Northern Highlights

Newsletter of the New England Regional Chapter of the Society of Quality Assurance

Volume 5 - Issue Number 7 **September 2002**

From the Desk of Kathy V.

By Kathy Vanderhoof

NERCSQA President 2002

Greetings NERCSQA Members! I know it was a real treat for those of you, who were able to attend the NERCSQA Summer Meeting, "**Part 10 _ Reaching for Part 11,**" held at Abbott Bioresearch Center, Worcester, MA. The meeting covered gap analysis, vendor assessment for part 11 compliance and recent enforcement activities by the FDA on 21 CFR Part 11. The presenters were Jane Snell, QA Validation Specialist from Charles River Discovery & Development; Kathleen Francis, Associate Director of Corporate Quality Assurance from Biogen; and Ron Armstrong, Computer Systems Compliance Auditor from Boehringer Ingelheim Pharmaceuticals, Inc. The meeting received rave reviews on the meeting evaluation forms. Once again, kudos to Linda Chin and the Program Committee.

Summer's now winding down and autumn will soon be upon us, bringing with it fresher, crisper air and the start of school for many. For NERCSQA, autumn is also an exciting time. Some of us will have the opportunity to attend the SQA 18th Annual Meeting in Albuquerque.

For those who can't attend, the NERCSQA Program Committee is already cooking up a great meeting on "Ethics" for November. The meeting will be held at 1:00 PM on November 6th at the Doubletree Hotel in Waltham. Presentations will be given by Kim Watson, QA, Stone Environmental Engineering and Gary Cohen, General Counsel, Millennium Pharmaceuticals. Our Annual Member's Meeting will follow the presentations. This is your chance to hear what goes on behind the scenes as the Board members present their Annual Reports. The Member's Meeting will be followed by our third annual Member's Social. Enjoy a drink and some hot hors d'ouevres as you mingle and network with fellow members.

The Nominating Committee, chaired by Joan Covino, is also busy, beginning to prepare for the November elections. There are three positions, that need to be filled.

- Vice President (a 3 year commitment including 1 year as Vice President, 1 year as President and 1 year as Past President/Historian)
- Secretary (a 2 year commitment)
- Board Member (a 2 year commitment)

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INSIDE

2002 NERCSQA Board Members

President
Kath Vanderhoof (508) 890-0227

Past President / Historian
Richard Streeton (508) 890-0229

Vice President
Linda Chin (508) 849-2853

Secretary
Deb Glancy (617) 679-7476

Treasurer
Sharon Mercado (860) 715-1052

Directors
Joan Covino (781) 279-4519
Paul Callahan (978) 658-6000
Aimee Conlan (860) 674-6482

Northern Highlights

would like to thank all of the people who contributed articles to this edition of our newsletter!

- **Joan Covino**
- **Chris Lautz**
- **Kathy Vanderhoof**

Our next issue is scheduled for December 2002. Submissions for the next issue will be accepted through November15th. Please send to:

Sharon Mercado
Pfizer, Inc.
Mailed MS 9120-26 (Bldg. 126)
Eastern Point Road, Groton, CT 06340
Phone (860)715-1052
Fax (860)441-0515

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New England Regional Chapter
Society of Quality Assurance

For their continued dedication and ongoing support NERCSQA wishes to honor

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From the Desk of Kathy V.

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If you are interested in running for office, or in nominating someone, please contact Joan Covino.

As always, I'm encouraging you to become involved. If you want to affect the types of meetings we have, contact Linda Chin, our Program Committee Chair. If you are a people-person, and would like to see our organization grow, contact Aimee Conlan, our Membership Committee Chair. Above all, thanks for being a member.

-Kathy V.

NERCSQA Nominating Committee News

By Joan Covino
Nominating Committee Chairperson

The NERCSQA Board has the following positions open effective January 1, 2003:

Vice President * (3 yr. Commitment): 1st as Vice President
2nd as President;
3rd as Past President/Historian

- **Secretary** * (2 yr. Term)
- **Director** (2 yr. Term)

*Officers must also be SQA members in good standing.

