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RICRO is pleased to welcome our newest staff member, Catherine (Cat) Bens. Cat joins RICRO as the Quality Assurance Manager (QAM). This is a new position at the University designed to assist the CSU research community in an area that the Office of the Vice President for Research has noted is increasing in relevance for the institution.

As a land grant institution, CSU’s research and outreach mission includes much work directed at solving human and animal health problems and fostering economic development. As such, CSU faculty are actively engaged in developing new vaccines, treatments, drugs, and devices for intractable diseases and health conditions. Others are engaged in testing new products and devices developed by outside companies for debilitating human and animal diseases, to mention just a few areas of focus for CSU’s highly productive researchers. Bringing new drugs and devices to market involves significant federal regulatory oversight by the US Food and Drug Administration and US Environmental Protection Agency.

As a longtime professional in the field of quality assurance, Cat brings significant expertise to CSU to help researchers maintain compliance with these agencies’ regulations. Please read Cat’s article below to find out how she can assist your lab.

Welcome aboard, Cat!

Bill Moseley
RICRO Assistant Director and Senior IACUC Coordinator

Quality in Science: A New Support Program Is In Town To Help!

Catherine Bens, Quality Assurance Manager

I recently joined CSU, and have been fortunate enough to have already had the opportunity to meet and work with many research groups across campus. Thank you all for your warm welcome! While all research that is reviewed by the committees associated with the Research Integrity and Compliance Review Office (RICRO) are subject to federal regulations, my focus is on research endeavors involved in taking a new product to market or contracting with companies that will submit your data to the federal government in support of a research or marketing permit. In order to protect and assist researchers who will be conducting or who are planning to conduct such research, I am working to develop a Quality Assurance Program (QAP). This program is housed in RICRO and can assist you in developing the appropriate Quality Systems, Standard Operating Procedures, and data collection and validation processes to support such regulated research.

The Quality System is often defined in terms of personnel responsibilities and their training, research protocols or project plans, Standard Operating Procedures (SOPs), Quality Assurance monitoring, good documentation, final reports, and archiving. In other words, a Quality System is an organized and documented approach to activity planning, conduct, monitoring, reporting, and archiving that is defined within the appropriate regulation and federal guidelines. Unfortunately, failure to understand and follow the specific requirements of these regulations can have serious negative consequences, including failure of your research to be accepted by the government and even criminal and civil penalties for CSU, faculty and study personnel. And that’s where the Quality Assurance Program comes in.

Cont. on page 2
What is the Quality Assurance Program?

Working together, my job is to ensure that you as principal investigators, study directors, monitors, or research staff are well informed of the regulatory requirements, that systems are in place that are efficient and effective at meeting regulatory compliance, and that the project is adequately resourced and funded by the sponsor.

As with most regulatory fields, there are a few terms and acronyms that you should know in association with this type of regulated research:

**Regulatory science** is that subpart of research and manufacturing activities that is governed by quality standards promulgated by federal law, and then described by regulations enforced by the Food & Drug Administration and Environmental Protection Agency. The goals of these standards are to ensure the generation of reliable data or products of known quality for use by the federal agencies and the public.

- **GLP** = Good Laboratory Practices
- **GCP** = Good Clinical Practices
- **cGMP** = current Good Manufacturing Practices

**Collectively, these are commonly referred to as the ‘GXPs’**

The CSU Regulatory Research Quality Assurance Program (QAP) provides information and training for researchers about federal Good Laboratory Practices (GLP), Good Clinical Practices (GCP), and Good Manufacturing Practices (GMP), the recognized rules governing the conduct of non-clinical safety studies, clinical trials and regulated product manufacturing, respectively, that ensure the quality, integrity, and reliability of the study data and products. The QAP also offers the service of an independent QA Unit with inspection and auditing capabilities.

How do I know if my Research is under the QAP umbrella?

