



MARSQA Monitor

NEWSLETTER OF THE MID-ATLANTIC REGION SOCIETY OF QUALITY ASSURANCE

Volume 14, Issue 2

LOOKING FORWARD TO THE 2011 SQA ANNUAL MEETING



As I begin my latest letter to the MARSQA Monitor, I have to share the fact that I'm working from home today preparing to leave for a business trip in a few hours. To my front, I'm being serenaded by the sweet hum of a sawzall as it cuts off pieces of sheathing and studs away from my humble abode with

(hopefully) surgical precision...at least no one's uttered the infamous "uh-oh" yet. And to the rear a vacuum cleaner growls at the closed door. I can't help but imagine them to be the agitated recipients of an audit trying to come in and calmly discuss findings. This is what happens when you take work home with you!

So I take myself back to happier times, and as I crawl out from hiding from under my desk, I have visions of the April 2010 SQA Annual Meeting and Training in Cincinnati dancing in my head. What a great opportunity to have attended as the MARSQA President this year! I met many new people, including fellow officers from the other SQA Regional Chapters as well as the SQA Board of Directors, and got to share ideas and common issues we face with our regional SQA chapters. I had the opportunity to rekindle several friendships going all the way back to my first 'real job' in the industry after college. And there was the embarrassing moment at one session when I sat next to a colleague of mine from California (who I've met on more than one occasion) and didn't notice her until she asked me if I knew who she was...good times!

Academically, I didn't have the opportunity to attend the pre- and post-meeting day-long courses, but during my time in Cincinnati I chose to follow the 11 sessions in the Clinical track, each session featuring 2-3 speakers who addressed a broad spectrum of topics. Being relatively new to Clinical, it was a great experience to hear presentations and exchange questions and ideas from other Clinical professionals, IRB members, and even a few FDA employees. This brings me to the point of my letter: The MARSQA SQA Award. When I tallied my expenses, I realized that I could have attended a one day-long course in addition to the expenses I had incurred over my 3 day stay, and would still have been completely covered by the \$2000 award. Of course Board Members aren't eligible to apply, as well as with previous award winners. Still, approximately 90% of the current membership would be eligible to write a page to the Board expressing why they'd like to attend next year's meeting in San Antonio for a shot at the award! And considering that 82% of MARSQA members would like to attend a future SQA meeting, and 57% would be more likely to attend if they won the SQA Award (according to the results of the recent MARSQA Membership survey), I hope that we'll see many more letters for 2011.

In closing, today I'm asking for you to take advantage of the benefits that MARSQA has to offer to its members! The SQA Award and the new RQAP award being the most notable monetary awards. Now off on that trip.... And hopefully this time I'll recognize my esteemed colleague from California when I see her!

Tony Borisow
2010 MARSQA President

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HERE'S A CHANCE TO GET YOUR MESSAGE ACROSS



MARSQA's Program Committee organizes three excellent and well attended membership meetings per year.

Would you like to be part of this effort? Are you interested in giving a presentation? Do you have an idea that would provide a theme or topic for an entire meeting? Would you like to volunteer to help organize and manage a meeting?

If the answer to any of these questions is yes, just e-mail Jane Pasquito, Program Committee Chair at jane.pasquito@spcorp.com

MARSQA MISSION STATEMENT

- Continually strive to advance the research quality assurance professions by providing the resources, programs and training necessary for the professional development and recognition of its membership.
- Serve as a forum for the open discussion of the theoretical, practical and ethical applications of the quality assurance profession.
- Foster a partnership between the quality assurance profession and the regulatory agencies that results in the attainment of mutually beneficial compliance
- Support and advance the goals and mission of the Society of Quality Assurance.

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Jane Pasquito

MARSQA Program Committee Chair

The March 2010 Membership meeting was a great success. Raneé Henry from the Computer Systems Validation Committee suggested we do a round table discussion meeting. The Program Committee and the Computer Systems Validation Committee worked together to present the March 2010 meeting. We had a wonderful turnout with about 125 people in attendance. The word on the street was that attendees greatly appreciated this style of meeting. They were grateful to participate in the smaller setting so that they could ask questions and bring home valuable information. The one drawback to the meeting's success was that we were a little cramped and the noise level was a little high. But the attendees made the most of the meeting and seemed to accept the small inconveniences. The topics presented were:

