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On Volunteerism...

"But where was I to start? The world is so vast. I shall start with the country I know best, my own. But my country is so very large. I had better start with my town. But my town too is large. I had better start with my street. No, my home. No, my family. Never mind. I shall start with myself."

Elie Wiesel
Nobel Laureate

A Message from your Section Chair

To My Fellow Members,

Well, it's springtime again, and things are changing as they always do; the weather is getting nicer and daylight is getting longer. Things are also changing at LI ASQ. The current leadership group is making way for a new leadership group. I would like to extend my congratulations and best wishes to Kerry Donelan (our new Treasurer), Andrea Isear (our new Secretary), and Sam Prasad (our new Section Chair). My very best wishes go out to them, as they lead our section into a new year starting July 1st. I wish nothing but the best of luck for them and the other committee members that Sam will select. It has been an honor and a privilege to serve as your Chair for the last 2 years, and I am looking forward to serving in any capacity I can to help the Section and our new leaders.

Looking back, I have to say we have been very busy since I last wrote to you. We held our 3rd Annual Awards and Networking Dinner in which we honored Sartorius Group North America, and long-time Section Officer and Volunteer, John Lombardi. We will be officially inducting them into the Quality Hall of Fame on May 3rd at Farmingdale State College. We also held an Overview of Lab Weighing and Filtration Technologies after work meeting at Sartorius, as well as rolled out a Certified Quality Auditor Exam Prep class (at a new venue - Fougera Pharmaceuticals in Melville) and a Lean Six Sigma Green Belt class at Farmingdale State College. As of now, we are immediately planning at least another 3 after work meetings, including a Tour of the Morrelly Homeland Security Center in Bethpage on Tuesday, April 10th (registration is still open and is going quite well) , another Green Belt Course at Farmingdale, and of course our Fall Conference. In the meantime, we are in the process of transitioning our business processes to the new section leaders. It's going to be a very busy spring.

As always, I need to thank our volunteers. Without their hard work, we would not be able to bring you the different programs we offer. I would like to thank James Anderson, Will Bagnasco, Kelvin Campbell, MaryEllen DeCicco, George DeMott, Kerry Donelan, Rupal Doshi, Meegan Dowling, Joe Franco, Andrea Isear, Joe Labas, Sam Prasad, Mary Sansone, Jackie Tordik, and Mark Trotter. I would also like to thank our Vice Chair, Rick Calabrese for not only his hard work, but also for his ideas and his advice. His experiences as Past Chair helped me to better understand the needs of our section and how we can best serve it. I will always be grateful to not only him, but to all the people I mentioned above. I learned a lot from these people and I enjoyed working with them. I am proud to know them and I am honored to have worked with them. If you would like to help us plan or speak at one of our events, please contact us at info@asqlongisland.org. We always need help and we would love to hear from you.

Again, please join me as I wish the new Section leaders the best of luck. I am looking forward to what the rest of my term brings, as well as what we will be planning for the upcoming year. I also wish you, our members, good health and continued success, and I look forward to meeting more of you in the future.

Thank you,

Richard Lombardi

Long Island Section 303
The Global Voice of Quality™

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From the Editor

I have been a software engineer for most of my adult life. The good news is that software still fascinates me. We are going through an incredible period of technological innovations, which has forced the software industry to constantly change to accommodate new programming paradigms. We started with procedural programming; moved to structured, functional, event-driven, object-oriented and a host of other programming methodologies. The bad news is that software quality continues to be terrible when compared to hardware, pharmaceutical, manufacturing and other industries. . Reportedly, about 70% of software projects fail according to the Standish Report. There have been several studies by organizations like Mercer Consulting, British Computer Society, National Institute of Standards and Technology (NIST), Tata Consultancy and Association of Computing Machinery (ACM), who have attempted to estimate the cost of software failures. While these studies do not agree on the percentage of failed projects, there is general consensus that the cost is upwards of $100 billion per year.