Position descriptions are detailed on our website: www.nercsqa.org
Just click on the "Officers" button to read about these exciting board opportunities! If you are interested in any of these roles (yes, we do accept self-nominations), or if you have a member in mind that "fits the bill," please contact any member of the Nominating Committee **no later than September 15, 2002**:

Judy Andrews
617.576.0900 x.231
jandrews@cytologix.com

Mary Donohoe
508.890.0257
mary.donohoe@primedica.com

Joan Covino (Chair)
781.279.4519
jcovino@strategicqualityconsulting.com

Gordon Schnaper
978.851.5052
gorschn58@attbi.com

Elections are in November 2002: watch your mail for ballots and please vote early!

Member's Spotlight

Do you know of any NERCSQA member's personal or professional achievements? Let us know so we can spotlight them in our next newsletter. Please forward to:

Sharon Mercado
Pfizer, Inc.
Bldg 126 MS 9126-20
Eastern Point Rd
Groton, CT 06340

email:
sharon_r_mercado@groton.pfizer.com

Boston Section of the American Society for Quality (ASQ)

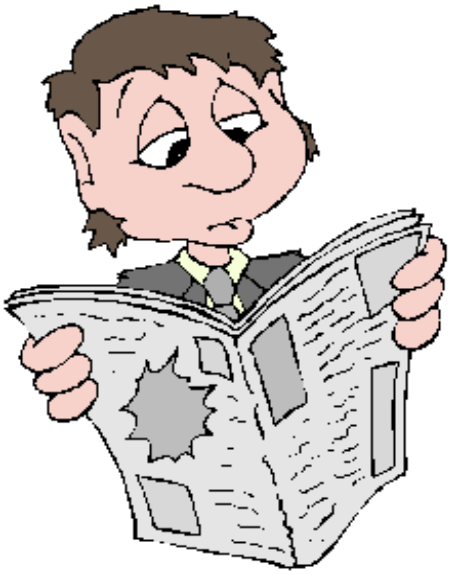
Submitted by: Joan Covino

CALL FOR PAPERS

The Boston Section of the American Society for Quality (ASQ) is soliciting papers for its 23rd Annual Boston Quality Conference: **BOSCON 2003 – "Quality: The Common Denominator."** The one-day event will be held on Thursday, April 10, 2003 in Burlington, MA. **Deadline for submissions is November 2, 2002.** Please access the link below for specific information:

www.asqboston.org/BOSCON/callfor papers.html

Place an ad in our classified section!



Making Strides Against Breast Cancer Walk

Submitted by: Joan Covino

Please Help "Make Strides" on Sunday, October 6th

WHAT/WHERE: 10th Anniversary Making Strides Against Breast Cancer Walk (raising awareness and funds for the fight against breast cancer)…5 miles along the Charles River in Boston

WHEN: October 6, 2002 - registration/rolling start 8am-10am (rain or shine)

CONTACT: Joan Covino…to contribute as a sponsor or to join her walking team.

Phone: 781.279.4519;
E-mail: jcovino@strategicqualityconsulting.com

THANK YOU FOR YOUR SUPPORT!

FDA CVM's

Phased Submissions

Submitted By: Chris Lautz

Taken from Center for Veterinary Medicine (CVM); Document and Submission Information; An Update Nov 1995

A sponsor may submit individual completed technical sections (such as target animal safety, effectiveness, human food safety, freedom of information (FOI), and labeling) for "phased review" under the Investigational New Animal Drug (INAD), or the entire requirements for approval may be provided in one submission as an New Animal Drug Application (NADA).

Direct Review was instituted within the Office of New Animal Drug Evaluation (ONADE) on Nov 11, 1994. This policy allows submissions containing technical information, not part of a pending application, to be reviewed and administered by the reviewer responsible for the technical evaluation. Previously, all submissions were funneled into the center through a "primary" reviewer who coordinated the Center's interaction with, and responses to, the sponsor. This person was responsible for the administration of the document file and, in a manner similar to a project manager, saw everything associated with the drug during data development.

