From training activities to a training program: A case study in animal research

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ABSTRACT

Within an animal research facility, the customers include the organization (who benefits from the successful conduct of research procedures), the trainees (who benefit from the use of those skills to maintain their job or advance their career), and the animals, who benefits from humane and proficient care by animal users. Animal use training programs must be designed to meet the unique and interconnected needs of all three of these customers to achieve success. Adequate training of personnel involved in the care and use of animals is not only vital to the success of a research program, but also required by law within the United States and many other countries. An inadequate training program can lead to deficiencies in animal care and use, which can cause the research institution to face government citations, fines, loss of accreditation status, loss of grants or business, delays in project deliverables, decreased employee morale, negative media reports, and adverse public attention.

American Biotech Company is an organization which develops and manufactures pharmaceuticals, vaccines, diagnostic test kits, and other biomedical devices. As such, the use of animals in research is a critical component to its success. The company's Animal Care and Use Department (ACUD) is responsible for managing all animals used in its research and development (R&D) initiatives. In recent years, the company has encountered numerous challenges such as mitigating changes in the regulatory landscape, supporting changing research portfolios and business objectives, and adapting to an evolving workforce. These challenges have exposed deficiencies and risks in the way the department conducts animal use training.

Currently, there is no systematic oversight of training activities within the ACUD. The existence of silos between groups has led to inconsistency in training resulting in portfolio support constraints and difficulties sharing people resources across teams and worksites. Gaps in the facilitation of knowledge transfer and the lack of clear training guide points have contributed to a "drift" in processes. The inefficient management of training databases, content, and records within the department has contributed to a chronic overdue training phenomenon, rendering many employees "out of compliance" with regulatory or corporate standards and limiting scheduling capabilities. The absence of a unified training program has also negatively impacted employee engagement and limited the ability of the department to assess skills and training activities and apply appropriate improvement strategies when needed.

The overall purpose of this thesis is to propose the implementation of a comprehensive training program that will position the ACUD to overcome the current challenges and mitigate the risks to animal use training within the department. Development of this program will require a thorough characterization of the internal (organizational background, attributes and current conditions) and external (regulations/legislation, accreditation standards, and industry recommendations) influences, and identification of recommended tools and methods, in order to answer the question: How will development and implementation of the proposed training program address the deficiencies and risks associated with the ACUD's animal use training activities?

The proposed comprehensive training program can address the needs of its customers by supporting four key success pillars: 1) Performance, 2) Compliance, 3)

Engagement, and 4) Assessment/Continuous Improvement. Designating a training manager and developing the strategic direction for the program will ensure that performance, compliance, and engagement needs, risks, and trends are consistently assessed and mitigated across all groups and worksites within the department. The implementation of a core training team is key to optimizing training capabilities, as it will allow training experts to execute training activities according to newly established standards, while offering dynamic learning opportunities to meet the needs of a wide range of employees. Standardization of training processes, expectations, and information will ensure the ACUD is meeting its regulatory obligations. And by proactively supporting professional development and continued learning, the department can increase retention of highly skilled, motivated and compassionate animal users.

This comprehensive approach will better equip American Biotech Company to continue developing products that support the health and wellness of its customers and the proposed tools have the potential to support innovation and sustainability throughout the animal research and welfare industry as a whole.

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CHAPTER I: INTRODUCTION

1.1 The Importance of Animal Use Training within the Research Environment

Animal use training programs must be designed to meet the unique and interconnected needs of all of its customers. Within an animal research facility, these customers include the trainees who benefit from the use of learned skills to succeed at their job or career; the organization which benefits from the successful conduct of research procedures; and the animals, who deserve and benefit from humane and proficient care and use by animal users. Adequate training of personnel involved in the care and use of animals is not only vital to the success of a research program, but also required by law within the US and many other countries.

For companies involved in human and animal health research and development (R&D), animal use training programs must be designed to meet the requirements and specifications of complex external and internal standards. The external standards for animal use training are derived from regulatory requirements, legislative activity, voluntary accreditation programs, and industry standards. Internal specifications consider organizational size and scope, business objectives, corporate policies, research protocols, personnel roles, and animal types. Combined they have a major impact on the design and function of an animal use training program.

In addition to the internal and external drivers for a successful and compliant training program, companies using animals for research must balance the influence of public expectations and opinions, and mitigate the risks associated with animal rights activism and anti-animal research legislation.

An inadequate training program can lead to deficiencies in animal care and use, which can cause the research institution to face government citations, fines, loss of accreditation status, loss of grants or business, delays in project deliverables, decreased employee morale, negative media reports, and adverse public attention (Pritt and Duffee 2007). For these reasons, it is critical that companies conducting research with animals embody a philosophy of high standards for animal welfare, which is best achieved through establishment of a strong foundation of compassionate, skilled, and adaptable animal users, supported by a comprehensive and effective training program.

1.2 Animal Use Training at American Biotech Company

American Biotech Company (ABC) develops and manufactures pharmaceuticals, vaccines, diagnostic test kits, and other biomedical devices. The company's Animal Care and Use Department (ACUD) is responsible for managing all animals used in its research and development (R&D) initiatives involving animals. That means, ACUD has the overall responsibility of managing not only the animals used in ABC's R&D initiatives but also the responsibility of developing the skills and capabilities of technicians, researchers and other staff who handle and work with these animals to ensure maintenance of standards and compliance with regulations.

American Biotech has a philosophy of maintaining high animal welfare standards, which is communicated through its corporate animal welfare policy. The ACUD has dedicated its efforts to meeting corporate expectations, maintaining accreditation status and regulatory compliance, and supporting R&D portfolio needs. In recent years, the company has encountered challenges mitigating changes in the regulatory landscape, supporting changing research portfolios and business objectives, and adapting to changing workforce

dynamics. These challenges have exposed deficiencies and risks in the way the department conducts animal use training.

The historical reliance on personnel expertise, focus on specialized procedures, and individualistic training and management practices has resulted in the lack of a department-wide training philosophy or strategy and limited programmatic monitoring of capabilities and compliance across the department. Changes in the company's project portfolio needs, increased workload and an evolving workforce have exacerbated the impact of ACUD's training deficiencies. The absence of a unified training program has reduced the ACUD's ability to meet compliance and performance expectations, has negatively impacted employee engagement, and limited the ability of the department to assess skills and training activities and apply appropriate improvement strategies when needed.

1.3 Thesis Purpose Statement and Objectives

The overall purpose of this thesis is to justify the strategic importance of a comprehensive training program and propose the migration of the company's approach in utilizing ad hoc training activities to a more integrative approach. This thesis provides insight into the challenges posed by the current approach to training and offers an implementation process aimed at enhancing ABC's competitiveness. In essence, this thesis proposes strategies to position the ACUD to overcome its current challenges and mitigate the risks to animal use training within the department.

To achieve this broader objective, a thorough characterization of the influences, goals, needs, and deficiencies within the ACUD was conducted. Based on the results of the evaluation, tools and methods for developing a training program that addresses the challenges and risks faced by the ACUD will be recommended.

Understanding the purpose of the training program means defining the customers (ACUD, trainees, and animals) and designing the service (training) to meet the customer's needs (high performance, employee engagement, and compliance with standards). In the following subsections, an overview is provided of the four supporting key success pillars: (1) Performance; (2) Compliance; (3) Engagement; and (4) Assessment and Continuous Improvement.

1.3.1 Performance

The comprehensive training program must improve the department's ability to meet its performance objectives. Creating standardized basic training expectations and processes across groups will allow the ACUD to consistently achieve operational excellence and adapt people resources between groups with agility, to meet portfolio needs. Optimization of training capabilities will ensure that personnel receive the right training at the right time from the trainer who is best equipped to meet their training needs, while expert technicians can focus on the successful conduct of research studies. Harmonization of training concepts will create an environment where the various sites and specialty groups can support unique portfolio needs and function collaboratively to accomplish joint business objectives.

1.3.2 Compliance

Compliance is typically defined as adherence to regulatory and other legal requirements. With respect to the ACUD, adherence to accreditation standards, and internal policies, SOP's, and training guidelines will also be considered under the "compliance" umbrella. The proposed training program must ensure that animal work conducted within the ACUD follows the rules, meaning that training procedures align with compliance and animal welfare standards and that personnel are sufficiently educated about those standards. There must be a framework for active monitoring of compliance within the department,

which works to reduce/prevent overdue training and errors and to provide root cause analysis support during investigations.

1.3.3 Engagement

The importance of a successful animal use training program stretches beyond just equipping employees to do their job and follow rules. The proposed training program must create an environment that actively engages participants by providing the tools they need to succeed at their job, creating safe spaces to communicate concerns, supporting professional development and continuing education, and supporting a culture of compassion resiliency.

1.3.4 Assessment and Continuous Improvement (CI)

The proposed training program must provide a framework for asking "how well did we do" and "what can we do better". By proactively incorporating CI principles and assessment parameters into the fabric of the program, the ACUD will create a space for innovative thinking, efficiency, adaptability, risk mitigation, advances in animal welfare , and will provide a competitive edge for the company.

1.4 Outline of Thesis

The thesis is structured as follows. Chapter II presents an overview of the literature on training in animal research facilities and the regulatory boundaries surrounding them. Chapter III describes the role the ACUD's organizational structure plays in the current function of training activities. This chapter summarizes the threats and weaknesses in the training activities approach that make a transition to a training program necessary and imperative as well as the strengths and opportunities which may be leveraged to ensure a successful transition. Chapter IV provides the transition from utilization of training activities to a training program that is aimed at enhancing the overall competitiveness of ABC. The final chapter (Chapter V) summarizes and provides some lessons learned from

the research. It also provides a process template that can be used for future transitions from activities to programs. The chapter also identifies some of the challenges that limited the full scope of how this study could have been executed.

CHAPTER II: LITERATURE REVIEW

The purpose of this literature review is to identify the external factors including regulatory requirements, oversight activities and legislative actions, that the ACUD is subject to, as well as accreditation standards and industry guidelines that the company voluntarily subscribes to. These factors significantly influence the current training practices within the ACUD. In addition, it will highlight industry recommended training methods and best practices that could be applied in the development and implementation of a comprehensive training program to address the ACUD's key objectives.

2.1 External Influence on Animal Use Training

Companies using animals for research, teaching, and/or testing must carefully mitigate the impact of various external factors with direct and indirect influence on their animal use training programs. Regulatory requirements, oversight activities, and legislative actions have direct and legally enforceable influence on the care and use of animals in research facilities. Although animal rights activism has long been an indirect influence on the animal research industry, modern activism methods such as targeted political lobbying and anti-animal research legislation are changing the animal research landscape in an increasingly direct manner. Voluntary accreditation programs, if subscribed to by an organization, can have a direct impact on the operation of an animal facility.

2.1.1 Regulatory Requirements – United States Animal Welfare Act

The US Animal Welfare Act (AWA) of 1966 sets standards for the humane care and treatment of certain animals that are exhibited to the public, sold for use as pets, used in research, teaching, or testing, or transported commercially within the United States (USDA APHIS 2023). The AWA does not cover all animal types. The term "animal" means any live or dead dog, cat, monkey (nonhuman primate mammal), guinea pig, hamster, rabbit, or

such other warm-blooded animal, as the Secretary may determine is being used, or is intended for use, for research, testing, experimentation, or exhibition purposes, or as a pet. The term excludes the following:

(1) Birds, rats of the genus Rattus, and mice of the genus Mus, bred for use in research;

(2) Horses not used for research purposes;

(3) Other farm animals, such as, but not limited to livestock or poultry

a. Used or intended for use as food or fiber;

b. Used or intended for use for improving animal nutrition, breeding, management, or production efficiency; or

c. Used for improving the quality of food or fiber.

