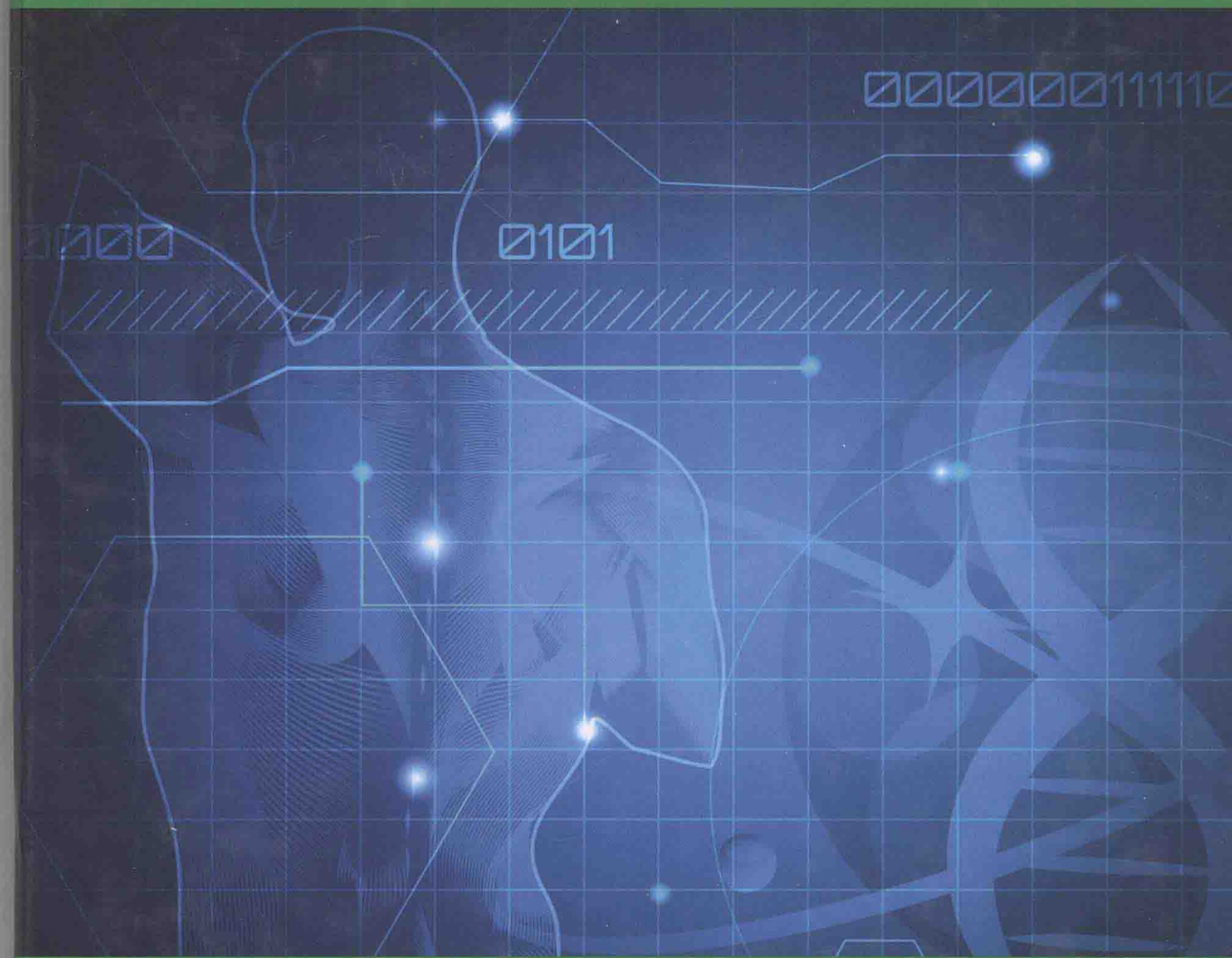
Biomaterials, Medical Devices, and Combination Products

Biocompatibility Testing and Safety Assessment



Shayne Cox Gad
Samantha Gad-McDonald

CRC Press
Taylor & Francis Group

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Shayne Cox Gad
Gad Consulting Services
Cary, North Carolina, USA

Samantha Gad-McDonald
Gad Consulting Services
Cary, North Carolina, USA

CRC Press
Taylor & Francis Group
Boca Raton London New York

CRC Press is an imprint of the
Taylor & Francis Group, an **informa** business

CRC Press
Taylor & Francis Group
6000 Broken Sound Parkway NW, Suite 300
Boca Raton, FL 33487-2742

Printed on acid-free paper
Version Date: 20151020

International Standard Book Number-13: 978-1-4822-4837-1 (Hardback)

