Canadian Chapter of the Society of Quality Assurance
CCSQA
FCSQA
Filiale Canadienne de la Society of Quality Assurance

Newsletter/Journal

Volume 5, Issue 1 July 2006

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2006 CCSQA Board of Directors

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President's Message

Deborah L. Dragoon

Greetings to all of you. This year has been a challenge. Our chapter faces many interesting questions. As we continue to address the GLP Monitoring issue, we need the help of the members.

Are you interested in holding a leadership role in our chapter? If so, contact one of the Board Members and we'll include your name on the upcoming ballot. Perhaps you'd like to offer your expertise as a presenter at our annual meeting…Are you good at Web Page development? Our page needs a lift and a New WebMaster. We welcome any contribution that you are able to make towards the success of our chapter.

Part of our job as a society is to provide members with training and resources related to QA. We have held a Meet and Greet to solicit ideas. In August we will be holding a WebEx addressing the GXP inspectional experiences. In October, we will be offering our annual meeting with varied topics covering the major disciplines. Last year's meeting was very enjoyable and informative. Even if Field Studies or Clinical Trials are outside your comfort zone, there's so much to learn. Mark your calendars and join us.

We can shape the regulations and industry as a group. Ms. Tyas has initiated discussions about the GLP Monitoring Program. EMEA has taken the position that greater scrutiny will be placed on Canadian studies due to the lack of a GLP Monitoring Authority. As QA professionals, it's our job to assess compliance and make a difference. After all, as consumers, we all want safe, effective products whether it's drugs or chemicals.

Send your comments to

dragood@wyeth.com

Financial Report

CCSQA Treasurer – Janine Johnson

May 20, 2005 Balance $3703.41

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Income

Membership renewals - $124.06

2005 Meeting Registrations $4757.35

Income Total $4881.41

Expenses

Bell Conferencing Inc. $313.73

2005 Meeting Expenses $4072.20

Total Expenses - $4385.93

Jul 2006 Balance - $4198.89

DID YOU HEAR ???

If you did, please let us know so we can share with the group.

The SQA Computer Validation Initiative Committee (CVIC)

Submitted by Michael A. Maddix

In February 2005, I was accepted as a member of the SQA CVIC. Prior to joining, I knew little or nothing about the function of this SQA specialty group. The CVIC's vision is to focus on the development, promotion and dissemination of information, ideas, and standards surrounding the global regulatory requirements of computer system development, testing, implementation, and decommissioning, and their mission is to:

a) Identify issues submitted by SQA members, develop researched responses, and publish results or post the information on our web page.
b) Stay informed and maintain awareness of current industry, government, and technical trends.
c) Develop computer validation training that is current, up to update, and relevant for the Quality Assurance Professional.
d) Communicate to the SQA Membership about CVIC activities through articles, presentations, questions and answer sessions, and workshops.
e) Proactively partner with other SQA committees.
f) Keep information on the web page current and develop an archive of previously published information.

The CVIC meets quarterly and in conjunction with the SQA Annual Meetings. The CCSQA is well represented on the CVIC committee. Drew Finney, Stephan Cote, and myself are all members of both organizations.

More information on the CVIC and other specialty sections can be located at www.sqa.org.

Applying the Pareto Principle to Quality Assurance Processes

D. Gregoire, J-F. Poirier & M. Vasilatos

Under GLPs, the role of the QA unit is to assure test facility management that the processes and operations are in compliance with the regulations. Although there are specific activities that ought to be performed, there is flexibility as to how this is to be achieved. This flexibility, in turns leads into different procedures and approaches that are usually tailored to a company's culture and needs. These factors however may change over time. So how do we ensure that the quality procedures in place are conducted in the most efficient way and in accordance with our current needs? One answer comes from a 19th century Italian economist: Vilfredo Pareto.

In the late 1880's, Vilfredo Pareto observed that 80% of the land in Italy was owned by 20% of the population. Later on, management icon Dr. Joseph Juran transposed this idea to quality Management. He stated that 80% of measurable results and progress arise from just 20% of the resources invested; Pareto's 80/20 Principle. It follows then, that the key to maintaining an efficient system would be to identify these cornerstone activities, improve the lagging processes and support the successful ones.