(4) With respect to a dog, the term means all dogs including those used for hunting, security, or breeding purposes.

While birds (other than those bred for research) are covered under the AWA, the regulatory standards related to their welfare have not yet been established.

The AWA establishes qualifications and training requirements for people working in research facilities handling animals as defined under the Act. This is specified under Part 2.32 (Personnel Qualifications) and is as follows:

> "(a) It shall be the responsibility of the research facility to ensure that all scientists, research technicians, animal technicians, and other personnel involved in animal care, treatment, and use are qualified to perform their duties. This responsibility shall be fulfilled in part through the provision of training and instruction to those personnel. (Sect. 2.32 (a))
> (b) Training and instruction shall be made available, and the qualifications of personnel reviewed, with sufficient frequency to fulfill the research facility's responsibilities under this section and § 2.31. (Sect. 2.32 (b))
> (c) Training and instruction of personnel must include guidance in at least the following areas: (Sect. 2.32 (c))
> (1) Humane methods of animal maintenance and experimentation, including: (Sect. 2.32 (c)(1))

(i) The basic needs of each species of animal; (Sect. 2.32 (c)(1)(i))
(ii) Proper handling and care for the various species of animals used by the facility; (Sect. 2.32 (c)(1)(ii))
(iii) Proper pre-procedural and post-procedural care of animals; and (Sect. 2.32 (c)(1)(iii))
(iv) Aseptic surgical methods and procedures; (Sect. 2.32 (c)(1)(iv))
(2) The concept, availability, and use of research or testing methods that limit the use of animals or minimize animal distress; (Sect. 2.32 (c)(2))
(3) Proper use of anesthetics, analgesics, and tranquilizers for any species of animals used by the facility; (Sect. 2.32 (c)(3))
(4) Methods whereby deficiencies in animal care and treatment are reported, including deficiencies in animal care and treatment reported by any employee of the facility. No facility employee, Committee member, or laboratory personnel shall be discriminated against or be subject to any reprisal for reporting violations of any regulation or standards under the Act; (Sect. 2.32 (c)(4))
(5) Utilization of services (e.g., National Agricultural Library, National Library of Medicine) available to provide information: (Sect. 2.32 (c)(5))
(i) On appropriate methods of animal care and use; (Sect. 2.32 (c)(5)(i))
(ii) On alternatives to the use of live animals in research; (Sect. 2.32 (c)(5)(ii))
(iii) That could prevent unintended and unnecessary duplication of research involving animals; and (Sect. 2.32 (c)(5)(iii))
(iv) Regarding the intent and requirements of the Act. (Sect. 2.32 (c)(5)(iv))"

The AWA also requires research facilities maintain oversight of the animal care and use program under Part 2.31 (Institutional Animal Care and Use Committee) and is as follows:

> The Chief Executive Officer of the research facility shall appoint an Institutional Animal Care and Use Committee (IACUC), qualified through the experience and expertise of its members to assess the research facility's animal program, facilities, and procedures. Except as specifically authorized by law or these regulations, nothing in this part shall be deemed to permit the Committee or IACUC to prescribe methods or set standards for the design, performance, or conduct of actual research or experimentation by a research facility.

The AWA is administered by the USDA Animal Care Unit, which has authority to conduct routine, unannounced inspections of all entities licensed/registered under the Animal Welfare Act (USDA APHIS 2023). Inspectors conduct three types of inspections:

1) Pre-licensing inspections, which verify the applicant can meet the federal standards prior to being licensed/registered;
2) Routine, unannounced compliance inspections of all entities to make sure they are adhering to the federal standards and regulations; and
3) Focused inspections based upon public complaints or allegations of unlicensed activities.

During routine inspections, USDA reviews the premises, records, husbandry practices, program of veterinary care and animal handling procedures to ensure the animals are receiving humane care. The frequency of inspections is based on several factors – including an entity's compliance history. The USDA inspects research facilities that use regulated animals at least once a year. Inspection results are compiled within a report posted on the USDA public database and available to the public via FOIA request.

2.1.2 Regulatory Requirements – Product Development, Licensing, and Manufacturing

Animal research and testing conducted in support of the development, licensing and/or manufacturing of drugs (pharmaceuticals) or biologics (vaccines) in the US, may fall under the scope of certain regulatory requirements and oversight actions. The US Food and Drug Administration (FDA) has the authority (under the Food, Drug, and Cosmetic Act) to conduct inspections to verify the reliability, integrity and compliance of clinical and non-clinical research conducted in support of pending new drug applications. When conducted under Good Laboratory Practice (GLP) or Good Clinical Practices (GCP) conditions, study animal procedures and study data collected from animals may fall within the scope of FDA inspections. Agency inspections can consist of a comprehensive review of the entirety of operations at a facility or can be limited inspections, to cover a particular issue or issues. FDA inspectors have the authority to observe study procedures and to

request training records for all personnel involved in the conduct of observed procedures. The USDA Center for Veterinary Biologics (CVB) has the authority (under the Virus, Serum Toxin Act) to "direct the inspections [announced or unannounced] of licensed establishments, prospective licensees, foreign manufacturers, and recipients of imported biological products".

Failure to meet the standards of the USDA or FDA as it pertains to the data collected through use of animal research or testing to support product development or manufacturing can have serious impact to a business. Citations, fines, rejection of new product applications, and even an order to stop manufacturing or sale of products can have a serious impact on a company's regulatory standing, public perception, revenues, and shareholder confidence. Animal users must be adequately trained and informed of the regulatory expectations within the research setting (and other environments).

2.1.3 Animal Activism, Emerging Legislation and Policy Changes

Historically, animal rights activism has focused on direct actions to discredit, discourage and push for discontinuation of the use of animals in research. These types of actions include public demonstrations and advertising, trespassing, damage and infiltration of animal facilities, theft, or release of research animals, recording of perceived or confirmed animal welfare concerns or abuse, and "smear" campaigns or release of research personnel information. Many of these tactics have also been used against other industries involved in the use of animals, including the entertainment, agriculture, zoological, and animal byproducts sectors. In recent years, animal rights activists have undertaken the strategy of capitalizing on published USDA citations, publicly visible animal welfare controversies or other incidents to influence public perception and legislation related to animal use, animal breeding, and research facilities via incremental policy changes at both

the state and local levels. The ever-present, innovative, and increasingly effective influence of animal rights activism further elevates the significance of ensuring personnel involved in the use of animals for research are adequately trained and supported by an environment of compassionate care.

Over the past several years, animal welfare controversies in several states and efforts put forth by animal rights activists have precipitated introduction of bills which could seriously impact the use of animals in research. For example, the Virginia 2024 SB411, and Michigan 2023 SB0149 and 2024 HB4849, bills, came to fruition after animal facility infiltrations and animal welfare controversies that occurred within those states. Similar incidents in Wisconsin and New York have led to unsuccessful attempts to ban or greatly restrict the breeding and/or sale of animals for research at the local level. Even though not all attempts to incite new legislation are successful, these incidents create additional publicity for animal rights groups and damage public trust in animal research.

2.1.4 Voluntary Accreditation Program - AAALACi

In addition to regulatory requirements, organizations conducting research, teaching, or testing may choose to participate in voluntary accreditation and assessment programs. One such program is operated by the American Association for the Accreditation of Laboratory Animal Care International (AAALACi). Institutions accredited by AAALACi are subject to onsite inspections and review of their animal care and use programs by industry experts; which include related training activities. AAALACi uses the Guide for the Care and Use of Laboratory Animals (2011 edition), the Guide for the Care and Use of Agricultural Animals in Research and Teaching (2020 edition); and the European Convention for the Protection of Vertebrate Animals Used for Experimental and Other Scientific Purposes, Council of Europe (also known as ETS 123) as its three primary

standards for their accreditation standards. One of the organizations key standards is that "all animal care personnel should be suitably qualified by training and experience in the care of laboratory animals" including the qualification of personnel involved in animal use (AAALACi). According to AAALACi, some of the benefits of maintaining accreditation include providing an assurance of quality and validity within the scientific and animal welfare community, harmonization of practices throughout the global marketplace, independent and confidential peer-reviews of animal care and use programs, and stimulation of continuous improvements.

2.1.5 Limitation of Regulations, Policies, and Accreditation Programs

USDA authority only applies to animal species covered within the Animal Welfare Act, and regulations are meant to provide minimal acceptable standards that can be equally applied and assessed in the hundreds of registered/licensed facilities across the country. Depending on the scope of a company's R&D or manufacturing portfolio, the types of animals used within their facilities can be limited to a few species or vary across numerous species. Additionally, USDA inspections are not perfect, and they may not catch or fully address every problem. It is possible for a facility to be "citation-free" and still have problems within its animal care and use department that have yet to rise to the level of regulatory visibility. Companies involved in the use of animals are challenged by modern industry standards, ethical considerations, and public perception to pursue high standards of care and welfare for all animal used in their activities, which means exceeding minimum regulatory and accreditation standards when and where possible.

Regulations and accreditation programs provide the mandate for the existence of personnel training and documentation within the research environment and the requirement or recommendation of concepts which should be covered through training. However, these

directives generally fall short of providing detailed directives for how training programs should be designed and managed, how specific animal procedures should be conducted, or how specific personnel skills should be assessed. Industry standards and training methods can be useful in providing effective tools to establish and manage a successful training program.

2.2 Industry Standards and Recommendations

Training programs must be dynamic and customizable to meet the unique scope and needs of an organization involved in animal use. There are, however, industry-recognized training and management strategies which share relevance across many organizations. This section of the literature review will discuss some of the recommended strategies and tools used by other organizations and industry experts, which could be applied in the development and implementation of the new training program at American Biotech Company.

2.2.1 Understanding Training Needs

Planning of a training program starts with understanding the purpose for the training, who needs it, when its needed, how it can be provided, and what information should be covered. For an R&D organization, the purpose for training is to ensure animal users meet the ethical standards of humane use, to ensure scientific quality in the research conducted, and to support staff in completing work more efficiently and effectively (Medina, et al. 2007). Dyson and Rush believe that appropriate animal care and use training should be provided to "all individuals directly involved in animal research". These personnel can include animal husbandry staff, the veterinary team, study technicians, researchers, principal investigators, and members of the IACUC (Dyson and Rush 2012). Personnel who support the animal care and use program but may not have direct interaction

with animals should also receive introductory training regarding the program. This training should give them an understanding of the animal care and use program, safety and security considerations, what activities they may see within the animal facility, and how to report concerns (Medina, et al. 2007). As emphasized by Dyson and Rush, personnel have varying needs for training based on their "levels of responsibility with projects, or animal use, type of contact with animals, and types of procedures conducted." These details inform the content which should be covered in training and the timing at which this content should be provided. The types of procedures trained on must be based on the research portfolio objectives of the organization. The style of training, however, should be adaptable to the learning needs, experience level and general sentiments of each trainee. Forbes suggests that knowing the "tenor and tone of how people feel", "asking their ideas and recommendations on how they want to engage with learning opportunities", and "accounting for different experience levels", are just some of the steps an organization can take to achieve successful implementation of training activities (Forbes 2021). These considerations also better equip training personnel to understand and meet the expectations of trainees.