Don't get me wrong. The evolution of software engineering has been a tremendous success. We only need to look at our computers, tablets, e-book readers, smart phones and other hand-held devices to understand how they have dramatically transformed our everyday lives, primarily because of the software applications that run on them. But that success has a darker side to it - one that is plagued with catastrophic failures. Some examples of these major software failures can be found at:

Software Hall of Shame (from IEEE article, *"Why Software Fails"*)
http://spectrum.ieee.org/computing/software/why-software-fails

History's Worst Software Bugs (*Wired*)
http://www.wired.com/software/coolapps/news/2005/11/69355

Why haven't we learned from these failures? Why does software quality continue to be an issue even in 2012? Watts Humphrey, a senior fellow at the Software Engineering Institute at Carnegie-Mellon University, says that unrealistic construction schedules is the primary reason. He writes, "Two questions have often bothered me about software work. First, why do competent software engineers agree to completion dates when they have no idea how to meet them? Second, why do rational executives accept schedule commitments when the engineers offer no evidence that they can meet those commitments? Where software is concerned, many otherwise hardheaded executives willingly accept vague promises and incomplete plans."

Unrealistic schedules force engineers to skip quality control checks during the elaboration and construction phases of the software project. Management and business stakeholders push to deliver the software to market with little testing. The end result is usually not good. There is an old adage in software engineering, "If it doesn't have to work, we can build it really fast."

As software engineers, it is our primary responsibility to build software that meets specifications. There are no short cuts. A robust set of quality assurance standards together with a comprehensive quality control test plan must be part of any software project.

Join ASQ and learn how to improve software quality in your company.

The Quality Club at Farmingdale State has been quite active. This issue has an article by Kenneth Johnson, a member of the Quality Club, on the Dominic A. Murray Foundation, whose goal is to promote sports health and safety.

There is a Latin proverb that says, "By learning you will teach; by teaching you will understand." Kerry Donelan recounts her experience teaching a Green Belt training class at ICON Laboratories.

Rich Lombardi and Rick Calabrese write about our third annual awards and networking dinner at Peppercorn's in Hicksville.

In an article that originally appeared in the March 2005 issue of Strategy & Innovation, the pharmaceutical industry was taken to task because of its high cost of prescription medications and its worrisome reliance on blockbuster drugs. A common root cause is the decline in research and development dollars. In this issue of Quality Islander, Mark Trotter writes eloquently on the best practices for biomedical research and drug development aimed at boosting R&D productivity.

Look for our next issue to be published in July 2012.

Sam Prasad

Dr. Joseph Juran's 10 steps to quality improvement:

- **Build awareness of the need and opportunity to improve**
- **Set goals for that improvement**
- **Create plans to reach the goals**
- **Provide training**
- **Conduct projects to solve problems**
- **Report on progress**
- **Give recognition for success**
- **Communicate results**
- **Keep score**
- **Maintain momentum**

Dominic A. Murray Foundation Promoting Sports Health and Safety By Kenneth Johnson

On October 5, 2009, 17 year old student, Dominic A. Murray died from sudden cardiac arrest (SCA) after collapsing on the basketball court at Farmingdale State College. This tragic event happened a few weeks after Murray received medical approval to play college sports. On February 25, 2010, The Dominic A. Murray Foundation, Inc., a not-for-profit organization was founded and incorporated by his mother, Melinda Murray and the New York State Department of State.

The purpose of the Dominic A. Murray Foundation is to promote sports health, education and safety. Contrary to what many think, SCA is not a heart attack. A heart attack occurs if blood flow to a part of the heart muscle is blocked, usually the heart does not suddenly stop beating. SCA is the sudden and unexpected stop of the heartbeat. It affects athletes as well as non-athletes. It can occur regardless of a history of heart problems and can strike at any time. Their goal is to raise awareness of SCA and prevent its occurrence in young athletes. The two programs under the foundation are DomHeart21 and the Dominic A. Murray 21 Scholarship and Award Program. DomHeart21's goal is to provide heart screening programs in educational and youth athletic establishments. The Dominic A. Murray 21 Scholarship and Award Program provide funds to college students for education.