- Current Clinical Topics: **Doreen McGirl**, ASQ CQA, Merck, Sr. Manager Global Quality Audits & Compliance – GCP
- Basic GLPs, For Those New to the World of Good Laboratory Practices: **Alyssa Colon**, RQAP-GLP, Hoffman-La Roche, Sr. Quality Assurance Auditor, PRNQ –GLP Quality Assurance
- Issues in Handling Multi-Site Studies: **Amy Stawicki**, J&J PRD, Program Manager, GLP Compliance Training, GLP QA
- Current Bioanalytical Topics: Jane Nelson, Tandem Labs, Sr. Quality Assurance Director, Pam Agelopoulos, Tandem Labs, Group Leader. Mass Spectrometry and Laboratory Support and LaKenya Williams, Tandem Labs, Project Manager, Biotechnology Services Division
- Archival of e-Records: Paula Eggert, Merck, Sr. Quality Assurance Auditor, Worldwide Nonclinical Quality Assurance
- How to Identify Systems that Need/Should/Must be Validated: Frank Moschetto, Hoffman-La Roche, Director, GLP - Quality Assurance
- Disposition/Decommission of Validated Systems: Allen Chin, Charles River Laboratories, Associate Director, Information Security and Compliance

Here are summaries from some of the table discussions.

Archival of E-records

Archival requirements are clarified through the predicate rule and Standard Operating Procedures. Main archival requirements include that there is secure, limited access but the information must be readily retrievable and indexed. Also, the archives are to be environmentally controlled, waterproof and fireproof. These requirements differ for GLP purposes compared to other areas, specifically because there is a dedicated archivist assigned the responsibility of controlling access to the record.

Quality Assurance involvement in the archival process consists of several approaches: checking records against the index, checking data backups and transfers, checking change controls and validation. These checks may be included within the facility inspection and may occur at a specified frequency. Inspections may include a sample of records or a sample study. They may include verification that information is archived, retrievable and can be opened but access is restricted. As retrieval of data may be more important than the actual archival, QA can also review the contingency plans and tests of those plans.

We also discussed handling an agency inspection of documents that contain e-signatures. The group preference was to present the paper copy of the document for review instead of the “official” file through the computer to avoid challenging the integrity of the system. The e-signature certification can be provided, if needed. Ultimately, it is important to ensure that the format being presented to the inspector/auditor is in a readable format.

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Disposition / Decommission of Validated Systems

Commissioning of a “computerized system” means “officially authorized for use by management within a defined scope (place and time) following validation.” System retirement/decommissioning is the point where we remove a system from active service and put it into another status. Red Apple II defines retirement as “the final stage in the system development segment of the system life cycle.” A “computerized system” includes hardware, software, personnel, policies, and procedures, so must the decommissioning. All aspects of the “computerized system” must be addressed when removing it from use.

Retirement planning should include an assessment of “why the system is not needed anymore. Can anyone else in your organization use it?” Determine if you are decommissioning to remove the system from a particular regulatory use. Retired systems must still continue to meet the regulatory requirements regarding records it has produced, which are to ensure accuracy, reliability, and consistent intended performance, as well as the ability to discern invalid or altered records. Components of the Retirement/Decommissioning Plan must outline the requirements that will need to be met, test those requirements (such as data retrieval, data integrity, etc) and summarize in a report, identifying any known limitations.

A variety of strategies are available to address the need to ensure compliant retrieval of the system’s archival records post decommissioning. Some validated systems to be decommissioned may not produce archived E-records and decommissioning will simply document the removal of the installations and assessment of the ability to retrieve records post decommissioning. A primary method for addressing systems that have produced archived E-records is identification of alternate installations of validated systems in your organization that can be proven to

read the archived files. Other approaches include putting the system into a “archive time capsule status” for later use (which may complicate the actual “decommissioning” of the system), or identification of vendor resources with the ability to retrieve the archived records that can be proven during testing and contractual service level agreements can be established to ensure future suitability.

“
Red Apple II defines retirement as “the final stage in the system development segment of the system life cycle.”

Basic GLP

Alyssa Colon, from Hoffmann La-Roche, hosted the, “Basic GLPs, For Those New to the World of Good Laboratory Practices”, table. The table was a good mix of extremely bright people; some from small companies that wear various regulatory hats, some people were new to GLP QA and some who after years were finding their way back into the GLP Arena. The table discussions got off to a quick start with some ice breaker topics that Alyssa had provided. We discussed how we, as GLP QA auditors, handled reviewing protocol amendments. We found that most companies do a review but not all send out a formal audit report.

