Biotechnology Specialty Section

Celebrating 50 Years of Service in Science

Founded in 2009

Executive Committee 2010

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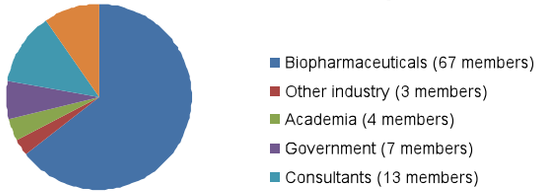
Our mission is to create a forum via this specialty section for all SOT members interested in biotechnology. This includes those working in academia, government, regulatory organizations such as FDA and EPA, industrial areas such as agriculture, environmental health and sciences, chemical and products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

BTSS Membership



Our goals are

- 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

The Toxicology of Biotechnology timeline 1961-2011, and beyond…

1960 mRNA is Discovered.

1965 Genetic code is elucidated by Nirenberg.

1969 An enzyme is synthesized *in vitro* for the first time.

1972 Khorana completes synthesis of a gene.

1972 Boyer and Cohen produce recombinant DNA.

1976 Genentech, the first biopharmaceutical company, is founded.

1977-1981 Laboratories of Boyer and Markham produce first recombinant proteins.

1982 First drug using biotechnology, recombinant human insulin, is approved.

1982 Renewable Fuels Association is formed in the United States.

1982 After US Supreme Court ruling , first patent for an engineered oil-eating bacterium is issued.

1986 The first genetically-modified crop, a tobacco plant is deregulated in the US.

1989 The first engineered enzyme, a chymosin used for cheese production, is introduced in the US.

1989 First gene therapy clinical trial, treating adenosin deaminase deficiency, is started.

1989 First monoclonal antibody, moromonab against CD3, is approved.

1992 A transgenic mouse sensitive to carcinogens is the first European patent issued for an animal.

1992 U.S. energy law sets goal for biofuels to be 30% of market by 2010.

1993 The use of recombinant bovine somatotropin for increased milk production in cows is approved.

1994 The first whole-food biotechnology product, the FLVRSAVR tomato, is approved.

1997 First cell therapy, autologous chondrocytes is approved.

1997 ICHS6, the first regulatory guidance designed for biopharmaceuticals is approved.

1997 "RoundUp-Ready" soybeans and cotton are commercialized.

1998 The first genetically-modified tree, papaya is deregulated in the US.

2004 The Institute of Medicine of the National Academy of Sciences publishes "Safety of Genetically Engineered Foods: Approaches to Assessing Unintended Health Effects"

2005 Significant clinical safety events in a monoclonal antibody clinical trial (TGN1412) emphasizes need for relevant toxicology program for Biopharmaceuticals.

2006 The first plant-made vaccine receives regulatory approval to protect poultry from Newcastle disease.

2007 The UN International Biofuels Forum is formed.

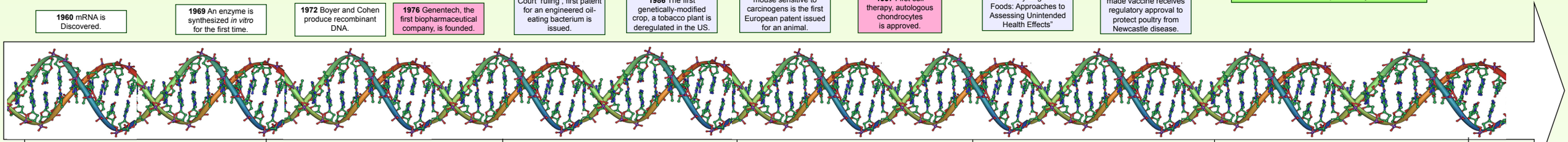
2010 Preparation for ICHS6 addendum, to address evolving biopharmaceutical safety testing, continues.

2010 Genetically engineered salmon is determined to be safe by FDA advisory panel.

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 if the presence of introduced proteins or intended or unintended changes in plant metabolite levels were above or below a level of toxicological concern.

Biopharmaceuticals
- Efforts to increase "relevance" of the animal models and studies performed.
- Unique biopharmaceuticals such as bi-specific monoclonal antibodies, antibody fragments and other proteins will require unique approaches.

Biofuels and bioremediation
Enviornmental impact assessements, etc.
Development of algal biofuels and use of biotechnology to increase productivity



1960 1970 1980 1990 2000 2010 Beyond