Now, if the submission contains data that relate to only one technical section and therefore, can be evaluated by one Division, then the reviewer within that Division will also assume all administrative responsibilities associated with the submission. To qualify for this streamlined review policy, the submission must be limited to one technical section so it can be administered and reviewed by one review organization. Because there will be no one person in charge of the project in CVM until the NADA is filed, the sponsor is responsible for ensuring all technical sections are compatible and support the approval of the same drug product.

An INAD request is the initial request by a sponsor, as per 21 CFR 511.1(b) to open an Investigational New Animal Drug file. Before a sponsor can ship or receive an investigational drug for use in a clinical trial, the sponsor must first have an INAD file and an assigned file number. Shipments (or receipt) of an investigational drug for clinical studies must be reported to CVM in a "Notice of Claimed Investigational Exemption for a New Animal Drug" (Form 3458). In addition to reporting shipment of investigational drugs, the file routinely contains other required administrative information, including sponsor's requests for authorization to slaughter treated animals for human food, reporting slaughter and final disposition of animals, and minutes of meetings.

An NADA is established with the submission of a completed FDA Form 356V and all required information and data to support the conditions of use requested for the drug. The Original NADA is the initial submission of the application and is regulated by 21 CFR 514. The application must address all applicable sections of Form 356V and 21 CFR 514.1(b) and contain complete information supporting all technical sections, labeling, FOI Summary, and Environmental Assessment (ES).

The phased review submission policy is defined in the Center's Policy & Procedures Manual (1240.3040) and commits the Center to review appropriate technical sections or useful pieces of technical sections to enhance the efficiency of the drug development policy. Six technical sections are currently recognized by the Center. The sections are: Effectiveness; Environmental Safety; Manufacturing Methods and Controls; Public Safety; Residue Chemistry and Regulatory

An administrative NADA is a compilation of NADA-level decisions regarding technical sections submitted under an INAD. It provokes no consultative reviews, but rather proceeds to the preparation of the approval package and to its administrative review at the level of the primary division, office, and general counsel. So a phased Methods; and Target Animal Safety. Each submission of data for review to the INAD file should be accompanied by a debarment statement, an affirmative statement attesting to the truth and completeness of the submission (the language on the current 365V

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Next NERCSQA Training

WHEN: Wednesday, November 6th
***WHERE*:** Doubletree Hotel
Waltham, MA
TIME: **1:00 - 4:00 PM**
Presentations
Speakers: **Kim Watson**
QA, Stone Environmental Engineering
Gary Cohen
General Counsel, Millennium Pharmaceuticals

4:00 - 5:00 PM
Member's Meeting
5:00 - 6:00 PM
Annual Member's Social

More details coming soon!!!

FDA CVM's Phased Submissions

Continued From Page 5

will meet this requirement), and any necessary supporting information such as the applicable portions of the labeling, FOI Summary, or EA. Each submission should be limited to one technical section, but bundling of multiple studies supporting a single technical section is encouraged.filing done under the INAD would result in a technical section complete letter for each section. Then an administrative NADA is submitted to complete the submission process.

An administrative NADA provides all necessary portions of an NADA by adequately identifying the nature of the application, by providing a bridge to INAD's, and by documenting prior CVM commitments regarding the acceptability of technical sections. The bridge to INAD's is provided as a list of references as described under Section 2(ii)(e) of the 356V, and by providing a regulatory chronology for each of the technical sections, including copies of "complete letters".

The regulatory chronology or "road-map" is intended to provide a bridge, which links data submitted under an INAD to a "technical section complete" decision cited in the administrative NADA. It is intended to provide a brief record of the pertinent submissions and correspondences leading up to the completion of each technical section. The regulatory chronologies are included for completeness of the NADA file, to facilitate administrative review, and for future reference to the file.

Documentation of CVM's pre-NADA commitments regarding the acceptability of individual technical sections is provided by including of a copy of the technical section complete letters for all pertinent technical sections.

