Curriculum Vitae

Angela Blackwell, M.S.
angela@blackwelldevice.com
Senior Consultant
Blackwell Device Consulting.
Portland, OR

EDUCATION

M.S. *Biomedical Engineering*, University of Alabama Birmingham (1992)
B.S. *Biomedical Engineering*, Tulane University (1989)

EXPERIENCE

Blackwell Device Consulting, *Senior Consultant and Proprietor*
Portland, OR (July 2012 – Present)
Advise clients on many aspects of pre-market decision making such as testing, classification, regulatory path, and implications of device design changes. Write or edit regulatory submissions of all types including 513g, RFD, pre-sub, IDE, 510k, and PMA. Has extensive experience with decisions regarding combination products, particularly dental and wound products.

Biologics Consulting Group, Inc., *Senior Consultant*
Catawba, NC (Oct. 2007 – July 2012)

- Advised companies on engineering, preclinical and biocompatibility testing
- Experienced with regulatory submissions for many types of devices and combination products
- Examples of device types include dental implants, dental implant abutments (including patient specific CAD/CAM abutments), dental impression materials, wound dressings, and bone filling materials

FDA/CDRH/ODE/DAGID, Dental Devices Branch, *Biomedical Engineer*
Rockville, MD (Mar. 1994 – Sept. 2007)

- Extensive experience in review of 510ks including some for implantable devices which contain clinical data and some for device /drug combinations (oral wound dressings).
- Over thirteen years of experience reviewing IDEs including those which result in both PMAs and 510ks.
- Nine years of experience as a PMA team leader for 5 companies' products. This involves coordinating with reviewers from different areas, editing their reviews, and making everything into an overall review. Also involves writing the PMA summary which is released when the product is approved.

- Reviewed many requests for classification (513g) and requests for designation, and am familiar with these processes and how they involve interaction with the Program Operations Staff and the Office of Combination Products.
- Long term projects with combination products involved working with CDER, ODE clinicians, statisticians, and patient labeling staff to approve clinical trials for dental bone filling materials containing therapeutic proteins and then reviewing the PMA.
- Served as team leader for the first bone filling material PMA approved which contained PDGF and also for the first dental bone filling material PMA approved which contained rhBMP-2.
- Worked on the rhBMP-2 project for thirteen years and the PDGF project for six years.
- Served as senior engineer for the following product areas:
    - tissue engineered dental bone grafting materials,
    - oral wound dressings,
    - lubricants for dental hand pieces,
    - endosseous dental implants, including their abutments and CAD/CAM systems used for designing them in the dental office
    - temporomandibular joint prostheses,
    - oral and maxillofacial bone plates, screws and distractors

CONTINUING EDUCATION

Course Title	Sponsor	Date
American Association of Dental Research Annual Meeting	IADR/AADR	March 2007
TMJ Bioengineering Conference	NIH, University of Kansas	May 2006
American Association of Dental Research Annual Meeting	AADR	March 2006
Advancing the Frontiers of Bioscience and Nanotechnology	NIST	June 2005
Methods for Enhancing the Efficiency of Dental/Oral Health Clinical Trials: Current Status, Future Possibilities	NIH	May 2004
American Association for Dental Research Annual Meeting	IADR/AADR	March 2004
Syposium on Metrology and Standards for Cell Signaling: Impact on Tissue Engineering	NIST	October 2003
Engineering Tissue Growth International Conference and Exposition	Pittsburgh Tissue Engineering Initiative	March 2003
Combination Products: Intercenter Collaborative Review	FDA	October 2002
21st Southern Biomedical Engineering Conference	Southern Biomedical Engineering Conference	September 2002
Surfaces in Biomaterials	FDA	Jan. and Feb. 2002
Advances in Tissue and Genetic Engineering	The Knowledge Foundation	September 2000

