CCSQA Newsletter

Northern Hemispheres

Volume 2, Fall Issue Newsletter Date November 2009

Message from the President

Greetings fellow members of the CCSQA! I'm pleased to present to you the Fall Edition of the Newsletter, our second of the year!

It has been a time of change for many of us this year due to the current economic slowdown. However, change can be positive as we have seen with Health Canada issuing their guidance regarding GLP monitoring. This is an important event for many of us and as such the Chapter Board has been busy trying to get clarification for the membership so that we all can better understand what is required and how this change will affect us. Firstly, the Board has submitted to Health Canada a listing of comments compiled from questions that you the members have asked. Additionally, as part of the planning for this year's annual meeting we have organized presentations and a panel discussion specifically on the topic of the new GLPMA so that we all can get some answers to questions that we all have in order to plan and prepare for this change.

Speaking of the Annual Meeting, we have assembled speakers that cover a range of topics that will hopefully provide you information that is pertinent to your area of research or that will provide you with new understanding for what others in industry are doing. I hope that the meeting topics will be interesting to you and I encourage you to attend our meeting November 18th and 19th which will also provide all of us an opportunity to catch up with some old colleagues/friends as well as meet and discuss issues with other QA professionals.

Next, we are charging ahead with the changes to our website. Discussions have occurred with SQA Head Office in order for them to help us make the changes necessary to vastly improve the look and functionality of the site. With what we have planned the site will link into the main SQA website, will allow for a members only section and we will finally be able to make payments online. I hope that we will have it up and running in the next few weeks.

Lastly, it is that time of year again where the Chapter is looking for some fresh faces and ideas that can lead the team into the future. Information will be sent out soon regarding this year's elections for the vacant Board positions. I encourage you to think about stepping forward and volunteering some of your time so as to ensure that Canadian Chapter continues to provide the Canadian QA Professional information and services that we need to stay at the forefront of quality and compliance.

Take care and I hope to see you at the meeting later this month.

Andy

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Special points of interest:

- *CCSQA Annual Meeting*
- *Update on the MHRA*
- *Update on the DIA*
- *Suggest the CCSQA membership to your colleagues to spread the word. Also membership to the CCSQA gives you 1 point towards your RQAP.*

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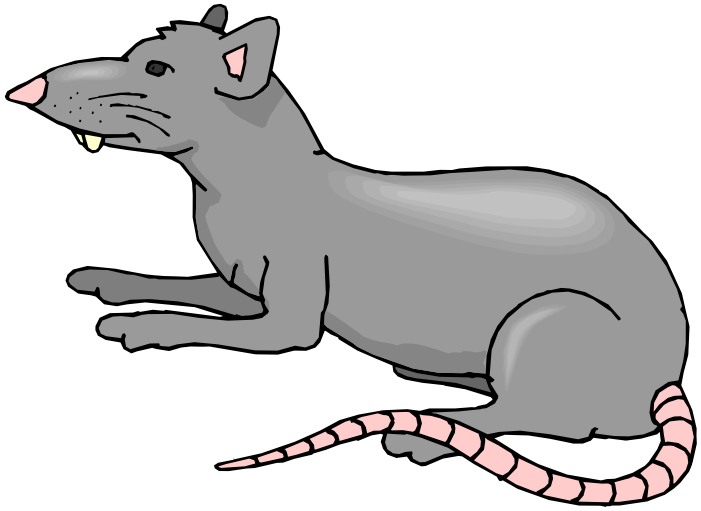
Submitted Member Article: A Note on Our Furry Little Friend: The Rat!

Most of us have not thought of them as friends, but the more we learn about the necessaties of animal models in advancing our knowledge in science and medicine, the more we realize how invaluable rats are to us.



It is believed that rats originated in Asia. Rodent fossils were first noted in Asia and North America about 45 million years ago (5). Interestingly, rats and rabbits descended from the same rodent-like ancestor anagalid. It is believed that albino rats, first to be used in breeding and in the laboratory, were Norway rats (*R. norvegicus*). The Norway rat originated in the territories that are now northern China and Mongolia and it is believed to have traveled to Europe with humans, consequently reaching North America in 1755 by means of ships (6).

In Europe, infestation of rats in its cities has fueled the popular activity called ratbating (1). This event would involve trapping the rodents by rat catchers and filling a pit with them while timing how long it would take a terrier dog to destroy all the rats. During this time, distinctively-looking rats, such as rats that lost natural ability to produce melanin, i.e. albino rats, may have been preferentially captured. This has marked the beginning of rat breeding.

