



SFV Quality Quill



SECTION 0706

2008-2009 ISSUE V



SCHEDULED SECTION EVENTS



Monthly Meetings

ASQ Sections plan monthly meetings to provide colleagues an opportunity to network, and to increase their knowledge. This is an opportunity to enhance your knowledge at minimum cost.

The ASQ Section 706 Section Events are held on the **THIRD Tuesday** of every month.

You can join us for dinner and presentation or presentation only. All reservations should be made through Acteva. Recertification Units (RU's) are awarded for attending presentations.

San Fernando Valley, Section 0706

Refer to www.asqsfv.org

Other Sections' Activities

Los Angeles, Section 0700

Refer to www.asqla.org

Orange Empire, Section 0701

Refer to www.asqorangeempire.org

San Gabriel Valley, Section 0702

Refer to www.asq702.org

Channel Cities (Ventura/Santa Barbara, Section 0709)

Refer to www.asq709.org

Important Date:	Program Title:	Location:
June 06, 2009 Saturday	ASQ Summer Certification Exams (includes CQA and CQE Exams)	Exams will likely be held at NORTHROP GRUMMAN - NSD Woodland Hills, CA

MEMBER INFO

Events - Locations and meals may be changing for every section event so please review the flyer carefully.

Hosting an event - We are looking for local companies who can offer their facility. Contact P. Musti.

Section Website - Bookmark our new one www.asqsfv.org

Recertification Units - Contact M. Gorgzedah if you need assistance.

Unemployed? Contact membership and ASQ HQ for possible payment reductions.

ARTICLES

Region 7 Leadership Training and Conference 2009



It was a Quality Day in Palm Springs!!

More than a Leadership training, the conference became a link to pull together all of us, Quality practitioners from ASQ Region 7.

There was a dynamic exchange of best practices and applicable information for current and future Board members and leaders. The sharing of Quality knowledge motivated people to think creatively and find new solutions on the on-going Quality journey.

Excellent presentations and speeches that characterize our line of work were experienced throughout the day.

Good people, good weather, good work...what else can we ask for?

Nice to see you all!

Luis Echeverria

ARTICLES

Highlights from the 44th Annual DIA Meeting: EMEA and Industry Perspectives on Defining Quality in Clinical Trials—April 08, 2009

Presented by: Ana Sharma, Compliance Manager, Global Research and Development Compliance, Amgen Inc.

EMEA and Industry Perspectives

- EMEA Perspective — Fergus Sweeney, Principal Scientific Administrator, GCP and Pharmacovigilance Inspector, EMEA
- Industry Perspective — Michael Sobczyk, Director, Corporate Quality Compliance, Genzyme Corporation

EMEA and Industry Perspectives: How Do We Define Quality in Clinical Trials?

- * “Meets customer needs” or “fitness for use”
- * “The total set of characteristics of a product or service that affect its ability to satisfy a customer’s stated or implied needs” – ISO 8042

EMEA and Industry Perspectives: What are Quality Requirements?

- * Quality should be prioritized in relation to its impact on risks and benefits.
- * Quality principles should be inclusive of all phases of clinical trials, commercial and academic trials and large and small sponsors.

EMEA and Industry Perspectives: What Influences Quality in Clinical Trials?

There are many factors and controls driving the behavior and practice of clinical trials.

- * Regulatory agency review
- * Ethics committee review
- * Monitoring
- * Audits
- * Inspections
- * Medical environment
- * Corporate culture
- * Legal influences
- * Public expectations

EMEA and Industry Perspectives: How Can We Achieve Quality in Clinical Trials?

- * A **quality system** is a method to produce a reliable and high quality end product.
- * The quality system should consist of **verifiable standards for processes that can control the variation of quality** such as FDA regulations, ICH GCP guidelines, SOPs, etc.

EMEA and Industry Perspectives: Where Can We Build Quality in Clinical Trials?

- * Protocol – delineate between required vs. recommended procedures in the protocol
- * Electronic systems (EMR, EDC) – utilize electronic systems, as they are prone to fewer errors
- * Monitoring – ensure the monitoring is consistent with the protocol design and complexity
- * Data management – standardize data through CDISC, CDASH and HL-7
- * Investigator sites – train and certify sites

PLAN FOR QUALITY! BE PROACTIVE!

There are many opportunities to improve quality in clinical trials!