In many cases, the research being done here at CSU will be submitted to either FDA or EPA as part of a regulated product registration application. In these cases, the research must be conducted in accordance with the appropriate ‘GXP’ because the results of these activities will directly or indirectly affect a public health decision, usually by contributing to the federal agency’s understanding of the safety or efficacy of regulated products, such as foods, cosmetics, human and animal drugs, medical devices, pesticides, or toxic substances. Studies conducted under GXPs do this by defining the quality system that must be in place when the activity is occurring. If you are considering conducting research either as a self-sponsor or at the request of an outside sponsor, please contact me.

The QAP provides the following services:

- An independent Quality Assurance Unit capable of inspecting studies and conducting audits of facilities, data and research reporting to ensure GLP, GCLP and GCP compliance.
- Basic and advanced training in GLP and GCPs and can provide training in GMPs QA roles and responsibilities, auditing procedures, CAPA, data capture and form development and SOP development.
- SOP and data documentation training and review.
• Tips and guidances in quality assurance and quality control methods.
• A pool of SOPs and templates for use by researchers.
• SOP and data collection form development.
• Regulatory Gap Analysis in the GXPs, if requested.

As you know, quality cannot be tested-in after the fact. It can only be built or embedded into each project. SO, as you are thinking of your next project remember to take advantage of the QAP services highlighted on page 2, and keep the following tips in mind:

✔ Be sure to budget time, resources, systems and training into your project if you intend to or are required to meet a regulatory standard.
✔ Be sure to understand the regulatory standard under which you will conduct your research.

Even if you are not conducting research that is regulated by FDA or EPA GXPs, there are advantages to developing a quality system for any research activity that you do, including:

- Increase the quality, integrity and reliability of data
- Create a product or data set of known, documented quality
- Support ‘bench-top to market’ research and manufacturing
- Access to funding otherwise not available
- Support Industry needs

Please feel free to contact me to discuss your research ideas and needs!

Cat Bens, MS
Quality Assurance Manager
Quality Assurance Program (QAP); cat.bens@colostate.edu, 970.491.5445
Website: http://ricro.colostate.edu/fed_regs.htm

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**IBC News:**

The *NIH Guidelines now include Synthetic Nucleic Acid Molecule*

The NIH Office of Biotechnology Activities (OBA) has recently revised the *NIH Guidelines for Research Involving Recombinant DNA Molecules (NIH Guidelines)* to include the use of synthetic nucleic acid molecules under the purview of the Institutional Biosafety Committee (IBC). The amended *NIH Guidelines* now apply to research with synthetic nucleic acids that presents biosafety risks equivalent to recombinant DNA research that is subject to the *NIH Guidelines*. For example, research with a genetically modified virus or a vector derived solely by synthetic techniques is subject to the amended *NIH Guidelines*. Several sections of the *NIH Guidelines* have been modified and the full title has been changed to: *NIH Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules*.

In the context of the new *NIH Guidelines*, recombinant and synthetic nucleic acids are defined as:

i. molecules that a) are constructed by joining nucleic acid molecules and b) that can replicate in a living cell, i.e., recombinant nucleic acids; or

ii. nucleic acid molecules that are chemically or by other means synthesized or amplified, including those that are chemically or otherwise modified but can base pair with naturally occurring nucleic acid molecules, i.e., synthetic nucleic acids, or

iii. molecules that result from the replication of those described in (i) or (ii) above.

Cont. on page 4
**Is my work exempt from these regulations?**

In keeping with the exemptions for recombinant DNA molecules, certain synthetic nucleic acid molecules are exempt from the amended *NIH Guidelines*. Specifically, synthetic nucleic acids molecules that meet the following criteria are exempt: Synthetic nucleic acids that:

1. Can neither replicate nor generate nucleic acids that can replicate in any living cell (e.g., oligonucleotides or other synthetic nucleic acids that do not contain an origin of replication or contain elements known to interact with either DNA or RNA polymerase), and;
2. Are not designed to integrate into DNA, and;
3. Do not produce a toxin that is lethal for vertebrates at an LD50 of less than 100 nanograms per kilogram body weight.