Historical records show that the first albino rats to be bred for scientific research in 1828 were born to a single albino rat captured in a graveyard in England by a royal, and famous rat-catcher Jack Black (2, 3). Shortly thereafter, many laboratories realized the advantage of using rats as research models given the similarity between their internal systems with our own, and began to use rats from the wild, usually with the help of ratcatchers (4). In 1906, neurologist Henry Donaldson, who worked at the Wistar Institute in Philadelphia, produced a first standardized rat. Other laboratories, such as Sprague-Dawley Farms of Wisconsin, came up with their own strains.

As a result, a number of diverse strains evolved, some with interesting differences. Among them is **Long-Evans**, which was a product of crossing several Wistar females with a wild gray male in 1915. **Zucker** rats were bred mostly to be genetic models for research on obesity and hypertension. Interestingly, one of the two kinds of Zucker rats – the fatty one – is capable of weighing up to 1 kilogram (2.2 lbs) and has high levels of lipids and cholesterol in their blood with resistance to insulin.

As mentioned before, the **Wistar** strain was discovered at the Wistar Institute in 1906. More than half of all laboratory rat strains are descended from the original colony established by physiologist Henry Donaldson and his colleagues, including Long-Evans and Sprague Dawley strains. It is characterized by its wide head, long ears, and having a tail length that is always less than its body length.

The **Sprague Dawley** breed of rat was first produced by the Sprague Dawley farms in Madison, Wisconsin. These type of rats posses interesting anatomical characteristics, such as an inability to vomit due to its esophagus entering the stomach at the lesser curvature through a fold of tissue of the stomach. In addition, they do not have a gallbladder, and their left lung has only one lobe while the right has four. Another fun fact that you probably may not have known is that during periods of stress Sprague Dawley rats produce dark tears, which contain a pigment that fluoresces under UV light.

Throughout the years, the reputation rats have had changed from that of frightful, to appreciation and gratitude for their invaluable contribution for our well-being.

References

1. Laboratory rat - http://en.wikipedia.org/wiki/Laboratory_rat

2. Interesting facts about rats: http://hubpages.com/hub/Interesting-Facts-About-Rats

3. Rats join genome club by Carl T. Hall. San Francisco Chronicle. http://www.sfgate.com/cgi-bin/article.cgi?file=/chronicle/archive/2004/04/01/MNG325U-LAM1.DTL&type=science

4. Rat: How the World's Most Notorious Rodent Clawed its Way to the Top. Jerry Langton.

5. Meng, J. A. R. Wyss, M. R. Dawson, R. Zhai. 1994. Primitive fossil rodent from Inner Mongolia and its implications for mammalian phylogeny. Nature. 370. 134-136.

6. Grzimek 1968. Animal Life Encyclopedia. Van Nostrand Reinhold Co., New York. 579 pp

Thank you!!! to Irina Mosesova, Senior Inspector, QA from CRL Preclinical Services for the submission of this article.

Did you know?

The CCSQA now has two new email addresses for you to directly contact the board members!

Email us at:

membership@ccsqa.org

newsletter@ccsqa.org

We want to hear from you!!!

Did you know?

The Nuremberg Code was published in 1947 in response to the discovery of unethical medical experimentation by German Scientists during World War II. This set out the standards for the conduct of research involving human subjects including, voluntary consent of the subjects, results of test must be fruitful and not available by other methods, trial design must be based on animal experimentation.

CCSQA Fall Annual Meeting and Training Sessions

The CCSQA Fall meeting is going full steam ahead. The meeting is scheduled for November 18th and 19th at the Hampton Suites (see page 6).

Expect to enjoy 2 days of education and networking opportunities with your colleagues in Canada.

Planned speakers have been confirmed from the Health Canada Protection Branch to give you precise up to date information regarding the GLP monitoring authority update. A session is also planned to discuss the recent MHRA guidance and its effect on Canadian GLP laboratories and submissions. Current topics in Bioanalysis, and GCP training will be sure to interest all. Other presenters will offer a variety of topics on Bioanalytical validation, computer systems, clinical issues and regulatory updates.

The CCSQA fall meeting will also offer a chance for you to network and meet your colleagues in the industry of GLP, GMP and GCP. The meeting will once again be held at the Hampton Suites hotel on the west island. This location was chosen for its easy access and parking and we hope you will all come and become an active member of our CCSQA Society!

Meet and greet your fellow colleagues in our industry or catch up with some old friends!

Update on the DIA Annual Conference, June 2009

The 2009 DIA Conference was held in beautiful San Diego. There were close to 7000 attendees from all over the world and more than 500 conference sessions to attend. The areas covered included GCPs, Biomarkers, Round table discussions with the EMEA, FDA, EPA, among other regulatory authorities. Sessions in the management of clinical trials, efficacy, safety testing, IRB and many other areas of interest kept this meeting very informative.

There was a town hall discussion which included members of the EMEA and FDA to discuss the harmonizing of regulations in clinical trials. Clinical trial testing is now a global initiative, the FDA must accept data from many other countries (some of them not as developed as North America and Europe). This causes issues of data integrity, language, cultural differences and ethical issues.