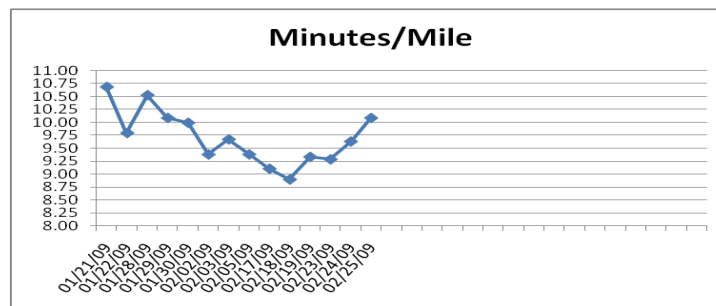


Ana Sharma

Behavior Charts in My “Other” Life Doug Forman

I am an avid runner (perhaps borderline obsessive, but that may be another topic for a different publication). I will talk about my running adventures with anyone who dares to ask and is polite enough to listen. I find that just by talking about it with others helps to keep me focused on my training. So when a coworker/friend mentioned to me earlier this year that he was starting to run to stay in shape, it was the only invite I needed to start a regular dialog regarding our respective training and goals. A couple months into this, he expressed some disappointment in his previous day’s run since it had been slower than recently. He showed me the following from his Excel log:

Date	Distance	Minutes/Mile
01/21/09	4.8	10.69
01/22/09	3.2	9.80
01/28/09	3.2	10.53
01/29/09	3.2	10.09
01/30/09	3.2	9.99
02/02/09	3.2	9.38
02/03/09	4.8	9.67
02/05/09	4.8	9.38
02/17/09	3.2	9.10
02/18/09	3.2	8.90
02/19/09	3.2	9.33
02/23/09	3.2	9.29
02/24/09	4.8	9.63
02/25/09	3.2	10.09



After a quick look through the data and the chart, one of the first things I said was “You’re going to have good days and bad days—this looks like normal variation, with perhaps a special cause for the slow run—you ran a decent longer run the day before. You’ve had a nice downward trend, but you can’t expect it to keep going without giving the body some rest”.

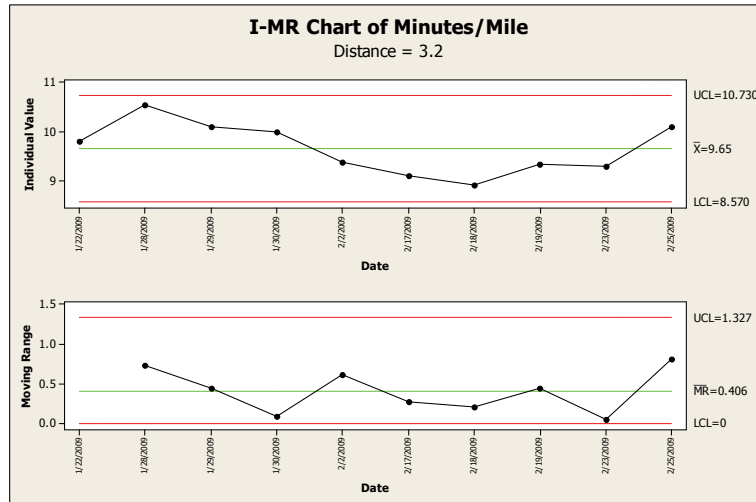
Normal Variation...Special Cause...Trend. Where have I heard these terms before?

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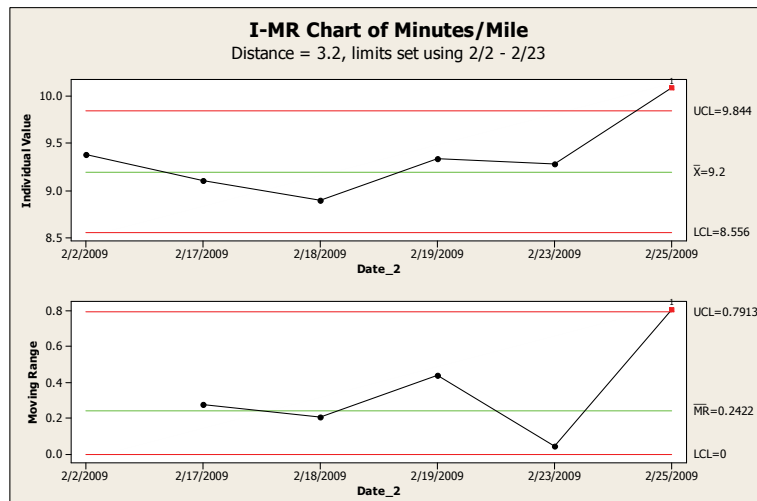
ARTICLES

As Quality Professionals, most of us are quite familiar with Behavior Charts. Known more traditionally as Control Charts, this Quality Tool helps us to determine the natural behavior of a process, monitor changes, and determine when to take actions. Personally, I prefer the term “Behavior Chart”, if for no other reason than I think that it provides a great analogy regarding the monitoring of the process. Treat the monitoring of the process like your child. The better it behaves, the less you need to be concerned about watching it. Just be sure that you base that monitoring frequency on all the necessary information (i.e., just like you may not be able to judge how your child behaves at school based on how he acts when at home, you can’t judge what will happen on the 3rd shift based on data taken on the 1st shift).