So the intent of the phased filing of technical sections under an INAD is to shorten the review time of an NADA by allowing technical section reviews, which lead to NADA level decisions before the actual submission of an NADA. Submissions for human pharmaceuticals do not have the phased filing option under an Investigational New Drug (IND).

WELCOME NEW MEMBERS!

Shaun Kenny
Gel Tex Pharmaceuticals

Christine Shoemaker
Harvard Clinical Research Institute

Rhonda Fendelet
Pharm Eco, A Johnson Mathhey Co.

Ellen Bellantoni

Christine Jacobs

Randall Porcella

Ken Eglinton
Waters Corporation

Arthur Ramos
Waters Corporation

Tracy Tibedo
Waters Corporation

Heidi Welch
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Carole Acombe
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Classified Ad Special!

All prepaid classified ads submited for publicatiom in our newsletter, Northern Highlights, will receive 3 months of FREE advertising on the NERCSQA website.

Check out the NERCSQA website at:

www.nercsqa.org

MEMBERSHIP INFORMATION

To become a member of the New England Regional Chapter of the Society of Quality Assurance, please contact:

Deb Glancy
NERCSQA Secretary
C/O Millenium Pharmaceuticals., Inc
640 Memorial Drive
Cambridge, MA 02139.

FDA Unveils New Initiative To Enhance Pharmaceutical Good Manufacturing Practices

The Food and Drug Administration (FDA) today announced that it is undertaking a significant new initiative to enhance the regulation of pharmaceutical manufacturing and product quality and to bring a 21st century focus to this FDA responsibility.

The initiative focuses on FDA's current good manufacturing practice (cGMP) program and will cover veterinary and human drugs, including human biological drug products such as vaccines.

"Americans expect that their medicines will be of the highest quality, and assuring that quality is one of FDA's core missions," said FDA Deputy Commissioner Dr. Lester M. Crawford. "FDA's regulatory and quality control systems for pharmaceutical products have become a gold standard for the world, and we Americans should be proud that the quality of the medicines we have available to us and our animals is second to none. Any system can be improved upon, however, and with this risk-based, highly integrative cGMP initiative we intend to do just that. We know we can make even a very good system better. Publicizing today this blueprint for action is just the first step."

This initiative is designed to improve public health promotion and protection by focusing on three major goals that will augment FDA's pharmaceutical product quality assurance programs across the board.

The first goal will be to enhance the focus of the agency's cGMP requirements more squarely on potential risks to public health, by providing additional regulatory attention and agency resources on those aspects of manufacturing that pose the greatest potential risk.

The second goal will be to help ensure that FDA's essential work in establishing and enforcing pharmaceutical product quality standards does not impede innovation and the introduction of new manufacturing technologies in the pharmaceutical industry.

The third goal will be enhancing the consistency and predictability of FDA's approach to assuring production quality and safety among the FDA's centers and field components.

FDA cannot accomplish these goals alone. Given the global nature of pharmaceutical production today, FDA fully intends to undertake this initiative in close concert and consultation with its regulatory counterparts internationally. In addition, the success of this initiative is strongly dependent on active participation and input from manufacturing quality control experts from industry, academia, government, and consumer groups, and FDA will be actively soliciting such participation as the initiative progresses.

More than 40 years ago, Congress instructed FDA to require that all drugs be produced according to current good manufacturing practice. This requirement came in response to significant concerns about substandard drug manufacturing practices at that time, and it brought modern quality assurance and control principles to drug manufacturing. In announcing this cGMP initiative, Dr. Crawford emphasized that it will be overseen by a steering committee that includes representatives from all the affected FDA centers: the Office of Regulatory Affairs, the Center for Drug Evaluation and Research, the Center for Biologics Evaluation and Research, the Center for Veterinary Medicine, and the Office of the Commissioner. He noted in addition that this task will be driven by the latest science and technology and will strengthen the public health protection achieved by FDA's regulation of pharmaceutical manufacturing. He added that FDA remains committed to strong enforcement of the existing regulatory requirements, even as we are examining and revising our approach to these programs. He also pointed out that this work may take time - potentially up to two years, or more, for certain aspects of this initiative.

