Tissue Engineered Medical Products (TEMPs)

Eliane Schutte, Grace L. Picciolo, and David Kaplan, editors

ASTM Stock Number: STP1452

ASTM
100 Barr Harbor Drive
PO Box C700
West Conshohocken, PA 19428-2959

Printed in the U.S.A.
Foreword

This publication, *Tissue Engineered Medical Products (TEMPs)*, contains papers presented at the symposium of the same name held in Miami Beach, Florida, on 4-5 November, 2002. The symposium was sponsored by the ASTM International Committee F4 on Medical and Surgical Materials and Devices and its Division IV on Tissue Engineered Medical Products, in cooperation with Biomat.net, The Society for Biomaterials and The Tissue Engineering Society. The symposium co-chairpersons were Eliane Schutte, IsoTis BV, The Netherlands, Grace L. Picciolo, USFDA (Retired), Rockville, MD., and David S. Kaplan, FDA/CDRH, Rockville, MD.
Contents

FOREWORD iii

WHAT TECHNOLOGY DO WE HAVE AND HOW IS IT DOING?

Measurement of Pore Size and Porosity of Tissue Scaffolds—P. TOMLINS, P. GRANT, S. MIKHALOVSKY, S. JAMES, AND L. MIKHALOVSKA 3

Development and Validation of a Detection Method for a Broad Range of Human Papillomavirus Types—D. N. GALBRAITH, T. COLLINS, J. BLACK, B. MC MANUS, D. MC MUTRIE, AND A. LOVATT 12


NIST and Standards for Tissue Engineered Medical Products—J. A. TESK AND L. R. KARAM 40


Method to Determine Germicidal Inactivation in Allograft Processing—C. R. MILLS, M. R. ROBERTS, J. Y. CHANG, J. R. BIANCHI, AND M. C. SUMMITT 54


Age Related Differences in Chondrocyte Viability and Biosynthetic Response To Mechanical Injury—D. D. D’LIMA, A. BERGULA, P. C. CHEN, C. W. COLWELL AND M. LOTZ 77
A Comparative Study of Biomarkers of Oxidative DNA Damage Used to Detect Free Radical Damage in Tissue-Engineered Skin—H. RODRIGUEZ, P. JARUGA, M. BIRINCIOGLU, P. E. BARKER, C. O’CONNOR, AND M. DIZDAROGLU

Endpoint Verification of Bone Demineralization for Tissue Engineering Applications—C. B. THOMAS, L. JENKINS, J. F. KELLAM, AND K. J. L. BURG

Comparative Study of Bone Cell Culture Methods for Tissue Engineering Applications—C. B. THOMAS, J. F. KELLAM, AND K. J. L. BURG

A New Method for Real-Time and In-Situ Characterization of the Mechanical and Material Properties of Biological Tissue Constructs—G. ZHANG AND J. L. GILBERT

What Standards Exist and What Standards are Needed?

Alginate and Chitosan Standards for Tissue Engineered Medical Products—M. DORNISH AND A. DESSEN


Development of Standards for the Characterization of Natural Materials Used in Tissue Engineered Medical Products (TEMps)—D. S. KAPLAN

Microbiological Safety and Adventitious Agents Standards for TEMPS—G. SOFER

Standards Used in Meeting Requirements for a Model Pre-Market Approval (PMA) of a Neural Guidance Conduit—L. STOVER AND L. HUBEL


What Standards are Used Globally and How by the Regulatory Bodies for Approvals?

The European Situation on Standards for Tissue Engineering Products—E. SCHUTTE

A European View on Risk Management Strategies for Tissue Engineered Medical Products (TEMps)—R. E. GEERTSMA, M. KALLEWAARD, AND C. WASSENAAR


A Useful Marker for Evaluating the Safety and Efficacy of Tissue Engineered Products—T. TSUCHIYA

Author Index

Subject Index