Since within my coworker’s data there is a mixture of 3.2 and 4.8 mile runs, I stripped out the 4.8 to look at just the 3.2 milers. In a sense, these are 2 different processes, and they should be evaluated independently. A check of the data shows that it is normal, and the following Individual-Moving Range chart was produced in Minitab.




The chart shows no statistical anomalies. However, it does clearly show what my coworker told me—after some nice improvement (5 points in a row downward with 5 points below the mean), he seemed to suddenly have a “bad day” (a point back above the mean). Should he be concerned? Had there been a change? Statistically, these points all belong in the same population. However, his concern is that the last point is different than the recent history. Looking at only the last 6 points, but setting the behavior limits on the first 5 of them, we get the chart:



In this chart, we do see that there is a statistical out-of-behavior point for both the Individual Value and the Moving Range for the last point. It is indeed different from the previous 5. If I was monitoring a manufacturing process, this point on this chart should prompt an investigation.

My conclusion in this case would be that this point should not be of much concern regarding the actual fitness level of my coworker. As identified above, there is likely a Special Cause for this point—the fact that he had run hard the night before. Like a tool wears and need routine maintenance, the body wears and needs maintenance—in this case, the body simply needs rest. In order to monitor his actual fitness level, I would recommend that he be as consistent as possible. For example, perhaps he should only monitor the time once or twice a week, ensuring that the day before was not a “hard” day. Another possibility would be to monitor based on a periodic X-bar & R chart, which would help by averaging out some of the variation, while showing trends over time. In any case, it has given me ideas for using these methods for monitoring my own progress over time, which I believe will help me stay focused in my efforts to continually improve.

SFV SECTION MEMBER BIO

	
Name	Tarek Elneil
Employment	Tarek's career has led him from Quality Specialist, Quality Engineer, QA CAPA Investigator, Compliance Manager, QA Operation Manager, and he now offers his consulting services in continuous quality improvement.
Education	Graduated from Kuwait University with a degree in zoology and biochemistry, and an MBA from California Lutheran University. Tarek has over 30 years of experience in many different fields, including information systems, records management, sales and project management. Tarek has also worked in many different regions, including the Middle East, which has given him an exposure to and understanding of different cultures throughout the world.
ASQ data	Tarek, is an ASQ certified CQMOE (Certified Quality Manager/Organizational Excellence), Six Sigma Engineer Senior member.
Volunteer experience	Program Chair
Personal Information	Tarek has applied his expertise in quality assurance and manufacturing, using Six Sigma and Lean Manufacturing principals to achieve impressive gains. His projects are primarily focused on reorganizing and improving quality system compliance and productivity. Tarek has also led a project that was successful in harmonizing the quality systems in three pharmaceutical facilities that improved and standardized their quality procedures and practices. Tarek also prepared and trained employees on Continuous Improvement, Lean Manufacturing and problem solving.

NOTES

ASQ SFV Section is currently seeking an Education Chairperson. If you would be interested in this opportunity to hone your leadership skills, please contact us at info@asqsfv.org.

World Conference on Quality and Improvement

May 18-20, 2009 . Minneapolis Convention Center . Minneapolis, MN

Also Featuring: + Quality Institute for Healthcare + Institute for Software Excellence + Quality in Sustainability

2nd Annual SoCal Quality Conference

ASQ Section Hosts: Los Angeles, San Gabriel Valley & San Fernando Valley

Saturday, October 24, 2009

Kellogg West Conference Center

Cal Poly University, Pomona, CA

ASQ SFV Section 0706 Contacts

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- PAID ADVERTISEMENT -

EMPLOYERS

The Quill will publish your job postings free of charge as a service to our members.

Posting guidelines can be obtained on the ASQ SFV website at:

http://www.asqsfv.org/index_files/Jobs.htm

or on the ASQ SFV website's Jobs Page.

Please contact
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