These changes went into effect March 5, 2013. Thus, the NIH now requires IBCs to review and approve proposed research involving synthetic nucleic acid molecules (in addition to rDNA). The IBC has modified the rDNA section of the Project Approval Request Form (PARF) to include synthetic nucleic acid molecules. All ongoing and proposed experiments with synthetic nucleic acids that are newly subjected to these amended *NIH Guidelines* need to be registered by the Principal Investigator with the IBC, by initiating a new (or amending a current) PARF.

If you have questions regarding these regulations, please contact:
Christine Johnson, IBC Coordinator, at christine.johnson@colostate.edu or Dr. June Medford, Chair of the IBC, at june.medford@colostate.edu.


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**Staffing Updates**

**Who’s On First?!**

Our front office support team has seen some changes in the last few months.

The RICRO Assistant Administrator since January 2012, Jenny Thompson, recently accepted a position at the University of Colorado, Denver. We thank Jenny for all her hard work and innovative ideas. We are sorry to see her go, but wish her all the best in her new endeavors.

RICRO is pleased to announce that Emily Bauer, a recent CSU graduate and a 4-year RICRO student employee, is now our front office Assistant Administrator. For those of you who have interacted with Emily, you know that she is a joy and pleasure to interact with, and we are pleased that she is able to continue on with RICRO. Emily has just completed her BS in Natural Resource Recreation and Tourism, and will begin a Master’s degree in Tourism Management this fall. In addition to her CSU studies and life at RICRO, Emily is an avid snowboarder, outdoor enthusiast, self-proclaimed “plant nerd,” and all-around ray of sunshine! Emily can be reached at: 491-1553 or Emily.Bauer@colostate.edu.

**RCR Coordinator**

The staff of the Responsible Conduct for Research (RCR) compliance initiative is also making some changes.

Marty Welsch, who has been involved with the program since 2009, has accepted the appointment of Human Resource Director of the Office of the VP for Research, effective March 1, 2013. Marty regretfully has to leave behind this part of her role at CSU. Thank you, Marty for all you have done for the program! Wishing you all the best in your new position!

The new RCR Coordinator is Margaret Saldana, Organizational Development and Learning Assessment (ODLA) coordinator in the Office of the VP for Research. Please update your RCR contact information for any questions regarding RCR to either Margaret at 491-1526 or Margaret.Saldana@colostate.edu or Kathy Partin, RICRO Director, at 491-1553 or Kathy.Partin@colostate.edu. Welcome to RICRO, Margaret!
Responsible Conduct of Research
Workshop on Plagiarism, May 8, 2013

Mark your calendars to attend a workshop that will focus on the important and often misunderstood topic of plagiarism. This day-long workshop will help you to recognize and avoid plagiarism in academia and research.

The workshop will feature panel discussions and presentations by:

◊ **Scott J. Moore, Ph.D., J.D.** - *To Cite or Not To Cite: The Plagiarist's Dilemma*, National Science Foundation Office of the Inspector General Investigative Scientist

◊ **John E. Dahlberg, Ph.D.** - *How the Office of Research Integrity handles the complex topic of plagiarism*, HHS Office of Research Integrity Director of Investigative Oversight

**Date:** Wednesday, May 8, 2013

**Time:** 9:00 a.m. - 4:30 p.m.

**Location:** Lory Student Center, North Ballroom

**Who can attend:** The workshop is free and open to the public, but we ask that you register by May 1, 2013.

**Register at:** [http://ricro.colostate.edu/Plagiarism2013/PlagiarismRegistration.html](http://ricro.colostate.edu/Plagiarism2013/PlagiarismRegistration.html)

For more information regarding the event, please feel free to contact Emily Bauer at 491-1553 or navigate to: [http://ricro.colostate.edu/Plagiarism2013/PlagiarismEvent.html](http://ricro.colostate.edu/Plagiarism2013/PlagiarismEvent.html)

**Sponsored by:** Colorado State University – Fort Collins, University of Wyoming, University of Northern Colorado, University of Colorado Denver, University of Colorado Boulder, Colorado State University - Pueblo, The CSU Institute of Learning & Teaching, and the CSU Graduate School.