2.2.2 Providing People Resources

Having a dedicated training staff supports the successful implementation of an institutional training program (Pritt and Duffee 2007). For example, the University of Michigan (U of M) Unit for Laboratory Animal Management (ULAM) transitioned to a model which consolidated animal care and uses training responsibilities under a "Training Core" to improve compliance, consistency, and quality. This Training Core includes a manager, administrative assistant, and four staff trainers and was allotted an annual budget of $435,000. Some of the responsibilities of the trainers include design of educational

programs and classes, evaluation of personnel technical skills, and review of SOP's. The program collaborates with other campus experts when the need arises for novel species or techniques which extend beyond the training cores knowledge or skills. (Dyson and Rush 2012)

While the need for a "high level of expertise in those who deliver training" is important, there are non-technical qualifications or "soft" skills which are also vital to supporting staff in acquiring the skills they need. Such qualifications, which can include "interpersonal skills, the ability to demonstrate procedures clearly and precisely, ability to communicate effectively through adjustments in speaking and teaching styles, and good computer skills" may be harder to acquire, as technical education programs and on-the-job-learning typically focus on technical proficiency (Pritt and Duffee 2007). Recommended resources which can aide trainers in further developing their skills include the Laboratory Animal Welfare Training Exchange (LAWTE), the American Society for Training and Development (ASTD), or the International Board of Standards for Training, Performance, and Instruction (Dyson and Rush 2012).

Modern skill and career building platforms such as LinkedIn Learning® offer personalized learning tools covering topics like Aligning Training with Learning Styles, Core Competencies of Effective Trainers, and Train the Trainer, which highlight the importance of various interpersonal or soft skills in training, teaching, and leading others (LinkedIn 2024). Soft skill training combined with technical skillsets round out an employee's attributes, making them more valuable to the organization (Pritt and Duffee 2007). Experts agree, achieving the desired outcome of training requires trainers to possess

(or be supported in developing) the ability to communicate effectively, adapt to different learning styles, and motivate others.

2.2.3 Assessing Training Outcomes

One key mechanism for determining how well the training program is working is evaluating training effectiveness. Experts within the animal research industry agree that assessing the skills acquired during training is essential to ensuring the effectiveness of training and successful performance of procedures. The article *Assessment of Proficiency and Competency in Laboratory Animal Biomethodologies* suggests that an "objective and standardized" assessment program can be a tool to "improve standards, ensure consistent training, and decrease research variables" while still ensuring animal welfare (Clifford, et al. 2013). The authors propose several concepts which should be considered when developing training evaluation programs. One of the concepts presented is the role of "learning domains" that should be considered within the training assessment process. Their discussion is summarized as follows:

> Assessment of biomethodologies is challenging for the LAS [Laboratory Animal Sciences] community for 3 primary reasons. First, the pool of trainees is diverse and thus complicates the design of a single type of training and assessment program. Second, the number and diversity of techniques is vast, and third, the student's ability to acquire skills typically falls into 1 of 3 challenging learning domains. These domains include concept learning (also known as category learning), cognitive skills (learning theory), and psychomotor (physical) skills. Concept learning requires the gathering and organizing of information. Cognitive skills require critical thinking and problem solving. Psychomotor skills are complex because they are acquired through the cognitive, associative, and autonomous stages. During the cognitive stage, the student learns theory and concepts. During the associative stage, the student practices the skill, and by the autonomous phase, the skill is performed with confidence and decreased mental effort. Therefore, biomethodologic training assessment must consider, and allow for, assessment of all 3 learning domains (Clifford et al., 2013)

The authors further explain that "adequate training should include assessment of competency to ensure proper techniques were learned and assessment of proficiency to ensure the consistent and appropriate application of learned techniques." The authors stress that competency (ability to perform a procedure and apply knowledge and skills through monitored practice) does not guarantee proficiency (advancement in knowledge and skill that qualify a trainee to perform the procedure independently).

Competency and proficiency are different, but equally important to the training process. A comparison of the two concepts is provided in Table 2.1. The article also recommends defining and developing "core competencies", which are specific details that must be observed to consider performance of a task proficient. The development process should be conducted by a committee, which includes, at a minimum, subject matter expert in the procedure and a veterinary staff member. These core competencies can be used to guide training, assess competency, verify proficiency, and ensure consistency in assessment criteria across groups. Assessments should use scoring sheets (only for competency assessment) or checklists to ensure all core competencies have been met. Implementation of assessment methods should involve integration into the training program and collection of data to support the effectiveness of the assessments. This approach may be helpful in overcoming the challenge of personnel reacting negatively to the institution of standardized assessments.

Table 2.1: Contrast of Assessing Skill Competency vs Proficiency

Competency	Proficiency
Achieved before proficiency	Achieved after competency
Demonstrates the knowledge and ability required to perform the biomethod and awareness of personal limitations.	Ability to perform consistently and accurately, with no deviation from correct technique.
Ability to correctly perform and apply knowledge and skills in a controlled environment.	May include measurements of speed and refined accuracy.
Assessment performed during or immediately after training	Assessment performed after training (after trainee has had the opportunity to practice and refine the newly learned skills)
Assessed through use of score sheets or grading scales to gauge a trainee's progress towards core competencies during the training period.	Verified against the same core competencies, but with a "pass or fail" outcome.

2.2.4 Supporting Employee Engagement and Professional Development

In the article*, Training Strategies for Animal Care Technicians and Veterinary Technical Staff*, Pritt and Duffee explain that while training for essential knowledge and skills is an "obvious priority" and professional development may seem to be a "second priority", it is critical that employees feel they are pursuing a meaningful career with opportunities for continued development. (Pritt and Duffee 2007) The authors recommend that organizations that are involved in the use of animals for research, teaching, or testing should support employee participation in laboratory animal science professional development programs such as AALAS, or the Laboratory Animal Management Association (LAMA). These types of programs offer certifications, which can benefit employees through professional distinction and higher pay and benefit the organization through retention of highly trained staff. Many biotech, biopharma, and contract research organizations offer incentives for technicians who complete AALAS certifications.

2.2.5. Adopting Continuous Improvement Strategies

Training programs need to have "built-in mechanisms for continual refinement and updates to reflect changes in the work environment such as new technologies, regulatory changes/updates, new biomethodologies or processes, new capabilities, and novel types of research." Participation in activities, such as the AALAS national or local conferences, can serve to expose technicians to "novel concepts and procedures that can be implemented to improve the institutional program (Pritt and Duffee 2007). Other organizations like the American Veterinary Medical Association (AVMA), National Association for Biomedical Research (NABR), National Institutes of Health (NIH), and Canadian Council on Animal Care (CCAC) also provide trainings, workshops, seminars, and conferences where industry best practices, new data technologies and innovative care and handling methods are exchanged.

In addition to participating in continuing education and professional development forums, organizations across various industries also choose to adopt the principles of Six Sigma to support internal process improvement and innovation. According to U.S. News "Six Sigma methodology uses data to improve processes and performance in a range of industries" thereby reducing costs and waste, improving morale and performance and elevating product quality" (Trent-Gurbuz 2021). Six Sigma involves characterizing problems, identifying the root cause(s), and implementing effective solutions through its DMAIC (define, measure, analyze, implement, and control) methodology. There are five main certifications within the Six Sigma framework, progressing from white belt, which focuses on problem solving fundamentals for everyday issues, and advancement up to master black belt level, which involves highly experienced individuals who lead or consult on high stakes, high complexity, and/or high value initiatives with impact at the senior

executive levels within an organization. Six Sigma also involves a mentoring scheme which uses certified colleagues to mentor colleagues seeking certifications or leading projects at levels below them. Six Sigma principles can be applied at all levels of an organization, and employees from all levels could have the ability to engage in identifying and solving problems that impact their role, team, department or the company as a whole.

2.2.6 Animal Use Alternatives: Replacement, Reduction, Refinement (3R's)

One of the most highly recognized and appreciated guiding principles of animal research is the "3R's", which promotes the use of animal use alternatives through replacement, reduction, and refinement. These concepts were first explored in the 1959 book *The Principles of Humane Experimental Technique* by Drs. William Russell and Rex Burch (USDA National Agricultural Library 2020). The National Agricultural Library defines the 3R's as follows:

(1) Replacement refers to technologies or approaches that directly replace or avoid the use of animals. Replacement can be broken down into two categories: Full/Absolute and Partial/Relative.

   a. Full/Absolute Replacement avoids the use of animals completely. Some examples include training manikins, human tissues and cells, computer models, and microphysiological systems.

   b. Partial/Relative Replacement still requires animal use, but the animals do not experience pain or distress during the study. Some examples include animal-derived tissue/organs for in vitro studies, zebrafish embryos, and transcutaneous electrical resistance test (TER).

(2) Reduction involves methods that help obtain comparable levels of information from the use of fewer animals. Scientists can reduce the number of animals used in research

through strategies such as appropriate experimental design, correct statistical evaluation, and sharing resources/animals.

(3) Refinement refers to modifications of husbandry or experimental procedures that minimize or eliminate animals' pain and distress and improve their welfare. A few examples of refinement are anesthetics and analgesics, humane animal handling, environmental enrichments, and humane endpoints.

These principles are not just suggestions for organizations involved in the use of animals for research, the Animal Welfare Act calls for IACUC's to ensure all proposed animal activities avoid or minimize discomfort, distress, and pain, that alternatives to procedures have been considered and justifications documented, and that written assurance has been provided that activities are not unnecessary duplications of previous experiments (USDA APHIS 2023). Animal research industry experts, consortiums, membership organizations, and accrediting bodies are strong proponents of 3R's principles and provide a wealth of resources on innovative techniques for animal care and use practices, including animal use training.

There are many benefits to implementing animal use training with non-animal models or simulators, including allowing trainees to develop hand-eye coordination, needle and syringe manipulation, dexterity, aseptic technique and safety skills without adding stress to an animal. Organizations such as veterinary teaching schools, universities and contract research organizations have instituted non-animal models within some aspects of their training programs. In a small study conducted by Charles River Laboratories, the use of non-animal models for mouse cardiac blood collection training prior to the use of actual mice resulted in an 82% competency rate (for trainees who were trained first on non-animal

models) compared with a 60% competency rate in the traditionally trained group (trained with live animals from the beginning). The alternative group (non-animal model first) was found to have used at least 10 fewer mice per technician than the traditionally trained group (George, et al. 2023). In an assessment of different available rat simulator models, Humpenoder et al. suggest that there is evidence of the positive impact of simulator-based training in surgical techniques and dissection and other aspects of medical and veterinary education (Humpenöder M 2021). Although there are many companies now specializing in the production of non-animal models for rodents, there are only a few companies which produce partial dog, pig, and equine models as the costs per model are generally expensive. Other organizations participating in shared animal research consortiums have also shared anecdotal experiences with creating and using in-house or "homemade" non-animal models. More extensive research on the use and effectiveness of non-animal models, especially for non-rodent species, is still needed to further characterize the full capabilities. This creates an opportunity for companies involved in animal use training to take a leadership role in innovating new non-animal models to increase animal welfare and nurture a culture of caring and achieving the 3Rs.

CHAPTER III: ORGANIZATIONAL ANALYSIS

The objective of this organizational analysis is to characterize the internal conditions which currently exist within the ACUD and then to analyze the impact of those conditions as perceived by ACUD stakeholders on animal care and use training.

First, this review will discuss internal factors which influence current training practices such as the ACUD's background, organizational scope and structure, available training resources, corporate policies and oversight activities.

Next, the process used to gather information from stakeholders to conduct the situation analysis of ABC's training activities will be described and the results presented. The analysis of this information will be discussed in four subsections – Strengths, Weaknesses, Opportunities, and Threats (SWOT).

The final section makes the case for moving from the numerous and disconnected training activities at ABC to a systematic, transparent, effective, and mission-focused training program.

