Northern Highlights

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

Volume 5 - Issue Number 6 **June 2002**

President's Message

Spring is here, and along with nature NERCSQA is bursting with new growth.
Our March meeting on "**Negotiation in a Regulatory Environment**," with Deb Kolb, Ph.D. from Simmons College, held at the Hyatt Regency in Cambridge, MA. was an enjoyable time of personal growth, as we practiced negotiating skills during interactive sessions. Now back to the nitty-gritty of the Regs!
The Planning Committee has once again put together a great program, "**Part 10 _ Reaching for Part 11**." This Summer meeting will be held at Abbott Bioresearch Center, Worcester, MA and will cover gap analysis, vendor assessment for part 11 compliance and recent enforcement activities by the FDA on 21 CFR Part 11. Presenters will be 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. So mark your calendars…Thursday, June 13th.
The NERCSQA Board met for the second time this year on April 24th. Highlights of the Board Meeting are as follows:

- Deb Glancy, our Secretary, reports that membership is up 10% from this time last year.
- The Board voted to have one of our NERCSQA members, Donna Stegner, maintain the new website, www.nercsqa.org. Be watching for some coming changes.
- The Membership Committee has drafted a NERCSQA tri-fold brochure.
- The Program Committee plans to put together a Basic GLP Training package, with interactive activities and possibly a mock-inspection, ready to roll out next year. Also, planning is already underway to give you a great November Meeting.

Once again, I encourage folks to be involved. If you want to affect the types of meetings we have, contact Linda Chin, our Program Committee Chair. The Program Committee is always looking for fresh ideas and would love to have you come to their meetings. If you are a people-person, and would like to see our organization grow, contact Aimee Conlan, our Membership Committee Chair. Again, looking forward to seeing you in June, and fine-tuning our Part 11 skills together!

-Kathy V.
NERCSQA President

Inside

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."

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Northern Highlights

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

- **Chris Lautz**
- **Laura Metzger**
- **Kathy Vanderhoof**

Our next issue is scheduled for September 2002. Submissions for the next issue will be accepted through August 15th. Please send to:

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Letter from the VP at SQA

Finally, A Strategic Plan for the SQA

After several years of deliberating, negotiating, and wordsmithing, the SQA Board of Directors, along with the advice of and nod from the Strategic Advisory Board, has approved a robust five-year strategic operational plan for the SQA. The strategic plan is organized into three subplans, (one-year, three-year, and five-year).

The one-year plan consists of three objectives. The first objective is "Lead in the globalization of regulatory compliance so that the SQA is recognized as the premier research QA professional organization. Develop programs to actively market SQA for the purpose of increasing partnerships with other international research and regulatory organizations." The second objective is to "Strengthen SQA's structure, operations, and communications to better serve a growing and developing membership." The third objective is to "Partner with regulatory authorities to promote regulatory coordination, consistency and continuity."

You may notice that all three objectives are interconnected. For the SQA to be recognized, as the premier research QA professional organization shouldn't we market our society more, otherwise how are the other organizations going to know the SQA exists? To become a better partner with the regulatory authorities, wouldn't it help if we first strengthened the SQA's infrastructure and streamlined processes, especially in the area of communication?

"Strengthen SQA's structure, operations, and communications to better serve a growing and developing membership."

The three-year plan is a continuation of the one-year plan with an added fourth objective, "Broaden the SQA professional umbrella to encompass a wider range of regulated disciplines. Develop a mechanism for the expansion of SQA into additional QA areas." The Board would like each regional chapter to evaluate the one and three-year plans and develop an action plan to implement these. The five-year plan only focuses on the first objective listed in the one-year plan since it will probably take the society that long to achieve it.

I am not going to describe all of the deliverables here since soon you will be able to access the complete strategic plan on the SQA website, but I will say that some of them have already been accomplished. For example, to achieve the objective about taking a lead in the globalization, the SQA has expanded regional chapters to outside the USA. The Canadian and International Regional Chapters are beginning to form and build a membership. The SQA has also started work on strengthening relationships with international QA societies (e.g. BARQA and JSQA).