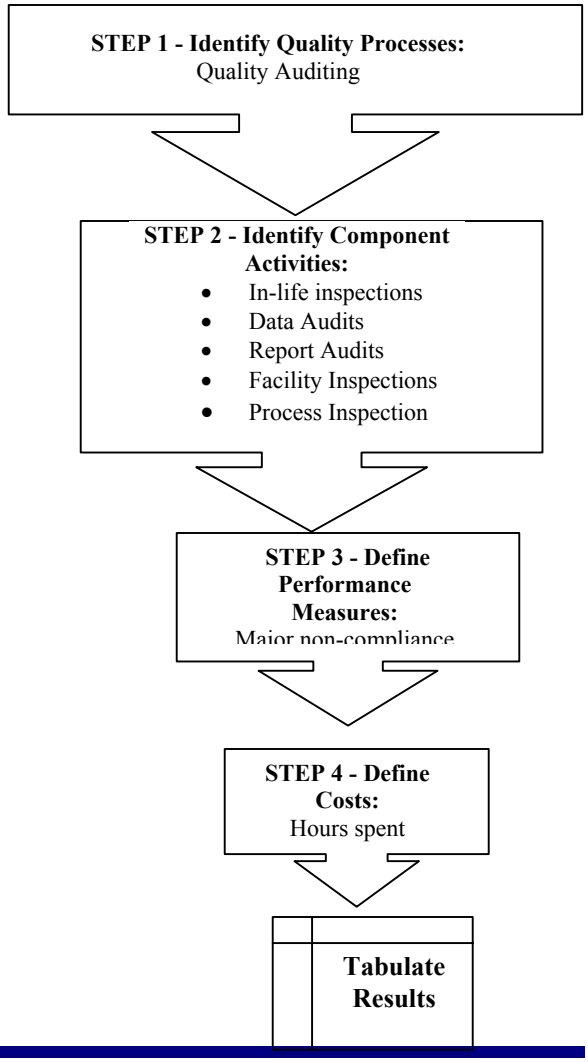
To apply the Pareto Principle to QA Processes, one would first need to identify a general work function and all the activities involved. For example, Quality Auditing can be divided into the following activities: data reviews, report reviews, in-life inspections, process inspections, and facility inspections. The same can be applied to training, reporting, monitoring, and any other process in the quality system.

Once all of the activities are categorized, it is necessary to define an appropriate "performance measure". Usually developed by QA management, performance measures should consider factors such as the variety of data available, past auditing history, and heterogeneity amongst auditors. In the following example, the numbers of non-compliance findings were used as our performance measure. However, since they do not involve the same compliance risks, only the ones deemed to be "major" were taken into consideration.

The next step is to define the cost associated with each activity. Though some types of activities may generate higher results, the resources invested in them may also be disproportionately higher. To further our example, we consider the number of hours spent on each activity within the process.

Once all of the activities, associated costs, and performance measures are established, one can proceed with the tabulation of data.

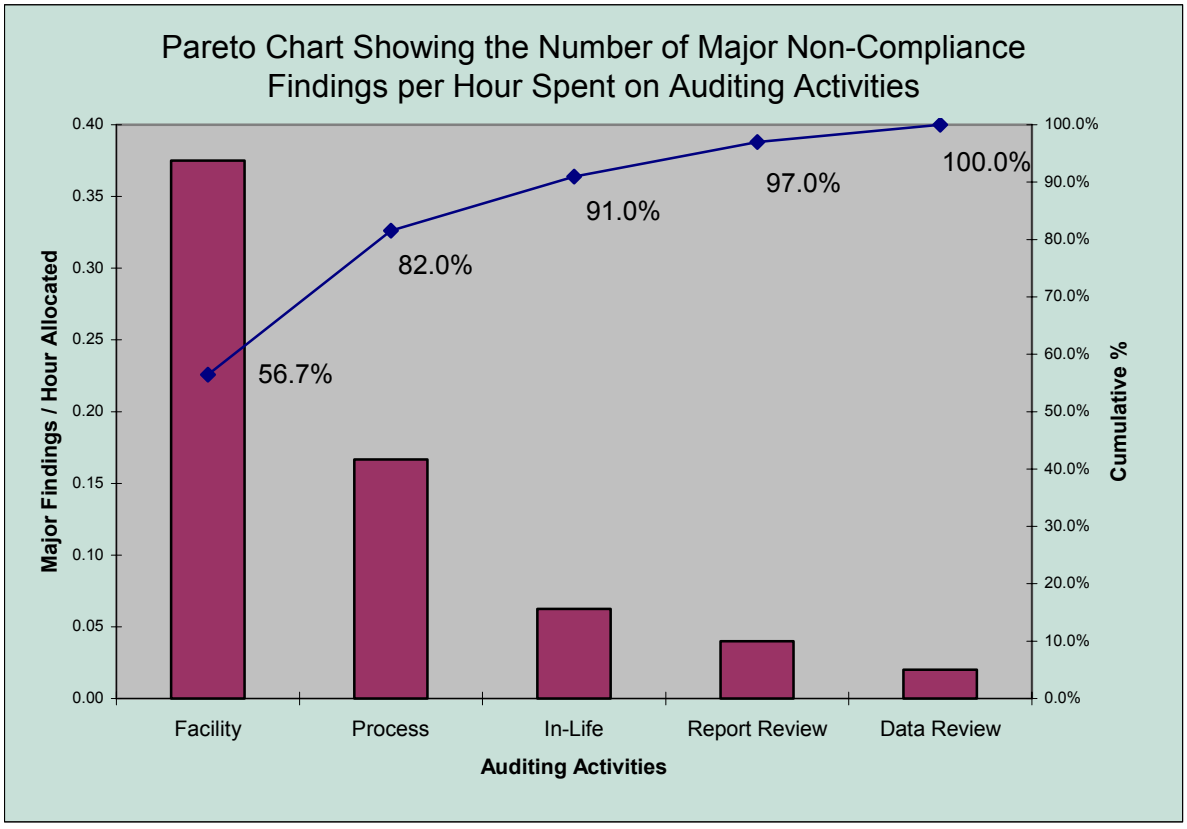
The following flow chart summarizes how to apply the Pareto Principle to our example:



Process	A Time (Hour)	B Significant Observations	(B/A) Result/Cost	Performance Rate	Cumulative % Performance Rate
Facility*	16	6	0.38	56.7%	56.7%
Process*	24	4	0.17	25.3%	82.0%
In-Life	64	4	0.06	9.0%	91.0%
Report Review	50	2	0.04	6.0%	97.0%
Data Review	100	2	0.02	3.0%	100.0%
Total	-	-	0.67	-	-

*Time spent on Facility and Process = 15.7% of total

Table 1. The Number of Major Non-Compliance Observations per Hour Spent on Quality Assurance Activities (Sorted by Descending Order)



When sorted in descending order of performance rate, this hypothetical data demonstrates that the two auditing activities (Facility and Process Inspections) that comprise 81.6% of the total performance arise from only 15.7% of the time allocated. In light of this, a progressive managerial approach would be to review the weakest activities to eliminate or improve on any non-essential practices. This would then allow for a better allocation of resources to the activities that yield better performance results while improving the efficiency of the system as a whole.

The dangers of the Pareto Principle is that it cannot be applied too rigidly. As we all know, in reality, few things fit the definitions of a formula as nicely as we would like. What it does well, on the other hand, is give a good indication of resource allocation and how Quality Processes can be streamlined and made more efficient.

As we get caught up in our routine operations, we might not always realize that processes, although efficient at the time of implementation, could become obsolete in a continuously changing environment. It is therefore essential to frequently re-evaluate our system to ensure that the investment of resources is maximized.

CCSQA Geographic Membership Distribution

(Map supplied by Ms. Penny Kirsch)

Each dot represents the location of our membership. Our goal is to have representation from each Province.

Upcoming CCSQA/SQA Events

CCSQA Membership Meeting/Training
13-14 October 2006

Delta Montreal at 475 President Kennedy Avenue – Agenda to follow – watch ccsqa.org

QA Poetry

These days there is an expectation for a closer relationship between QA and their customers. For a bit of fun, here are a couple of poems taken from well-known songs about that new relationship with QA (or QAU as some call it)! You be the judge.

May QA bless you and keep you (out of trouble) always
May your wishes not to get 483s all come true,
May you always do a quality job for others,
And let the FDA do for you…(sure)

May you build a quality foundation
And climb on every rung
And may you stay, forever 483-free.

….modified from the song, Forever Young, Bob Dylan

Lean on QA
When you're not strong,
They'll be your friend (what?),
They'll help you carry on manufacturing,

It won't be long,
'Til I'm going to need
Someone like QA to lean on…..

Why don't you call on your QA brother,
When you need a hand,
We all need QA
To lean on

I just might have a problem
That QA would understand
We all need QA
To lean on……

….modified from the song, Lean on Me, Phil Withers

Heather Light

Job Board

Aspreva Pharmaceuticals

A dynamic, global pharmaceutical company, Aspreva Pharmaceuticals is focused on addressing the needs of individuals with less common diseases.

Come and join our team of entrepreneurial, talented and passionate individuals who are leading the way in a new era of pharmaceutical partnering.

QA Manager (GCP)
Victoria, British Columbia

Purpose of Position
Reporting to the Head of Quality & Compliance, the primary responsibility of the GCP QA Manager will be the oversight and conduct of site audits and management of auditors.

