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

Newsletter / Journal

Volume 1, Issue 1 July 2002

Welcome to CCSQA / Bienvenue à FCSQA

A New Regional Chapter of the SQA

"GXP" Canadian Regulatory Community

CCSQA (by Paul Sidney)

The Health Care Product and Chemical regulatory community is diverse, however it shares a common purpose in ensuring high quality reproducible research or manufacturing. The goal of this Chapter is to promote the sharing of ideas and current regulatory and quality concepts.

We are fortunate to have a board with clinical, pre-clinical, CRO, Consulting, Pharmaceutical and Chemical Industry representation. This experience and inaugural membership provides an excellent platform for this chapter. Through active participation of all members and networking, we should be able to provide useful, current and insightful information to the GXP world. We welcome every member to this new Chapter and encourage active participation in the newsletter, website and/or upcoming seminars. Help us grow and provide the Society of Quality Assurance with an international perspective to the SQA. ■

Linking the Canadian "GXP" Community through our own Website

CCSQA/FCSQA Website

Development of Chapter Website

CCSQA (by Deborah Dragoon)

It was recognized early in the planning of the CCSQA that the best forum for creating a Canadian GXP regulatory community was to use the available electronic media (e.g. teleconference, web conferences, websites). This is particularly true with the Canadian Chapter due to the large geographic area covered and the regional interests (i.e. pharmaceutical research and manufacturing across Canada and field studies primarily in western

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Canada). The Website will be used to allow members to post requests and suggestions to the board, provide useful Canadian and International regulatory links and to keep the members informed of Chapter activities. The regional chapter welcomes any contributions of educational committee initiatives that can be posted in the website to assist your colleagues in the GXP community. The home page has the graphic listed (refer to Newsletter header). Be sure to visit the website http:\\www.ccsqa.org. We encourage you to provide content and suggestions. ■

Electronic Record Update (US-FDA Guidelines)

Part 11 Notes

CCSQA (by Andrew Finnie)

FDA has issued Guidance for Industry: General Principles of Software Validation; Final Guidance for Industry and FDA Staff. It was issued jointly by the Center for Devices and Radiological Health (CDRH) and Center for Biologics Evaluation and Research (CBER). It supercedes the previous document "General Principles of Software Validation", from June 1997.

General Principles of Software Validation is a draft guidance for industry published by the Center for Devices and Radiological Health in June, 1997.

The Environmental Protection Agency has published a proposed rule for managing electronic reporting and records. It is called Cross Media Electronic Reporting and Record-Keeping Rule, or CROMERRR. A copy of the rule is available at this link. More can be found at the EPA's Central Data Exchange web page.

FDA has established six dockets for managing development and publishing of guidance documents on 21 CFR Part 11. In late September 2001 a draft guidance was published in two of the dockets. It included a (Glossary of Terms (00D-1543)) and guidance for (Validation (00D-1538)). Guidance for timestamps was published in March 2002 (Timestamps (00D-1542)). The other three dockets address Retention of Electronic Records (00D-1539), Electronic Copies of Electronic Records (00D-1540) and Audit Trails (00D-1541).

The ESIGN Commerce Act was signed into law. Read the details of the Electronic Signatures In Global and National Commerce Act to see how electronic signatures may now be used legally based on federal law.

In a presentation late in Fall, 1999, Greg Brolund of CDER described CDER's 21 CFR Part 11 Implementation Study to analyze issues raised by industry, FDA inspectors and software companies. The study was conducted at the direction of Janet Woodcock and contains some interesting recommendations.

CDER has introduced an Electronic Regulatory Submissions and Review (ERSR) web page. It contains information about their program to enable the electronic submission of regulatory information to the Center and the review of it by CDER staff.

Paul N. D'Eramo and Rory Budihandojo published Computer Validation: Available Document Resources from FDA in the March, 1999, issue of Pharmaceutical Technology. It gives an excellent and complete listing of validation documentation, guidance and presentations published by FDA, including information on 21 CFR Part 11. The net version of the article has links directly to the FDA's website. In September, 1999, the authors collaborated with Sal Amato, Steve Baldwin, Jack

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Brinnier, Udo Gorsch, Grant Hodgkins, Ludwig Huber, and Graham Tinsley to create Computer Validation Resources Available on the Internet- Non-FDA Sources as a supplement to the original work.

A lawsuit (*Public Citizen, et. al., v. John Carlin, et. al., Civil Action No. 96-2840*) against the National Archives and Records Administration (NARA) is influencing the governments view of electronic records. A court decision originally forced NARA to require government agencies to submit electronic records for word processing and email rather than accepting printed paper copies. To manage this process, NARA formed the Electronic Records Work Group. However, NARA has successfully appealed the decision. See the details on this ruling at: US Court of Appeals Decision and Archivist Statement on US Court of Appeals Decision.