3.1 Internal Influence on Animal Use Training

3.1.1 American Biotech Company Background

American Biotech Company develops and manufactures pharmaceuticals, vaccines, diagnostic test kits, and other biomedical devices for worldwide distribution. The company earns between $5 to 10 billion in revenue per year and has over 200 product lines. The company has over 12,000 employees world-wide, approximately 1,400 of which are within the Research and Development (R&D) organization. As part of the R&D business, animals are used to conduct studies for various aspects of discovery, development, clinical and field research. There are approximately 100 to 160 employees within the Animal Care and Use

department (ACUD), including leadership team members, managers, coordinators, technicians, and administrative and support personnel.

3.1.2 ACUD Organizational Scope and Structure

The ACUD is made up of 3 main functional groups; 1) the Attending Veterinarian and Veterinary Staff, 2) the In-life Operations Teams and 3) Animal Welfare and Training Group. These groups also collaborate extensively with members from partner groups throughout the R&D organization.

The Attending Veterinarian (AV) is a Doctor of Veterinary Medicine (DVM) who has the authority, as given by the company, to ensure adequate veterinary care of animals within the facility and to oversee other aspects of the animal care and use program . There are approximately 16 veterinary staff members, which include licensed veterinarians (DVM's) and veterinary technicians (Vet Tech's) who are key in the execution of the veterinary care program. They ensure that animals receive appropriate veterinary care, including, but not limited to health assessments, preventive health maintenance, surgical procedures, and diagnosis and treatment of illness or injuries. Vet staff also ensure maintenance of medical records, appropriate storage and documentation of drugs and controlled substances and are involved in animal care and use training as well as the certification of trainers. As an extension of the veterinary staff, the animal behavior team ensures the well-being of animals through assessment of animals and their environments, application of methods and tools to promote well-being, and training of other staff in behavior methodologies.

In-life Operations is the largest of the functional groups, with approximately 100 members. There are a number of operations teams, across multiple worksites that support the various species and research types used within the ACUD. Each operations team

consists of an executive leadership member, facility managers, team managers, coordinators, animal technicians, and support staff. Operations' groups are generally divided up by species, including rodents, rabbits, canine, feline, poultry, equine, cattle, sheep/goat, and swine, which are housed at various worksites. Some groups cover multiple species, some work across multiple worksites, and some work under biological containment/biosafety conditions. The research specialties covered include pharmaceuticals, biologicals (vaccines), biopharmaceuticals, and other biomedical areas (biodevices, diagnostics, etc.). Operations groups are responsible for facility management, animal husbandry and care, research study activities, animal procedures, sample collections and scheduling of activities. Animal technicians and some managers play a key role as trainers based on their experience and line of expertise.

The Animal Welfare and Training group is comprised of three members; an executive leadership member, Institutional Animal Care and Use Committee (IACUC) administrator and training coordinator. This group is responsible for ensuring that animal care and use at the facility is conducted according to regulations and that animal welfare concerns are reported and investigated in compliance with regulatory requirements and company policy. The group is also responsible for the administration and coordination of ethical oversight committees, including the IACUC, promotion of animal welfare principles such as the "3R's", and storage and maintenance of all compliance and training related physical and digital records.

Partner groups (research personnel) consist of study directors or principal investigators, study managers, coordinators, project managers, and research associates within other R&D business lines. The ACUD and research personnel collaborate on

protocol design, scheduling of study activities, and conduct of animal procedures. Research personnel are typically subject matter experts in the specific diseases, pathogens, product types, formulations, affected species', product licensing/registration requirements and/or novel procedures being investigated during research studies. For this reason, there are many research team members who are also trainers within the ACUD training scheme.

The data generated through animal research within the ACUD support a number of partner groups within American Biotech Company. These partner groups are the internal customers of the ACUD, and the studies requested by these groups support development and registration of new products, methods or models and post-approval product support. ACUD often depends on the partner groups for training support in novel research methodologies which are required for specific projects. ACUD and the partner groups work with the Vet Staff to ensure a veterinary care strategy is in place based on the unique conditions of each research project, and with the Compliance group to ensure specific procedures are approved according to internal ethical oversight processes.

3.1.3 ACUD Training Oversight

American Biotech Company has a philosophy of maintaining high animal welfare standards, which is communicated through its corporate animal welfare policy. The policy provides the key corporate principles that ABC is dedicated to upholding during the use of animals within its facilities. These include abiding by all regulatory requirements and achieving "clean" inspections, maintaining AAALACi accreditation status, investigating animal welfare concerns, incorporating industry standards and 3R's principles where possible, and other animal welfare centered goals. The ACUD is also subject to internal audits by the ABC Global Internal Audit Division (GIAD). The overarching goal of the IA is to identify potential risks to humans, animals, and company assets. These types of audits

are rare, however their scope includes all aspects of the animal care and use program, including training activities and records.

By law, ABC is required to have an Institutional Animal Care and Use Committee (IACUC). This committee is involved in routine review and approval of the animal care and use program and animal use protocols, investigation of animal welfare concerns and inspection of animal facilities. IACUC program review topics include training; however, this largely serves as a high-level confirmation of the existence of a training program, but provides no detailed assessment of specific training processes, content, or personnel. Occasionally, the IACUC may provide recommendations and follow-up questions regarding training, in response to animal welfare concerns or facility inspection findings.

Currently, there is no systematic oversight of specific training activities within the ACUD. At the departmental level, training management is dispersed across groups, with a few administrative functions falling under the Animal Welfare Compliance group, and most other training activities managed by individuals or individual groups on a case-by-case basis.

3.1.4 ACUD Training Resources

Because of the wide range of study, product and animal types, animal use training within the ACUD is highly complex. Training resources are comprised of numerous training formats, materials, personnel, and processes depending on the applicable species, groups, worksites, and research types.

The available training formats within the ACUD include computer-based trainings (CBT) such as standard operating procedures (SOP's), policies, guidelines, videos, and slide decks provided in the Learning Management System (LMS); instructor-facing forums or sessions (IFS) which may be virtual, in person or pre-recorded; and training-on-job

trainings (TOJ) which are hands-on sessions conducted in person within the vivarium. TOJ's are sometimes referred to as "courses" by ACUD employees.

Most of the CBT's and some IFS's within the LMS are organized into standardized *curricula*, which are groupings of trainings within the LMS related in topic, species, worksite, or role, which can be assigned to multiple technicians (or other employees). For example, there are standardized curricula of CBTs for all technicians working at Worksite A, a curriculum for technicians working with poultry, one for all technicians working with swine within the biocontainment area, and so on. The courses included in a standardized curriculum are the same for each person it is assigned to. Changes to a standardized curricula affect all users to whom it is assigned.

TOJ's and some IFS's are not currently included in the standardized curricula, therefore it is necessary to build an individual curriculum for every technician, as well as veterinary technicians and partner group members who perform animal procedures. An individual curriculum is a unique grouping of TOJ's and IFS's, that is built specifically for one person. Each person is assigned a combination of these trainings based on their role, work site, assigned species, and experience level. In general, no two people have the same exact individual curriculum, however they may have many of the same training courses within their curricula. Every time a person completes a new TOJ or IFS, that course must be manually added to their individual curriculum by the training coordinator. If an individual is no longer performing a specific procedure in their daily role, they must request that the training coordinator remove the course from their individual curriculum. On average, animal users have approximately 154 assigned trainings within their LMS account.

Training content covers a robust range of topics and procedures including regulations, corporate policies, animal welfare, animal husbandry, handling of animals, collection methods, dose administration methods, species overviews, environmental monitoring practices, facility management procedures, safety, security, biosecurity, use of equipment, euthanasia, and much more. Other training content includes approved external training programs or repositories and industry-standard reference materials (Table 3.1).

Table 3.1: ACUD Approved External Industry Recognized Training and Reference Materials

Resource Title	Current Publication Year	Format or Web Location
American Association for Laboratory Animal Science - Learning Library	2024	https://www.aalaslearninglibrary.org/
American Veterinary Medical Association Guidelines for Euthanasia	2020	https://www.avma.org/resources-tools/avma-policies/avma-guidelines-euthanasia-animals
Association for Assessment and Accreditation of Laboratory Animal Care International (AAALACi)	NA	https://www.aaalac.org/
Fear Free Dog Handling Certification Program	2024	https://fearfreepets.com/about/what-is-fear-free/
Guide for the Care and Use of Laboratory Animals, 8th Edition (the "Guide")	2011	Print
Guide for the Care and Use of Agricultural Animals in Research and Teaching, 4th Edition (the "Ag Guide")	2010	Print, https://www.asas.org/services/ag-guide#_
Laboratory Animal Welfare Training Exchange	2021	https://www.lawte.org/
United States Animal Welfare Act (1964)	2022 (Amended)	https://www.nal.usda.gov

Responsibility for the management and storage of digital and physical training materials and related documents falls across various groups and personnel. CBT content is available on demand within the LMS and is managed by the training coordinator. IFS content is maintained by individual trainers and typically consists of Word documents, PDF's, PowerPoint presentations or other visual job aides stored on company intranet portals, individual personnel laptops, or on paper handouts. Currently, there is no central storage or control of these materials. TOJ's generally do not have any printed/digital

content, as they are hands-on training sessions, but many do have *training guide points*, which consist of a few suggested points for the trainer to cover with the trainee. Training guide points are stored digitally on the company intranet portal in individual documents for each species and are accessible and modifiable by various personnel, however not routinely used. Once a trainee completes a TOJ, the trainer documents the sign off on the paper-training form. The *training catalog* is a Word document stored on the company's intranet portal, which includes the course title, code, description, and approved trainers for the 21 IFS, 176 CBT and 322 TOJ courses used within the ACUD and is maintained by the training coordinator. The catalog does not include the training guide points or the actual training content.

3.1.5 ACUD Training Personnel

There are approximately 77 approved trainers listed in the ACUD training catalog. The number of trainers for one IFS or TOJ course ranges from as few as one to as many as 18. Trainers span across groups and worksites and include ACUD Operations technicians, managers and/or veterinary staff members, and/or non-ACUD research personnel with experience on the topic/procedure covered in a particular training. A person can be "signed-off" as a trainer by another trainer and needs only a signature by an ACUD veterinarian to be approved. Operations technicians who are trainers are expected to lead individual training activities while still completing their assigned workload (a "train as you go" approach). The training process is variable, depending on the trainer, type of trainee (new hire, or current employee in need of renewal training or a new skill set) and the specialty group to which they are assigned.

3.1.6 ACUD Training Processes

When a current in-life operations technician needs refresher training, or training for a new skill, they can reach out to any one of the approved trainers listed for the desired training and set up a time to work with them. This is often done after consultation with the operations manager. The operations manager manages the orientation and training for newly hired in-life employees. The operations manager ensures that new trainees have access to the necessary digital (email, company intranet, LMS, data collection systems, etc.) and physical (office space, computer, locker room, badge, etc.) resources. The operations manager also ensures that new employees are assigned and complete all relevant corporate, environmental/occupational health and safety (EHS/OHS), and site-, role-, and species-specific training. The operations manager often depends on experienced team members, who are trainers for the relevant topics or procedures, to provide the training. Managers or trainers also seek assistance from the training coordinator to have CBT training curricula and/or courses assigned within the LMS, and to submit paper training records (for TOJ and IFS courses) to be transcribed into the LMS by the training coordinator.

Training assignments within the first several days to weeks of employment consist of numerous courses, and sizable curricula with courses covering various topics. This is because the animal research environment is highly regulated, requiring numerous critically important policies and procedures to be transferred. They include site security, biosecurity, data integrity and privacy, safe handling of products and chemicals, safe operation of equipment, safety working with livestock, and how to handle human and animal emergencies, among others. Some of these trainings have to be completed before a person can even access the vivarium areas. This places a considerable amount of pressure on the

new hire to complete a lot of training materials in a short amount of time so that they can get into the vivarium to receive hands-on training.