Course Title	Sponsor	Date
for the Treatment of Arthritic Diseases		
Reference Data for Biomaterials Workshop	NIST	July 2000
Gordon Research Conference on Tissue Engineering, Biomaterials and Biocompatibility	Gordon Research Conference	July 1999
International Symposium on Advanced Materials with Biomedical Applications	NIST	June 1999
Regulations Writing Course	FDA	January 1999
Special Topics in Biomaterials	UMBC	August 1998
Tissue Engineering III	FDA	February 1998
Gordon Research Conference on Biomaterials: Biocompatibility/Tissue Engineering	Gordon Research Conference	July 1997
Assessment of Medical Devices Polymers	FDA	October 1996
Introduction to and Current Perspectives on Tissue Engineering	NIH	June 1996
Interface of Biomechanics and Cell Biology in Orthopedics	Johns Hopkins	June 1996
Cells and Materials	Scanning Microscopy International	May 1996
Biological Response to Orthopedic Implants	Johns Hopkins	April 1996
Tissue Engineering	FDA	February 1996
1996 Joint Symposium on Clinical Trial Design and Analysis in Periodontics	NIH	Jan-Feb. 1996
Gordon Research Conference on Biocompatibility and Biomaterials	Gordan Research Conference	July 1995
Total Joint Replacement Workshop	NIST	March 1995
Workshop on Tissue Engineering	NIST	November 1994

HONORS & AWARDS

Award (Date)	Awarding Organization	Citation
FDA Outstanding Service Award (2006)	FDA	CDRH Premarket Submission Quality Review Group: For exceptional performance and participation in the Center's pilot program to assess the quality of biocompatibility, sterilization, and statistical reviews of pre-market submissions.
Letter of Appreciation (2004)	FDA	For serving as a center standards liaison representative and STG member
Award of Appreciation	ASTM	In appreciation of your outstanding efforts on

Award (Date)	Awarding Organization	Citation
(2001)		ASTM Committee F4
CDRH Special Recognition Award (2000)	FDA	For significant service and dedication to the Office of Device Evaluation as ODE Division Focal Points.
Certificate of Appreciation (1997)	FDA	For your dedication to ODE as shown by your willingness to serve as an ODE Focal Point in addition to performing your regular duties.
FDA Group Recognition Award (1996)	FDA	For participation in the FDA Intercenter Tissue Engineering Working Group
FDA Group Recognition Award (1995)	FDA	For successful implementation of new initiatives, new management techniques and an increase in productivity since their inception in fiscal year 1994.

PARTICIPATION IN INTERNATIONAL AND NATIONAL STANDARDS ORGANIZATIONS

U.S. Expert to ISO TC 106 SC8 Dental Implants Working Group On Mechanical Testing
ADA/ANSI Subtag to ISO TC 106 SC8 Working Group Chairperson on Mechanical Testing of Dental Implants
FDA Liaison to ISO TC 106 Dentistry SC8 Dental Implants
FDA Liaison to ISO TC 106 Dentistry Working Group on Biocompatibility
FDA Liaison to ADA/ANSI Subtag of ISO TC 106

OUTSIDE PROFESSIONAL ADVISORY AND CONSULTING ACTIVITIES

Member of University of Alabama Birmingham Department of Biomedical Engineering Advisory Group

FDA SPECIAL ASSIGNMENTS AND ADVISORY ACTIVITIES

Chairperson of the CDRH Biocompatibility Assessment Group
DAGID Biocompatibility Focal Point
Mentoring of new DAGID biomedical engineers

PUBLICATIONS

Charlene M. Flahiff, Angela S. Blackwell, J. Marcus Hollis, and Dale S. Feldman. "Analysis of a biodegradable composite for bone healing," *Journal of Biomedical Materials Research*, 32,419-424 (1996).

A.E. Steedley (maiden name), R.C. Anderson, M.W. Bidez, D.S.Feldman. "Finite Element Model of a Biodegradable Intramedullary Rod," *Transactions of the Society for Biomaterials*, 16, 51 (1990).

OTHER PUBLICATIONS

ISO/CD 22794 Dentistry – Implantable materials for bone reconstruction in oral and maxillofacial surgery – Contents of a technical file.

ISO 22803 Dentistry – Membrane materials for guided tissue regeneration in oral and maxillofacial surgery – Contents of a technical file. September 1, 2004.

Dental Devices; Reclassification of Root-Form Endosseous Dental Implants and Endosseous Implant Abutments. Final Rule. *Federal Register* 69, 92 May 12, 2004.

Guidance for Industry and FDA Staff: Class II Special Controls Guidance Document: Root-form Endosseous Dental Implants and Endosseous Dental Implant Abutments. May 12, 2004.

ISO 14801 Dentistry – Fatigue testing for endosseous dental implants. May 13, 2003 and subsequent revisions.

Dental Products Devices; Reclassification of Endosseous Dental Implant Accessories. Final Rule. *Federal Register* 65, 196 October 10, 2000.

American National Standard/American Dental Association Standard No. 127 Fatigue Testing for Endosseous Dental Implants June 6, 2012.