Responsibilities include:

- Oversight and conduct of investigator site audits – planning, conducting and reporting
- Lead directed and for-cause audits as necessary
- Conduct due diligence audits as requested by Quality and Compliance management
- Provide supervision, training and guidance to GCP QA Auditors (in-house, contractors and consulting firms)
- Review and approve audit reports from GCP auditing staff
- Internal audits of GxP related tasks
- Maintenance of audit log and global audit plan
- Audit documentation review and maintenance
- Monitor audit responses and corrective actions to ensure accuracy and completeness
- Manage CAPA system and creative development of corrective action plans
- Interactions with partners QA/Auditing functions
- Internal guidance and consulting for trial GCP issues
- Represent GCP QA on study teams
- Take part as an active member during regulatory inspections
- Involvement in Quality Management Committee for procedurals documents review, maintenance and approval
- Keep Quality and Compliance management apprised of compliance and personnel issues through periodic reports
- Comply with all signatory limits as communicated by the finance function on behalf of the company.
- Comply with all Corporate Policies, rules, and regulations as set out and communicated by the company pursuant to good business practice
- Perform other duties as assigned

Requirements:

- 3 to 6 years of experience in GCP auditing with FDA/global regulatory requirements and ICH/GCP guidelines (monitoring and/or clinical operations experience will be considered) (auditing to non-FDA standards is a plus but not a replacement for US-FDA standards)
- University degree or equivalent in health sciences, nursing, pharmacy or related field
- Experience in regulated clinical environment, preferably pharmaceutical industry
- Experience in employee supervision
- Excellent communication and organizational skills
- High ethical standards and integrity
- Detail oriented
- Flexibility - Recognition of occasional unusual working hours due to international nature of operations (this role involves between 30 to 50% travel)
- Ability to work well independently, and in a team environment, and interact productively and effectively with peers, management and third parties
- Proficiency with MS Office including Word and PowerPoint
- Multilingual an asset
- Ability to offer options during audits to achieve ultimate compliance
- Ability to translate auditing skills to risk assessment process
- Ability to maintain a high level of confidentiality

For full details on this position, please visit www.aspreva.com. Interested, qualified candidates are invited to submit their resumes, referencing **#284,** by e-mail to: **careers@aspreva.com**, or by fax to: **(250) 744-2988.**

We thank all applicants for their interest, however, only candidates under consideration will be contacted.

GET NOTICED!!! Advertise HERE!

Advertisements are posted for 60 days on our webpage http://www.ccsqa.org/ and in each issue of our newsletter (average of 2 per year). The following rates are for non-members; members will receive a 25% discount off the published rates.

Full Page	(7in x 9 in)	150$
1/2 Page	(3.5in x 9in)	100$
Business Card	(3.5in x 2in)	50$

Newsletter only rates are as follows:

Full Page	(7in x 9 in)	75$
1/2 Page	(3.5in x 9in)	50$
Business Card	(3.5in x 2in)	25$

All ads must conform to the dimensions listed in the rates. The publisher is not liable for advertisements printed from faulty ad materials.

Newsletter Specifications:

Arial, 10 point, normal font
Wordperfect or Microsoft Word file format
High Resolution (at least 300 dpi)

Webpage Specifications:

Microsoft Word file format (The file will be converted to PDF prior to posting on the webpage)
High Resolution (at least 300dpi)

Note: Advertisements may be modified due to size limitations on the webpage and electronic transfer to members. Submitters will be notified and asked to approve any modifications, prior to publication.

Please refer to our webpage http://www.ccsqa.org/ for submission requirements and payment information.

Websites of Interest

Privacy Acts (Canada and US)

- **Canadian Personal Information Protection and Electronic Documents Act (PIPEDA)**

Canadian Privacy Act
http://www.privcom.gc.ca/legislation/02_07_01_e.asp

Provincial Privacy Acts and Oversight Offices
http://www.privcom.gc.ca/information/comms_e.asp

Canadian Institute of Health Research - Privacy
http://www.cihr-irsc.gc.ca/publications/ethics/privacy/index_e.shtml

- **United States Health Insurance Portability and Accountability Act (HIPAA)**

Office of Civil Rights
http://www.hhs.gov/ocr/hipaa/finalreg.html

Centers for Medicare and Medicaid Services
http://www.hipaa.com/

US Department of Health and Human Services
http://aspe.os.dhhs.gov/admnsimp/

OECD GLPs and Guidance Documents

OECD Principles on Good Laboratory Practice
http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem(98)17

Quality Assurance and GLP
http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)20

Compliance of Laboratory Suppliers with GLP Principles.
http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)21

The Application of GLP Principles to Field Studies.
http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)22

The Application of the GLP Principles to Short Term Studies.
http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)23

The Roles & Responsibilities of the Study Director in GLP Studies.
http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)24

The Application of the Principles of GLP to Computerised Systems.
http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/ocde-gd(95)115

The Role and Responsibility of the Sponsor in the Application of the Principles of GLP.
http://www.olis.oecd.org/olis/1998doc.nsf/LinkTo/env-mc-chem(98)16

The Application of the OECD Principles of GLP to the Organisation and Management of Multi-Site Studies.
http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)9

Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Deborah Dragoon (dragood@wyeth.com):

- GLP/GCP/GMP contributions
- Regulatory questions
- Advertisements or Job Postings
- Upcoming events