ICCVAM Workshop Series on Best Practices for Regulatory Safety Testing: Assessing the Potential for Chemically Induced Allergic Contact Dermatitis
January 20, 2011
William H. Natcher Conference Center - Bethesda, MD

Workshop Goals and Objectives

The primary objective of this workshop is to assist participants in gaining a practical understanding of the theory and application of available alternative methods for evaluating the potential for chemically induced allergic contact dermatitis (ACD) that can also minimize animal use and avoid pain and distress.

The specific goals of the workshop are to:

1) Provide an overview of the available methods, including the applications, strengths and weaknesses of each method.
2) Provide information on the procedures for conducting and interpreting data in accordance with regulatory testing requirements and guidelines.
3) Allow an opportunity to become familiar with data generated by each test method.
4) Provide a forum for scientists to share information on the appropriate use of results in regulatory safety testing.
5) Discuss challenges of incorporating alternative test methods into regulatory safety testing guidelines.
6) Identify and discuss new methods in the development and validation pipeline for each safety testing area, and ways to increase the availability of high quality data necessary for validating new methods.

Background

Skin diseases, including ACD, are the second most common category of occupational diseases. ACD frequently develops in workers and consumers exposed to skin sensitizing chemicals and products, results in lost workdays, and can significantly diminish quality of life. To minimize the occurrence of ACD, regulatory authorities require testing to identify substances that may cause skin sensitization, and this represents one of the four most commonly conducted product safety tests. Sensitizing substances must be labeled with a description of the potential hazard and the precautions necessary to avoid development of ACD.

The U.S. Public Health Service Policy on Humane Care and Use of Laboratory Animals and the U.S. Department of Agriculture's Animal Welfare Act Regulations[1] require that alternatives to safety testing procedures that can cause more than slight or momentary pain or distress be considered and used where appropriate. This workshop will raise awareness of available alternatives and provide information about their usefulness and limitations that can be used to determine when their use is appropriate.

[1] 7 U.S.C. Sections 2131-2159

Substantial progress has been made in recent years towards the development, validation, and regulatory acceptance of alternative test methods that reduce and refine (decrease or eliminate pain and distress) the use of animals for ACD hazard testing. In March of this year, U.S. Federal agencies accepted ICCVAM recommendations on an updated murine local lymph node assay (LLNA) protocol that uses 20% fewer animals. Federal agencies also accepted ICCVAM recommendations on the use of a modified procedure called the reduced LLNA that uses 40% fewer animals. ICCVAM also recently recommended two modified versions of the LLNA that do not require radioactive reagents, allowing more institutions to take advantage of the reduction and refinement benefits afforded by the LLNA compared to traditional guinea pig methods. These nonradioactive methods will also eliminate the environmental hazard associated with use and disposal of radioactive materials used in the traditional LLNA.

In order to implement the use of a new test method, the safety community must understand the method, as well as the manner in which agencies expect the method to be conducted and data interpreted. Users and regulatory agency staff need to become familiar with the technical procedures required to conduct the new method, and to understand the method's usefulness and limitations. Consequently, there is a need for in-depth training of individuals in the safety and regulatory community on the appropriate use of new tools for hazard, safety, and risk assessments.

This workshop brings together scientific experts representing relevant stakeholder organizations to discuss available alternative test methods. Participants will learn the strengths and weaknesses of available alternative test methods, become familiar with the types of data they provide, and learn how to use these data in hazard, safety, and risk assessments.

Who Should Attend

Scientists from industry, government, and academia that have an interest in learning more about the available alternative test methods for ACD hazard assessments are encouraged to participate. Topics discussed during this workshop will be of particular interest to involved in conducting ACD hazard tests (such as toxicologists and study directors), those responsible for reviewing study protocols prior to testing (such as chairpersons and members of Institutional Animal Care and Use Committees [IACUCs]), and regulators who will review data generated by the tests.

Workshop Program

The workshop will be convened January 20, 2010, from 8:30 a.m. to 5:00 p.m. U.S. requirements for the consideration of available alternatives, current regulatory requirements for ACD hazard testing, and acceptance status of alternative methods will be presented. Background information on the scientific development of the assay and discussion of the validation status of the assay will then be provided followed by detailed presentations to provide practical instruction on application of the assay including standard protocols and data interpretation.Workshop participants will also have an opportunity to apply knowledge gained from the program using case studies in breakout group discussion sessions. A poster session will highlight new methods and technologies applicable to ACD hazard assessment.