

## **Laboratory Quality Management Training: Guiding Principles to Promote a Culture of Biosafety, Biosecurity, and Responsible Conduct in the Life Sciences**

An organizational culture of biosafety, biosecurity, and responsible conduct in the life sciences fosters quality activities that aim to develop new treatments and therapeutics, strengthen health research systems, and promote public, animal, and environmental health surveillance and response activities. These elements are essential to protecting and improving health security and wellness of people, animals, and the environment.

Laboratories working with biological agents and toxins operate under rigorous regulations and requirements to provide the appropriate levels of protection for public and agricultural health through personnel training on biosafety and biosecurity, bioethics, occupational health, and quality management. Such training is designed to meet quality and regulatory objectives and to provide individuals with the knowledge, skills, and abilities necessary to be competent in their assigned duties and responsibilities. The training should also emphasize the need to exercise a general duty of care to protect the health and safety of individuals as well as the environment.

Laboratory incidents may lead to significant costs in time, personnel efforts, and patient outcomes as well as potential risks to the health security of individuals, communities, animals, plants, and the environment. A vigorous quality management system does not guarantee an incident-free organization but it can rapidly identify issues when they occur and help prevent them from reoccurring.

Strengthening an organizational culture of biosafety, biosecurity, and responsible conduct in the life sciences is an intrinsic part of a quality management system and it implies devoting training resources and consideration to: management systems (organization and leadership); leadership and personnel behavior; principles for guiding decisions and behavior; and beliefs and attitudes on biosafety, biosecurity and responsible conduct of research.

Performing assigned duties and responsibilities in a safe, secure, and responsible manner is a core competency and must be emphasized during the competency assessment (which affirms that training is effective and personnel competently apply knowledge, skills, and abilities to meet the standards of their professional practice).

### **Quality Management System:**

*Coordinated activities (including policies, processes, and procedures) on all aspects of a laboratory operation (including organization, personnel, and equipment) to direct and control the quality of research and results which are accurate, reliable, and timely.*

### **Culture of Biosafety, Biosecurity, and**

**Responsible Conduct:** *An assembly of beliefs, attitudes, and patterns of behavior of individuals and organizations that can support, complement or enhance operating procedures, rules, and practices as well as professional standards and ethics designed to prevent the loss, theft, misuse, and diversion of biological agents, related materials, technology or equipment, and the unintentional or intentional exposure to (or release of) biological agents.*

The organizational culture of biosafety, biosecurity, and responsible conduct in the life sciences may be addressed as part of the safety and security training component of laboratory quality management systems while taking into account that laboratory training and competency assessment approaches will vary with local context, including requirements (organizational, regulatory, accreditation), quality management systems, path of workflow processes and procedures, and composition of personnel.

### **Select references:**

1. Federal Experts Security Advisory Panel working group [training materials on strengthening the culture of biosafety, biosecurity, and responsible conduct](#), American Biosafety Association (ABSA) website.
2. [Responsible life sciences research for global health security: a guidance document](#), World Health Organization, 2010.
3. [Competency Guidelines for Public Health Laboratory Professionals](#), CDC and the Association of Public Health Laboratories, MMWR Supplements May 15, 2015: 64(01);1-81.
4. [Guidelines for Biosafety Laboratory Competency](#), CDC and the Association of Public Health Laboratories MMWR Supplements April 15, 2011 / 60(02);1-6.
5. [WHO Laboratory Quality Management System Training Toolkit](#).
6. [Laboratory Accreditation or ISO 9001 Certification?](#), International Laboratory Accreditation Cooperation.

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*These guiding principles were developed by the Federal Experts Security Advisory Panel (FESAP) Working Group established to implement FESAP recommendation to strengthen the culture of biosafety, biosecurity, and responsible conduct in the life sciences, with support from experts from professional organizations and academia. For more information, contact the working group co-chairs Dana Perkins [dana.perkins@hhs.gov](mailto:dana.perkins@hhs.gov) and Eilyn Fabregas [eilyn.n.fabregas@aphis.usda.gov](mailto:eilyn.n.fabregas@aphis.usda.gov).*