

Biotechnology Specialty Section

Founded in 2009

Mission

Create a forum via this specialty section for all SOT members interested in biotechnology. This includes those working in academia, government, regulatory organizations such as FDA and EPA, industrial areas such as agriculture, environmental health and sciences, chemical products and biopharmaceuticals, and finally for students and post-doctoral trainees pursuing a specific area of biotechnology and aiming for a better understanding of biotechnology.

Executive Committee 2010

- President: Barbara J. Mounho, Amgen Inc.
- Vice President: Janet B. Clarke, Biogen Idec.
- Vice President-Elect: Hanan N. Ghanous, FDA
- Secretary-Treasurer: Theresa Reynolds, Genentech
- Councilors:
 - Leigh Ann Burns Naas, Pfizer
 - Timothy K. MacLachlan, Novartis
 - Andrea B. Weir, Charles River Laboratories
- Postdoctoral Representative: Holly M. Mortensen, EPA
- Student Representative: Fanny L. Casado, U. of Rochester

Goals

- To serve as the focal point for interaction of members of the Society of Toxicology interested in biotechnology;
- To foster the evolution of scientifically relevant approaches to and interpretation of toxicological aspects that are unique to biotechnology-derived products;
- To develop, propose, and conduct a variety of cutting-edge programs and educational activities that emphasize the latest developments and issues in biotechnology;
- To relate the developments in biotechnology to the activities of the SOT and to the toxicology/environmental health sciences community-at-large;
- To facilitate education and discussion of, and the generation of position papers and review articles on key issues in the rapidly evolving biotechnology landscape such as translational pharmacology and toxicology (*in vitro* to *in vivo*; animal to human), biomarkers, mechanisms of toxicity and target validation, study design and endpoint validation, manufacturing processes and other quality attributes, safety strategies, and overall risk evaluation of these entities.

Future Directions of the Toxicology of Biotechnology-Derived Products

Agricultural Biotechnology

- Assess the applicability of the Threshold of Toxicological Concern risk assessment model for food/feed derived from biotechnology-derived agricultural crops. If applicable, this model could help determine whether the presence of introduced proteins, or intended or unintended changes in plant metabolite levels were above or below a level of toxicological concern.

Biopharmaceuticals

- Increase efforts to enhance the relevance of animal models and the toxicology studies performed.
- Develop unique approaches for assessing the safety of novel biopharmaceuticals such as bi-specific monoclonal antibodies, antibody fragments and other proteins.

Biofuels and Bioremediation

- Assess environmental impact of biotechnology-derived products.
- Assess risk of algal biofuels and biotechnology-derived strategies to increase productivity.