In most cases, once the trainer has provided initial training to the trainee (whether new hire or current employee) on a specific animal procedure, the trainee is allowed to perform that procedure as long as they are in the presence of another "experienced" technician who is signed-off on that skill. The initiation of a procedure may be documented on the paper-training form or kept as a mental note by the trainer and trainee. After allowing some time for practice of the procedure, when the trainer and trainee believe the trainee is "proficient", the trainer signs the trainee off as trained and completes the paper training record. The trainer that signs the trainee off on the skill does not have to be the same trainer that initially trained them. The paper-training record is mailed to the training coordinator, who transcribes the trainee's name, course title and completion date into the LMS account of that trainee. The training coordinator also files the original paper record within department archives.

It takes an average of 30.4 days for completed TOJ paper training records to be recorded in the LMS. During this delayed timeframe, three scenarios can occur: 1) Trainees who believe themselves to be signed-off on the skill conduct the procedure independently (without the presence of a trainer or experienced technician), but are actually out of compliance because the completion has not been officially documented in the LMS; 2) Trainees are unable to be added to the team schedule for the procedure, placing a workload constraint on team operations; and 3) The trainee must continue to perform the procedure only if an experienced technician is present, which also creates workload constraints.

Based on departmental policy, skill/course renewal (also referred to as "refresher") training must occur every three years. Within the LMS, training that is assigned within a curriculum provides an automatic reminder to users 30 days prior to the 3-year mark that the training is coming up for renewal. When the 3-year renewal for TOJ's and IFS's approaches, the technician must follow up with a trainer for that skill, to have them sign and submit a new training record. The process for refresher sign-off is inconsistent across trainers. Some trainers watch the technician demonstrate the procedure prior to signing-off, while others simply fill out the training form, basing their confirmation of the person's ability on prior knowledge or observation of that person performing that skill.

The automatic notice of an approaching renewal deadline does not occur if the course is not part of a curriculum. In these cases, the technician must remember to renew the training at the 3--year mark. With no automatic reminder, technicians often neglect to complete the renewal and become overdue. Performance of a procedure while training is overdue is considered out of compliance with company policy. This scenario increases the risk of errors, animal welfare concerns, and safety incidents and places the company at risk should this be observed during regulatory inspections, accreditation site visits or GIAD audits.

Occasionally, skill renewal is applied as remediation for an error, animal welfare concern, or safety incident. For example, in the event of a dosing error, operations management and clinical veterinary staff (as well as other members of the animal welfare incident investigation team) determined that re-training was needed for the technician(s) involved. Depending on the seriousness and scope of these types of situations it may be decided that re-training must occur for all technicians signed-off on the procedure.

The current opinion of some trainers is that they do not have to complete the 3-year refresher for procedures they are an approved trainer for. So, they either ignore the overdue training on their LMS account, or they have the training form submitted by a trainer and approved by a vet, with no in-person demonstration. Some trainers and vets choose to observe in person, but this is largely based on personal preference and team dynamics.

3.1.7 ACUD Training Assessment

With a few exceptions, the ACUD does not have a process for proactive monitoring, assessment, or audit of technical skill proficiency (post sign-off) or compliance to SOP's, guidelines, or other directives. Assessments are generally conducted in preparation for regulatory inspections, accreditation site visits, or GIAD audits. Some managers choose to assess the skills or work quality of members of their team, however most managers do not.

On rare occasions, procedures are observed by the Quality Assurance (QA) group as part of audits conducted for GLP studies. Confirmation that any personnel observed conducting a specific procedure has the required training is done through a training record review. The intent of these audits is to ensure the performed activities are conducted in line with GLP requirements and internal SOP's, policies, and other guidelines; however, it is important to note that assessment of skills or confirmation of proficiency is not within scope of these audits. Sometimes, assessments are conducted as a reactive measure (remediation) after errors, animal welfare concerns or safety incidents. Skill assessments are highly subjective based on the operations manager, vet staff member, or trainer observing the procedure.

3.2 SWOT Analysis

3.2.1 Stakeholder Feedback

Recent organizational changes within the R&D organization led to increased support for continuous improvement efforts within the ACUD. To understand the ongoing challenges with the current training process, stakeholders at various levels of the organization were engaged to gather feedback on the state and future of animal use training within the ACUD. The process involved direct conversations with individuals and groups within the organization during personnel interviews, focus groups, job shadowing sessions, and leadership forums. The qualitative data emanating from these conversations were organized into an analysis of the ACUD's strengths, weaknesses, opportunities, and threats (SWOT). Animal care and use stakeholders within ABC's Animal Care and Use Department identified significant challenges, and risks in the operation of training activities. They also saw many opportunities that could be seized and/or leveraged to enhance performance.

3.2.2 Strengths

The ACUD has been able to capitalize on a wealth of knowledge, experience, and skillsets within all levels of its organization for many years. This has allowed the department to amass a considerable amount of information and resources for various species, roles, and specialties. The department's strategy of empowering approved trainers to sign off other trainers has led to increased options for trainees, due to the large number of available trainers. Strong relationships within specialty teams and between teams and partner groups (clinical researchers, veterinary staff, other supporting groups), has created a collaborative environment where stakeholders work well together to accomplish research objectives while ensuring animal welfare standards. Personnel at all levels within the

ACUD support a culture of compassionate care for the animals and wellbeing for human caretakers (compassion resilience).

3.2.3 Weaknesses

There were some significant weaknesses identified by the stakeholders regarding the content and processes of the training activities. Several issues were identified by operations managers/leadership, trainers, and technicians/trainees during the various focus groups. These weaknesses are organized into four general categories: 1) rushing and/or multitasking during training, 2) variability in trainer knowledge, comfort, and practices, 3) broad/irrelevant/application of training assignments, and the 4) lack of a robust training strategy, which are further discussed in the following subsections.

Animal care and use trainers (technicians) disclosed concerns that training activities often feel rushed due to the need to have new technicians released to work independently as soon as possible. Trainers stated concerns about divided focus (multi-tasking) between training responsibilities and execution of animal care or study tasks since training activities are conducted during regularly scheduled assignments. Trainees (Technicians) expressed concerns about feeling pressure to be "signed-off" on animal care tasks as quickly as possible so that they could be more useful to their teams, but not always feeling confident in the procedures they were signed-off on. The concerns expressed by operations managers about new employee training processes may be summarized as being unclear, inconsistent, and overwhelming.

Some trainers expressed a lack of confidence in training on certain procedures. These concerns were due to some trainers having been approved to train in procedures they had not performed in a long time or never performed at all. Focus group conversations also revealed that trainers had different understandings of training expectations. Some were

under the impression that they do not have to renew their training on a skill every three years (as is department policy) because they are an approved trainer for that skill. Trainers also seemed to disagree on whether the approving veterinarian needed to be in attendance during sign-off as a trainer, or just notified to sign the training form.

Technicians expressed concerns that the characterization of "proficiency" differed from group to group, making it difficult for the different groups to work together. They argued that having such a high number of trainers contributed to variability in training practices and proficiency standards. Managers also reported that when personnel resources needed to be shared across groups, there were incidents of disagreement between technicians within the group and those "on loan" from other groups because the two groups perform certain basic tasks differently.

Trainers revealed that the current on-the-job training guide points go largely unused due to the steps required to locate them on the group's intranet site and their lack of relevance to current practices. The guide points were found to lack the details needed to ensure a standard interpretation of skill proficiency across trainers/groups. Managers commented that the training refresher process and lack of well-defined trainer guide points increased procedural "drift".

Trainees stated that the assignment of a large number of SOP's and other computer-based training within their first few days of employment was overwhelming. This also contributed to overdue trainings residing on trainee LMS accounts for extended periods of time. Technicians also felt that some of the required computer-based training assignments were irrelevant to their job, so they ignored them, contributing to chronic overdue training (compliance failures). Assessment by the training coordinator identified that many SOPs

were assigned within role and site-specific curricula, but that the related on the job trainings were assigned only after being completed. This meant that, for example, a trainee might complete the SOPs on observation of animals, feed storage, and animal enrichment weeks before they complete TOJ training on cat observations, and husbandry. With no reference to training guide points or SOPs by trainers, there was increased opportunity for drift in procedures. Operations managers explained that errors occurring during animal procedures revealed the existence of drift in techniques. There was an approximate 35% average increase per year in dosing errors over the previous 6 years.

Based on analysis of training records by the training coordinator, numerous cases have been identified of technicians performing procedures for which they had not completed skill refreshers in over 3 years (corporate policy). The coordinator also identified multiple cases where technicians had been trained in skills, but no documentation existed for this training. Other issues that were identified included trainings which had no description of the procedure being used, and personnel having never been assigned (and therefore never completing) trainings on information or procedures that were key to their role.

Managers expressed concerns that the process for qualification of trainers was not robust; many trainers were selected historically for their high proficiency with certain technical skills. However not all trainers possessed the interpersonal skills for successful transfer of knowledge to another person. Additionally, trainees were not comfortable coming forward to express their lack of full grasp of some of the training elements.

Trainers felt that there was limited opportunity for development or continuing support for growth as trainers, limiting their knowledge of regulatory requirements or

alternative training styles. Compartmentalized operations prevented the sharing of best practices, improvements, and close calls between different groups, contributing to duplication of efforts.

3.2.4 Opportunities

Stakeholders recognized several current and emerging conditions that they thought could be leveraged into opportunities for improving training. The department's record of maintaining AAALACi accreditation was a strength which stakeholders felt could be parlayed into an opportunity. The company has a good reputation and working relationship with AAALACi auditors, which allows for opportunities to leverage "mock" inspection support prior to official scheduled inspections. Mock inspections allow a company to identify and address potentially sub-standard conditions prior to official inspections.

Recent changes within the higher levels of leadership have resulted in increased visibility of issues within the ACUD. The company's response to these issues has been a willingness to invest in training improvements, continuing education/professional development, and improving the company's learning platforms and other digital tools, which has fostered confidence among employees and a willingness to contribute to improvement initiatives.

3.2.5 Threats

Managers commented that workforce changes including, general turnover, departure of longtime employees, and COVID impacts on staffing, have contributed to a largely newer/less experienced workforce and slow adaptability of the department to adjust training styles to the current generation of workers. Approximately 48% of the ACUD workforce are new to their roles. The difficulty exchanging people resources across groups

limited the department's ability to support research studies, thereby reducing ABC's competitive edge in moving products through the pipeline.

The high number of overdue trainings, frequency of errors, and ill management of training content and records place the department at risk for animal welfare compliance violations, and citations by QA, GIAD auditors, accrediting bodies or regulatory agencies as well as posing a risk to research study outcomes and to the welfare of the animals. Additionally, changes in the regulatory landscape such as the USDA's discontinuation of "Teachable Moments", changes to the veterinary care standards for dogs and changes to care standards for multiple animals have revealed deficiencies in the departments process for cascading regulatory information and in the retention of that information among technical personnel.

Citations by the USDA have visibility to the public and to competitors. through the Freedom of Information Act (FOIA) and are frequently used by animal rights groups to promote its cause for ending all use of animals in research. These methods have been used in the recent past to introduce changes in legislation relating to animal research at the state and local levels.

3.3 SWOT Summary

In order to meet the unique needs of the research portfolio over the years, ACUD has employed subject matter experts and technical experts to lead, manage and execute the various functions under the department's scope. By allowing the experts the autonomy to lead and run their respective areas, the department was able to establish numerous specialty disciplines that have supported a wide range of species, project types and product approvals

over the years. The downside to this strategy is that it has contributed to the formation of "silos", within the department, reducing consistency across groups.