We also discussed the role of QA in multi-site studies. Who do we send out audit reports to, do sponsor QAs review the final report from CROs and to what extent to they do this review. We also discussed if and when the sponsor QA should provide a QA statement. We discussed the concern in multi-site studies because the US does not have a certification program for their GLP laboratories and ways to lower the level of concern from our EU facilities. We also discussed bioequivalence GCP studies and the push to make them compliant with GLP regulations.

Alyssa did a wonderful job keeping up with the fast paced information that was being provided and the questions that were being asked. I have to say even though this table was labeled as a “Basic” GLP table our topics were very current and not so basic!

Current Bioanalytical Topics

Jane Nelson, Senior Director of Quality Assurance, Pam Agelopouos Group Leader, Mass Spectrometry and Laboratory Support and LaKenya Williams, Project Manager, Biotechnology Services, from Tandem Labs presented the Bioanalytical Session. They focused on Incurred Samples Reanalysis (ISR) and problems associated with them. ISRs are unknown samples used to determine the performance of your method. ISRs are not used for validation. Results should be able to be repeated within a study. ISRs must be run for bioequivalence, bioavailability, and pharmacokinetic studies. An SOP should be established to define the criteria for the reproducibility of the ISRs.

An SOP should be written for an investigation of failed ISRs in a study. An investigation must be conducted if an ISR fails in a study. The investigation should include analyst errors, instrument errors, dilution factors, contamination, carry over, metabolite interference, calculations, and previous runs. Plasma samples usually do not cause problems while blood samples may cause issues.

Since QC samples do not contain metabolites, the FDA expects ISRs in human studies. The FDA has given 483s for the omission of ISRs.

Issues in Handling Multi-Site Studies – Amy Stawicki (J&J Raritan Program Manager)

When performing multi-site studies the Study Director is the primary contact between the Test Site and Testing Facility. The Principal Investigator is responsible to sign a statement acknowledging the Protocol requirements. The Lead Quality Assurance is responsible to communicate all findings to the Testing Facility. Test Site audit findings are not always being reported to the Study Director in a timely manner; which can result in the FDA issuing a warning letter for the Test Site not notifying the Study Director within 60 days of audit findings. Once the study has been completed follow-up documentation to the Testing Facility pertaining to the archiving of study data and reports after submission of the final report is not always provided; however it is the Study

Director's responsibility to see that all records have been archived as stated in the Study Protocol. When performing multi-site facility audits it is recommended that the auditor review their archiving records. FDA 483 has been issued pertaining to key communication between the Test Site and Testing Facility not being maintained by the Study Director.

How to Identify Systems that Need/Should/Must be Validated

Determining the need for validation can be based on a few criteria. First and foremost is the requirement for validation for anyone working in a regulatory environment. Additionally there is an ethical obligation regarding patient safety when systems are used in the laboratory. In some cases you may validate purely because someone has indicated to you that this is required especially in the case of non-regulated areas.

Risk assessment is integral to determining the level of validation required for a system. Patient safety needs to be of the highest priority in the use of risk assessment. The User Requirements will discuss and cover the risks and is the backbone of the process. Vendor audit will assist in determining the risk associated with specific areas of any system. Qualification vs. Validation – The terminology is not important the critical issue is that the process is performed regardless if the system is considered an instrument or computer system.

Vendor performed validation may be claimed however the system is not completely validated without appropriate testing within your laboratory environment, under your specific User Requirements. Re-validation needs to be considered based on changes to the system. These changes might include, version upgrades, relocation of a system, major bug fixes, infrastructure changes.

Validation requirements can be found within 21 CFR Part 11. The Crystal City paper is also a good guide when validating scientific instrumentation.

Ray Leonard

Associate Coordinator and MARSQA Member



Overview

The Inter-Regional Research Project Number 4, (IR-4), Minor Crop Pest Management Program has been the major

resource for supplying pest management tools for specialty crop growers for over 45 years. IR-4 is a highly effective, collaborative effort among the state agricultural experiment stations (SAES), the USDA National Institute of Food and Agriculture (NIFA), the USDA Agricultural Research Service (ARS), the U.S. Environmental Protection Agency (EPA), commodity growers, and the crop protection industry. The mission of the IR-4 Project is to provide safe and effective pest management solutions for specialty crop growers.