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Spring 2013 Semi-Annual Animal Care and Use Facility Inspections

Six months have passed, again…. That means that the IACUC is conducting its required spring 2013 semi-annual animal housing and use facility inspections the second and third weeks of April. Members of the committee are visiting all facilities where animals are housed and where they are taken for procedures. PIs of protocols have been contacted by the RICRO staff regarding the timing of the inspections teams visiting the various facilities. The committee asks that Principal Investigators/Study Directors make themselves, or at least someone knowledgeable about the animal use in their laboratory, available during the inspection time. A tip sheet for preparing for semi-annual inspections can be found on the RICRO IACUC webpage at: [http://ricro.colostate.edu/IACUC/Documents/LaboratoryPreparationfortheSemi-AnnualInspection.pdf](http://ricro.colostate.edu/IACUC/Documents/LaboratoryPreparationfortheSemi-AnnualInspection.pdf)
Lunch-and-Learn Series Continues - Thank You to our Guest Presenters!

Continuing our series of outstanding Lunch-and-Learn events, RICRO wishes to thank our most recent guest presenters.

Mark Wdowik

On December 3, 2012 RICRO was pleased to host Mark Wdowik, Assistant Vice President for Research and Industry Partnerships, for a Lunch-and-Learn session. AVPR Wdowik provided our staff an overview of the Office of the Vice President for Research’s efforts at fostering greater partnerships with industry. This effort will become ever more critical as federal research dollars shrink. While such partnerships fit within CSU’s land-grant mission, they will require a different mindset from the research community so that both industry and academia find the relationship mutually beneficial. Following the presentation we discussed the challenges and opportunities that industry partnerships may pose for the research oversight committees RICRO assists. Thanks to AVPR Wdowik for his time.

Grant Calhoun, J.D. (CSU Export Control Administrator) presented an overview of Export Controls, outlining the basics from what is “Export Control,” what constitutes “export,” who controls exports at CSU, and how Export Controls could be a part of the research projects that we see here at RICRO. We share a special affinity with Grant and his regulatory work, and hope to meet with him again soon!

If you have questions regarding Export Controls, please take a moment to check out the information about this issue at the Export Control website: http://web.research.colostate.edu/OSP/export.aspx

Thanks again, Grant!

Jenna Burton, DVM, DACVIM (Assistant Professor and Oncology Clinical Trials Coordinator) and Kara Hall (Oncology Clinical Trials Nurse) visited our office on March 14th to talk with us about the clinical trials that take place at the Flint Animal Cancer Center (ACC). The ACC investigators conduct much cutting-edge research helping companion animals survive a cancer diagnosis. Much of that work is translational to and from human medicine. It was inspiring to learn about this group of CSU researchers who are collaborating with others across the country to address real-world problems with targeted solutions. Thanks for your time and kind presentation for us.
Notes from PRIM&R’s Webinar - “Online Research, Social Media, and the IRB: Assessing Ethics, Norms, and Risks”

The IRB recently had the opportunity to attend a webinar concerning “Online Research, Social Media, and the IRB: Assessing Ethics, Norms, and Risks” presented by the Public Responsibility in Medicine and Research (PRIM&R) group. The guest speakers for the webinar were Elizabeth Buchanan, Ph.D. (Endowed Chair in Ethics and Director, Center for Applied Ethics, University of Wisconsin), and Joseph Konstan, Ph.D., (Associate Dept. Head, Department of Computer Science and Engineering, University of Minnesota).

Keeping up-to-date with this constantly changing field is not easy, and we were especially anxious to learn all we could. Below are a few of the main points that we took away from the webinar, and if you have further comments or questions, please feel free to contact Janell or Evelyn.

The presenters shared with us draft comments regarding online research from the Secretary’s Advisory Committee on Human Research Protections (SACHRP) “Investigators and IRBs should remember that the Belmont principles...are as applicable to internet research as they are to any other form of human subjects research.” (http://www.hhs.gov/ohrp/sachrp/mtgings/2013%20March%20Mtg/internet_research.pdf)

When thinking about privacy, keep in mind that anything posted on the internet has a “greased” or “malleable” nature; what’s private one minute, may be public seconds later. For example, a Twitter post can move from being private to available to anyone on Twitter with just one re-Tweet to a non-private account. Due to this greased nature of information, a PI should carefully consider any possible “downstream harms” to participants.

