISTRATION FORM MN ASQ EDUCATION PROGRAM

*(please print)*

NAME: \_\_\_\_\_

COMPANY: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY / STATE / ZIP: \_\_\_\_\_

DAYTIME PHONE: \_\_\_\_\_

FAX: \_\_\_\_\_

EMAIL: \_\_\_\_\_

### REFRESHER CLASSES:

CQA  CQE  CRE  CQT  CMI  QM

CCT  CQIA  CSQE  QUALITY BASICS

CQA-BIOMEDICAL  SERVICE

### PAYMENT OPTION *(please check one)*

CHECK *(payable to Minnesota Section ASQ)*

AMERICAN EXPRESS  MASTERCARD  VISA

CARD NUMBER: \_\_\_\_\_

EXP. DATE: \_\_\_\_\_

CARDHOLDER'S NAME (PRINT): \_\_\_\_\_

CARDHOLDER'S SIGNATURE: \_\_\_\_\_

BILLING ADDRESS / ZIP: \_\_\_\_\_

\_\_\_\_\_

**SECTION MEMBERS** Did you find your membership number in this issue? If so, call the Section Office at (651) 779-9820 by the end of this issue month to receive a \$30.00 gift certificate. Three winning numbers are hidden in each issue.

# MN ASQ EDUCATION PROGRAM

## REFRESHER CLASSES

2004/2005 UPDATE

All classes will meet at Guidant,  
4201 Lexington Ave. N, Arden Hills, MN  
All classes from 6:00 - 9:00 pm.  
Prices Listed are for MN ASQ Section  
members.

### Tentative Fall schedule:

#### CQA

6 sessions

\$200

Start: Wednesday, Oct. 20, 2004

End: Nov. 24, 2004

Register by Oct. 15, 2004

#### CQIA

4 sessions

\$150

Start: Thursday, Nov. 4, 2004

End: Dec. 2, 2004

Register by Oct. 28, 2004

#### CQE

8 sessions

\$300

Start: Tuesday, Oct. 12, 2004

End: Nov. 30, 2004

Register by Oct. 8, 2004

#### CCT

5 sessions

\$180

Start: Nov. 1, 2004

End: Nov. 29, 2004

Register by Oct. 25, 2004

#### CMI/CQT

5 sessions

\$180

Start: Monday, Sept. 13, 2004

End: Oct. 11, 2004

Register by Sept. 8, 2004

#### Service/Transactional Quality

8 sessions

\$300

Start: Thursday, September 9, 2004

End: October 28, 2004

### Tentative schedule for Winter classes

#### Quality Basics

10 sessions

\$350

Start: Monday, March 7, 2005

End: May 9, 2005

#### CQMgr

8 sessions

\$350

Start: Week of Jan 12-16

End: Week of March 1-5

Register by Jan. 5, 2005

#### CRE

6 sessions

\$200

Start: Week of Jan. 19-23

End: Week of Feb. 23-27

Register by Jan. 12, 2005

#### CQA-Biomed.

4 sessions

\$150

Start: Week of Feb. 1-5

End: Week of Feb. 23-27

Register by Jan. 26, 2005

#### CSQE

8 sessions

\$300

Start: Week of March 1-5

End: Week of April 19-23

Register by Feb. 25, 2005

**CQA-HACCP** scheduled on demand.

**Six Sigma Black Belt** training offered by  
The University of St. Thomas.

## CERTIFICATION EXAM DATES

EXAM:

CMI, CQT, CRE, QM,

CQA - HACCP, CQA - BIOMEDICAL,

SIX SIGMA BLACK BELT

### APPLICATION DUE

TO NATIONAL:

8/20/2004 for 10/16/2004 exam

1/7/2005 for 3/5/2005 exam

EXAM:

CCT, CQA, CQE, CQIA, CSQE

### APPLICATION DUE

TO NATIONAL:

10/1/2004 for 12/4/2004 exam

4/1/2005 for 6/4/2005 exam

Certified Mechanical Inspector (**CMI**),  
Certified Quality Technician (**CQT**),  
Certified Reliability Engineer (**CRE**),  
Certified Quality Manager (**QM**),  
Certified Quality Auditor (**CQA**), Certified  
Calibration Technician (**CCT**), Certified  
Quality Auditor (**CQA**), Certified Quality  
Engineer (**CQE**), Certified Quality  
Improvement Associate (**CQIA**), Certified  
Quality Software Engineer (**CSQE**),  
**Exam Registration:** Contact ASQ at  
(800) 248-1946 or [www.asq.org](http://www.asq.org) for  
the exam application and information  
brochure. Review the examination  
brochure before enrolling in a refresher  
class. **Tentative Exam Location:**  
O'Shaughnessy Education Center,  
University of St. Thomas, 2115 Summit  
Ave., St. Paul, MN. The building location  
listed is tentative. If you are taking a  
certification exam and have not  
received a seating letter two weeks  
prior to the exam, contact ASQ at  
(800) 248-1946 for the time and exact  
building location.

*see up to date class information at [www.mnasq.org](http://www.mnasq.org)*

# CONFERENCE UPDATE

## MINNESOTA QUALITY CONFERENCE



**OCTOBER 4 & 5, 2004**  
**MARRIOTT CITY CENTER**  
**MINNEAPOLIS, MN**

### MONDAY OCTOBER 4, 2004: CONCURRENT SESSIONS

**State Quality Award Track** winners telling their success stories

**Software Quality Track** featuring presenters from Stat-Ease,  
 The University of Minnesota, IBM, and Medtronic

**Quality Systems Track** with audits, risk analysis and more

**Six Sigma Track** with valuable information on applying Six Sigma

**Quality Techniques Track** includes quality techniques for  
 use in any company/ industry

### TUESDAY, OCTOBER 5, 2004: FULL DAY WORKSHOPS

**Workshop One:** TRIZ

**Workshop Two:** LEAN Manufacturing/ Things Gone Wrong  
 Sustaining and Enterprise-Wide Six Sigma Initiative  
 (a two-part workshop)

**Workshop Three:** DOE Simplified-An Intro to Breakthrough  
 Tools for Planned Experimentation

**Workshop Four:** Implementing an Effective CAPA System

**Workshop Five:** Most Common Project Mistakes:  
 Identify and Avoid Them

**Workshop Six:** Quality Audits for Improved Performance  
 Presented by Dennis Arter

Workshop and session descriptions will be available at  
[www.mnasq.org](http://www.mnasq.org)

**COME OUT THIS FALL AND TAKE A CLOSER LOOK!**

### REGISTRATION FORM

#### MINNESOTA QUALITY CONFERENCE

*(please print)*

NAME: \_\_\_\_\_

COMPANY: \_\_\_\_\_

ADDRESS: \_\_\_\_\_

CITY / STATE / ZIP: \_\_\_\_\_

DAYTIME PHONE: \_\_\_\_\_

FAX: \_\_\_\_\_

*confirmations will be sent via fax only*

EMAIL: \_\_\_\_\_

Conference Fees:  Full Conference  
 Monday, October 4  Tuesday, October 5

#### WORKSHOP PRE-REGISTRATION REQUIRED

W1: TRIZ  W2: LEAN Manufacturing / Six Sigma  
 W3: DOE Simplified  W4: CAPA  
 W5: Project Management  W6: Quality Audits

I am a full member of Minnesota ASQ or the Minnesota  
 Council for Quality. Membership #

	Member Rate	Non-Member Rates
Single day rate		
<input type="checkbox"/> On or before 9/24/04	\$235	\$265
<input type="checkbox"/> 9/25/04 and after	\$265	\$295