Specialty crop growers produce high-value, small-acreage crops throughout the United States. Twenty-six states derive more than 50 percent of their agricultural crop sales from specialty crops. These include food crops such as fruits, vegetables, nuts, and herbs and nonfood crops such as turf and ornamental landscape plants. These crops have a value of approximately \$45 billion, or about 33 percent of the total farm crop value in the United States. In many cases because of lower acreages or limited usage volume, the agricultural chemical industry cannot justify the time and expense required to research much-needed crop protection products on these high-value crops. The success of the IR-4 project is proven and can be measured in its development of data to support over 20,000 food use and ornamental horticulture label clearances.

Since 1977, IR-4 has assisted with the registration of crop protection chemicals and biological pest control agents on nursery stock, flowers, and turfgrass. The ornamental industry accounts for more than 35 percent, or \$16 billion, of the total specialty crop value in the United States.

Additionally, biopesticides have been an important IR-4 focus since 1982. The IR-4 Biopesticide Program assists small companies, USDA, and university

scientists by consulting and preparing regulatory packages to obtain registration of microbial and natural products. The primary objective of the IR-4 Biopesticide Research Program is to further the development and registration of biopesticides for use in pest management systems for specialty crops or for minor uses on major crops.

The Strategy

IR-4's strategy in assisting specialty crop growers includes:

- Facilitating regulatory clearance of lower or reduced risk crop protection products for specialty crops.
- Assisting, when appropriate, in the development of risk mitigation measures for existing minor use registrations.
- Assisting with the registration of biologically-based crop protection products for specialty crops.
- Registering and maintaining products essential to Integrated Pest Management (IPM).

The cornerstone of the IR-4 Strategic Plan has been to focus projects on lower-risk products. More than 80 percent of IR-4 efforts focus on lower-risk products.

The Four-step Approach

IR-4 receives requests for assistance from growers, commodity groups, and research and extension personnel. In responding to these grass-roots needs, IR-4 leads the coordination and focus of generating data to support the regulatory clearances of crop protection chemical and biological products for food crops through the EPA. IR-4 also coordinates efforts to generate efficacy and crop safety data to support chemical and biological crop protection products for ornamental horticulture crops. To accomplish this, IR-4 has developed a 4 step approach:

1. Research prioritization, 2. Research planning, 3. Research implementation, and 4. Data submission and approval.

Step 1. ARS and university research is prioritized through annual workshops involving growers, commodity organizations, university research and extension specialists and EPA staff who collectively determine the project priorities based on the importance of the pest and the ability of the control

tactic to manage the pest. Prior to and during the workshops, IR-4 industry partner representatives are consulted to confirm their support for adding new specialty crop uses to their product labels.

Step 2. Research planning is accomplished when research protocols are drafted, sent out for review by stakeholders and field research directors, revised to integrate comments received, and issued as a final research protocol.

Step 3. For food crops, research is implemented in two phases – field and laboratory research. During the field phase, researchers apply the crop protection agent to the target crop according to the specified protocol. Samples of the crop are harvested and transferred to the laboratories, where crop matrices are analyzed for potential residues. All field and laboratory research is conducted under EPA Good Laboratory Practices. For non-food specialty crops (i.e. ornamental plants), Step 3 is accomplished with field and/or greenhouse research on the targeted crop or for a specific disease, insect, or weed.

Step 4. For food crops, IR-4 critically reviews the field and laboratory data, drafts formal regulatory packages, and submits reports for the research study to EPA for review. EPA will review the reports and, if appropriate, approve the registration of a particular chemical on a specialty crop by establishing a maximum residue limit, or tolerance. For ornamental horticulture crops, IR-4 prepares summaries of the research conducted. These summaries are sent to each manufacturer who, in turn, uses them to register new products or expand existing labels. These summaries, along with the researcher's reports are posted on the IR-4 website.

Fieldwork for food use and ornamental horticulture is coordinated by Regional Field Coordinators in California (western region) Florida (southern region), Michigan (north central region), and New York (north eastern region) and by the USDA ARS in Maryland for various sites throughout the United States. For food crops, these sites meet specific EPA requirements for geographic distribution of data. Most field research on food crops is conducted at field research centers

in Arizona, California, Colorado, Florida, Georgia, Hawaii, Idaho, Illinois, Maine, Maryland, Michigan, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oregon, South Carolina, South Dakota, Tennessee, Texas, Washington, and Wisconsin. All sites are subject to EPA inspections. For ornamental crops, IR-4 generates data with researchers in 31 states.

