TISSUE ENGINEERED MEDICAL PRODUCTS STANDARDS (TEMPS)

Grace Lee Picciolo

The field of tissue engineering is evolving and rapidly impacting medical products. These products may incorporate cells, biomaterials and biomolecules and require multidisciplinary science and expertise. Development of consensus standards for the new products is necessary and timely to ensure uniform products that are safe and effective.

You are invited to participate in a dynamic, ongoing effort of the American Society for Testing and Materials for the development of standards for Tissue Engineered Medical Products.

Information on this effort and list of the standards under development are provided in the handouts and at the following web sites:

1. http://www.fds.gov/CDRH/Tisseng/temps.html
2. http://lindacuster.com/temps
3. http://www.astm.org/
   Then go to Alphanumber Committee F04 for the ASTM Committee F-04 Division IV page by Teresa Cendrowska, Staff Manager.

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June 1, 2000

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40.02	generic Classification for TEMPS	Picciolo, Grace Lee	picciolograce@mail-me.com		
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41.06	cartilage biology				
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43.08	ligament/tendon biomaterials				
43.09	cardiovascular biomaterials	Wolfinbarger, Lloyd	altmolec@aol.com	Gantt, A. Doyle	adg@cdrh.fda.gov
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45.05	biomarkers				
45.06	in vitro production and testing				
46	DELIVERY SYSTEMS	May, Michael	maymi@chem-eng.utoronto.ca	Stegmann, Jan	gte38f@prism.gatech.edu
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46.02	encapsulation of TEMPS	Stegmann, Jan	gte38f@prism.gatech.edu		
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47.03	liver assessment				
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47.07	ligaments/tendon assessment				
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Standard Number	Status of TEMPS Standards June 2000	Status	Facilitator
F04.40.01	Definition of Tissue Engineering and Tissue Engineered Medical Products	3	Smith
F04.40.02	General classification of TEMPS	3	Picciolo
F04.41.02	Normal biology of heart valves	3	Nerem
F04.41.03	Normal biology of liver	4	Custer
F04.41.04	Normal biology of islets	4	O'Neill
F04.41.05	Normal biology of adult bone	3	Boyan
F04.42.01	Guide for imaging and analysis methods to characterize TEMPS	4	Shah
F04.42.02	Analysis of mechanical testing for cardiovascular TEMPS	4	Sacks
F04.43.01	Substrates guide for materials used for TEMPS	1	Kuhn
F04.43.02	Guide for scaffolds used for TEMPS	3	Mukherjee
F04.43.03	Guide for characterization of collagen used for TEMPS	3	Parr
F04.43.04	Guide for the Characterization and Testing of Alginates as Starting Materials Intended for Use in Biomedical and TEMP Applications	2	Kaplan
F04.43.05	Classification of bimaterials used in TEMPS for skin	3	Cahn
F04.43.06	Guide for the Characterization of biomaterials used for articular cartilage	3	Frondoza
F04.43.07	Guide for fabricated biomaterials used in TEMPS that substitute for, repair or regenerate bone	4	Larson/Blackwell
F04.43.10	Guide for the Characterization and Testing of Chitosan as Starting Materials Intended for Use in Biomedical and TEMPS Applications	3	Kaplan
F04.44.01	Standard test method for in vitro biological activity of recombinant human bone morphogenetic protein-2 (rhBMP-2) using the W-20 mouse stromal cell line	2	Porter
F04.44.02	Guide for proteins used in TEMPS	4	Porter
F04.45.03	Guide for preservation	4	Hubel
F04.45.04	Impedance test method for cell counting	3	Szabo
F04.45.05	Guide for biomarkers of viability	4	Zeltinger
F04.45.06	Standard guide for in vitro production and processing	4	Zeltinger
F04.46.01	Classification of delivery systems used in TEMPS	3	May
F04.46.02	Standard guide for cell encapsulation technology	3	Stegemann
F04.47.01	Standard guide for the assessment of bone inductive materials	3	Boyan
F04.47.02	Guide for the Assessment of Heart Valve TEMPS	3	Carlyle
F04.47.03	Guidance for assessment of liver TEMPS	4	Custer
F04.47.04	Guidance for assessment of Islets TEMPS	4	O"Neill
F04.47.05	Guidance for assessment of skin TEMPS	3	Schutte
F04.47.06	Standard Guide for the Assessment of Implantable Devices	4	Ingram
F04.47.08	Guidance for assessment of bone TEMPS	3	Boyan
F04.47.09	Assessment framework and template for guidance standards	4	Boyan
F04.47.10	Assessment of meniscus TEMPS	4	Malaviya
F04.47.11	Assessment of pancreas TEMPS	4	O"Neill
F04.48.02	Guidelines for surrogate endpoint analyses in Clinical Trials for TEMPS	4	Watkins
F04.49.01	Framework for Microbiological Safety and Adventitious Agent for TEMPS	4	Citron