Electronic Records; Electronic Signatures (21 CFR Part 11) links to an FDA web page that contains documents produced by the agency over the time that the rule evolved. One of the documents is the rule itself, which became effective on August 20, 1997. FDA also published a Compliance Policy Guide on May 13, 1999, "which represents the agency's current thinking on what is required to be fully compliant with 21 CFR Part 11."

Computerized Systems Used in Clinical Trials is guidance for industry published in April, 1999, and includes discussion of requirements for use of electronic records and electronic signatures with clinical computer systems.

Regulatory Submissions in Electronic Format; General Considerations and Regulatory Submissions in Electronic Format; New Drug Applications were released on January 27, 1999, as guidance to assist with making regulatory submissions in electronic format to CDER and CBER.

Guidance for Industry: Providing Regulatory Submissions to CDER in Electronic Format - Investigational New Drug Application (INDS) march 2002.

Guidance for Industry: Preparing Data for Electronic Submission in ANDAs was published in September, 1999, by CDER's Office of Generic Drugs. Although OGD does not have a comprehensive electronic submission process yet, this guidance describes a process that allows the submission of some types of data and certain text information in electronic format.

To help sponsors follow guidance documents, FDA has posted an example of an Electronic New Drug Application Submission. FDA also has established an email address, esub@cder.fda.gov, for sponsors who have questions about guidance and the example electronic NDA.

Security and Electronic Signature Standards; Proposed Rule (45 CFR Part 142) was a Health and Human Services proposal for standards around security of individual health records and use of electronic signatures by health plans and providers. The final rule was published with substantial changes as a portion of 45 CFR Part 160 and 164. See more information at this link.

Docket 92S-0251 - Electronic Submissions is an electronic docket established by FDA to list the types of submissions that are acceptable in electronic form.

The Current Codified CGMP Regulations, 21 CFR Parts 210 and 211 are the GMP's, which can be very handy to search for specific types of information in the regulation.

Good Laboratory Practice for Nonclinical Laboratory Studies, 21 CFR Part 58 are the GLP's.

Current Good Manufacturing Practice (CGMP) Final Rule, 21 CFR Parts 808, 812 and 820; Quality System Regulation for Medical Devices are updated

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regulations with emphasis on added design controls and quality systems.

Human Drug CGMP Notes are published quarterly within FDA to distribute information about issues on human use pharmaceuticals manufacturing practices. It includes a section at the end called "Toward the Electronic Government", which often features issues around the ESig Rule. ■

New Health Canada Regulation for the Conduct of all Clinical Trials

HPFB (Health Products and Food Branch) Inspectorate

CCSQA (by Shelley Antel)

- Implementation of the inspection component of this inspection strategy started January 2002. Activities related to investigations will be performed as needed.
- Implementation of inspections is in two phases:
  - January 2002 - voluntary phase
  - January 2003 – final phase with selection of sites for inspection by Inspectorate, in consultation with TPD and BGTD
- Inspections can be made anywhere clinical data is being generated including Sponsors, CRO, Site Management Organizations and Qualified investigators
- Two key elements of the Inspection Strategy:
  - Protection of subjects/patients enrolled in clinical trials
  - Validation of data submitted to evaluation Directorates (TPD and BGTD)
- Assessment of compliance will be performed according to GCP as outlined in the new Division 5 of the Food and Drug Regulations
- Inspection Strategy for Clinical trials can be found on www.hc-sc.gc.ca/hpfb-dgpsa/inspectorate

Clinical Trail Review and Approval

- IND review process includes Clinical Trial Review and Approval (1997), ICH adopted guidelines including the GCP Consolidated Guidelines and TPD guidelines for studying of special populations (women, children, etc.)
- New regulatory framework (C.05.006(1)(b)) effective September 1, 2001 includes:
  - 30 day default review period for clinical trial applications
  - 7 day target for bioequivalence and appropriate Phase 1 clinical trial applications (policy statement)
  - framework for inspection program for all clinical trials against generally accepted principles of Good Clinical Practices
- Topics include:
  - Definition of Research Ethics Boards (C.05.001)
  - Qualified Investigators (C.05.001)
  - Sponsor Obligations (C.05.010)
  - Suspension and Cancellations (C.05.16)
- Guidance documents found on the TPP website; www.hc-sc.gc.ca/hpb-dgps/therapeut/htmleng/draft_guide_industry.html. These are Regulations Amending the Food and Drug Regulations (1024 Clinical Trials) Division 5, Drugs for Clinical Trials Involving Human Participants. ■