It was indicated that the FDA, Canada, Japan and the EMEA have signed a confidentiality agreement in that they are able to share submission data between member states. Their goal is to set up a global regulatory framework since drug development is now global.

This also includes the sharing of scientific knowledge and expertise. It was acknowledged that the scientists working with the regulators must be current in the technologies at the same high level of science that is emerging in the industry. The only way to keep abreast of the changes are to share information between the two large governing bodies. The EMEA and FDA have created "cluster" groups to share information. The following clusters are now formed: 1. Oncology, 2. Vaccines, 3. Pharmacogenomics, 4. Advanced Therapy Drugs, 5. Pediatrics, 6. Orphan Drugs (ie joint applications). The confidentiality agreements in place allow the regulators to share submission and application information. They are not required to advise the Sponsor of this sharing of information however according to the panel, this is commonly done.

Other courses attended included updates on the recent regulatory findings in clinical trials, how the regulators choose which sites to focus on, and examples of recent fraudulent data in clinical trials. There was also much discussion on the qualification of principal investigators, if a general certificate should be issued in lieu of repeat GCP trainings for each trial. This is an ongoing initiative.

Did you know?

In 1941 nearly 300 people were killed or injured by taking sulfathiazole tablets (a sulfa drug tainted with Phenobarbital). This incident caused the FDA to revise its manufacturing requirements leading to what will later be called the GMPs

FDA News

The FDA website has been revamped and thus previous links have been moved.

The FDA has announced that any warning letter issued after September 2009, may also have an official close out letter when all findings have been addressed.

A close-out letter may be issued when, based on FDA's evaluation, the associated firm has provided the adequate corrective action to address the violations contained in the Warning Letter.

The close out letter will only be issued if the corrective actions have been verified as acceptable by the FDA (follow up inspection). If it is noted the corrections are not adequate (or could not be corrected) no follow up letter will be issued. Here is the link to the warning letters page.

http://www.fda.gov/ICECI/EnforcementActions/WarningLetters/

Check out recent warning letters posted by issuing office depending on your area of expertise, (CDER, CBER, GLP, GCP, GMP) these warning letters and responses contain a wealth of information that can help you in your area of compliance.

Thank you to all of you who submitted comments to the Canadian GLP Directive, because of you, our CCSQA voices will be heard when key decisions are made prior to finalizing this directive in Canada, Stay Tuned!

MHRA (Medicinces and Healthcare Products Regulatory Agency Update

August 24, 2009:

The MHRA has published a GLP update regarding the use of test sites in Canada. They have indicated that the current situation in Canada is that we are an OECD member country and are represented at the OECD working group. We have different government agencies to monitor the various industrial sectors namely:

1. Environment Canada manages a GLP compliance monitoring program for facilities testing industrial chemicals.

2. Standards Council of Canada manages a GLP compliance monitoring program for facilities testing agrochemicals.

3. Health Canada is responsible for facilities testing pharmaceutical products. Health Canada has not established a GLP monitoring program for these facilities.

As of now, Health Canada has transferred this responsibility to the Standards Council of Canada to for the GLP monitoring.

The MHRA is recommending that for any study director as part of their legal responsibility to ensure the work they are contracting to Canada be done in compliance with GLP. They must exercise due diligence in determining the GLP compliance status of sites in Canada.

The MHRA is recommending that if the test sites are used in Canada, if the site has been inspected by Environment Canada or Standards Council of Canada, it may have already been verified for GLP compliance. If the facility has not yet been inspected by these government agencies, the GLP compliance status cannot be officially verified by the MHRA. It is thus recommending that the Canadian facility be excluded from the study director claim of GLP compliance.

In summary, the MHRA published this information to make the testing facility management, study directors and QA aware of our situation in Canada and the study director must determine whether or not the GLP compliance status of the Canadian testing facility could be officially verified.

For the complete report, please verify the website at

http://www.mhra.gov.uk/Howweregulate/Medicines/Inspectionandstandards/GoodLaboratoryPractice/Whatsnew/index.htm

Did you know?

Following the Tylenol incident of 1982 where 31 million bottles of Tylenol were recalled, the FDA issued tamper resistant packaging regulations and Congress passed the Federal Anti-Tampering act of 1983 to make it a crime to tamper with consumer products. The Tylenol criminal tamperer was never found or prosecuted.

