The ATCC SDO was proud to be a part of the worldwide celebration of World Standards Week, October 5-9, 2009. Initiated in 1970 by the International Organization for Standardization (ISO), World Standards Day was created to raise awareness of the importance of global standardization to the world economy and now has 123 nations involved in the event. The events of the week promote the role of global standardization in meeting the needs of business, government and consumers and recognize the contribution of countless volunteers involved in standardization activities.

The ATCC SDO joined the global standardization community during World Standards Week in highlighting the critical role of standards throughout the world. Standards specialist, Christine Alston-Roberts attended the Open Forum for Standards Developers, fifth in a series of ANSI-sponsored annual events focused on bringing together leaders of both accredited and non-accredited standards developers. The 2009 Open Forum was held in Bethesda, Maryland on October 6 as part of the World Standards Week series of events.

We are very grateful for the time and effort contributed by our members, volunteers, and staff who work every day to advance our mission to improve the quality of life science laboratories worldwide. Through the consensus process, volunteers from industry, academia, and government develop high-quality standards that improve the quality of global laboratory systems, practices and biomaterials for the life science laboratory. We are very proud of the ASN-0001 and ASN-0002 workgroups and the accomplishments that they have made in establishing new standards for the global life science community. They continue to author commentaries and journal articles on the need for consensus standards in research laboratories. We have highlighted several of the accomplishments of the workgroups in this newsletter.

Please note that our newsletter has a new look and we encourage you to share copies with your friends and colleagues. A new membership application is included inside this issue. Membership in the ATCC SDO is free and it connects you with a diverse network of organizations and their representatives concerned with quality in the life science laboratory. Maximize your voice in the global life science community.

Take part in developing the standards that affect the work you do each day. Join your colleagues in the governmental, industrial, and professional sectors of the life science field and set the standard. We look forward to future opportunities in serving our membership and the life science community worldwide.

Liz Kerrigan
Director, ATCC SDO
The formal United States standardization system was established nearly a century ago with the formation of the American Engineering Standards Committee, forefather of the American National Standards Institute (ANSI). Today, standards offer benefits to all segments of business and industry, government, and consumers. They simplify product development, reduce unnecessary duplication, lower costs, increase productivity, promote safety, and facilitate compatibility and interoperability. They also help to advance scientific discovery and keep people safe by minimizing injuries and protecting key environmental resources.

Voluntary consensus standards are at the foundation of the U.S. economy. Market-driven and highly diversified, these documents are used on a voluntary basis by industry, government agencies, and consumers across the United States and around the world.

ANSI does not develop standards; rather, we foster the U.S. standardization system by accrediting the procedures of standard-setting organizations – such as the ATCC Standards Development Organization (SDO) – and subsequently approving their documents as American National Standards (ANS). Accreditation by ANSI signifies an SDO’s compliance with the Institute’s cardinal principles of openness, balance, consensus, and due process. Demonstrating a commitment to high-quality, market-driven standards that are responsive to public needs, the ANS designation also increases market recognition and acceptance by both U.S. government and industry.

There is a great deal of variety in the types of organizations that apply to become ANSI-accredited SDOs, and the industries that they represent. In 2007, the ATCC SDO became the first biological resource organization to be designated an ANSI-accredited SDO. Just one year later, your organization has completed an ANSI public comment period for ATCC ASN-0001, Standardization of in vitro Assays to Determine Anthrax Toxin Activities; and six months later, and received approval for the document. ATCC ASN-0002, Authentication of Human Cell Lines, Standardization of STR Analysis is also currently under development. You’ve made great progress in a short time. We look forward to continuing a strong working relationship with the ATCC SDO as you develop standards that meet the needs of your industry and your stakeholders – both in the U.S. and abroad.

As both of our organizations are well aware, today’s global economy has raised the stakes in standards development. Competition for the advantages that accompany widespread adoption of technology has reached a new level and the impetus to develop globally accepted standards is greater now than ever before. The United States Standards Strategy – with ANSI as its staunch advocate – strongly supports the concept of “one standard – one test – accepted everywhere.” We work extensively with both national and international standards bodies to ensure that American interests are well represented. As the official U.S. representative to the International Organization for Standardization (ISO), the International Electrotechnical Commission (IEC) through the Institute’s U.S. National Committee to the IEC, the International Accreditation Forum, and several regional standards and conformity assessment organizations, ANSI offers U.S. stakeholders a voice on the global stage.

