Northern Highlights

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

Volume 6 - Issue Number 9 **MARCH 2003**

President's Message

Linda Chin
NERCSQA President 2003

Greetings to all our new and returning NERCSQA members. The new year is well under way as are the activities of our newly elected Board Members and Committee Chairs.

As documented in our Mission Statement, the New England Regional Chapter of the Society of Quality Assurance was organized to serve as a focal point for Quality Assurance "GXP" professionals in the New England Region by establishing a forum for education, training, communication and information exchange among QA professionals in the environmental, pharmaceutical and biotechnology fields of government, private industry, research and academia.

To this end each successive Board has built upon and improved the programs and benefits created for our membership. The newly formatted website and the NERCSQA newsletter are two very important forums for education and communication within our Chapter.

Our Webmaster, **Donna Stegner** has done a terrific job of spicing up our website and providing a tool for the membership to find out about Chapter events, interact with other members in the Q&A forum, investigate new career opportunities in the Career Center or use the advertising space on the site to recruit new employees.

The NERCSQA newsletter, under the leadership of **Sharon Mercado**, is another forum for members to voice issues, present new ideas and communicate with the Chapter membership. The challenge is going out to each member to prepare an article for the newsletter sharing your expertise in a particular area, summarizing a seminar that you have recently attended or perhaps discussing an issue that you are particularly concerned about within the Regulatory arena. Please contact Sharon regarding the submission of articles.

The vitality of an organization is reflected in the growth of its membership. We must nurture our existing membership involvement for continued success while also looking for initiatives to attract new members. There is a large untapped pool of QA professionals in the New England Region, specifically in the area of the GMPs that we have yet to reach and we are

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SQA Publication Policy

"The information contained herein are the opinions of the authors but not necessarily the opinions of the society of quality assurance (SQA). The information document may not be reprinted without the approval of the author."

2002 NERCSQA Board Members

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Past President / Historian
Kath Vanderhoof (508) 890-0227

Vice President
Sharon Mercado (860) 715-1052

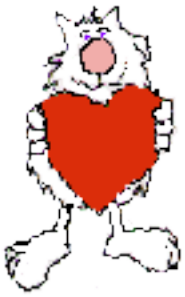
Secretary
April Brunelle (860) 715-3204

Treasurer
Paul Callahan (978) 658-6000

Directors
Aimee Conlan (860) 674-6482
Mary Ellen Streeton (781) 795-4222
Tracy Tibedo (508) 482-6238

Northern Highlights

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



- **Gene Burnett**
- **Lina Chin**
- **Aimee Conlan**
- **Chris Lautz**
- **Sharon Mercado**

Our next issue is scheduled for June 2003. Submissions for the next issue will be accepted through May 15th. Please send to:

Sharon Mercado
Pfizer, Inc.
Eastern Point Road,MS 9126-20
Groton, CT 06340
Phone (860)715-1052
Fax (860)441-0515

NERCSQA PROGRAM COMMITTE UPDATE

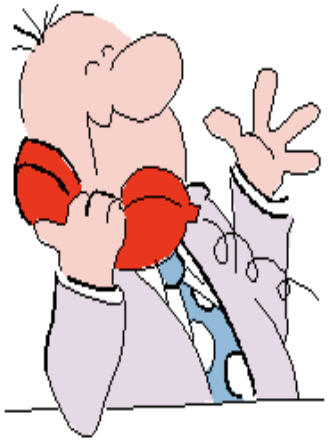
By Sharon Mercado

Currently the program committee is finalizing last minute details for the upcoming spring training to be held on Wednesday, April 30th in Hartford, Connecticut. The topics for the spring training are "Current FDA Computer Validation activities including the new Part 11 Guidance Document". and "Data Security including network security, backups, archiving and contingency planning". In addition, Jeff Cummings, the SQA treasurer, will also give a quick update of what's happening at SQA. Watch for the training flyer in the mail, and take advantage of the $10 discount for prepaid registrations postmarked by April 15th.

Planning is underway for our June training.The 2nd training will be held somewhere in Rhode Island on Thursday, June 19th (tentative). We hope to offer a full day training, with at least one session focusing on the GMPs. If you know of anyone who would be interested in presenting or volunteering at future trainings, please contact Sharon Mercado at 860-715-1052 or sharon_r_mercado@groton.pfizer.com.