Where 1= Finalized 2=Ballot 3=Draft 4=Predraft

INTERNATIONAL TECHNOLOGY RESEARCH INSTITUTE (ITRI) WORLD TECHNOLOGY (WTEC) DIVISION

R.D. Shelton

International Technology Research Institute (ITRI) World Technology (WTEC) Division

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To inform scientists, engineers, and policymakers of global trends in science and technology in a manner that is timely, credible, relevant, efficient and useful

Goal:
Identify global centers of R&D excellence; seek opportunities for international cooperation

WTEC Functions

- **Benchmarking for strategic planning by government and industry**
- **Technology transfer to the U.S.**
- **International cooperation opportunities identified**

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- **ITRI measures progress towards this goal -- peer review of foreign achievements vs. American ones**
- **ITRI has done most public studies in this arena -- over 50 international S&T assessments by expert panels, all with a study tour.**

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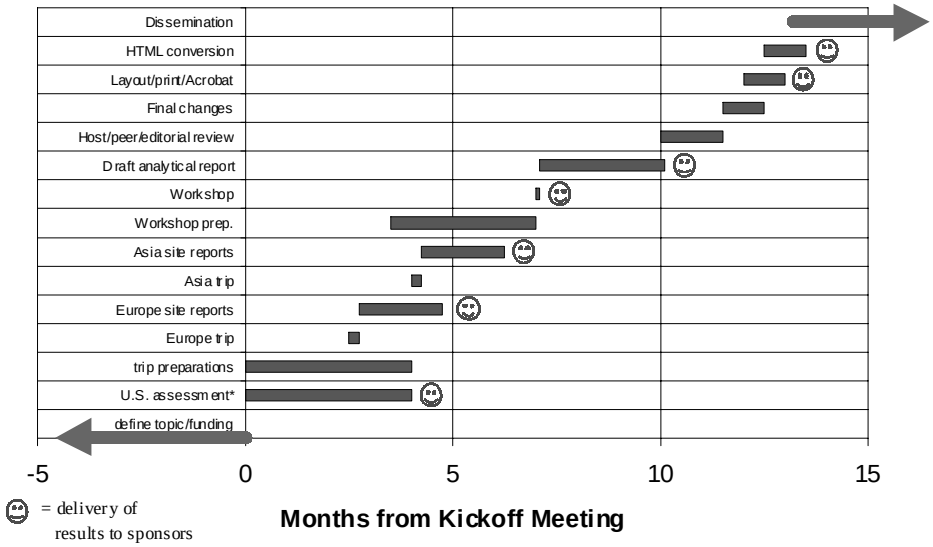
WTEC Study Milestones



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Samples of WTEC Reports, 1998-9

- **Electronic Applications of Superconductivity in Japan (Rowell)**
- **Composites in Civil Infrastructure in Japan (Karbhari)**
- **Nanostructure S&T -- published by Kluwer (Siegel/Hu/Roco)**
- **Global Satcom Technology & Systems (Pelton/MacRae)**
- **Digital Libraries in Japan (Reddy)**
- **High Density Data Storage in Japan (Esener/Kryder)**
- **High Temperature Electronics in Japan (Dmitriev)**
- **Japan's Key Technology Center (Feller)**
- **Russian R&D on Nano Materials (Siegel/Hu/Roco)**

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Reports Produced by WTEC for National Nanotechnology Initiative

- **Nanotechnology Research Directions**
- **Nanotechnology: Shaping the World Atom by Atom**
- **National Nanotechnology Initiative: Leading to the Next Industrial Revolution**
- **National Nanotechnology Initiative: The Initiative and its Implementation Plan**

(See http://www.nano.gov for all NNI reports)

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WTEC Studies In Progress

- **Molecular Modeling (NSF, DOE, NIST, NIH, ONR, DARPA; Westmoreland and Kollman; workshop 3/14/00)**
- **Benign Manufacturing: (NSF; Gutowski, workshop ~7/14/00)**
- **Tissue Engineering (NSF, FDA, NIH, NIST, et al.; McIntire; workshop 11/2/00)**
- **National Nanotechnology Initiative -- Staff Support (OSTP, NSTC ;Roco)**

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WTEC Tissue Engineering Study