Two day rate		
<input type="checkbox"/> On or before 9/24/04	\$420	\$480
<input type="checkbox"/> 9/25/04 and after	\$480	\$540

#### PAYMENT OPTION *(please check one)*

CHECK *(payable to Minnesota Quality Conference)*  
 AMERICAN EXPRESS  MASTERCARD  VISA

CARD NUMBER: \_\_\_\_\_ EXP. DATE: \_\_\_\_\_

CARDHOLDER'S NAME (PRINT): \_\_\_\_\_

CARDHOLDER'S SIGNATURE: \_\_\_\_\_

BILLING ADDRESS / ZIP: \_\_\_\_\_

To register by mail: Send this form with payment to  
 Minnesota Quality Conference, P.O. Box 9370, No. St. Paul,  
 MN 55109. To register by fax: Fax this form with credit card  
 payment to (651) 773-1981. To register on line: Visit  
[www.mnasq.org](http://www.mnasq.org). For more information call (651) 779-1824  
 or email [Mnqualconf@aol.com](mailto:Mnqualconf@aol.com).



# BIOMEDICAL FOCUS

## RISK ANALYSIS AND MANAGEMENT WORKSHOP

### HOW MEDICAL DEVICE FIRMS CAN DEVELOP AND MANUFACTURE SAFER AND MORE EFFECTIVE PRODUCTS

The Biomedical Focus Task Group of the Minnesota Section of ASQ is pleased to present: a Risk Analysis and Management Workshop. This workshop is based on the requirements of FDA's Quality System Regulation and ISO14971.

In 2000, the Risk Management Standard-ISO 14971 came into effect. The FDA will allow companies to use conformance to ISO 14971:2000 as a way of meeting the risk management requirements of Quality System Regulation. In Europe, ISO 14971 is replacing EN 1441 as Risk Management Standard to be used in compliance with Medical Device Directives.


As we all know, Product Risk Management is an integral part of the development and support of product and its lifecycle for the companies to produce safe and effective medical devices. This session will have hands-on exercises to give participants a good feel of the subject.

The workshop will address the following questions:

- What is risk analysis?
- What are the expectations of regulatory agencies?
- What is the best approach to meet the requirements of the regulatory agencies and at the same time do what is best for the business?
- How to conduct FMEA and Fault Tree Analysis?
- Under what conditions should we conduct one or the other or both?
- What are the pitfalls and how to avoid them?
- How to manage identified risks?

Check the September edition of *The BenchmarkQ*, or visit the Section website at [www.mnasq.org](http://www.mnasq.org) for more details and for registration information.

The Workshop presenter will be Ashweni Sahni, recognized expert in the field of Risk Analysis.

Ashweni is President of Ash and Associates, specializing in training, assessments, consulting and assistance. Contact Ashweni at (651) 631-8307 or the Section office at (651) 779-9820 for more information. 



## Manufacturers Alliance

Sharing Education & Resources Peer-to-Peer

*Where leading companies go for . . .*

### Six Sigma Green Belt Training

— Beginning October 15

### Lean/Six Sigma Practitioner Certification

— Open enrollment

#### *Our participants appreciate:*

- ▲ Instruction from working practitioners
- ▲ Experiential learning methods
- ▲ Choice of public sessions or at your site
- ▲ Member discounts

*"Having a local resource like the Manufacturers Alliance just makes my job easier. That is, I know that there is expertise there whenever I need it. That's reassuring."*

*- Steve Murray, Alliance Member*

Web Site: [www.mfrall.com](http://www.mfrall.com) ▲ Email: [ma@mfrall.com](mailto:ma@mfrall.com) ▲ Phone: 763-533-8239

# BIOMEDICAL FOCUS

## SPONSORS TRACK AT MEDEGE

The Minnesota Section's Biomedical Focus Task Group sponsored the Quality Track at the June 23-25 first annual MedEdge International Conference, presented by Medical Alley. The track (one of seven) featured eight speakers presenting topics related to quality in the biomedical industry. Overall, this track was very well attended, as was the conference in general, with nearly 1400 participants.