Quality assurance plays a vital role in all industries. Each industry functions differently but quality is valued by all. Through effective awareness, events and clear and concise communication; their actions have the power to save a life. A key factor of effective speaking is to know your audience. "Depending on the audience I am speaking to, I know what material to bring, what terms to use, and which experiences to share," said Melinda Murray. When a delicate life may hang in the balance, nothing less than the highest quality can be accepted. Faith, Integrity, Heart, Passion and Awareness are what leads the foundation's choices.

The foundation provides training in the use of Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) to coaches, teachers, and youth athletic organizations. The DomHeart21 program heart screenings and the other events the foundation sponsors are efficient methods to meet their objective. The Dominic A. Murray Foundation exemplifies quality through their endeavors to increase awareness and advocate for youth athletic health. "This is an epidemic, so quality and sharing validated research is important to the foundation to educate individuals and raise awareness," insists Murray.

Kenneth Johnson,
Quality Club Student,
Farmingdale State College

Upcoming Events

April 10, 2012: Tour of the Morrelly Homeland Security Center, Bethpage NY

May 3, 2012: 3rd Annual Quality Hall of Fame Induction, Lupton Hall, Farmingdale State College

May 21–23, 2012: ASQ World Conference on Quality and Improvement in Anaheim, CA.

Sep 4, 2012: Lean Six Sigma Course at the Green Belt Level at Farmingdale State College

Visit http://asqlongisland.org for more details.

Green Belt Training at ICON Laboratories
By Kerry Donelan

I'm just back from conducting a Green Belt training class in Dublin, Ireland, for 10 colleagues. The language of process and quality improvement is quite universal. As a Process Improvement Specialist, training is probably my favorite part of the job. Truthfully, there isn't much I don't enjoy about my job because there's always something new to tackle. It's certainly never boring.

Management is very supportive of our Green Belt program. This class was 8 days over two separate weeks, four weeks apart. Green Belt training gives me so much energy. Teaching others about the various tools of process and quality improvement always inspires me to recommit to using them in all that I do.

In conducting training, we try to provide real-life examples and do hands-on activities. When you experience or actually use a tool, you remember much more than if you just hear or read about it. There are many ways people learn, and a variety of approaches seems to be effective.

Many Green Belt classes will cover the same material in general. You'll learn about the DMAIC method. You'll learn about various tools and statistics that are useful during DMAIC. For example, in Define we talk about tools such as the project charter, stakeholder analysis and the SIPOC. We have students come to class with ideas about what improvement project they'd like to work on. Then, we demonstrate the tools, and during exercises, they use them to begin to define their own projects. Then in Measure we review techniques such as the fishbone and affinity diagrams, the Pareto chart, and sampling. We talk about brainstorming and various approaches to it. We review the five whys and the importance of getting to the root cause. We also talk about assessing your measurement system. Measure offers a great opportunity to do hands-on exercises to demonstrate these tools. For example, having the group do an affinity diagram to identify the requirements for their next vacation, or judging a 'good cookie' during an exercise to assess a measurement system. These experiences allow participants to connect to the materials in a far more personal way than just reading about them.

One of the best parts of Green Belt training is during the second week when we finish up the Lean unit by holding an office simulation. I get to sit back and watch the group put into action many of the things they've learned. They really experience confronting problems, getting to the root cause, brainstorming and then piloting solutions. Amazingly, each class approaches it a little differently and comes up with new ideas and solutions. I try to show them that even if one never does a DMAIC project, process improvement tools are powerful in helping quantify and solve problems.

Perhaps the greatest advantage of attending a Green Belt class is the shared learning. Hearing about what others plan to work on and how they think they can use the tools, and being there for questions and feedback are invaluable to the learning experience. They're also invaluable to the instructors. I get so many ideas with every new Green Belt I train. After class is done, my students often thank me, but I really wish to thank them. Sharing my knowledge with them leaves me energized and excited to start the next improvement project with a new team that is sure to have new ways of looking at problems and solutions.