To achieve the objective about strengthening SQA's structure, the Board and the Program Committee has restructured the SQA annual meeting to integrate all applicable components within the program (e.g. GLP, GMP, GCP, Computer validation and subcomponents therein). Additionally, the Board assigned the SQA VP as the liaison to the Regional Chapters to serve in the role of enhancing communications between the Board and the Regional Chapters.

Introducing an income and expense budget, which holds chairpersons of committees accountable for projected revenues, has also strengthened financial planning. The Board has identified the hidden costs of the SQA annual meeting, education programs, etc. so that a more realistic fee projection can be made.

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Member's Spotlight

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

Sharon Mercado
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Place an ad in our classified section!

FINALLY, A Strategic Plan for the SQA

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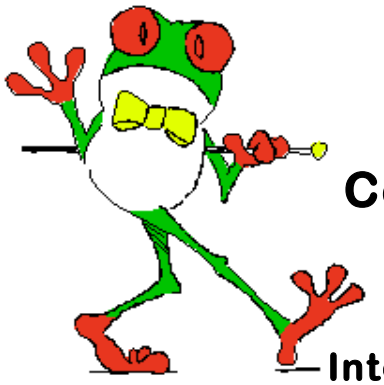
Currently the Board is developing innovative mechanisms for enhanced and timely communication to the membership (e.g. email, fax, website, restructuring the Regulatory Review Committee).

To achieve the objective to broaden the SQA professional umbrellas, the SQA has expanded into other regulatory arenas (e.g. GCP, GMP), as evident during the last year's annual meeting.

Accomplishing the strategic operational plan's objectives will be no small task. From a bird's eye view the objectives seem lofty and daunting. However, by creating "deliverables" which are smaller, "micro" objectives, the overarching "macro" objective can be achieved. Additionally, by the Board assigning each deliverable to a person, committee, regional chapter, or specialty section, for example, the workload can be spread out so no one individual or group is overly burdened. The famous saying, "1 % of 100 people is better than 100% of one," fits well here.

In conclusion, developing the strategic operational plan was necessary if the society expects to continue to grow and meet its membership's needs. Having this plan in place, along with the objectives and deliverables, which can be measured and accounted for, will finally allow the members to see where their society is heading. Now all that is needed is to monitor progress so the Society can ensure that the Board and the membership travel down the same path.

By Laura Metzger
SQA Vice President 2002



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CVM UPDATE

April 22, 2002

NEW VERSION OF BSE INSPECTION CHECKLIST RELEASED

FDA's Center for Veterinary Medicine (CVM) has released a new version the Bovine Spongiform Encephalopathy (BSE) Inspection Checklist, that is available on the Center's Home Page on the Internet. This checklist is to be used by all Federal and State inspectors to determine compliance with FDA's ruminant feed (BSE) regulations, Code of Federal Regulations, Title 21, Part 589.2000. This newest checklist version coincides with the release of a new database module that will record the results of all inspections conducted under this regulation.

This rule that prohibits the use of most mammalian protein in feeds for ruminant animals was implemented to prevent the establishment and amplification of BSE through feed in the United States. The rule became effective on August 4, 1997. Inspections of over 13,000 renderers, feed mills, ruminant feeders, and others (such as protein blenders) have been conducted to determine compliance with the BSE feed regulations. The majority of these inspections (around 80%) were conducted by State officials, and the remainder by FDA. A checklist has been used to record information on the compliance with the rules. This newly revised checklist supercedes all previous versions, and should be used in future inspections.

April 15, 2002

RUMINANT FEED (BSE) ENFORCEMENT ACTIVITIES

To help prevent the establishment and amplification of BSE through feed in the United States, FDA implemented a final rule that prohibits the use of most mammalian protein in feeds for ruminant animals. This rule, Title 21 Part 589.2000 of the Code of Federal Regulations, became effective on August 4, 1997. To date, active monitoring by the U.S. Department of Agriculture (USDA) has found no cases of bovine spongiform encephalopathy (BSE) in U.S. cattle.

This is an update on FDA enforcement activities regarding the ruminant feed (BSE) regulation. FDA previously provided information on this issue in four CVM UPDATEs, most recently one on October 30, 2001.