The first day featured two FDA speakers, Tim Philips from the Minneapolis District Office of Compliance and Kim Lewandowski, Consumer Safety Officer from Milwaukee. They spoke to FDA issues and QSIT. Mark Ames, President, AQS Management Systems, addressed ISO 13485.

The second day started with Susan Alpert, M.D., Ph.D., and Vice President, of Medtronic speaking on management responsibility and compliance. Toni Grabinger, Principal, Project Leadership Services, presented later in the morning on design controls. In the afternoon two Medtronic quality engineers, Mike Fedock and Michelle Reinert, spoke on supplier quality management. Closing the day was Douglas Older, President/CEO of Techlogic, who presented on CAPA.

On the final day of the conference the

speaker was Dan Olivier of Certified Software in San Diego who spoke on Optimizing Medical Software Development Practices.

We thank this group of prominent speakers who provided track attendees with valuable information and current insight into issues affecting the biomedical device industry today. Participants also were able to enjoy approximately 120 exhibitors representing various quality consulting services, education, media, research and our own Minnesota Section booth. The Section booth and its neighbor, the ASQ Biomedical Division booth, saw quite a bit of traffic. A lot of interest was shown in becoming members and in certifications offered by ASQ. Numerous contacts were made with persons and organizations interested in the Society and our Section in particular.

Finally, Biomedical Focus wants to thank all the volunteers who made ASQ participation in this event such a success. Biomedical Focus invites all of you to visit the Section website and the link to Biomedical Focus. More events are being planned. For more information or to volunteer, contact the Minnesota Section office (651) 779-9820 or one of the Co-chairs, Ashweni Sahni (651) 631-8307 or Ralph Arnott (651) 633-0265. 

[www.mnasq.org](http://www.mnasq.org)

## WE ARE LOOKING FOR A FEW GOOD COMPANIES

Last May the Program Committee tried something new. We held our Section meeting at a local company, Medtronic, instead of our usual selection of hotels and schools. The response was positive so we would like to try doing this again. The Program Committee is asking to hear from members who would like to help us arrange a meeting at their company's location. It certainly does not have to be as large as Medtronic. We would like to hear from lots of locations, big and small. Don't worry about the arrangements. Our committee can work with internal services or bring in catering. We are thinking that this will be an interesting way to introduce our membership to some of the fine companies in the area. We are also contemplating offering breakfast and/or lunch meetings to add to our program this year. These will be one and a half to two hour meetings on a single topic.

If you think your company would be interested in hosting one of our Section meetings, please give us a call at (651) 779-9820 or email at [mnasq@aol.com](mailto:mnasq@aol.com). 


**IMPORTANT NOTICE:** THE DEADLINE FOR SECTION MEETING REGISTRATION HAS BEEN CHANGED FROM 12:00 NOON THE FRIDAY BEFORE THE MEETING TO 5:00 PM THE THURSDAY BEFORE THE MEETING. IF YOU CALL TO REGISTER AFTER 5:00 PM ON THURSDAY, YOU WILL BE PLACED ON A WAITING LIST AND SEATS WILL BE GIVEN IF CANCELLATIONS COME IN.

# NOTEWORTHY NEWS

## FROM THE CHAIR

### Note to all members of changes in our guiding documents:

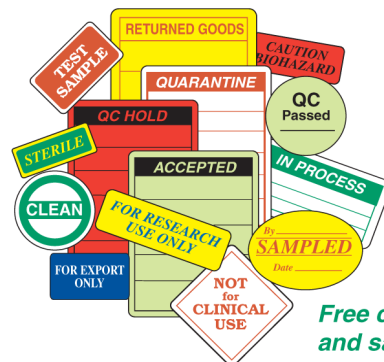
A new set of common Simplified Section Bylaws, approved by National ASQ, became effective July 1, 2004 for all Sections. The new Bylaws provide definition for minimum requirements expected of any ASQ Section and replaced our Section Bylaws. The greatest benefit of this new document is to improve operations for smaller Sections that can't afford the effort we have invested in the Minnesota Section 1203 Bylaws. 00104721