Visit the Taylor & Francis Web site at
http://www.taylorandfrancis.com

and the CRC Press Web site at
http://www.crcpress.com

Printed and bound by CPI Group (UK) Ltd, Croydon, CR0 4YY

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Preface

Biomaterials, Medical Devices, and Combination Products: Biocompatibility Testing and Safety Assessment constitutes a completely revised and much expanded version of the third edition of *Safety Evaluation in the Development of Medical Devices Combination Products.* While continuing to focus on the objective of the earlier editions (to serve as a single-volume utilitarian guide for those who are responsible for or concerned with developing and ensuring patient safety in the use and manufacture of medical devices, it also reflects the vast changes that have come to pass in the 7 years since the third edition was published. It not only updates throughout, but also adds two new chapters: 16, Special Case Devices, and 19, Leachables and Extractables, which incorporates coverage of current analytical methods (authored in part by Dr. Dave Albert) and the use of quantitative structure–activity relationship methodology as a tool for use in supplementing actual testing.

Foremost, this new edition has been recast throughout to address the fact that device markets are global, that technology continues to advance, and that global device safety regulation has been increasingly harmonized. Each aspect of device safety evaluation is considered in terms of International Organization for Standardization (ISO), U.S. Food and Drug Administration (FDA), European Union (EU), and Japanese Ministry of Health, Labour, and Welfare (MHLW) perspectives. Additionally, the continuing growth of technology has led to the incorporation of science (particularly in the areas of immunotoxicology and toxicokinetics). Also incorporated are new case examples and citations with the means of access to Internet-based regulatory and scientific sites, reflecting the universal adoption of this technology into our world.

Authors

Shayne C. Gad earned a BS in chemistry and biology from Whittier College, California, in 1970, and after active-duty service in the U.S. Navy, earned a PhD in Pharmacology/Toxicology (Texas, 1977) DABT. He is currently Principal of Gad Consulting Services, a 23-year-old consulting firm with 7 employees and more than 500 clients (in the pharmaceutical and device industries). He is past president of the American College of Toxicology, the Roundtable of Toxicology Consultants, and three of the Society of Toxicology's specialty sections, and recipient of the American College of Toxicology Lifetime Contribution Award in 2008. He served on council, membership, program, and research committees for the American College of Toxicology, and previously at Carnegie Mellon Institute of Research (CMIR) Chemical Hygiene Fellowship, Allied Chemical, Searle, Becton Dickinson, and Synergen. He has authored or edited 47 published books and more than 350 chapters, articles, and abstracts in the fields of toxicology, statistics, pharmacology, drug and device development, and safety assessment. He has more than 37 years of broad-based experience in toxicology, drug and device development, statistics, and risk assessment, and has specific expertise in neurotoxicology, *in vitro* methods, cardiovascular toxicology, inhalation toxicology, immunotoxicology, risk assessment, and genotoxicology. Dr. Gad has served as a grant reviewer for the U.S. Environmental Protection Agency, Center for Alternatives to Animal Testing (CAAT), the National Institutes of Health, and Canadian Health. He has direct involvement in the preparation of investigational new drugs (107 successfully to date), new drug applications, Product Listing Approvals (PLA), Abbreviated New Drug Approvals (ANDA), 510(k), investigational device exemption, Common Technical Document (CTD), clinical databases for phase 1 and 2 studies, and premarket approvals. Dr. Gad has also served as the chief operating officer of two pharmaceutical companies while a consultant. He initiated and has conducted the triennial toxicology salary survey as a service to the profession of toxicology for the last 25 years.

Samantha Gad-McDonald earned her BS in chemical engineering from the University of Cincinnati in 2004. She began her career as a production leader in good manufacturing process manufacturing facilities. During this time, she helped design processing systems and procedures, and validated equipment for a new good manufacturing process processing facility.

Samantha joined Gad Consulting Services (GCS) permanently in 2009, where she is a staff chemical engineer and consulting associate. For companies large and small, she has assessed the biocompatibility of medical devices, compiled and maintained investigational new drug applications, conducted audits, and maintained drug master files. She has familiarized herself with the regulation and guidelines of the U.S. Food and Drug Administration, the International Conference on Harmonization, and other international regulatory agencies necessary to evaluate the safety of chemical compounds. She has published 1 paper and contributed 40 entries to the *Encyclopedia of Toxicology*, as well as having two poster presentations and being an invited speaker of the FDA. Finally, she is proud to have passed her knowledge on by teaching several courses on drug development, medical device safety evaluation, and risk assessment methods, alongside giving presentations for professional meetings such as for the American College of Toxicology and for corporate clients.

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