For information on Green Belt training classes available on Long Island, visit LI ASQ's website at ASQLongIsland.org

Kerry Donelan
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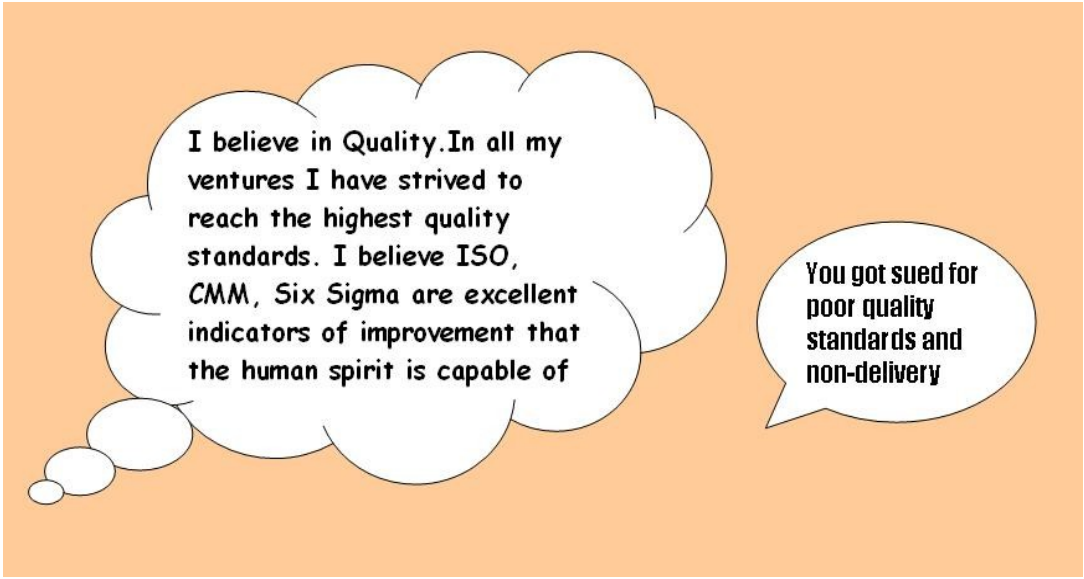

Hall of Fame Dinner
By Rich Lombardi and Rick Calabrese

Introduction

On January 19th 2012 the LI ASQ held its third Annual Awards and Networking Dinner. The meeting was held at Peppercorn's located in Hicksville, NY. The meeting was well attended with over 30 people in attendance. In 2009, to celebrate our 50th Anniversary of service to Long Island, we instituted our Quality Hall of Fame (housed at Farmingdale State College) to honor Long Island companies and individuals who go above and beyond what is needed to simply satisfy regulations or efficiency. "This year, we celebrated the induction of a Long Island company into our Quality Hall of Fame that has dedicated itself to the pursuit of quality through robust quality systems, its people and its management. We also celebrated the induction of a man who held many positions on the Long Island ASQ's Board of Directors, including Chair, Vice Chair, and others. He devoted many years of volunteerism and enthusiastic leadership to Long Island ASQ.

Company Inductee

The first inductee was Sartorius Group North America. They are a leading provider of cutting-edge equipment and services for the biopharmaceutical industry. Its integrated solutions covering fermentation, filtration, purification, fluid management, and lab technologies support the biopharmaceutical industry to develop and produce drugs. In addition to having sites all around the world, there NA HQs is located right here in Bohemia. The global VP of Quality, Alan Burns was on hand to accept the award. Also on hand was the LI previous past chair and the Global Corporate director for Quality systems, Rick Calabrese.

Individual Inductee

The individual Inductee has been a member of our society for over 35 years. He served on the LI ASQ Advisory Board and Awards Committees as well as served on the Board of Directors - as Newsletter Chair, Vice Chair and of course, Section Chair. He was awarded the Section's 1990 McGrady/Seifer Award, and received the Engineers Joint Committee of Long Island 1993 Engineering Achievement Award. He has previously received a Lifetime Appreciation Award from the Members and Board of Directors of the American Society for Quality. This testimonial award was presented in recognition of Leadership and Distinguished Service from a grateful Long Island Section, which included past ASQ LI Section Chairman and Executive Board Committee Member, ASQ Fellow, and a lifetime spent as a quality leader, innovator, and teacher. It was our great privilege to induct John Lombardi into the Long Island ASQ Quality Hall of Fame.