Trainers have been afforded a great deal of autonomy in determining what trainees need to know, the "best way" to do the job, when it is ok for a procedure to deviate from the written directives, and what makes a trainee proficient. This inconsistency in training principles has resulted in portfolio support constraints and difficulties sharing people resources across teams and worksites.

The availability of employees with extensive institutional knowledge and capabilities for so many years has allowed training to become an afterthought for operational performance. Some trainers were selected based on their technical proficiency, while others were selected because they were the only technician available with some level of experience with a species or procedure. In either case, no consideration of training or mentoring capability was made. Training responsibilities are expected to be done during regularly assigned work, which leads to multi-tasking and rushing. Many of the experienced technicians had been with the company since its inception and were even co-architects of some of the procedures that are still in use today. The details of many procedures have never been committed to written policies or guidelines but transferred via memory from experienced technicians to others. The departure of many of these employees over the years and during the COVID pandemic has revealed gaps in the facilitation of knowledge transfer and contributed to "drift" in processes.

Employee engagement within the department has suffered due to the high volume of training content applied in short periods of time, the expectations to train while

conducting in-life activities, limited opportunities for new skill development, lack of comfort with procedures, occurrence of errors, and the impact of employee turnover.

The inefficient and ineffective management of training databases, content, and records within the department has contributed to a chronic overdue training phenomenon, rendering many employees “out of compliance” to regulatory or corporate standards and limiting operations scheduling capabilities.

CHAPTER IV: TRANSITION FROM TRAINING ACTIVITIES TO TRAINING PROGRAM

The review of the regulatory and other requirements as well as the SWOT analysis conducted using stakeholder feedback have revealed the importance of the existence of training activities. There is no coherence among these activities, which has led to confusion and poor performance of the ACUD in contributing to ABC's competitiveness. This chapter describes the transformation of the myriad of training activities in the company into a consistent, comprehensive, clear, compelling, and transparent training program.

The chapter is organized into four sections, each describing a phase of the transition process. The first describes the establishment of the training program leadership and its strategy. The second phase involved the establishment of priorities and standardization. It also describes securing the support of employees for the program. The rollout of the training program and the processes used to secure commitment are described in Phase 3. Phase for presents a few preliminary results from the implementation of the program.

4.1 Phase 1 - Establishment of Training Program Leadership and Strategy

4.1.1 Training Program Leadership

The first step in implementing a new training program was to designate program leadership to a newly proposed position; Training Manager, which would report to the Animal Welfare and Training Leader. The Training Manager would facilitate a "big picture view" of the needs, trends, and risks to animal use training which spans across groups and worksites by providing strategic direction, oversight, and continuity for the program. The ACUD approved this new training manager position, and the recommended key responsibilities (summarized below) for this position were tied directly to the 4 key pillars of success.

Table 4.1: ACUD Training Manager Responsibilities

Success Pillar	Responsibility
Performance, Compliance, Engagement, Assessment/CI	Implementation and management of training program
Performance, Compliance	Assessment of training needs and requirements and communication to stakeholders
Compliance, Assessment/CI	Evaluating training program effectiveness through analysis of compliance trends, knowledge and skill proficiency, and other training data
Performance	Administration and coordination of training activities
Compliance	Active monitoring of training activities to ensure compliance to corporate animal welfare policies, animal welfare act regulations, and other industry standards
Engagement, Assessment/CI	Supporting 3R's principles through use of innovative training methods, where possible
Engagement	Supporting professional development and continuing education
Compliance, Assessment/CI	Effective collaboration and communication across teams during strategy development and change management
Assessment/CI	Application of continuous improvement principles to identify, analyze, mitigate, and resolve issues within the animal care and use program

4.1.2 Training Program Strategic Direction

Equally as important as leadership, the strategic direction of the training program must be communicated via a unified vision, mission and objectives. Collaboration between ACUD leadership, the Training Manager, and Operations Managers for all teams resulted in the development of the following strategic direction for the new training program.

Vision

To lead a diverse workforce of highly skilled trainers and confident and compassionate animal users who uphold the highest standards of animal welfare in research, teaching and testing at American Biotech Company.

Mission

Harmonize training concepts across sites to achieve portfolio success. Standardize training processes, where possible, to ensure regulatory compliance and support organizational agility. Optimize training capabilities to achieve operational excellence and support growth through innovation.

Objectives

- Communicate and maintain training information (databases, materials, content) to facilitate easy access of animal use stakeholders to the information they need to conduct animal work within compliance.
- Develop, organize and coordinate training activities to create consistency in practices and standards across groups and worksites.
- Actively monitor compliance to ensure ACUD meets all corporate, regulatory, and accreditation standards
- Incorporate animal welfare, 3R's, and compassion resilience principles in all training activities and initiatives.

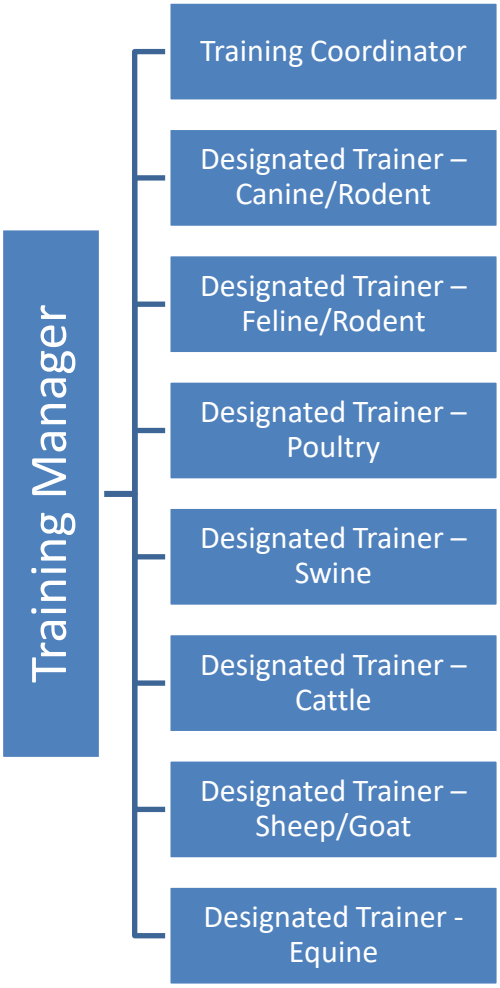
4.1.3 Proposal of a Core Training Team

To address concerns expressed by technical staff members regarding the practice of training while completing work assignments and inconsistent trainer knowledge, skills, and practices, the training program proposal included establishment of a core training team, and a training ambassadors' group, and reduction in the number of other trainers. The core team, led by the new training manager, would include the training coordinator (a position which already existed), and approximately seven new dedicated trainer positions representing each species or animal group (see proposed group structure in (Figure 4.1). This strategy would allow managers and technicians to focus on operational excellence by

transitioning most of the primary responsibilities for new hire, refresher, and skill enhancement training to a core training team, while still including a select few training ambassadors to provide secondary training support and mentorship and even fewer supplementary trainers, mostly supporting specialty training needs.

As an extension of the core training team, a training ambassadors' group was recommended. This group would be made up of the dedicated trainers and operations technicians (nominated by their manager) who are trainers within their specialty area and recognized as mentors within their teams (1-2 people per team). The purpose of this group would be to establish a consistent training philosophy between different groups and worksites and create a forum for continued development of trainers. The members of this group would also provide back-up training support to the dedicated trainers when needed, and function as mentor figures for recent new hires who have completed the orientation training phase. The ambassador group would meet monthly to assess and improve various training activities and assist in the execution of new training strategies and other continuous improvement initiatives, as needed.

Figure 4.1: Proposed Core Training Team Structure



The new training program recommended right-sizing of the total number of supplementary trainers throughout the ACUD. This would involve a review of every trainer listed in the catalog for every training and confirming if those personnel were still qualified through maintenance of refresher training requirements and skill proficiency assessments to perform and train others on the procedure, and if they were still essential in providing training coverage for the procedure, or if coverage of that training could be sufficiently supported by the dedicated trainers, with second line support from the training

ambassadors. In the case of advanced or specialty level procedures, supplementary trainers would remain on the list due to their subject matter and technical expertise.

4.1.4 Training Program Operating Plan

Development of any program requires a program description to set the stage for how the training program will function and who is responsible for its various aspects. The proposal for a new training program within the ACUD included a draft *operating plan* which outlines the processes, roles, responsibilities, and materials used in the management and execution of animal care and use training of ACUD staff and other animal users at ABC. This document provides details on all aspects of the training program as outlined below:

(1) The Purpose of the Training Program Operating Plan

(2) The Scope of the Training Program

(3) Commonly used Abbreviations

(4) Personnel Roles and Responsibilities.

   a. Attending Veterinarian

   b. IACUC

   c. Animal Welfare Compliance Group (including the proposed Training Team)

   d. ACUD Clinical Veterinary Staff

   e. ACUD Operations Managers

   f. ACUD Animal Users

   g. Non-ACUD Animal Users (Partner Groups)

(5) Training Materials and Tools.

   a. Training Formats

b. Training Standards and References

c. Course Catalog

d. Course Curricula

e. Course/Curricula Classifications

f. Training Plans

g. Documentation of Training

(6) Standardized Training Procedures

a. Animal User Training Process

b. Animal User Skill Refresher

c. Certification of Trainers

d. Post-Training Skill Assessment

This Operating Plan (OP) will aide ACUD in addressing a number of the identified issues within its animal use training program, firstly by identifying the roles involved in the training process and their applicable responsibilities, including designating a single point of control for maintenance of training materials/content and monitoring of training compliance data. Secondly, the OP would support ACUD's key success pillars, by establishing and communicating consistent expectations for the certification of trainers, the training process, and the assessment of technical skills to be applied across all in-life teams.

4.1.5 Training Program Communication Strategy

The final step in the first phase of implementing the new comprehensive training program, was to develop a communication strategy to ensure buy-in from ACUD leadership and management, foster collaboration across groups, increase awareness of training compliance trends, and provide transparency in decision making and future plans to all levels of the department. First, a monthly training update was implemented, which

communicated compliance trends, revisions to training courses or materials, and provided other key information related to training. Secondly, operations managers and technicians were familiarized with all proposed and planned changes prior to implementation. This allowed stakeholders to ask critical questions, provide feedback, gain an understanding of the "why" and "why now" for changes, and to begin to conceptualize how these changes would have a positive impact on their work experience.

Finally, the plan for the new training program was rolled out at an "all-hands" meeting attended by ACUD leadership, veterinary, management, technical and administrative personnel. The plan included summarization of the challenges identified through stakeholder feedback and assessment of environmental factors and the improvements to target those challenges. The plan also introduced the roles and responsibilities of the new core training team, training ambassadors and the supplementary training personnel. This group roll-out approach allowed personnel at all levels to have visibility to the plans and to see how their contributions were being recognized in the construction of this new training program.

4.1.6 Integration of the Core Training Personnel and Training Ambassadors

The ACUD Leadership team approved creation of the new training manager position and the training ambassador program right away, and later approved the creation of two dedicated trainer (DT) positions. One of the DT's would be focused on cat skills and the other would be focused on dog skills, however both would be cross trained in order to provide back-up support. The training manager had to focus on a number of high priority issues (mostly compliance related), but also right away wanted to set a tone of transparency, inclusion, and continuous improvement with the formation of this new role

and group within the department. This was done by directly engaging with operations managers and technicians as soon and as often as possible.