- **Sponsored by NSF, NIH, DARPA, NIST, FDA, NASA**
- **Larry McIntire, Rice University, Panel Chair**
- **U.S. review workshop 6/2000**
- **Europe trip 7/2000**
- **Japan trip 8/2000**
- **Workshop (preliminary findings) 11/2-3/2000**

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Prospective WTEC Studies

- **MEMS (Japan)**
- **Spin Electronics (Japan)**
- **Quantum Computing (Worldwide)**
- **Precision Casting (Europe)**
- **Your ideas?**

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JTEC/WTEC reports[1] are available on the Web at http://itri.loyola.edu, or from the National Technical Information Service (NTIS), 5285 Port Royal Road, Springfield, VA 22161. Call for prices and availability (703-487-4650; FAX 703-321-8547).

JTEC Panel Report on High Temperature Superconductivity in Japan (11/89) PB90-123126

JTEC Panel Report on Space Propulsion in Japan (8/90) PB90-215732

JTEC Panel Report on Nuclear Power in Japan (10/90) PB90-215724

JTEC Panel Report on Advanced Computing in Japan (10/90) PB90-215765

JTEC Panel Report on Space Robotics in Japan (1/91) PB91-100040

JTEC Panel Report on High Definition Systems in Japan (2/91) PB91-100032

JTEC Panel Report on Advanced Composites in Japan (3/91) PB90-215740

JTEC Panel Report on Construction Technologies in Japan (6/91) PB91-100057

JTEC Panel Report on X-Ray Lithography in Japan (10/91) PB92-100205

WTEC Panel Report on European Nuclear Instrumentation and Controls (12/91) PB92-100197

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JTEC Panel Report on Database Use and Technology in Japan (4/92) PB92-100221

JTEC Panel Report on Bioprocess Engineering in Japan (5/92) PB92-100213

JTEC Panel Report on Display Technologies in Japan (6/92) PB92-100247

JTEC Panel Report on Material Handling Technologies in Japan (2/93) PB93-128197

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JTEC Panel Report on Knowledge-Based Systems in Japan (5/93) PB93-170124

NASA/NSF Panel Report on Satellite Communications Systems & Technology (7/93): Executive Summary (PB93-231116); Analytical Chapters (PB93-209815); Site Reports (PB94-100187)

WTEC Monograph on Instrumentation, Control & Safety Systems of Canadian Nuclear Facilities (7/93) PB93-218295

JTEC/WTEC Annual Report and Program Summary 1993/94 (3/94) PB94-155702

JTEC Panel Report on Advanced Manufacturing Technology for Polymer Composite Structures in Japan (4/94) PB94-161403

ITRI Monograph on Benchmark Technologies Abroad: Findings From 40 Assessments, 1984-94 (4/94) PB94-136637

WTEC Panel Report on Research Submersibles and Undersea Technologies (6/94) PB94-184843

JTEC Panel Report on Microelectromechanical Systems in Japan (9/94) PB95-100244

WTEC Panel Report on Display Technologies in Russia, Ukraine, and Belarus (12/94) PB95-144390

JTEC Panel Report on Electronic Manufacturing and Packaging in Japan (2/95) PB95-188116

JTEC Monograph on Biodegradable Polymers and Plastics in Japan (3/95) PB95-199071

JTEC Panel Report on Optoelectronics in Japan and the United States (2/96) PB96-152202

JTEC Panel Report on Human-Computer Interaction Technologies in Japan (3/96) PB96-157490

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JTEC Panel Report on Japan's ERATO and PRESTO Basic Research Programs (9/96) PB96-199591

JTEC/WTEC Panel Report on Rapid Prototyping in Europe and Japan: Vol. I. Analytical Chapters (3/97) PB97-162564
Vol. II. Site Reports (9/96) PB96-199583

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WTEC Panel Report on Electronic Applications of Superconductivity in Japan (7/98) PB98-150139

WTEC Monograph on Use of Composite Materials in Civil Infrastructure in Japan (8/98) PB98-158215

WTEC Panel Report on Nanostructure Science and Technology (12/98 -- available from Kluwer Academic Publishers)

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WTEC Workshop on Russian R&D Activities on Nanoparticles and Nanostructured Materials (12/99) PB99-150518

WTEC/MCC Strategic Technology Tour Report on MEMS and Microsystems in Europe (1/2000) PB2000-104945

WTEC Panel Report on Wireless Technologies and Information Networks (7/2000) PB2000-105895

[1] Note: see the WTEC WWW server (http://itri.loyola.edu) for a list of earlier JTECH reports (1984-89) available from NTIS.