Scholarship Recipients

The scholarship recipients were announced at the dinner as well. "Each year, LI ASQ awards scholarships to family members of our membership as well as to students at Farmingdale State College. This year's recipients were Karen Ascetta, Joseph Calabrese, Richard Doyle, Ben Groel, Darnelle Toussaint, and Cathy Tam."

Conclusion

We would like to congratulate on behalf of the Board of Directors and our section, our newest inductees - Sartorius Group North America for their induction into our Quality Hall of Fame and their continuing quality achievements, and also to John Lombardi for his dedication and service to Long Island ASQ. The Hall of Fame Ceremony will be held in May at Farmingdale State College's Lupton Hall.

The following Board members volunteered to put this event together: James Anderson, Rick Calabrese, MaryEllen DeCicco, George Demott, Kerry Donelan, Rupal Doshi, Meegan Dowling, Andrea Isear, Sam Prasad, Mary Sansone, and Jackie Tordik who got this event off the ground. Without their efforts, we would not have been able to put the evening's event together.

A human being should be able to change a diaper, plan an invasion, butcher a hog, conn a ship, design a building, write a sonnet, balance accounts, build a wall, set a bone, comfort the dying, take orders, give orders, cooperate, act alone, solve equations, analyze a new problem, pitch manure, program a computer, cook a tasty meal, fight efficiently, die gallantly. Specialization is for insects.

Robert Heinlein
Science Fiction Writer

You can always find a capable helping hand at the end of your own sleeve.

Zig Ziglar

Motivational Speaker

Best Practices for Biomedical Research and Drug Development

By A. Mark Trotter, MS, MBA

Trotter Biotech Solutions

Introduction

Drugs and therapeutic products touch our daily lives in a myriad of ways. From the vitamins and aspirin we take for common ailments to the cardiac and cancer treatment medicines for serious illness to the hormones in animal feeds, these drug products find their way into everyday use. The public's interest is captured by the expectations provided by biomedical research and drug development. Besides the commercial value, the governmental and private funding support in the developed countries, primarily the USA, provides the overarching hope of curing human illness and suffering, while providing the additional benefit of greater economic development. One aspect all drug developments have in common is specific government regulations known as Good Manufacturing Practices or GMP . These regulations ensured that the drug products are safe, pure, and efficacious. The GMP regulations ensure that all aspects of the manufacturing processes use 'good practices' and science to produce drugs with the integrity and validity the process was intended to produce. These regulations can all be found under their respective sections of the Code of Federal Regulations CFR Title 21, parts 210, and 211 in the US. Similar documents exist in Canada, Europe and globally through World Health Organization's guidances.

Routine medical laboratories involved in patient care are covered by well-defined international quality standards (ISO 15189) and national laws (42 CFR 493). In pharmaceutical research and development, only the non-clinical laboratory safety studies are governed by the Good Laboratory Practices (GLP) regulations 21 CFR Part 58. There are no other well-defined quality standards existing for other non-GLP laboratory research, including biomedical research that may lead to new drug discovery. This potentially causes an incongruous situation in a biomedical research laboratory, where for example, a blood sample from a rabbit is subjected to stricter quality standards than a human sample. The FDA expects that "sound quality principles" are applied to the processing of human samples, but these principles are not well defined or delineated.

Much of the aforementioned investment, both financial and research comes from the United States. For example, the proportion of the global drug development pipeline belonging to organizations headquartered in the United States has increased to 70% in the past decade.[1]