Collaboration with leadership and management is key to receiving the endorsement and investment needed from the company to start a new program. The engagement and communication with frontline operations team members is equally important to ensuring a smooth transition and ultimate sustainability of the program going forward. The training manager recognized that previous programmatic changes within the ACUD were met with resistance from operations technicians. While many technicians would agree that there were issues within the training process that needed to be fixed, they were slow to accept proposed changes. The implementation of dedicated trainers and application of new training standards are major changes that were anticipated to be challenging for the group to adapt to. The training manager's main approach to overcome these and other challenges was to engage in direct interaction with operations technicians. Job shadowing, one on one conversations and training ambassador meetings were used as relationship building opportunities, in addition to information and feedback collection. By engaging the technicians directly to discuss their concerns, ideas, and experiences with training and including their feedback in the summary provided to leadership and management, the technicians remarked that they felt included and "heard" in the process and confidence in the new training manager to help make improvements. Technicians have also been included in other aspects of the implementation, which has allowed them to be contributors to the design of the new program, and therefore invested in its long-term success.

The people who were ultimately hired to fill the DT positions were chosen based on their experience level and technical acumen, with special consideration of their

interpersonal skills. Specifically, they had to be able to communicate professionally and effectively; provide instruction to others with simple, clear language and modify styles to meet different needs, and to adapt to unexpected events; troubleshooting, problem solving and applying conflict resolution tools. They were also AALAS certified at the LATG level, which spoke to their knowledge of animal research regulations and industry recommended laboratory animal management practices.

While technicians agreed that assistance with training was needed, they were hesitant about the prospect of relinquishing training responsibilities to perceived "outsiders". In order to build a positive, collaborative relationship between the new DT's and the technicians, the DT's shadowed training ambassadors and technician-trainers from each team assisted them with various procedures. This time was used for the DTs to hear directly from these technicians what the unique aspects of their daily jobs were, and what skillsets they felt were necessary to successfully complete the work. Technicians were asked what aspects of the training program would be most helpful to them and how the dedicated trainers can best support them. This time provided the opportunity for technicians to organically observe the skills and capabilities possessed by the DT's. This relationship building allowed technicians to develop trust and confidence in the dedicated trainers' abilities to train, and again, allowed them to feel included in the building of the new program.

The training ambassador program was initiated early in the process. Initially the group met to discuss issues, needs, and goals in the training program and progressed to conducting continuous improvement projects together, including piloting the new electronic training form, and drafting new trainer guide points and proficiency standards.

4.2 Phase 2 – Targeting of the Highest Priorities

The next phase of implementation was centered around addressing a few of the highest priority needs and a few of the easiest issues to tackle in a short period of time ("low hanging fruit"). This strategy was chosen in order to rectify urgent compliance risks as soon as possible, to develop the plan for supporting projected portfolio needs, and to re-assure confidence in the technical staff of the organizations dedication to improving support for employee engagement and development.

4.2.1 Addressing Urgent Compliance Risks

Two of the most urgent compliance risks identified during the organizational analysis were the inefficient/inconsistent training documentation practices and the perpetual overdue training within the LMS accounts of ACUD animal users.

Transitioning training documentation from paper forms to an electronic format (e-form) was one of the urgent and "easy" improvements to make. Development of the e-form was achieved through use of internal intranet systems and did not require the need to invest in additional technologies or programs. Piloting of the new form was aided by the training ambassador group. The e-form provides trainers the ability to complete and submit training records contemporaneously using a system which is connected to the digital training catalog. Implementation of the e-form eliminates the risks associated with paper (loss, damage, storage, errors, regulatory citations) and reduced the amount of time from training completion to documentation within the LMS from an average of 30.4 days to an average of 4.35 days.

A number of steps were initiated to deal with the chronic overdue training problem. The training manager worked with the training coordinator to implement monthly compliance tracking, which was included in the monthly training update communication as

a proactive measure to have managers check their teams' records. Meetings between the training manager or coordinator and operations managers and their teams were scheduled to provide tutorials on reviewing LMS training records and understanding how to navigate the system to identify overdue trainings and other information. The training manager and coordinator also performed in depth reviews of individual personnel training records and training curriculum (discussed further in a later section) to remove out of date or irrelevant trainings, and to aide in getting out of compliance technicians up to date on their refresher trainings. These combined efforts reduced the average overdue training per person down to 1.07, from an average of 1.51 in the previous year.

4.2.2 Standardization of Training Expectations

The proposed training standards will include revised training guide points, and creation of knowledge checks, proficiency sign off standards for every TOJ within the ACUD to create consistency in conduct of procedures across groups/sites/trainers. The goal of revising the trainer guide points was to clearly indicate specific skills that must be displayed in order to successfully complete the procedure, and any necessary pre-requisite skills, indicate parameters for "successful completion" that ensure consistency between trainers/trainees, establish realistic proficiency expectations that are thorough, yet concise, and reflect skills and practices that are reflective of current best practice. New trainer guide points will also indicate the frequency of successful completion of a procedure needed to achieve final sign off. This is to ensure trainees demonstrate reproducibility of success prior to the final sign off (which may require a specific success rate).

For the 322 TOJ's used within the ACUD this was anticipated to take a considerable amount of time. Therefore, the process was started with basic level companion animal training, with the long-term goal of progressing to other species when

available until all are completed. The core training team worked with training ambassadors to draft new training guide points for the companion animal basic skill TOJ's and began the process for revising intermediate level TOJ's.

4.2.3 Preparing for Upcoming Project Portfolio Needs

During the process of assessing the training needs to support the project portfolio of the ACUD, it was identified that urgent preparation was needed for forecasted increases in companion animal (cat and dog) projects. Managers were concerned that there were not enough team members with the skills and capabilities required to support the anticipated study work. They also had concerns about supporting the incoming work and skill enhancement for current team members, while also managing the onboarding of new hires. The new training programs proposal for Dedicated Trainers (DT) would aide in addressing these concerns. This discussion was the catalyst for the approval by ACUD leadership to hire two of the proposed dedicated trainer positions.

The proposal set forth a new hire orientation training process which would be managed by the core training team, who would collaborate with the operations manager to construct the training plan. Dedicated trainers would conduct the new hire training and then collaborate with the team's training ambassador to provide follow up mentorship for new hires post-orientation training. The DTs would also provide skill enhancement and refresher training for current companion animal technicians. The training team would focus training standardization efforts (discussed in a later section) on companion animal training first, based on the business need.

Once through their onboarding phase, the two DTs would help to fill the training gaps for mostly basic-intermediate companion animal skills such as animal room

management, data collection, husbandry, health observations, sample collections, and dosing (all of which were identified as necessary to support forecasted study work).

4.2.4 Supporting Employee Development

The new training program proposal recommended active support for technical and professional development of technical and managerial staff. ACUD managers sought approval from leadership to implement an AALAS Certification incentive program. This program would provide reimbursement of up to $810 in costs for training courses, study guides, and testing registration, as well as a one-time bonus payment up to $1,000 for successful completion of the certification (passing the final exam). The amount of reimbursement and bonus payment are dependent on the certification level achieved. Leadership approved this proposal, and the information was covered during the all-hands training meeting, with subsequent discussions during the monthly training ambassadors' meetings.

The training program proposal also recommended the inclusion of animal care and use personnel in the Six Sigma continuous improvement methodology trainings that ABC analytical, manufacturing, and other R&D employees often participated in. This would introduce technicians to concepts of problem characterization (definition and measurement) and analysis, steps to implement changes and the importance of well-defined process control methods. ABC Research and Development leadership decided to implement white belt level training for all employees within the R&D organization (ACUD included).

4.3 Phase 3 – Long-Term Strategies

Establishing direct oversight for the training program will facilitate proactive management, assessment, and improvement of training process, and mitigation of risks in support of the 4 success pillars. The initial actions proposed with the new training program

serve as the foundation for establishing a culture for prioritizing training within the research environment and creating a "rallying" effect by harmonizing training stakeholders from all levels to a joint mission. The proposed long-term strategies will support the continued improvement and sustainability of the new training program.

4.3.1 New Training Process

The new training philosophy is focused on balancing standardization of training expectations with provision of dynamic learning opportunities. The new training process uses a customized training approach that layers written, visual, and hands on learning to give learners of varying learning styles a robust understanding of the policies and procedures within the ACUD. This process is applied to every skill (or group of related skills), procedure, or topic being taught, whether the trainee is a new hire or a current employee.

The dynamic training process (summarized graphically in Figure 4.2) is detailed as follows:

Introduction: When training in a new skill or procedure involving direct animal contact, trainers should begin with an introduction to the species/skill/procedure. The Introduction should consist of the following steps:

- Reading – The trainee completes written/digital materials such as guidelines, SOP(s) and/or CBT(s), as applicable to the specific topic/procedure in question based on the pre-determined training plan.
- Discussion – After completion of the Reading step, the trainer reviews critical points from the written/digital materials with the trainee and answers any outstanding questions. The trainer also introduces the trainee to any data collection or documentation systems (electronic/digital, or paper) which may be required to

conduct and record the procedure appropriately. Then the trainer provides background information relevant to the procedure, introduces the trainer guide points and provides an overview of what to expect during the Observation step.

- Observation – The Trainer escorts the Trainee to in-person observation of the procedure (conducted by trained personnel), in order to facilitate further discussion and understanding of the species and the procedure before moving into initiation of hands-on participation.

Initiation of Hands-on Learning - The trainer initiates the trainee in hands-on learning of the procedure in order to establish a basic level of competency. During this stage, the trainer demonstrates the procedure and related preparation activities according to the trainer guide points and the trainee participates or assists, while under direct supervision of the trainer. Basic competency means that a trainee has the background knowledge, a general understanding of preparation activities for the procedure and the ability to perform the steps for the procedure but has not yet reached a level of consistent success and/or still requires assistance or guidance from the trainer in order to successfully complete the procedure. Once the trainee has established basic competency, training may be moved into the practice stage.

Practical Application through Monitored Practice - During this stage, the trainee practices the procedure in order to build proficiency, while under supervision of the trainer. The trainee should be able to independently perform the procedure according to the trainer Guide Points, while needing less assistance or guidance from the trainer than during the Initiation stage. The trainer must ensure that the trainee has had sufficient practice with consistent success prior to moving into the proficiency assessment and sign off stage.

Knowledge checks consist of verbal, written, and/or practical assessments, designed to ensure that a Trainee has a comprehensive understanding of background information, in addition to the practical knowledge (Trainer Guide Points) needed to successfully perform a procedure or set of related procedures in compliance with company policies, SOP's, and guidelines. The trainer may use Knowledge Checks throughout the stages of the training process to gauge the trainee's progress.

Proficiency Assessment and Sign-off: The trainer must assess the proficiency of the Trainee prior to signing the trainee off to perform a procedure independently. Proficiency is established when the trainee meets the following criteria:

- The trainee is able to perform the procedure while limiting undue stress to the animal. The trainee should have the ability to adapt to unexpected events/animal behavior, recognize the point at which it is best to pause or abandon the procedure in the interest of animal welfare, and when an ACUD Veterinarian should be contacted.
- The trainee passes the related Knowledge Checks, as applicable.
- The trainee is able to independently perform the procedure, with no assistance or guidance needed from the trainer.
- The trainee successfully completes the procedure according to the guide point steps and in compliance with company policies, SOP's, and guidelines.
- The trainee successfully completes the minimum number of animals/occurrences recommended per the proficiency sign off standard, as applicable.

As part of the proposed training program, the skills (or group of related skills), procedures, and topics covered during training would be categorized into technical skill

levels. These categories include basic, intermediate, advanced, and specialty skills for each animal species used within the department. The benefit of these categorizations is that training can be focused on establishing basic high use skills used across all teams, in order to increase cross functional support capabilities across teams.