IR-4 laboratory analyses are conducted primarily at the California, Florida, Michigan, and New York agricultural experiment stations, and ARS laboratories in Georgia, Maryland, and Washington. Protocol development, data assimilation, petition writing, and registration processing are coordinated through IR-4 Headquarters, the crop protection industry, food processors, and state and federal regulators.

IR-4 Accomplishments for 2009

US EPA established 203 permanent tolerances and five exemptions based on IR-4 submissions. These decisions support 628 new specialty crop use registrations for conventional and reduced risk pest control products and 19 for biopesticides for a total of 647. New use registrations were spread over 33 pest control products.

IR-4 conducted 644 field trials associated with 95 high priority studies on food crops to support eventual registration of conventional/reduced risk pest control products to answer specialty crop grower pest management needs.

IR-4 along with industry continues to work to implement the provisions of the Pesticide Registration Improvement Act of 2007 (PRIA II). The new provisions are more complicated and cumbersome. However, IR-4 packages are reviewed by EPA within an extremely rapid time frame, where most decisions are made in less than one year.

IR-4 Project Headquarters:

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CINCINNATI IN REVIEW: A REPORT FROM THE 2010 MARSQA SQA ANNUAL MEETING AWARD WINNER

Janet Emeigh

MARSQA Member

As previous winners of this award have done, I first must thank the MARSQA Board for selecting me to receive this award this year. I had made the commitment to attend the meeting to participate as a training session presenter and meeting session chair and then learned that funding to do so would probably not be available from my company. The \$2000 award went a long way to help defray the cost of attendance, and for that I am very grateful.

I decided to take full advantage of attending and signed up for pre- and post-conference training classes, “Current Topics in Good Laboratory Practice” and “GLP in the Bioanalytical Lab”. Even though I’ve been in the GLP QA field for over 12 years now, I still gained some new perspectives by attending these sessions.

The meeting was also a great place to catch up with colleagues I haven’t seen in a while as well as to make some new contacts. I even ran in to the person who was responsible for recruiting me out of academia into my very first position with a pharmaceutical company working in a GLP analytical lab. I hadn’t seen him in over 15 years and was surprised that he had finally “seen the light” and had become involved in the QA arena! Just kidding, he was always focused on quality and was probably one of the first people to demonstrate to me that good science could actually benefit from quality.

The Keynote Speaker, Dr. Kurt Weingand moved me to tears in revisiting the 2007 pet food recall. He relayed his experience with managing the crisis for his company, Procter & Gamble Pet Care, and how they actually were a key in identifying the problem. It was quite clear that he felt deep sympathy for all of the pet owners who had lost a beloved pet during this time. While moving us to tears to open the meeting, he had us all rolling in the aisles with laughter with his



Downtown Cincinnati, OH

Closing Plenary Address on “A Peculiar Career in Life Sciences With and Without Quality Assurance”.

In between Dr. Weingand’s talks, there were many presentations in all aspects of quality (GLP both EPA and FDA, GCP, cGMP, computer validation, and academia) as well as a few sessions on career development. As this industry continues to become more global, it was nice to see several sessions on the emergence of China as a player in the conduct of GLP studies. Several speakers presented their experiences either working in China or working with Chinese CROs. We also received an update on the initiative in Canada to establish a GLP monitoring authority.

It felt like old times when SQA President Dr. Jim McCormack (former FDA, now Corporate VP for Charles River Laboratories Regulatory Affairs and Compliance) stepped up to the mike to give the FDA GLP update. It was unfortunate that a representative of the FDA was unable to provide this update, but fortunately SQA was able to get all the information they needed for this presentation through the Freedom of Information Act. Dr. McCormack also presented a summary of his meeting earlier this year with key FDA officials from different Centers in an attempt to increase the interaction between FDA and SQA. The fruits of his efforts were evident by the attendance and participation of a number of FDA representatives at the SQA Annual Meeting this year.