What's In It For Americans (WIIFA)

CCSQA (by Deborah Dragoon)

If your company does business in Canada either to market in Canada or to research in Canada you can benefit:

- Interact with other QA professionals in your discipline
- Learn about Canadian regulations
- Interact with personnel outside your scope (GLP, GCP, GMP, EPA, FDA, OECD)
- Share perspectives on changes to the regulations
- Keep abreast with the current regulations and upcoming changes
- Utilize the CCSQA Web Page (Coming Attraction)
- Utilize the CCSQA for Questions and Answers
- Networking, networking, networking

Join today! ■

CCSQA Board Member Biographies

Paul Sidney, B.Sc., - CCSQA President

Paul is the Director, QA & Support Services of CTBR, Senneville, Quebec, Canada. Managing a QA group which supports a laboratory conducting GLP research for submission to regulatory authorities throughout North America, Europe and Japan has afforded Paul a broad experience in the practical application of GLP regulations in a pre-clinical research facility. Paul is an Active Member of the SQA, RQAP, ISQA, American Society of Quality Control and Regulatory Affairs Professional Society. ■

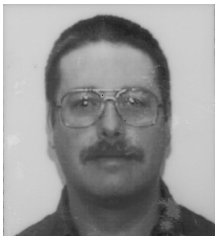
Keith Burch - CCSQA Vice-President

Keith is a Technical Agrologist and QA Officer with ICMS Inc. in Portage la Prairie, Manitoba. As Vice President of the newly formed CCSQA, Keith will bring information and issues to the membership as the education committee chairperson.■

Anne Beaubien - CCSQA Director

Anne has worked in the QA GLP division of an analytical lab since 1991. Anne began work in the lab as an analyst before moving on to the QA division. This background helps in the auditing/QA process. As well as auditing final reports and in-phase audits for the lab, Anne has also done field auditing which has given her a rounded view of the process. Anne's area of expertise includes EPA FIFRA & OECD GLP regulations. Anne is presently expanding her knowledge to include GMP.■

Andrew (Drew) Finnie, BA - CCSQA Director



Drew is the Systems Manager at McDougall Scientific Ltd., Toronto, ON. Drew is responsible for the day-to-day management of the company corporate network. Drew also establishes and maintains validation programs for all computer systems, and provides 21CFR11 information to company staff (training classes and periodic briefings of FDA updates and clarifications of 21CFR11 issues). Drew hopes to enhance the Education Committee by highlighting the 21CFR11 regulation regarding computer systems and electronic files in the form of teleconferences, evening seminars and educational material.■

Deborah L. Dragoon - CCSQA Director

Deborah is a Senior Research Auditor, Wyeth-Ayerst Research - 15 years. Experienced in Toxicology and Computer Validation. Deborah has been an Active Member of the SQA since 1993.■

Linda Kraft, RN, CCRA - CCSQA Director

Linda was a Registered Nurse for 10 years prior to entering the field of Research, as a Clinical Research Coordinator with expertise in phase I-III pneumonia, influenza and oncology trials. Linda entered the pharmaceutical industry working as a Clinical Research Associate for Eli Lilly in the UK and then CroMedica in Ottawa as a Project Manager. In 2000, Linda moved into the QA Department where she is responsible for promoting Quality Assurance, fielding GCP questions/issues, preparing GCP workshops, as well as reviewing and drafting SOPs while assisting with Sponsor Audits and internal process audits. Linda is a Member of the SQA and a member of the Association of Clinical Research Professionals. She is certified as a Clinical Research Associate.■

Janine Johnson, B.Sc. (Agr.) - CCSQA Secretary

Janine is a QA Specialist for Cato Research Canada in Montreal, Quebec. GLP auditor for FDA, OECD, JMHW, EPA, and JMAFF regulated laboratory toxicology studies for 8 years; and GCP auditor for FDA and ICH regulated studies for 2 years. One year experience as Food Residue Evaluation Scientist for the PMRA. Active Member of the SQA since 1999 and Registered Quality Assurance Professional-GLP since 1997. As the CCSQA Secretary, and membership committee chair, Janine hopes to keep everyone motivated and focused on the task at hand, i.e., provide current and accurate information and services to our members.■

Shelley Antel - CCSQA Treasurer

Shelley is the Quality Assurance Manager, on-site auditor, and training coordinator for Hill Top Research, Inc. in Winnipeg, Manitoba, Canada. Shelley conducts study audits and facility audits at numerous clinical research sites throughout the US, Canada and the UK in FDA:GCP and ICH and FDA and EPA GLPs environments. She has developed and delivers training modules in clinical quality assurance and regulatory issues. As an Active Member of the SQA for over 5 years, Shelley is interested in seeing a network develop in Canada for QA professionals, "I see the CCSQA as a forum for learning and sharing information on Canadian Regulatory issues".■