OECD Issues/Updates new Guidances

The OECD has issued and updated 10 guidances on the 9th of September 2009. Here is a summary: Updated:

- Section 2: Effects on Biotic Systems
- Section 4: Health Effects
- Corrected Test Guideline:
- Section 4: Health Effects
- Updated Work Plan for the Test Guidelines Program (TGP)

New Documents:

- Retrospective Performance assessment of the TG 426
- Report of the Validation Peer Review for the Amphibian Metamorphosis Assay

- Report of the Validation Peer Review for the 21-Day Fish Endocrine Screening Assay
- DRP on Fish Life-Cycle Tests
- Guidance Document on Mammalian Reproductive Toxicity Testing and Assessment
- Background Review Document on the Hershberger Assay
- DRP on Metabolism
- Several Validation Reports

- Further information is available at their website: http://www.oecd.org/department/0,3355,en_2649_34377_1_1_1_1_1,00.html

Canadian Chapter of the Society of Quality Assurance

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Mark Your Calendars!!!

Continental Breakfast, Lunch and Afternoon Tea/Coffee are included!

CCSQA ANNUAL MEETING CONFERENCE

REGISTRATION DEADLINE: NOVEMBER 11th!

When? Wednesday/Thursday November 18 &19, 2009

Where? Hampton Inn and Suites
1900 Transcanada Highway, Dorval, Quebec

In November 2009, the CCSQA is proud to present our annual meeting. This meeting will highlight recent developments and changes in the industry dedicated to Canadian professionals in the Quality Assurance field or related fields. This conference is a must for anyone who is interested in improving quality and staying current with changes in our regulatory profession. Be sure to attend!

You should have recently received an email including the registration form and list of Confirmed Speakers.

If you would like more information please email Janine Johnson at janine.johnson@pfizer.com and she will resend you the registration package.

Anticipated Highlights

- Canadian Monitoring Authority Update from Government, and Industry Representatives
- GLP Certification for Canadian Test Sites, what are the implications for your Company?
- Scientific Training Sessions (ISR, Validation, IT)
- GLP, GCP and GMP areas will be covered

2 days of training for only 250$ (CDN)! This includes registration for the two day meeting, 2010 CCSQA membership, and up to 5 RQAP credits for re-registration.

Location Details

1900 Transcanada highway on the West island in Montreal. The beautiful Hampton Inn & Suites is conveniently located on the TransCanada Highway, in close proximity to great shopping and restaurants, and only 10 minutes from Montreal's International Airport.

CCSQA FUN PAGE

According to the regulations, what unit is required in order for a study to be considered for approval to run clinical trials?

F	I	N	D	I	N	G	S	S	Q
R	U	Y	R	A	L	T	G	I	T
A	Y	T	E	A	I	A	P	L	P
E	A	I	G	D	L	O	S	M	P
L	P	L	U	F	S	T	G	W	V
C	R	A	L	R	D	C	D	E	A
D	O	U	A	A	E	E	C	I	L
O	T	Q	T	T	S	P	E	V	I
H	O	A	I	E	U	S	O	E	D
T	C	R	O	S	A	N	A	R	A
E	O	N	N	T	C	I	E	P	T
M	L	L	O	R	T	N	O	C	E

Use the following commonly used terms in QA to get the answer:

Audits	FDA	OECD	SOP
cGMP	Findings	Protocol	Report
Clear	Flags	QA	Review
Control	GLP	Quality	Test
Data	Inspect	SR (sample reception)	Regulation
EPA	Method		Validate

More! Canada Quiz questions

1. In Newfoundland, what is a "skiff"?
2. The town of Baddeck, Nova Scotia has a museum in honour of this inventor?
3. What do the letters CBC stand for?
4. This Canadian pushed his way across Canada in a wheelchair?
5. The name Canada comes from an Indian word which means what?
6. What does the French word "adieu" mean?
7. What is the name of Canada's northern-most ocean?
8. In what year was Canada "born"?
9. This Canadian actor starred in the movie "Back to the Future"?
10. This is Canada's first officially bilingual province?

Aristotle once said:

"Quality is not an act, it' is a habit"
384 BC-322 BC

Want to join the fun? Email me your quiz, puzzle or cartoon and it can go in the next CCSQA Northern Hemispheres Edition!!

newsletter@ccsqa.org

Career or Classified Section:

Are you interested in posting a position of interest to the CCSQA membership directory? If so, send it to newsletter@ccsqa.org and we will post it in the next edition of the newsletter or by email to all members.

CALLING ALL QA JOURNALISTS!!!

If you would like to write an article for the next edition of the CCSQA journal, let us know, we are looking for QA journalists to share their experience and knowledge!

CCSQA Newsletter

Do you have comments or suggestion for the newsletter, want to contribute? Contact us!
newsletter@ccsqa.org

Word Search Answer: Quality Assurance

Canada Quiz Answers

1. A boat
2. Alexander Graham Bell
3. Canadian Broadcasting Corporation
4. Rick Hansen
5. meeting place or village
6. good bye
7. Arctic
8. 1867
9. Michael J. Fox
10. New Brunswick

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