FDA's enforcement plan for the ruminant feed regulation includes education, as well as inspections, with FDA taking compliance actions for intentional or repeated non-compliance. FDA's Center for Veterinary Medicine (CVM) has assembled data from the inspections that have been conducted AND whose final inspection report has been submitted to CVM (i.e., "inspected/reported") as of March 11, 2002. There is a lag time between the completion of an inspection and the submission of a final inspection report to CVM. This lag period includes the time required to conduct quality assurance on the report and to evaluate the findings before a final report is submitted.

As of March 11, CVM had received inspection reports covering inspections (both initial inspections and re-inspections) of 10,458 different firms. The majority of these inspections (around 80%) were conducted by State officials under contract to FDA and the remainder by FDA officials.

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CVM UPDATE

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Various segments of the feed industry (e.g. renderers, feed mills not licensed by FDA) had different levels of compliance with this feed ban regulation. The results to date are reported on the web site both by "segment of industry" and "in total".

For more information go to the FDA's Center for Veterinary Medicine's website at http://www.fda.gov/cvm

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Classified advertisements may be submitted for publication in the NERCSQA newsletter to:

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SQA Greetings to Animal Health Enthusiasts and Industry

Dear Colleagues:
The Society of Quality Assurance (SQA) is pleased to propose a new specialty section dedicated to specific Animal Health Industry related issues. Mr. Steve Rogers (Manager, Animal Health QA, Pharmacia Corporation) will chair the new group while Mr. Kevin Yount will serve as the board liaison. The new specialty section is expected to cover a broad range of issues relating specifically to the Animal Health discipline (e.g. veterinary products intended for use in companion and food animals). Initial focus will be on the application of QA principles on Good Clinical Practice (GCP) studies, specifically as they relate to the new VICH GCP guideline issued in the summer of 2001. However, the long-term goal is to focus on any GxP issue that would relate to the industry or US regulators (FDA-CVM, USDA-APHIS and EPA) who govern it. We also hope to add an international flavor to the group. It is anticipated that we would set up a strong liaison with our BARQA counterparts in the UK --- specifically with their Animal Health Committee. This will allow both groups to have a strong regulatory insight into the two largest Animal Health markets in the world. And finally, we would propose to facilitate specialized training. Basic topics would include the application of GLP/GCP in Animal Health studies. We are looking for members and other interested individuals to join the Animal Health Specialty section, provide ideas for meeting topics, aid with presentations, and basically to get this group off and running. So we're calling for all of those Animal Health nuts who share the same enthusiasm as we do to e-mail SQA regarding your interest in this new Specialty Section. It is anticipated that we'll hold our first informal general information meeting during the Albuquerque conference the week of October 14th. More specifics will follow to those responding to this e-mail. Even if you are not going to attend the 18th Annual SQA meeting, please e-mail SQA to join... we'll keep you updated on any and all matters relating to this new specialty section. If you are not yet a member of SQA, you can learn more about the Society and obtain a membership application from our website, www.sqa.org. If you have any questions about SQA or membership, please contact Ms. Elliott Graham, Executive Director: elliott.graham@sqa.org or 434/297-4772.

Sincerely,
Steve Rogers and Kevin Yount

Food and Drug Administration
Center for Veterinary Medicine

Updated July 5, 2000 at 8:23 PM ET
Taken from the CVM website

OFFICE OF NEW ANIMAL DRUG EVALUATION (ONADE)

The Office of New Animal Drug Evaluation's (ONADE's) major responsibility is to review information submitted by drug sponsors who desire to obtain approval to manufacture and market animal drugs. A new animal drug is deemed unsafe unless there is an approved new animal drug application. Virtually all animal drugs are "new animal drugs" within the meaning of the term in the Federal Food, Drug, and Cosmetic Act.

ONADE determines whether or not an animal drug should be approved for marketing. Before a new animal drug receives FDA approval, it must be clinically tested for effectiveness and safety. If a product is intended for use in a food-producing animal, it must also be tested for safety to human consumers, and the edible animal products must be free of unsafe drug residues. The sponsor must also develop analytical methods to detect and measure drug residues in edible animal products. It is the responsibility of the drug sponsor (the individual or firm seeking FDA approval of the drug product) to conduct the necessary tests.