In the U.S. alone, about $100 billion per year is spent on biomedical research. Due to poorly designed studies and / or the irreproducibility of biomedical research data and studies, the consequences of pursuing a drug development dead end have becoming an increasingly serious issue. The credibility of this biomedical research data has lead to costly and often futile attempts at repetition of these studies. These efforts are a terrible waste of scarce valuable funding resources. Is it not better that the spending on these drug development programs find new therapeutics for the many unmet medical needs than wastefully expended on irreproducible or worse, fraudulently reported research? The National Center for Dissemination of Disability Research published a white paper that support this concept…' the widespread belief that the quality of scientific research is often uneven and lacking in credibility, making it difficult to make a confident, concrete assertion or prediction regarding evidence for improving practice or consumer outcomes (Levin & O'Donnell, 1999; Mosteller & Boruch, 2002; Shavelson & Towne, 2002). ...is also due, in part, to the lack of consensus on the specific standards for assessing quality research and standards of quality for assessing evidence (Gersten et al., 2000; Mosteller & Boruch, 2002). For example, several researchers have contended that some of the current peer review processes and standards for assessing quality are not well suited for research in the disability arena (Gersten et al., 2000; NCDDR, 2003; Spooner & Browder, 2003).[2]

There has been an overall significant decline of productivity in pharmaceutical biomedical research over the last 15 years when comparing the number of new medicines to the equivalent funding spent in R&D. Obstructions to new drugs entity breakthroughs of has receive much scrutiny since the recent decade long decline in new drug approvals. Thus, notwithstanding the doubling of biomedical research funding and the shift toward clinical research by pharmaceutical companies,…' the number of new molecular entities approved by the FDA has fallen…as a consequence, pharmaceutical productivity decreased over the last 10 years, and it is lagging behind that of the biotechnology and device sectors… Financial return to investors has paralleled those changes in productivity.' [3]

One of the root causes for the reproducibility problem is the lack of a common quality standard for non-regulated biomedical research. Traditionally, non-regulated biomedical research has been considered off-limits for formal quality standards. Scientists in general regard their work as a highly intellectual activity where quality is knowledge and experience is an integral part of the scientific rigor that they apply. A longstanding tradition of quality control in science has been peer review of the results, but modern pharmaceutical research has become so complex that peer review has a limited value today. Also,' ...some scholars suggest that while standards such as peer review and standardized reporting are important benchmarks, research should not be judged solely by whether or not it is published in the leading journals (Boaz & Ashby, 2003). , While journal publication and citation analysis provide quantitative

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data, it is a faulty assumption that all "research" that is published in journals or cited by others is accurate, reliable, valid, free of bias, non-fraudulent, or of sufficient quality (Boaz & Ashby, 2003). Further, citation analysis is primarily a measure of quantity and can be artificially influenced by journals with high acceptance rates' (COSEPUP, 1999).[4]

The scope and sheer dimension of modern research is moving science out of the individual

scientist's domain and into a globalized team space where standards, transparency, and

reproducibility have become key requirements. Scientific work that cannot be reproduced or independently verified by others is a waste of valuable, limited resources. Also, biomedical research generates intellectual property, which has become increasingly subject to internal and external scrutiny and is often challenged in litigations. The authenticity and integrity of scientific data underlying an intellectual property claim are therefore of utmost importance. To prove the authenticity and integrity of scientific data, studies and experiments must be conducted under controlled and verifiable conditions.

A common quality guideline when utilized in biomedical research and drug development will ensure the validity and credibility of scientific data from different research institutions and facilitate the mutual acceptance of research results. Such a document will help to eliminate unnecessary duplication of existing research work, make published research data more reliable and increase the overall lagging productivity of biomedical research. These attributes will benefit patients worldwide by speeding drugs to market, meet global regulatory compliance requirements, enhance the investor interest in developing new innovative drug product that produce a solid return on investment.[5]

Summary of Technical Report Content:

Scope

This guideline specifies the general quality requirements for non-regulated biomedical research in drug development in order to ensure credibility of biomedical research results. This includes both large and small molecule discovery and non-clinical development that is not covered by GxP.

The target audience for this report is the scientific staff at institutions and companies involved in drug development. Compliance with applicable regulatory and safety requirements is not covered by this report.

Management system

Management of the research institution shall establish and document policies and procedures for its activities. Management shall ensure appropriate organizational structures, resources and processes to implement, maintain, and continuously improve the quality system.

Organization

The research institution shall: have necessary authority and resources to perform duties and responsibilities, policies restraining external influences, protection of intellectual property, accountability of data /reports, effective, independent Quality Management Systems, and proper facilities and equipment to perform study.