Elizabeth Buchanan shared a graphic from FredCavazza.net (also: http://www.fredericavazza.com/blog/in-english/and http://www.forbes.com/sites/fredcavazza/) that showed the complex array of social media sites (and this is just a sampling of these sites!). She suggested that investigators provide the IRB a snapshot of the website screen so that the reviewers can have a better understanding of that particular site’s architecture. While we are fairly familiar with Facebook, most reviewers will have little or no knowledge of sites such as “Crowdstorm” or “Phorum.” Letting the IRB see the online environment will help facilitate the review process.

To make the online consent process more interactive, the presenters suggested that instead of having a single “I consent” radio button at the end of your online cover letter, consider engaging the participant by asking a series of Yes/No questions to obtain consent.

The Belmont Principle “Respect for Persons” includes consideration of protecting participant’s privacy and maintaining confidentiality. When informing your participants how you will keep their data private, it’s probably no longer accurate to say that their data will only be stored in a locked file cabinet for three years. Know the end-user’s agreements for the social network site you will be using, and let the IRB and participants know how long their data will remain online and who (in addition to the PI) will have access to it.

Website suggestions from the presenters included:
Fred Cavazza: http://www.fredericavazza.com/blog/in-english/
Univ. of S. California IRB: http://oprs.usc.edu/education/internet/
Association for Internet Researchers: http://ethics.aoir.org/index.php?title=Main_Page

The CSU IRB has developed tip sheets regarding online research, and plan to be adding more to our tips section soon: http://ricro.colostate.edu/IRB/tips.htm. If you have any questions regarding your online research, please feel free to contact Janell or Evelyn.
Research Administration is a Team Effort:
Frequently Forgotten Important Amendments

Conducting research at CSU requires interaction with a team of CSU personnel that may include members of your research group, your Department Head, departmental accountant, RICRO coordinators, the review committees (IACUC, IRB, IBC), and Sponsored Programs. In order to be sure that each team member has the information that they need when they need it, it’s important that information on the protocol is up-to-date and accurate. We’ve found that researchers frequently overlook a few updates that can be critically important to other members of the research administration team: updating the funding & personnel for your project.

Linking Sponsored Projects Funding to Protocols

The appropriate regulatory committee approvals (IBC, IRB, and IACUC) must be in place before Sponsored Programs can set up 5-3 accounts for grants and other sponsored projects. That is one reason that the IBC, IRB, and IACUC protocol application forms ask about the funding source.

In order to facilitate the process of Sponsored Programs accepting your awards and setting up accounts so you can begin utilizing the funding for your research projects, please be sure to indicate the funding source and PASS number(s) for the correlated grant or contract application.

If a funding source is added after the protocol is approved, please submit an amendment in the respective online system. Such amendments can be handled administratively by RICRO staff, and therefore can be done quickly.

Updating the Research Personnel on the Protocol

Has the Department Head for your department recently changed? Did a student who is listed on your protocol(s) recently leave CSU? These are common scenarios, but do you know that when the Department Head in your department changes, the Department Head listing on your protocol in eProtocol is NOT automatically updated? RICRO staff are not always aware that the department head for your department has changed, and they cannot edit your protocol to make these minor changes unless you have submitted a form to RICRO (i.e., we can only open your protocol in view mode unless a form has been submitted for review). Please remember to take a quick look at the personnel listed on your protocol and submit an amendment if there have been any changes. These updates are your responsibility, and as with updating the funding information, this amendment can be quickly handled administratively by the coordinators.