CINCINNATI IN REVIEW: A REPORT FROM THE 2010 MARSQA SQA ANNUAL MEETING AWARD WINNER (CONTINUED)

Overall, this was probably one of the better SQA Annual Meetings I've attended. I again want to thank the MARSQA Board for this award. Having served as a member of the MARSQA Board in various positions, I'm baffled that more MARSQA members don't apply for this award every year. The award was resurrected about 4 or 5 years ago and while I don't know how many applications were received this year, when I was on the Board the average was about 2-3 applications each year. I remember one year literally having to beg someone to take the money. With more and more companies cutting back on funding for meeting attendance, I would have thought MARSQA would receive a flood of applications. I have always found the SQA Annual Meeting an invaluable meeting to attend. I wish it were possible for me to attend every year. Experienced and novice QA professionals alike can benefit from the opportunity to network with colleagues from across industry, academia and representatives from FDA and EPA. I would strongly encourage members to apply when the notification goes out for next year's meeting. This award is just one of the benefits of MARSQA membership and I would encourage everyone to take a chance and apply. Who knows, perhaps next year, you will have a byline in the MARSQA Monitor as the SQA Annual Meeting Award Winner!

UPDATE FROM THE SQA GLP SPECIALTY SECTION

Kim Evans

MARSQA Member



The SQA GLP Specialty Section (GLPSS) meets regularly by teleconference to discuss current trends in the regulatory world and the impact they have on the industry. This year in the GLPSS, there has been a lot of discussion about recent FDA 483 findings and various companies' responses to these findings in relation to timing of signatures on contribution reports. Is it okay to use a draft report to start making conclusions in the full report? How soon before a full report is signed should a contribution report be signed? There have been varied responses from companies ranging from changing processes to ensure all contributions are signed before the drafting of the full report has begun to making no changes in current processes. This is obviously an issue that affects sponsor and CRO companies so it may be advisable to evaluate what you do at your company and think about the potential impact. Just something to think about.

Upcoming this year in the GLPSS:

Monthly TC/webinars

GLP Fall Symposium (October in San Jose, CA)

If interested in learning more about the current regulatory atmosphere on a more regular basis, consider joining SQA (www.sqa.org) and the GLPSS.



Dear MARSQA Martha,

I have a question surrounding electronic document systems. When the FDA visits (inspection) are they allowed direct access to our electronic document systems or is a demonstration enough? They may want to see “live” if the system works! This was a discussion here and we were wondering than, if we would need to have a “blank” laptop available for them?

Thanks,
Ramblin Ray

Dear Ramblin Ray,

They FDA should not be given any direct access to electronic document systems or a “blank” laptop. Any documentation that the FDA would request should be given in hard copy form as much as possible. Even electronic signatures can be verified and reviewed by the FDA with hard copies of the signature verification documentation making the signatures valid. If absolutely necessary, a trained professional (trained with the system being accessed and trained on communication with the FDA) could access a system while the FDA observes, but the FDA cannot directly use the computer or access the business systems. Part 11 of Title 21 of the Code of Federal

Regulations specifically details:

- limiting system access to authorized individuals
- use of authority checks
- determination that persons who develop, maintain, or use electronic systems have the education, training, and experience to perform their assigned tasks.

Allowing an FDA inspector use of a computer owned by the facility being inspected for direct access to an electronic document system would be a violation of this regulation. They do not have a system user ID or authorization to access these systems owned by the inspected facility. In section 4 of part 11 the FDA details how copies of electronic records can be submitted to the FDA.

Thank you,
MARSQA Martha

Do you have a QA question for MARSQA Martha? Write to askmartha@marsqa.org!

Please note: Any MARSQA Martha answers are the opinion of the communications committee for MARSQA. Please refer to the FDA Regulations for any items discussed (www.fda.gov)

COMMITTEE CORNER: HIGHLIGHTING THE HISTORICAL COMMITTEE

Links to all MARSQA Action Committees and the dates of their Meetings and TCs are now posted on the MARSQA Website at <http://www.marsqa.org/>. It's easier than ever to volunteer!

COMMITTEES

MARSQA has seven committees. They are listed below along with the Chair for each.

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Somewhere in Sherwood Forest, Robin Hood receives an unannounced visit from an FDA inspector...



"I understand you gave all the medical devices to the poor, ...but do you have shipping records and lot number tracking for recalls?"

An original cartoon by Ana-Maria Rodriguez Rojas, MARSQA Member