NERCSQA MEMBERSHIP COMMITTEE

By Aimme Conlan



CALL FOR IDEAS

Looking for a fun and exciting way to get involved in NERCSQA? Do you have ideas for new and innovative ways of attracting new members? Maybe you're handy with computer graphics or have a great idea for a design scheme for the membership brochure? If so, we would like to hear from you. The Membership Committee is gearing up for its second year, and plans on furthering the mission of attracting new members in order to grow and diversify the membership base. We recognize that having a diverse membership base is crucial to the mission of NERCSQA and it will be an important goal for the committee this year. We also plan on re-designing the membership brochure this year. There's much to do so if you're interested in getting involved, please contact Aimee Conlan for details (aconlan@emisphere.com).

Update from the CVM website

February 6
Registration of Food Facilities Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002. Proposed Rule, Pages 5377--5428 [FR Doc. 03-2443] The Food and Drug Administration (FDA) is proposing a regulation that would require domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA by December 12, 2003.

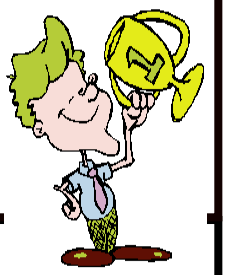
January 22
Advance notice of proposed rulemaking -- Substances Prohibited From Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed The Food and Drug Administration (we) is soliciting information and views on some potential changes to its current regulation prohibiting the use of certain proteins in ruminant animal feed. We put this regulation in place to prevent the spread through animal feed of the agent of bovine spongiform encephalopathy BSE) were it to enter the United States. In this regulation we determined that protein derived from mammalian tissues for use in ruminant feed is a food additive under the Federal Food, Drug, and Cosmetic Act (the act), and that use of certain mammalian proteins in ruminant feed causes the feed to be adulterated under the act. We are considering revising this regulation, and therefore we are asking the public for comment on certain possible modifications to the rule. This information may be used to help draft a proposed rule in the near future. DATES: Submit written or electronic comments by February 4, 2003.

CVM Names Two to Senior Posts
The Center for Veterinary Medicine has recently filled the positions of Director, Office of Research and Deputy Director of the Office of New Animal Drug Evaluation. Effective January 15, 2003, Dr. Linda Youngman accepted the position of Director, Office of Research (OR), on a permanent basis succeeding Dr. Norris Alderson. Dr. Youngman has been acting director for the past 1_ years. Dr. Bernadette Dunham joined CVM on December 16, 2002, as the new Deputy Director for the Office of New Animal Drug Evaluation (ONADE). ONADE's major responsibility is to review information submitted by drug sponsors to determine if data are adequate to support a drug's approval for marketing.

For more information go to the CVM website at http://www.fda.gov/cvm/

Christine A. Lautz
Regulatory Affairs Scientist
Veterinary Medicine Research and Development
Animal Health Group
Pfizer Inc

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

Place an ad in our classified section!

President's Message

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looking this year and beyond to focus in on reaching those potential members with new incentives and providing greater opportunities for their active involvement with the Chapter.

We need the commitment of each current member to encourage a colleague, or new networking contact, to become a member. **Aimee Conlan**, is the Chair of the Membership Committee and is also the liaison with the SQA Membership Development and Retention Committee. This partnership and exchange of ideas with SQA will provide new and creative initiatives for the expansion and retention of membership for both the National and Regional groups.

Providing the educational training seminars as mandated by our Mission Statement falls on the shoulders of the Planning Committee. The Planning Committee chaired by **Sharon Mercado** is busy coordinating the first of the three sessions planned for the year. Input from the membership is very important in determining the type of programs planned during the year. I would like to request that Members who have experience in specific GMP auditing techniques such as batch record review or investigation review think about sharing your expertise by volunteering for this Committee and possibly conducting one of these sessions. Please contact Sharon for more information

The Board this year met in January and plans to meet three more times this year. At these meetings the Minutes of the SQA Board meeting are presented and discussed, Chapter business is addressed and any issues that are felt to need input by or that may be of interest to other Chapters are tagged to be discussed at the Regional Chapter Presidents Committee Meeting which occurs once a month.

