by John A. Tesk

Reference Data and Materials Needed

The needs for reference data on properties of biomaterials were identified at a workshop held at the National Institute of Standards and Technology (NIST) on July 27, 2000 and co-organized by NIST and the Society For Biomaterials. The 65 registrants from industry, the National Institutes of Health, the Food and Drug Administration, and academia joined with NIST staff to determine the extent of needs for reference data for biomaterials. Special attention was paid to critiqued reference data as traditionally found in NIST data bases (critiqued data have been critically evaluated for issues such as such how well components of uncertainty have been described, the description of experimental methods, how appropriate were the experimental methods for obtaining the data reported on, and so forth). Individual, concurrent breakout sessions addressed orthopaedic, cardiovascular, ophthalmologic, tissue-engineered, dental, and general biomaterials.

Although the workshop was organized with the focus on reference data for biomaterials, the conclusion from participants was that there were often needs for reference biomaterials. Both were seen as necessary for facilitating the deployment of new health care delivery devices and for the development of national and international standards. Owing to the rapid pace of innovation the timely availability of reference data and reference biomaterials was deemed more critical to progress than completeness of the data in most situations. The importance and extent of critical review of reference data depended on the specific biomaterial category, with orthopaedic, cardiovascular and ophthalmologic data being assessed as more in need of critique than dental data. It was emphasized that timely development of reference data was important and that the delay of development of reference data bases for the purposes of adding information to the accompanying critiques of data would be counterproductive in these rapidly developing fields, i.e.; just-in-time development was important. In general, data on properties of interest included mechanical properties, surface and bulk physical and chemical properties, biological responses to materials, and clinical responses.

In addition to reference data, over 17 reference materials of polymers, monomers, alloys, composites and ceramics were identified; for example, three ophthalmic reference materials (and data for them) were identified: poly(methylmethacrylate), poly(hydroxy-ethyl methacrylate), and poly(dimethylsiloxane). The same general theme evolved for Reference Materials as for Reference Data, i.e.; it was considered more important to have a Reference Material available in time than to have the better-characterized Standard Reference Material for which delivery might be needlessly delayed just to achieve the higher level of characterization (Reference Materials do not have the same level of characterization as Standard Reference Materials). For the newly emerging tissue-engineering arena, a standard, porous, polymer scaffold that is characterized physically, chemically, and for cellular response, was a high priority need as scaffolds are key components of tissue-engineered products.

The participants agreed that follow-up meetings would be needed with participants from each of the various constituencies. These meetings will focus on the forming of alliances to help facilitate the enormous effort that will be required to meet the needs of industry, researchers, regulators, and standards-setting organization committees.

A more extensive report is planned for publication in the *Journal of Applied Biomaterials*. The workshop was co-sponsored by the Reference Materials Subcommittee of the Society For Biomaterials.