Throughout ANSI’s ninety year history, we have worked to actively promote American business in the international arena while protecting the health and safety of consumers. Continued active participation from organizations such as the ATCC SDO will ensure that consensus standards continue to provide countless valuable benefits for people and industry everywhere. On behalf of all of us at ANSI, thank you for your support and continued engagement.
FIRST STANDARDIZED CONSENSUS PROTOCOL RELEASED
New Standard is an Approved American National Standard

The ATCC’ Standards Development Organization published its first voluntary consensus standard, ASN-0001: “Standardization of In Vitro Assays to Determine Anthrax Toxin Activities” in May. The document is an approved American National Standard that provides recommended protocols to facilitate comparison of data among laboratories. The overall objective of the standard is to provide stakeholders with a uniform methodology for assaying the in vitro activities of the anthrax toxins, lethal toxin and edema toxin. The consensus standard will be subject to revisions over time to reflect changes in the field and new methodologies.

The human anthrax cases resulting from the intentional dissemination of spores through the United States postal system in 2001 led to a substantial increase in basic and translational research conducted on Bacillus anthracis and its virulence factors, including anthrax toxins. The standard document was created in response to the recognized variability in how investigators currently utilize various anthrax toxin reagents and assays and how they interpret their results.

In March of 2008, the ATCC SDO assembled a workgroup to develop these essential guidelines, chaired by Molly A. Hughes, M.D., Ph.D., of the University of Virginia and co-chaired by Stephen A. Morse, Ph.D., of the Centers for Disease Control and Prevention. The standard represents a collective experience and expertise that led to a refinement and consolidation of multiple methods and protocols that should be of critical value to investigators who are working with anthrax toxins. This standardization better enables investigators to compare data and interpret the biological relevance of the effect. As recombinant protein toxins become available, an important next step is to standardize the use of the reagents so that investigators determine which reagent is most appropriate for their studies. “This standard will give investigators, researchers, and all stakeholders a means to compare toxin activities prepared within the same group or between groups,” said Dr. Hughes. “To our knowledge, the ATCC approach of assembling consensus standards is new to our specific field, Bacillus anthracis research, as well as to the broader area of microbial pathogenesis and host response.”

To order the ASN-0001-2009 Standard, visit the ANSI eStandards Store at http://webstore.ansi.org.

Members of the ASN-0001-2009 Workgroup:

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Charlottesville, VA

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ATCC SDO Welcomes 37 New Consensus Standards Partnership (CSP) Members

1. Brian Bishop, Ph.D. University of Chicago
2. George S. Bova, M.D. Johns Hopkins University School of Medicine
3. Elizabeth Bryda, Ph.D. University of Missouri
4. Chen Chuguang, Ph.D. Beijing Microread Genetic Technology Co. Ltd
5. Kristen Clement, Ph.D. Battelle Memorial Institute
7. Wilhelm Dirks, Ph.D. DSMZ, German Biological Resource Center
8. Brian Douglass ATCC
9. Linda Eaton, Ph.D. List Biological Laboratories, Inc.
10. Ian Freshney, Ph.D. University of Glasgow
11. Michael Gibbon, Ph.D. Cordstemcellresearch.com
12. James Hadfield UK Cambridge Research Institute
13. Katherine S. Hale, Ph.D. UT M.D. Anderson Cancer Center
15. Jim Johnson, Ph.D. Aspera Corp.
16. Stephen Juris, Ph.D. Central Michigan University
17. Margaret Kline NIST
18. Arihiro Kohara, Ph.D. National Institute of Biomedical Innovation
19. Christopher Korch, Ph.D. University of Colorado
20. Georgyi V. Los, MD, Ph.D. Promega Corporation
21. Kunapuli Madhusudhan, Ph.D. Clean Earth Technologies
22. John Masters, Ph.D. University of London
23. Jeffrey Myers, MD, Ph.D. UT M.D. Anderson Cancer Center
24. Roland Nardone, Ph.D. Catholic University
25. Raymond Nims, Ph.D. Consultant
26. Ruth Peat UK Cancer Research
27. Bradford Powell, Ph.D. USAMRIID
29. Yvonne Reid, Ph.D. ATCC
30. Gordon Robertson, MBA, Ph.D. Archivex LLC
31. Thomas Rudge, Ph.D. Battelle Memorial Institute
32. Steve Ryder ATCC
33. Greg Sykes ATCC
34. Jim Thomson, Ph.D. LGC
35. Anita Verma, Ph.D. FDA
36. Maria Vias, Ph.D. UK Cambridge Research Institute
37. Melissa Willis, Ph.D. ATCC
Update on the development of a consensus standard for the authentication of human cell lines: standardization of STR profiling

An international workgroup of scientists representing academia, regulatory agencies, major cell repositories, government agencies and the biomedical industry has been assembled and tasked with development of ASN-0002, a consensus standard for human cell line authentication using Short Tandem Repeat (STR) Profiling. The standard will represent a major step forward in correcting the pervasive and long standing problem of cell line misidentification. The intent of the standard is to delineate a standardized, relatively inexpensive and universally applicable method for authenticating new and established human cell lines and their criteria for use.