ONADE performs the following tasks in their review of applications:

Determines the adequacy of information submitted for proposed use of investigational new animal drugs (INAD).
Evaluates the safety and effectiveness of new animal drugs.
Evaluates the safety for human consumption of drug residues in food derived from treated animals.
Evaluates the effect of animal drugs on the environment.
Evaluates manufacturing methods and procedures for new animal drug products.
Recommends to the Center Director appropriate action on new animal drug applications and abbreviated new animal drug applications (for generic drugs).
Coordinates the development and implementation of regulations and policies pertaining to new drugs intended for animal use.

There are two main processes involved in regulating the interstate shipment of animal drug products. The first process, the Investigational New Animal Drug exemption (INAD), involves the interstate shipment of experimental drugs used for testing in animals. This testing may require drugs be given to animals that will later be used to produce human food products. FDA must ensure that the food products derived from these experimental animals will be safe for human consumption. The second process is the NADA review. It includes the evaluation of data regarding an animal drug's safety to the target animal and to humans who might consume products from the treated animal; the review also evaluates effectiveness for the purposes claimed. To be legally marketed, a new animal drug product must be approved under an NADA.

ONADE is divided into several different groups charged with the evaluation of both INAD and NADA submissions. Efficacy and safety information for the animals is evaluated by two therapeutic use groups (food animals and non-food animals) and one group which evaluates production drugs. Additional groups in the Office are responsible for reviewing other aspects of submissions. The human food safety group evaluates the safety to the public, the user (the producer or veterinarian), analytical methods, withdrawal times, and provides the drug tolerances so that safe residue levels and conditions of use are provided to the public. The manufacturing chemistry group evaluates the manufacturing processes, quality control and environmental safety. The biometrics group provides statistical support to ONADE and the rest of the Center.

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Food and Drug Administration
Center for Veterinary Medicine

OFFICE OF NEW ANIMAL DRUG EVALUATION (ONADE)

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The various groups in ONADE review the information and any amendments in the NADA. A determination is then made as to whether the information provided in submissions concerning a new animal drug shows the product will be safe and effective for its intended use. If the information shows the drug is safe and effective, a recommendation is provided to the Center Director that the NADA should be approved. If the Director agrees, he/she approves the application and a notice of approval is published in the Federal Register.

INAD and NADA sponsors usually include university researchers, contract researchers, private practitioners, drug manufacturers, and/or feed or food manufacturers in their protocols. The activities of the investigators are monitored through the bioresearch monitoring program. The sponsor's data generation processes are validated through on-site inspections by FDA field personnel. Reports covering laboratory practices relating to toxicology and safety research, and the functions of clinical investigators and sponsors are forwarded to CVM for evaluation.

A sponsor must conduct certain tests to show that a drug is safe for the target animal, has the intended effect, and that edible products derived from treated animals are safe for human consumption. If animals receiving an investigational drug are to be slaughtered for consumption, authorization to do so is needed from the FDA. These animals must be slaughtered in a Federally-inspected facility. The USDA, in coordination with the FDA, provides for a USDA inspector to monitor the slaughter of research animals intended for human consumption.

Usually drug approval process begins with the sponsor submitting a request for an exemption to use a particular substance for experimental purposes. CVM can grant this under an INAD. Once an INAD exemption has been granted according to the requirement of the FFDCA, the sponsor must do the following:

- Assure the proper and safe packaging and labeling of investigational drugs.
- Report the names and locations of investigators to whom drugs are shipped.
- Maintain records of all drug shipments and of all reports received from investigators.
- Notify FDA immediately if a safety problem is observed.
- Notify FDA or USDA prior to slaughter of animals treated with the investigational drug.
- A request for a categorical exclusion from an Environmental Assessment.

An important function in the INAD process for all ONADE staff is review of submitted protocols for experimental work conducted to provide the necessary information needed for the approval of the NADA.

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 INAD, or the entire requirements for approval may be provided in one submission as an NADA.

An "original" NADA (the initial application for approval of a new animal drug) should contain all of the following information:

- A signed copy of the FDA 356V (New Animal Drug Application).
- A well-organized summary of the information in the application.

Submitted By

Chris Lautz
Regulatory Scientist
Veterinary Medicine Regulatory Affairs
Pfizer Global Research and Development

WELCOME NEW MEMBERS!

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MEMBERSHIP INFORMATION

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