Contact the appropriate committee coordinators (http://ricro.colostate.edu/contact.htm) with any questions on how to submit the amendment requests. For the IRB and IACUC, amendments can be done via eProtocol (https://csu.keyusa.net), and in the IBC system you can contact the IBC Coordinator (http://ricro.colostate.edu/IBC/contact.htm).
Updated IACUC Policies and Guidelines Posted

There are some IACUC policy and guideline changes that have been made in the past few weeks of which investigators and their staff should be aware. The IACUC has just approved a revision to the “Policy on Ascites Fluid Production” relating to the use of mice for production of monoclonal antibodies. Additionally, the IACUC has revised the “Guidelines for Euthanasia of Rodents Based on Humane Criteria.” Finally, the committee has approved a new set of “Guidelines for Rodent Survival Surgery.” Please take the time to look over this revised policy and new guidelines if you use rodents. All IACUC policies and guidelines are posted on the IACUC pages on the RICRO website at [http://ricro.colostate.edu/IACUC/policies.htm](http://ricro.colostate.edu/IACUC/policies.htm). If you have not looked at those documents recently, please take a few minutes to do so.

Schedule of Events

April 2013 - June 2013

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<th>April</th>
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<tr>
<td>3 IBC Deadline 12:00 pm</td>
<td>1 Basic Research Techniques with Mice - UV</td>
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<td>4-5 &quot;Cardiovascular Research at CSU: Molecules, Models, and Mankind&quot; Event</td>
<td>1 IBC Deadline</td>
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<td>9 IACUC Deadline 12:00pm</td>
<td>8 IBC Meeting</td>
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<tr>
<td>10 IBC Meeting</td>
<td>8 RICRO Workshop on Research Plagiarism</td>
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<td>10 Basic Research Techniques with Mice - UV</td>
<td>9 IRB Deadline 5:00 pm</td>
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<td>11 IRB Deadline 6:00 p.m.</td>
<td>14 IACUC Deadline 12:00pm</td>
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<td>16 OVPR Presents: An Evening with novelist Barbara Shapiro</td>
<td>15 Mouse BSL-3 Training - UV</td>
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<td>17 Mouse BSL-3 Training - UV</td>
<td>16 IRB Meeting</td>
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<td>18 IRB Meeting</td>
<td>20 IRB On-campus Human Subjects Training</td>
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<td>22 IRB On-campus Human Subjects Training</td>
<td>22 Rodent Anesthesia Training - UV</td>
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<td>23 IACUC Meeting</td>
<td>27 Closed</td>
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<td>29 Rodent Necropsy/Dissection Training - UV</td>
<td>28 IACUC Meeting</td>
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June

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<td>13 IRB Deadline 5:00 p.m.</td>
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CSU Quality Assurance Program (QAP)

The CSU Regulatory Research Quality Program (QAP) provides information and training for researchers about federal Good Laboratory Practices (GLP), Good Clinical Practices (GCP) and current Good Manufacturing Practices (cGMP), and the recognized rules governing the conduct of non-clinical safety studies, clinical trials, and regulated product manufacturing, respectively, that ensure the quality, integrity and reliability of the study data and products. The QAP also offers the service of an independent QA Unit with inspection and auditing capabilities.

WHAT DOES IT REALLY MEAN?
There is often a lot of confusion regarding the GXP terms and lexicon. The following is a brief summary of each regulation and their regulatory reference.

**Good Laboratory Practices - GLP**

**Summary:** Standards of conduct for non-clinical research intended to be submitted to either the US Food and Drug Administration (FDA) or the Environmental Protection Agency (EPA) in support of an application for a marketing or research permit. GLPs encompass both lab and field research and dictate the organization, process, and conditions under which laboratory and field studies are planned performed, monitored, recorded, and reported. Product research may include drugs for human and animal use, aroma and color additives in food, cosmetics, biological products, medical devices, pesticides, insecticides, fungicides, and toxic substances.

**Regulatory Reference:**
- 21 CFR Part 58 FDA Good Laboratory Practice Standards
- 40 CFR Part 160 EPA FIFRA (pesticides, etc)
- 40 CFR Part 792 EPA TSCA (toxic substances)

**Guidance Documents and Other Resources:**
- OECD Good Laboratory Practice (GLP) guidelines – Internationally recognized consensus documents for the conduct of GLP studies
- FDA 1981 Questions & Answers - Good Laboratory Practice Regulations
- Comparison Chart of FDA and EPA Good Laboratory Practice (GLP) Regulations and the OECD Principles of GLP
- EPA Good Laboratory Practices - Advisories