Figure 4.2: New Dynamic Training Process

4.3.2 The New Hire Orientation Training

The proposed new hire training process has 3 phases: 1) Orientation, 2) Skill Proficiency Building and 3) Mentoring and Study Leadership Training. Prior to initiation of the orientation phase, the training coordinator and operations manager develop the training plan, which details what skills, procedures, and topics need to be covered based on the role of the trainee and in what period the training will be conducted. The orientation and skill proficiency building phases will be led by the assigned dedicated trainer. The mentoring and study leadership phase will be led by the training ambassador for the applicable team.

The orientation phase is focused on completion of corporate training activities, introduction to the company and assigned business area/group, acclimation to the physical (office/desk area, locker rooms, facility, etc.) and digital (electronic communication platforms, documentation systems, and information databases) work environments, and completion of any basic safety, security, and biosecurity-related training prior to entry into the animal facility.

The skill proficiency building phase is where the bulk of new hires initial TOJ training will occur. Training during this phase is focused on helping the trainee to develop proficiency in the core basic level skills needed to work with their applicable species. Basic level skills include:

(1) Animal Welfare Introduction

(2) Animal Records, Use of Data Capture Systems, Introduction to Protocols

(3) Species-Specific Introduction

(4) Animal Macro-Environment Management

    a. Animal Room Setups

    b. Environmental Conditions and Monitoring Equipment

    c. Animal Food Storage

    d. Approved Enrichment Items

    e. Assessing Light, Air, Water, and Feed

    f. Room Sanitization

(5) Animal Handling and Care.

    a. When to Contact a Vet

    b. Species Specific Husbandry

    c. General Health Observations and Temperature Collections

    d. Handling and Restraint

    e. Grooming and Body Weights

    f. Blood Collection Restraint Methods

Once the trainee has achieved proficiency in all of the basic level competencies, they progress to the core intermediate level skills (as needed based on the training plan). Intermediate level skills include:

(1) Blood Collection

(2) Dosing

    a. Oral Dosing

    b. Topical Dosing

    c. Subcutaneous Dosing

    d. Intramuscular Dosing

Following successful completion of the skill proficiency building phase, trainees are transitioned into the mentoring phase where they are paired with a training ambassador from their team. The mentor's role during this time is to create a culture of inclusivity for the new team member by: checking in with them daily, helping them acclimate to the team's day to day operations, being the go-to resource for questions and providing tips for success, having them shadow during work assignments, and/or shadowing the new team member during their assignments. The mentor is also expected to use available opportunities to teach the new team member the concepts of in-life study management, including: helping them to better understand the types of specialty studies the team is responsible for, helping them understand how to review study protocols and what key information to look for, bringing them along for pre-study meetings and other study events, and introducing them to partner group personnel, and teaching them about study-specific room/supply prep or documentation. Depending on the needs of the team (as determined by the manager), the trainee may receive training in additional study-specific skills (which

may be intermediate, advanced, or specialty level). The mentor or dedicated trainer may conduct or coordinate this training for the new team member. By the time an employee completes the three phases of the new hire orientation training process, they will be a well-functioning member of their team capable of completing assigned tasks, assisting other team members when needed. Additionally, with the new training process, new team members will possess the core basic and intermediate skills needed to provide much needed cross-site support to other teams with only minimal site-specific training needed.

4.3.3 Revision of Training Curricula

To address the irrelevance and untimely application of training curricula a plan was developed for the training manager and coordinator to audit all current curricula to identify out-of-date, missing, or irrelevant courses. Out-of-date courses and/or curricula which were no longer in use in the department were unassigned from personnel LMS accounts and deactivated. Active curricula were reviewed for relevance to current department, worksite, and species-specific scope. Based on feedback provided by operations managers, veterinary staff, and training ambassadors, revisions were made to the curricula to add missing relevant courses. Finally, new more manageable curricula were developed to facilitate sequenced assignment of required topics.

4.3.4 Skill Proficiency Assessment / Gap Analysis

Assessing the skills of current ACUD technicians is considered to be vital in determining the department's ability to support project needs. The training manager worked with ACUD leadership and operations managers to establish an assessment plan that would capture the information needed to understand the department's current capabilities, while avoiding negatively impacting employee engagement. The group decided on a four-stage approach. First, the technicians would be asked to conduct self-

assessments of their skill proficiency levels. This information would be collated within a database for each team and used by the gap analysis committee as a starting point. Then the committee would compare the self-assessed proficiency levels against the priority skills needed for the incoming study work beginning with the technicians who identified as having the highest proficiency ratings. Next, the committee would audit the selected technician's skills against the newly developed trainer guide points and any "gaps" in their current technique identified. Lastly, a list of technicians identified as having gaps in technique for the applicable skills would be compiled and a schedule developed to complete skill enhancement training. The committee is currently completing the technician self-assessment stage.

4.3.5 Right-sizing of Overall Number of Trainers

Reducing the total number of supplementary trainers was considered a long-term goal due to its complicated nature. Some of the trainers listed in the training catalog had left the company or moved to different departments where they were no longer involved in animal work, which made retiring them from the list of trainers easy. However, other situations were more complicated, for example, some trainers had not performed or refreshed training on a procedure in many years, and some managers preferred to remove certain trainers from the list due to proficiency concerns or the occurrence of errors. Some trainers were highly proficient at performing a procedure, but lacked the soft skills needed to effectively train people with a wider spectrum of learning needs. ACUD leadership members decided that this change would be undertaken in phases as a long-term strategy so as not to abruptly and negatively impact employee engagement.

4.3.6 Use of Non-Animal Models

In support of American Biotech's commitment to the 3R's, the proposed training program will take a proactive approach to implementing the use of non-animal models where possible. The training team will lead the effort to identify potential models and collaborate with vet staff and training ambassadors to pilot their use for training on certain procedures. The goal of using these models would be to reduce the number of animals needed for training activities and refine training techniques that require the use of live animals. This will be accomplished by allowing trainees to establish certain base fine motor skills before using actual animals and allow for the use of efficient formats such as classroom or group learning which are currently limited within the ACUD due to constraints in available live animals for training. The costs of investing in non-animal models, the number and type of animal uses reduced or replaced by non-animal models for training activities should be tracked, in order to demonstrate how this strategy has aided the department in achieving 3R's objectives.

4.3.7 Limitations

While this training proposal called for creating a training team which included dedicated trainers for all species/species groups used within the ACUD, the departments leadership officials only approved the training manager and the additional headcount for two companion animal positions, with the potential for approving other positions in the future. This stage of implementation should be used to show proof of concept of the dedicated trainer model by successfully integrating the two new training positions, working through any challenges to implementation and evaluating the results. Successful achievement of the performance goals will be the key to demonstrating the value and transferability of this model to other species to leadership officials.

4.3.8 Training Program Assessment and Continuous Improvement

Monitoring of the performance of the new training program will be conducted through monthly tracking of compliance trends, and assessment of training outcomes. The compliance trends include lag-time between TOJ training events and documentation of training in the LMS, percent of overdue trainings per person, and occurrence of dosing errors. Training outcomes include training satisfaction surveys for trainees, operations managers, and trainers. Satisfaction surveys will be conducted within 30 days post-training and again at six months post-training. Training outcomes will also include skill proficiency assessments at six months post-training (for new hires), and at the 3-year skill renewal period, and during random skill assessments for all technicians. The purpose of post-training skill assessments will be to detect potential drift on procedures and proactively implement skill enhancements.

Monthly tracking, survey results, and skill assessment outcomes will be collected by the training manager and shared with the Animal Welfare and Training Leader as well as ACUD leadership. Survey results will also be shared with trainers to recognize their successful efforts and identify any opportunities for improvement. Where skill deficiencies are identified, the training team will initiate re-training or skill enhancement for the identified personnel. In the event of increases in errors or deficiency trends, the training team will work with ACUD operations management and/or leadership to apply relevant six sigma-based root cause analyses and continuous improvement tools.

CHAPTER V: CONCLUSIONS

The requirement for the presence of an animal use training program within the animal research setting is made clear through the various regulatory standards. While they may be paramount to the basic function of a training program, the mere existence of training resources (access to training materials, or the presence of trainers), does not necessarily constitute a training program. In the case of the American Biotech Company's Animal Care and Use Department, many resources were available to facilitate individual training activities. But based on an analysis of the internal conditions within the company, the Department lacked a comprehensive infrastructure to effectively support those resources and the strategic planning and oversight to manage and maintain them. The result of these limitations was the presence of risks and deficiencies which impacted the ability of the department to achieve project objectives, maintain compliance standards, create an engaging environment for employees, assess training outcomes, and adopt continuous improvement strategies to help resolve ongoing issues.

A review of available literature regarding the regulation of facilities engaged in the use of animals for research, teaching, or testing, revealed that there is a plethora of legal, regulatory, and legislative oversight of activities involving the use of animals. However, this oversight does little to inform research facility leaders of what training strategies, technical procedures, or management tools will facilitate the most effective execution of a training program within their company. As discovered in the literature review, the sharing of knowledge, techniques, and experiences across the industry through recognized publications, consortiums, conferences, seminars, professional development programs, accrediting associations, and other membership forums offers organizations a chance to

identify strategies that may be applied internally to help improve training capabilities and outcomes. A number of these industry recommendations can help the ACUD achieve its key pillars of success : Performance; Compliance; Engagement; and Assessment/Continuous Improvement

The training program proposed within this thesis was designed to equip the ACUD to meet its objectives by first establishing program leadership, strategic direction, operating guidelines, communication strategies, and a dedicated team to execute the program. Then the proposal targeted high priority compliance requirements, performance standards and employee needs. And finally, the proposal laid out the improvements which may require a more extended period to effectively implement. Creating standardized training expectations and processes across groups will allow the ACUD to consistently achieve operational excellence and adapt people resources between groups with agility, to meet performance objectives. Instituting more efficient training documentation practices, proactive monitoring of training data, and improving visibility and accessibility to training content, and regulatory requirements will ensure that ACUD personnel meet compliance expectations. Supporting employee development and continuing education, providing tailored training support based on individual learning needs, and enlisting stakeholders in the assessment and improvement of training methods will create an animal care and use program which actively engages employees to seek out new opportunities and innovative methods to do their jobs. Implementing technical skill assessments and training surveys will ensure that training activities meet the needs and expectations of trainees, managers, and the department and maintain high animal welfare standards. And building CI principles

into the fabric of the training program will encourage stakeholders to recognize opportunities to improve the way they work.

Phased implementation of many of these strategies has already resulted in initial improvements in training compliance, performance capabilities, and employee engagement. But more time is needed to fully implement all aspects of this new comprehensive program and pressure test its long-term success and sustainability.

5.1 Recommendations for Further Analysis

It is recognized that the absence of a unified training oversight or monitoring scheme within the ACUD limited the availability of certain quantitative parameters relevant to this analysis. To ensure measurable and sustainable success of the new training program, the ACUD training manager and leadership will need to identify appropriate metrics which can be used to quantify the costs of the current state of training and the benefits seen after implementing the new program. Relevant data collection should include, but may not be limited to,

(1) the cost of training activities

(2) the costs associated with completing fewer studies due to restraints in employee capabilities.

(3) the costs associated with animal-related errors occurring in the study.

(4) the impact of training and training deficiencies on employee turnover

(5) the benefits associated with implementing the new training program (reduction in turnover, errors, and compliance violations, etc.)

The programs assessment strategy should use this information to establish performance benchmarks (goals). Proactive assessment of compliance trends and other training

outcomes against the program goals must be a continuous and routine component of program operations and the results must be used to inform strategic decisions.

5.2 Conclusion

The ABC Animal Care and Use Department has the potential to maintain a competitive advantage in successful development of pharmaceuticals and biologics through the use of innovative training and animal research techniques, including non-animal capabilities, and retention of highly skilled and motivated animal users.

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