Section 1203's old Bylaws will be converted into operational regulating documents to maintain the integrity of our operation created with our Bylaws. Our Bylaws originated 53 years ago and have been constantly maintained over this period. They have served us well, and we intend to retain the value they hold for defining the operating structure of this Section. I have organized a committee to review and convert our Bylaws to oversight documents/manual. Anyone interested in participating in the conversion process may contact me via phone or email at [townsg1@earthlink.net](mailto:townsg1@earthlink.net). 

Gary Townsend  
2004-2005 Section Chair

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# PLACEMENT LISTINGS

## QUALITY CONTROL LAB SUPERVISOR

This team leader position is responsible for the overall function and impact of the QC laboratory and sanitation department, including operating at a high level of quality, safety, and efficiency. The position is also responsible for development and continued implementation of the company's quality, food safety, cGMP, and HACCP programs. In addition to supervising the performance of the Quality Control and Sanitation Departments (6 people), the QC Supervisor works with the Sales, Customer Service, Product Development, Production, and Packaging teams, as required.

Knowledge, training, and experience in laboratory procedures with a minimum of a Bachelor level degree in a scientific curriculum along with excellent verbal and written communication skills are required. Other skills include knowledge and experience in food production, lab equipment, calibration, method development, SPC, cGMP's, HACCP, packaging, and plant sanitation and 3-5 years of lab supervisory experience. Desired computer skills include Windows, Word, and Excel.

Please submit resume, cover letter, and salary requirements by mail to: IFP, Inc, Human Resources, 2125 Airport Drive, Faribault, MN 55021, or email: [alyon@ifpinc.biz](mailto:alyon@ifpinc.biz). For more information, visit: [www.ifpinc.biz](http://www.ifpinc.biz)

## QUALITY ASSURANCE MANAGER

Quality Manager to oversee all aspects of the organization's quality improvement efforts. Duties include developing and administering the program, training and coaching employees, and facilitating change throughout the organization. Responsible for establishing strategic plans, policies, and procedures at all levels so quality improvement efforts will meet or exceed customers' needs and expectations.

The successful candidate will have a Bachelor's degree in Engineering and at least

5 years Quality Assurance experience in a manufacturing environment. Experience with ISO 9001-2000 preferred.

Send resume to: Tekna Seal, 5301 East River Road, Fridley, MN 55421 or [sjohnson@teknaseal.com](mailto:sjohnson@teknaseal.com)

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## TWO SR. QUALITY ASSURANCE SCIENTISTS/AUDITORS

Responsibilities:

- Act as lead auditor for our internal audit program.
- Work with site employees to have documented corrective action plans for audit actions.
- Follow-up on open audit actions to allow for closure.
- Maintain quality system procedures as needed to be continually compliant.
- Assist as needed in quality system initiatives, typically setting up improved ways to reach compliance.

Requirements:

- These positions require a BS/BA degree and 6 years of relevant experience
- Relevant majors include Biology, Chemistry, Medical Technology, Mechanical, or Electrical Engineering.
- Must have auditing experience working in the medical device industry and experience working with the FDA or Notified Bodies.

To be considered, apply online at [www.beckman.com](http://www.beckman.com) for Job # 02342 or #02370.

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## DIRECTOR OF QUALITY IMPROVEMENT

The Director of Quality Improvement will lead 3 Quality Managers and 13 quality professionals in four U.S. plants. In addition, the Director will develop close working relationships with leaders in manufacturing, materials, engineering, and others throughout the organization. The mission for the Director

of Quality Improvement will be to lead the establishment of a World Class quality culture.