**Helpful Links:**
- [http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/NonclinicalLaboratoriesInspectedunderGoodLaboratoryPractices/ucm072738.htm](http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/NonclinicalLaboratoriesInspectedunderGoodLaboratoryPractices/ucm072738.htm)
- [http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm135197.htm](http://www.fda.gov/ICECI/EnforcementActions/BioresearchMonitoring/ucm135197.htm)
**Good Clinical Practices - GCP**

**Summary:** Standards under which clinical research intended to be submitted to the US Food and Drug Administration (FDA) must be conducted. The regulations cover a number of different aspects of clinical research and include both human and animal clinical trials. An additional guidance for laboratory research conducted in support of a clinical trial are known as the Good Clinical Laboratory Practices (GCLP).

**Regulatory Reference:**
- Electronic Records; Electronic Signatures (21 CFR Part 11)
- Protection of Human Subjects (Informed Consent) (21 CFR Part 50)
- Additional Safeguards for Children in Clinical Investigations of Food and Drug Administration-Regulated Products (21 CFR Parts 50 and 56)
- Informed Consent Elements (21 CFR 50.25(c))
- Exception From General Requirements for Informed Consent (21 CFR 50.23(e))
- Financial Disclosure by Clinical Investigators (21 CFR Part 54)
- Institutional Review Boards (21 CFR Part 56)
- FDA IRB Registration Rule (21 CFR 56.106)
- FDA IRB Registration Rule (21 CFR 56.106) (printable PDF version)
- Good Laboratory Practice for Nonclinical Laboratory Studies (21 CFR Part 58)
- Investigational New Drug Application (21 CFR Part 312)
- Foreign Clinical Trials not conducted under an IND (21 CFR 312.120)
- Expanded Access to Investigational Drugs for Treatment Use (PDF - 216KB)
- Charging for Investigational Drugs (PDF - 204KB)
- Form 1571 (Investigational New Drug Application)
- Form 1572 (Statement of Investigator)
- Applications for FDA Approval to Market a New Drug (21 CFR Part 314)
- Bioavailability and Bioequivalence Requirements (21 CFR Part 320)
- New Animal Drugs for Investigational Use (21 CFR Part 511)
- New Animal Drug Applications (21 CFR Part 514)
- Applications for FDA Approval of a Biologic License (21 CFR Part 601)
- Investigational Device Exemptions (21 CFR Part 812)
- Premarket Approval of Medical Devices (21 CFR Part 814)

**Guidance Documents and Other Resources:**
- GCP for Animal VICH GL9
- DAIDS Guidelines for Good Clinical Laboratory Practice Standards
- WHO Good Clinical Laboratory Practice (GCLP)
- MHRA Good Clinical Practice - Guidance on the maintenance of regulatory compliance in laboratories that perform the analysis or evaluation of clinical trial samples.

**Helpful Links:**
- [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm114928.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm114928.htm)
- [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm155713.htm#FDARegulations)
Good Manufacturing Practices - GMP

Summary: Standards under which products are manufactured “which is aimed at ensuring that products are consistently manufactured to a quality appropriate to their intended use.” GMP practices are the minimum standards and methods to be used in, and the facilities or controls to be used for, the manufacture, processing, packing, or holding of a drug or medical device to ensure that the drug or device meets safety, identity, strength, quality, and purity characteristics that it purports or represents to possess.

Regulatory Reference (examples):
21 CFR Part 210 Current Good Manufacturing Practice In Manufacturing, Processing, Packing, Or Holding Of Drugs
21 CFR Part 211 Current Good Manufacturing Practice For Finished Pharmaceuticals
21 CFR Part 11 Electronic Records; Electronic Signatures
21 CFR Part 600 Biological Products: General
21 CFR Part 610 General Biological Product Standards
21 CFR Part 820 Quality System Regulation

Industry recognized current Good Manufacturing Practices (cGMP)

Guidance Documents and Other Resources:

Helpful Links:
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/QualitySystemsRegulations/default.htm

OTHER STUFF
Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment
Good Tissue Practice (GTP)  21CFR1271 “Human Cells, Tissues, and Tissue-based products”

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