Press Release from the FDA News at www.fda.gov.

CLASSIFIEDS - JOB OPENINGS

Manager, Quality Assurance

The Cardiovascular Research Foundation ("CRF"), a world-renowned, NYC-based organization specializing in cardiovascular research and education, is seeking a Manager of Quality Assurance (QA). The individual in this role will be responsible for developing, implementing and maintaining quality assurance systems and activities in compliance with in-house specifications and FDA regulations, including Good Clinical Practice (GCP) guidelines. This position reports to the President of CRF.

Responsibilities:

- Formulate and implement QA policies and programs applicable to all CRF research departments (independent laboratories and data coordinating center).
- Research, interpret and integrate current governmental regulations and GCP requirements into CRF's QA procedures and Standard Operating Procedures (SOP's).
- Provide guidance and training to research department managers and staff in order to achieve goals related to QA policies and programs.
- Insure Information Technology (IT) systems are in compliance with the QA needs of the research departments. This includes hardware, software, validation, documentation and specifications.
- Develop and implement QA in-house audit plans, including validation and computer system audits.
- Coordinate and oversee all sponsor and FDA audits of the research departments.
- Respond to audit requests, perform risk assessments and devise corrective action plans, and communicate these recommendations to senior management. Insure resolution of compliance issues with good follow-up.
- Organize a budget for the development of QA policies and procedures, while monitoring expenditures.

Requirements:

- Bachelors or Masters degree in Life Sciences or equivalent.
- Minimum 7 to 10 years quality assurance experience in the pharmaceutical/biotechnology industry is required, with an emphasis on clinical research. Supervisory experience essential.
- A thorough understanding of the audit process and current GCP regulations. Knowledge of FDA regulations a plus.
- Excellent written and oral communication and presentation skills.
- Ability to persuade and motivate others, while working as a collaborative team.

For this position, CRF will offer an excellent salary and benefits package.

To apply, please send your resume, including salary expectations and start date availability, to the Director of Human Resources, fax (212) 434-6353.

For more information about CRF visit our website **www.crf.org**

CARDIOVASCULAR RESEARCH FOUNDATION

Submit advertisements for publication in the NERCSQA newsletter to:

Sharon Mercado
Pfizer, Inc.
Mailcode 9126-26 (Bldg. 126)
Eastern Point Road
Groton, CT 06340
Fax number:
(860) 441-0515
on line at:
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$30 for the first inch and $15 for each additional inch

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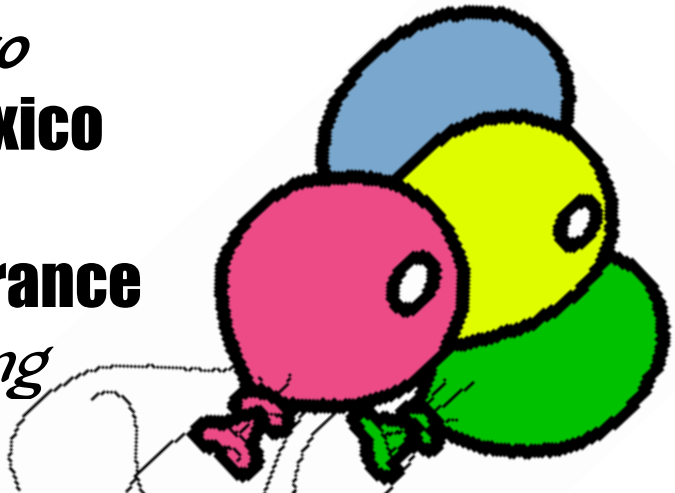
Up, Up and Away to
Albuquerque, New Mexico
for the
Society of Quality Assurance
18th Annual Meeting



Don't forget to stop by the exhibit area and check out our chapter's poster board.

See you there!