The workgroup, which is chaired by John R. W. Masters, Ph.D. of University College London, has been meeting monthly since early 2009. The effort has been divided between two subgroups which have been meeting independently at frequent intervals. The first subgroup is drafting the introduction to the standard, defining what is meant by human cell line authentication, describing the historical aspects from early discovery of cell line misidentification through the present, delineating the causes of cell line misidentification, surveying the existing technologies for cell line authentication and the providing the rationale for selection of STR Profiling for the standard. The subgroup is chaired by Raymond Nims, Ph.D..

The second subgroup is fleshing out the procedural details of the STR Profiling protocol to be recommended within the standard (how many and which loci, what degree of matching is required, gender confirmation, etc.). They are also busy determining the format and structure of a database of STR profiles of human cell lines, which has been determined to be necessary to support the standard. The subgroup is chaired by Yvonne Reid, Ph.D. of ATCC. The first draft of the standard is expected to be completed and ready for review by the Steering Committee at the end of the year.
1. Question: What is the proper way to reference membership or participation in ATCC SDO activities?

Answer: Individuals may list multiple citations for participation in different categories of ATCC SDO committees and/or workgroups.

Example: An individual may participate in the ATCC SDO as:

- A member of the ATCC SDO Steering Committee
- A member of the ATCC SDO Consensus Standards Partnership, and
- A member of one or more ATCC SDO Standards Development Workgroups

Citing participation in standards development may be thought of as similar to citing credits from or for a book or other intellectual property. Citations may be included under various headings such as:

- Committee Memberships
- Memberships and Working Groups
- Standards Organizations Memberships and Workgroups (Committees)

Citations should include the following information which may be listed in any order:

1. Category of participation
   
List the category of participation choosing from those listed above. Example: Member

2. Organization
   
List the organization in which individual participated. Example: ATCC SDO

3. Organizational Unit
   
List the organizational unit in which the individual participated such as a specific standards development workgroup. Example: ASN-0001 Workgroup for the Standardization of In Vitro Assays to Determine Anthrax Toxin Activities

4. Date(s) of Participation
   
List participation date(s). Example: November 2007 – Present

Additional Examples:

1. Memberships
   
Example: Member, ATCC SDO, Consensus Standard Partnership, November 2007 – Present

2. Committee Memberships
   
Example: Member, ATCC SDO, Steering Committee, November 2007 – September 2008

3. Standards Organizations Memberships and Workgroups (Committees)
   
Example: Member, ATCC SDO, ASN-0001 Workgroup for the Standardization of In Vitro Assays to Determine Anthrax Toxin Activities, November 2007 – Present
2. Question: What is the procedure and timeline for developing a consensus standard?

Answer:
The ATCC SDO Consensus Standard Development process is outlined in the following flowchart. The timeline included for each step is intended as a guide and many vary depending upon the complexity of the standard.
The new edition of the ATCC Standards Development Organization Handbook is now available. It has a new look and is packed with useful information such as the updated ATCC Policies and Procedures Manual for the Development of American National Standards, a Style Manual for authors of consensus standards and steps on how to navigate the SDO website! Each member will be sent a new copy of the handbook. The new version is currently available on the SDO website.

The ATCC SDO Style Manual was put together to make the drafting of consensus standards easier for workgroup members. It will familiarize authors of ATCC SDO consensus standards with the structural design and format required to develop a successful, easy to read and readily understood consensus document. Adherence to the style manual will assure that standards development workgroups and their individual members develop consensus standards that conform to the ATCC SDO recommended format and are uniform in style. The style manual includes recommended sections, formats for cover pages, indications for the use of abbreviations and symbols and formatting for references. It also includes a standard template for workgroups to follow.

Both the ATCC Style Manual and the ATCC Standards Development Organization Handbook are available on the SDO website at: http://www.atccsdo.org. Log on to the member’s only section of the website and both are available in the CSP Toolbox.