Project Management

The research program should follow good management practices: well defined work structure, tracking and communications reporting progress /performance, change control for study objectives and outcomes.

Quality Management System

Management shall establish, implement and maintain a quality management system (QMS) appropriate to the scope of its activities. The QMS established must be capable of ensuring reproducibility of biomedical research results to support effective drug development, e.g., deviation management, self-inspections (audits), research review, internal review, external reviews.

Documentation

Study plans, procedures, and activities shall be documented in writing to assure data quality, integrity, authenticity, and reproducibility. Research institutions shall therefore establish and maintain procedures to control all documents that prescribe how studies and experiments are to be conducted and describe how studies and experiments were conducted. Documents can therefore be divided into two broad classes: Prescriptive documents, which give specific instructions on how a study or experiment is to be conducted, e.g., Standard Operating Procedures, (SOP).

Descriptive records, which describe what was actually done and what happened during the course of a study or an experiment, e.g., Data / Reports / Lab Books /Publications.

Document control / Document approval and issue:

Research institutions must establish procedures for the control of prescriptive and descriptive documents. Procedures must include a formal review, approval, and distribution policy such that only the most recent approved documents are available for staff use. In addition, such procedures must include the following:

Document changes:

The research institution shall establish and maintain a change control process for impact, repeatability, approval, traceability, and implementation. Training must be documented.

Document storage

Documents shall be stored in a secure and suitable environment that provides confidentiality and prevention from loss, deterioration and destruction. Retention times shall be established and, if applicable, be in compliance with appropriate laws and regulations.

Technical requirements

Personnel

Training is critical to develop and maintain competence; all personnel should be made

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aware of the importance of training and its impact on the quality objectives. Research institution management shall ensure that those staff assigned to perform research activities has the appropriate combination of education, experience, and training to be competent with their assignments. Records are typically kept to document the qualifications of the personnel used as trainers.

Facility and infrastructure

The research institution shall have facilities and equipment sufficient for the conduct of the study and to maintain the infrastructure. Infrastructure includes, Buildings and workspace, Utilities, Storage areas, Computer and communications networking, Safety Equipment,

Premises shall be carefully maintained, ensuring that repair and maintenance operations do not present the possibility of affecting the integrity of the testing. They shall be cleaned and, where applicable, disinfected according to detailed written procedures.

Test equipment

Equipment Design - Equipment shall be designed, located and maintained to suit its intended purpose and meet good practices, cleaning calibration, validation etc.

Test methods / Method validation

Validation is the confirmation by examination and the provision of objective evidence that the particular requirements for a specific intended use are fulfilled. Validation of methods used in a research institution is critical for the integrity and authenticity of study results.

Sampling and chain of custody

Adequate and correct sampling is critical for ensuring that the sample taken is a true representative of the whole. The research institution shall therefore have a sampling plan and procedures for collecting samples of substances, materials, or products for subsequent testing.

Materials

Receiving, handling, and storage

The handling, storage, and types and quality of materials used in the conduct of biomedical research can affect the outcome of the research.

Test articles, control articles, and test systems

The purity, concentration, and stability of test articles and control articles (where used) can greatly affect the outcome and repeatability of a study or an experiment. Therefore, the purity, concentration, and stability and storage of test articles and control articles shall be specified and evaluated and documented periodically following standard operating procedures.

Legal and ethical considerations

All personnel involved in biomedical research activities are to act in an ethical manner. Examples of non-ethical behavior include but are not limited to: Plagiarism, Fabrication, selective / biased data reporting, financial / external influencing of study results. Protection of intellectual property – an understanding between the parties regarding ownership of intellectual property. In addition, a non-disclosure agreement may be established to ensure that the confidential nature of the study and study results are maintained.

Vendor Selection and Qualification

Research institutions may outsource a portion of their research activities to a third party. The subcontracted work may be subject to the research institution's quality system. As such, care must be taken to place such work with a competent subcontractor. The research institution shall have a policy and procedure(s) for the selection and purchasing of services and supplies it uses that affect the quality of its research work.

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This guideline was created by a working group from the ASQ FD&C Division.

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