Web Sites

Recent Canadian Government initiatives can be located on the following web sites:

Health Canada

■ Good Manufacturing Practices

- Natural Health Products Directorate

+ "Draft - Guidance Document Good Manufacturing Practices for Natural Health Products" www.hc-sc.gc.ca/hpb/onhp/gmp_guide_e.html

+ "GMP Information Workshop Schedule"

- Health Products and Food Branch Inspectorate (HPFB)

+ "PIC/S - Pharmaceutical Inspection Co-operation Scheme" www.hc_sc.gc.ca/hpfb/inspectorate/pics_co_operation_scheme_e.html

+ "Guide-0023: Risk Classification of GMP Observations (Draft for Comments)" www.hc_sc.gc.ca/hpfb/inspectorate/gui_0023_risk_class_gmp_obs_tc_e.html

+ "Site Reference Guideline" www.hc-sc.gc.ca/hpfb/inspectorate/srf_tc_e.html

+ "Good Manufacturing Practices Guidelines 2002 Edition" www.hc-sc.gc.ca/hpfb/inspectorate/gmp_guidelines_2002_tc_e.html

+ "Modification to Good Manufacturing Practices (GMP) Guidelines 2002 Edition" www.hc-sc.gc.cs/hpfb/inspectorate/02_108159_446_tc_e.html

■ Food Program

+ "Novel Food and Ingredients" www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_novel_foods_and_ingredient.html

+ "Novel Foods and Ingredients - Frequently Asked Questions" www.hc-sc.gc.ca/food-aliment/mh-dm/ofb-bba/nfi-ani/e_faq_1.html

■ Electronic Record

- Health Products and Food Branch Inspectorate

+ "Good Practices for Computerized Systems in Regulated "GxP" Environments - Draft - Pharmaceutical Inspection Co-operation Scheme (PIC/S) Guidance" www.hc-sc.gc.ca/hpfb/inspectorate/goodprac_comp_syst_pics_tc_e.html

■ Biotechnology

- Canadian Food Inspection Agency Office of Biotechnology

+ "Regulation of Biotechnology in Canada" www.inspection.gc.ca/english/ppc/biotech/bioteche.shtml

- Health Products and Food Branch Inspectorate

+ "Biologics and Genetic Therapies; Information Kit" www.hc-sc.gc.ca/hpfb-dgpsa/bgtg-dpbt/info_kit_e.html

+ "Draft Issue Analysis Summary on the Regulatory Framework for Positron-Emitting Radiopharmaceuticals" www.hc-sc.gc.ca/hpfb-dgpsa/bgtd-dpbtg/per_dias_tc_e.html

■ New Substances Notification

"Guide to New Substances Notification for Products Regulated Under the Food and Drug Acts" www.hc-sc.gc.ca/ear-ree/guide_new_sub_e.html

■ Pest Management Regulatory Agency

+ "The PMRA Initiative for Reduced-Risk Pesticides" (http://www.hc-sc.gc.ca/pmra-arla/english/pubs/jrupdates-e.html)■

SQA and CCSQA Calendar of Upcoming Events

■Part II E-Record Evening Seminar

End of August

Speaker: Industry expert TBD

■Canadian Inspection Strategy for Clinical Trials

End of August

Marianne Vanderwel, Pfizer Canada, Inc.
Marianne Vanderwel is the Associate Director of Standards in the Medical Division of Pfizer Canada Inc. In 1987, after 9 years of academic research, she moved to the healthcare industry. Marianne has specialized in the area of clinical quality assurance during the past 9 years.

In her current position of Pfizer Canada Inc., Marianne facilitates the adoption of the best effective medical and regulatory processes. She extends this role of promoting quality to the clinical research community outside of Pfizer by actively participating in industry and academic collaborations. Marianne chairs the Clinical Research Practices and Ethics Committee of the industry trade association, R&D, and is a member of the Canadian Institute of Health Research (CIHR) Standing Committee on Ethics.

■**PDF Presentation** will be forwarded to participants with only the cost of the conference call required. ■

Comments & Contributions

Please forward any comments or contributions for the CCSQA Newsletter to Janine Johnson (jjohnson@cato.com):

■ Environmental Research issues.

■ GLP/GCP contributions.

■ Regulatory questions.

■ Corporate Sponsors.

■ Upcoming events. ■