As President, I have the responsibility of sitting on the Regional Chapter Presidents Committee. This committee was started last year, is made up of all Chapter Presidents and the SQA President and meets monthly to keep each other informed of Regional Chapter and SQA activities. The goal is to exchange information on various topics and address issues that Chapters may have with lessons learned from other Chapters or best practices already established.

The Board this year so far has discussed such issues as Website content, advertising pricing and incentives in the Newsletter and on the Website, increasing Membership, defining Corporate Membership/Sponsorship benefits, revising policies and setting Committee budgets. To serve the membership, the Board needs your input and I encourage all members to write, call or e-mail myself or the other Board Members with your ideas, issues and concerns. Lets make this another year of continued growth for our Chapter.

Council on Professional Registration Report

Tammy White, RQAP-GLP
Chair, CPR
Fran Pattillo, RQAP-GLP
Chair Elect, CPR
Debra Wallace, RQAP-GLP
Secretary/Treasurer, CPR
Gene Burnett, RQAP-GLP
Past Chair, CPR

Happy (Belated) New Year! The Council on Professional Registration (CPR) welcomes the New Year, an aggressive and challenging "work" slate, and… Fran Pattillo as the Chair Elect of the CPR. Fran will work with Tammy and the rest of the CPR in 2003, then chair the CPR in 2004. We welcome Fran and look forward to working with Fran in the coming years! Thanks again to Deb Wallace and the Nominating Committee, Brian Bowman, RQAP-GLP, Carol Hoffman, RQAP-GLP, and Don Mayer, RQAP-GLP.

Sixty-one (61) quality assurance professionals sat for the 2002 GLP Quality Assurance Professional Registry Examination. The examination was administered according to the standard procedures of AMP at three test centers, Chicago, Philadelphia, and Raleigh, NC on October 13, 2002 and at the SQA National Meeting in Albuquerque, NM on October 14, 2002. The passing point for the October 2000 examination was 99 raw score units out of 150 possible points and did not change for the October 2002 administration. Raw scores were converted to scaled scores such that a raw score of 99 was equal to the minimum passing scaled score of 75 pre-established by the SQA. After final scoring was completed, score reports were generated, checked for accuracy, and mailed to candidates on November 18, 2002. Each score report included the candidate's raw score and scaled score, the minimum passing scaled score, and sub-scores by content area to facilitate candidate understanding regarding test performance strengths and weaknesses. Final results for the October 2002 examination are provided in the table below. Brief results from the 2001 exam are also presented for comparison. For additional details, please feel free to contact any CPR Officer.

Candidate Group	Total Number	Number Passing	Number Failing	Per Cent Passing
All	61	51	10	83.6
First time	56	49	7	87.5
Repeat	5	2	3	40.0
2001	51 (9 absent)	35	7	68.6

The CPR, with Headquarters assistance, has been critically reviewing and overhauling the 2003 contract with Applied Measurement Professionals, Inc. (AMP), the professional testing agency contracted by SQA to administer the examination. The CPR is ensuring that the contract is the most cost effective program for the SQA. Led by Debra Wallace, the CPR is also updating the GLP Quality Assurance Professional Registry Examination Candidate Handbook. The CPR is ensuring that the Handbook is up-to-date and additional details are being added to clarify examination eligibility requirements and re-registration criteria and procedures. The Handbook is available via the RQAP-GLP link on the SQA web site, or from AMP. The RQAP-GLP link will also be updated. Also, also… all (16) of the Council Polices is currently being reviewed and updated.

The CPR Registration Examination Committee met January 15 – 16, 2003 in Baltimore to complete the examination item review process. Tammy White, Gene Burnett, Trisha Franz, RQAP-GLP, Missy Miller, RQAP-GLP, Mary Shawgo, RQAP-GLP, and Kevin Yount, RQAP-GLP, met over the two-day period to activate OECD specific questions for incorporation in the 2003 examination. The 2003 examination will be offered Saturday, October 11, 2003 in Seattle, Chicago, and Montreal, and at the SQA Annual Meeting in Arlington, VA, on Sunday, October 12, 2003. For additional details, and an application for the examination (Candidate Handbook), please go to the RQAP-GLP site.