The fully qualified candidate will possess an engineering or related technical education and at least 10-15 years of combined manufacturing, engineering and quality leadership experience. At least 5 years of experience should be in establishing and leading similar quality improvement objectives in a multi-plant manufacturing environment. Mechanical equipment industry experience is required, and experience with a company that also has international manufacturing divisions is preferred.

Technically, the individual will have experience in at least one well-developed quality system such as ISO 9000, Six Sigma, TQM, etc. A demonstrated ability to implement quality systems and lead cultural acceptance of more rigorous quality systems will be required.

Contact: Marisa Hinnenkamp, Telephone: (612) 252-9305, Fax: (612) 343-0305, email: [marisa@woessner.com](mailto:marisa@woessner.com)

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## PRODUCTION ENGINEER/SIX SIGMA BLACK BELT

We are seeking a Production Engineer to manage all activities and processes related to productivity, efficiencies and profitability of our laboratory operations division.

Responsibilities will include the design, coordination, and implementation of LEAN and Six Sigma processes in our laboratory operations department. These responsibilities will include the development of overall production schedules, standard work processes, and production flow. This position routinely interacts with other directors on process and procedural changes including implementation requirements, budgeting of resources, instruments/equipment, and identification of Six Sigma projects and assignment of Black Belts as appropriate.



# PLACEMENT LISTINGS (CONTINUED FROM PAGE 13)

Position requirements:

- Master's degree in Engineering, Biological, Chemical, Physical or Laboratory Science and ten years in Industrial or Laboratory Operational Experience or Bachelor's degree with equivalent experience required.
- Six Sigma Black Belt candidate, certification or experience preferred.
- Thorough understanding of Lean Manufacturing concepts preferred
- Strong computer (Windows, Excel and Access), oral, written, and interpersonal skills required.
- Minimum 5 years operations management experience.

Please mail/fax/email your resume and cover letter indicating your salary requirements to: MEDTOX Laboratories, Inc., Human Resources, 402 W. County Road D, St. Paul, MN 55112, Hr2@medtox.com, Fax: (651) 286-6296

**QUALITY ENGINEER OPENING**

Plymouth, MN

Position Description:

- Propose and implement product and process quality improvement programs throughout the organization.
- Perform routine trend analysis on key quality indicators using industry-accepted statistical techniques.
- Design and develop programs for reporting quality and reliability.
- Perform failure analysis and work with engineering design teams, other departments, and vendors to resolve quality problems. (May require occasional travel to vendors.)
- Process evaluation bids.
- Direct and perform evaluation tests on components/circuits. Compile and record results and make recommendations based on findings.

Qualifications:

- Minimum Bachelors degree in Electrical Engineering, Physics, or related discipline
- At least 5 years engineering experience
- At least 2 years of statistical analysis experience in a quality department for a manufacturer of electrical or mechanical products.
- Computer literacy (MS Office, databases, and statistical computer programs)
- Excellent written and verbal communication skills. Proven ability to communicate with personnel in all areas of an organization.

To Apply:

If you, or someone you know is interested in applying for this position, please email a cover letter, resume, and salary requirements to resume@bannerengineering.com.

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*This service is offered at no charge to all companies and ASQ members. Members may submit their resumes to the Section Office where they will be kept on file for 6 months. They will be sent a list of job openings on file and their names will be submitted to companies who are seeking applications. Companies may submit job openings that will be kept on file and published one month in The BenchmarkQ if received in time for publication. They will also receive a list of members whose resumes are on file. Please send job openings electronically to the Section Office at mnasq@aol.com. We do not recommend applicants or offer job counseling.*

**ASQ CONTACTS**

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 c2468@aol.com

**RECERTIFICATION CHAIR**

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 gagnerfamily@comcast.net

# MINNESOTA SECTION 1203

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### VICE CHAIR MEMBER SERVICES AND ADMINISTRATION

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