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Council on Professional Registration Report

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Eighteen (18) RQAP-GLP professionals' re-registration packages were processed during December 2002. Each package was reviewed and verified by two CPR Officers. Although there were no re-registration packages rejected, there were a few that had the package been a data package, or a report, it would have been returned due to inadequate documentation. Twenty-seven (27) professionals were due re-registration; thus, two-thirds renewed their quality assurance professional registration.

Pharmaceutical cGMPs for the 21st Century: A Risk-Based Approach

Progress Report of the 483 Communications Working Group

Comments on this report or on the activities of this working group should be submitted to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with Docket Number 03N-0059.

Electronic Management Comment Form: Docket 03N-0059 - Pharmaceutical Current Good Manufacturing Practices for the 21st Century: A Risk-Based Approach

The 483 Communications Working Group of the Pharmaceutical GMPs for the 21st Century Initiative was asked to determine the proper mechanism for communicating deficiencies to industry. The group reviewed FDA's process for creating and issuing the Form FDA 483 (483), assessed legal and practical requirements, interviewed internal and external stakeholders, and evaluated perceived misuse of and concerns with the 483. A conclusion was that the purpose and legal intent of the 483 as well as the Agency's process for developing and issuing it may be unclear to some inspected entities and the public. Because such perceived ambiguity may result in inaccurate conclusions about the compliance status of an inspected firm, both by the firm itself and by those seeking information through the FOI process, the group developed additional standard language to be provided to a sponsor along with the form.

We prepared the following language to be provided to the sponsor with the 483 to clarify the purpose and effect of the 483 and alert the recipient about how to object to an observation or how to bring new information to FDA's attention:

"This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above."

This language will also be added to FDA's website where any 483s and warning letters are posted. The disclaimer will clarify the purpose and scope of the 483. Although the language is addressed to the inspected firm, it will be observed by anyone reviewing the document, thereby setting the document in its proper context. This disclaimer will be implemented promptly for electronically generated forms, and as soon as practicable for printed forms.

Press Release from the FDA News at www.fda.gov.
http://www.fda.gov/cder/gmp/483commsreport.htm

WELCOME NEW MEMBERS!

Michon O'Neill
Parexel International

Keith Harris
Genzyme Corporation

Mary Baranow
Abbott Bioresearch Center

Nadene Hausmann
Sepracor Inc.

Carolyn Caramma
Altus Biologics Inc.

Helene Miletic
Genzyme Corporation .

Judith Luongo
Charles River Laboratories

Anthony Spencer
Charles River Laboratories

Randall Covill
Vertex Pharmaceuticals Inc.

Barry Reinbold
Consultant

Nancy Bakker
Biogen Inc.

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:

April Brunelle
NERCSQA Secretary
Pfizer, Incorporated
Eastern Point Road, MS 8200-4005
Groton, CT 06340.

NERCSQA
Mission Statement

To serve as a focal point for Quality Assurance "GXP" professionals *in the New England Region by establishing a forum for education, training, communication and information exchange among QA professionals in the environmental, pharmaceutical and biotechnology fields of government, private industry, research and academia.*

CLASSIFIEDS

Submit advertisements for publication in the NERCSQA newsletter to:

Sharon Mercado
Pfizer, Inc.
Mailcode 9126-20 (Bldg. 126)
Eastern Point Road
Groton, CT 06340
Fax number:
(860) 441-0515
on line at:
sharon_r_mercado@groton.pfizer.com

COST

$30 for the first inch and $15 for each additional inch

Quarter Page	$60
Half Page	$100
Full Page	$150

Corporate Sponsor Members of NERCSQA may advertise FREE OF CHARGE.

NERCSQA Spring Training

Date: Wednesday, April 30th
Time: 12:30 - 5:00 PM
Registration: 12:30 - 1:00 PM
Location: Sheraton Hotel
Hartford, CT

Pre-registration discount

Topics:

1) Current FDA Computer Valiation Activities including the New Part 11 Guidance Document
2) Data Security -including network security, backups, archiving & contingency planning