

GAIL E. RADCLIFFE, Ph.D.

Gail can be reached through
cdginc@clinicaldevice.com

SKILLS/ EXPERIENCE

- **Technical Assessment**
- **Project Plan Development**
- **Marketing Surveys**
- **Business Development**
- **Contract Negotiations**
- **International Clinical Studies**
- **Strategic Planning**
- **Regulatory Strategy**

1997- present

Radcliffe Consulting, Inc.

President

Management consulting- technical, market research, clinical & regulatory

2005-2006

Attogen, Inc.

Founder, VP Business Development

Monoclonal antibodies to protein isoforms for diagnostic and therapeutic applications

2002-2003

Dendriport Corp.

Founder

Drug delivery of antifungal drugs for toenail fungus using dendrimers

1995-1997

CYTYC Corporation, Boxborough, Massachusetts

Scientific Projects Manager

- * Supervised lab research group
- * Coordinated external studies for new product development
- * Internal development efforts led to patent application
- * Aided in the development of protocols for NCI ALTS study

1989-1995

GENE-TRAK Systems, Framingham, Massachusetts

Manager, Clinical Affairs

- * Project manager, cross sectional clinical team
- * Negotiated clinical trial contracts
- * Directed in-house studies to support PMA submission
- * Designed clinical studies for European registration

Senior Scientist, Sample Processing Group

- * Developed methods for releasing nucleic acids from infectious disease organisms
- * Worked with engineering on chemical compatibility studies and development of a sample processing instrument

Staff Scientist, Sample Processing Group

- * Conducted research investigating detection of *Mycobacterium tuberculosis*, *Chlamydia trachomatis*, Human cytomegalovirus

Staff Scientist, Virology

- * Modified isotopic assay for the detection of HIV
- * Developed amplified nucleic acid detection assays for HIV, HSV, HCMV

***EXPERIENCE
CONTINUED***

- 1986-1989 **University of Massachusetts Medical Center**
Postdoctoral research/Dr. Janet Stavnezer
 * Studied the structure and function of immunoglobulin germline transcripts and their role in heavy-chain class switching
- 1980-1986 **Thesis:** Instability of retroviral proviruses in a quail cell line and novel transduction of a cellular src gene.

EDUCATION

1986 Ph.D. Molecular Biology, Brown University, Providence, RI
 1980 Immunology, Washington University, St. Louis, MO
 1978 B.A. Biology, College of the Holy Cross, Worcester, MA

***PATENTS &
APPLICATIONS***

Patent # 5,942,700: Systems and methods for collecting fluid samples having select concentration of particles (1999)
 European Patent # 99962837.3-2116: Selection of DNA targets from stool for colon cancer detection (2001)
 Patent # 6,268,136: Methods for stool sample preparation (2001)
 Patent # 6,281,004: Synthetic controls for Immunohistochemistry (2001)

BOARDS

Massachusetts Biomedical Initiatives (Board of Trustees, Clerk,)
 Worcester Polytechnic Institute Venture Forum Executive Board
 Crescent Innovations, Inc. (Board of Directors)
 Optimum Technologies, Inc. (Board of Advisors)

***PROFESSIONAL
SOCIETY
MEMBERSHIPS***

Regulatory Affairs Professionals Society
 Northeast Regional Chapter Society of Quality Affairs
 Sigma Xi Scientific Research Society
 American Society of Microbiology

Publications

Stavnezer, J., Radcliffe, G. E., and E. Severinson, (1987). Specificity of immunoglobulin heavy-chain switching by cultured I.29 B lymphoma cells. *Monogr. Allergy*, 24, pp. 197-207.

Stavnezer, J., Radcliffe, G.E., Lin, Y-C, Nietupski, J., Berggren, L., and E. Severinson, (1988). Ig heavy-chain switching may be directed by prior induction of transcripts from constant region genes. *PNAS*, 85, pp. 7704-7708.

Radcliffe, G., Lin Y-C, and J. Stavnezer, (1989). The predominant RNA transcribed from unrearranged Ig C α genes in I.29 μ cells has an open reading frame and is present on polysomes. In *Seventh International Congress of Immunology*, p. 24.

Radcliffe, G., Lin, Y-C, Julius, M., Marcu, K.B., and J. Stavnezer, (1990). Structure of germline I α heavy-chain RNA and it's location on polysomes. *Mol. and Cell. Bio.*, 10, pp. 382-386.

An, Q., Radcliffe, G., Vassallo, R., Buxton, D., O'Brien, W.J., Pelletier, D.A., Weisburg, W.G., Klinger, J.D., and D.M. Olive, (1992). Infection with a plasmid-free variant chlamydia related to *Chlamydia trachomatis* identified using multiple assays for nucleic acid detection. *J. Clin. Micro.*, 30, pp. 2814-2821.

Shah, JS, Liu, J. Smith, J., Popoff S, Radcliffe G, O'Brien, WJ., Serpe G, Olive DM, King, W. (1994) Novel ultrasensitive Q-beta replicase amplified hybridization assay for detection of *Chlamydia trachomatis*. *J. Clin. Microbiol.* 32(11) pp.2718-24

An, Q., Liu, J., O'Brien, W., Radcliffe, G., Buxton, D., Popoff, S., King, W., Vera-Garcia, M., Lu, L., Shah, J., Klinger, J., and D.M. Olive, (1995). Comparison of characteristics of Q β -replicase amplified assay with competitive PCR assay for *Chlamydia trachomatis*. *J. Clin. Micro.* 33, pp. 58-63.

Shah, J., Liu, J., Buxton, D., Hendricks, A., Robinson, L., Radcliffe, G., King, W., Lane, D., Olive, D.M., and J. Klinger, (1995). Q-Beta replicase amplified assay for detection of *Mycobacterium tuberculosis* directly from clinical specimens. *J. Clin. Micro.* 33, pp. 1435-1441.

Dabbs, D.J., Abendroth, C., Genko, R.T., Wang, X., Radcliffe, G.E., (1997). Immunocytochemistry on the ThinPrep processor. *Diagn. Cytopathol.* 17 (5) pp 388-92.

Smith, J. H., Radcliffe, G., Rigby, S., Mahan, D., Lane D. L., and J. D. Klinger, (1997). Performance of an automated Q-Beta replicase amplification assay for *Mycobacterium tuberculosis* in a clinical trial. *J. Clin. Micro.* 35, pp.1484-1491.

Tabbara, S. O., Sidawy, M.K., Frost, A.R., Brosky, K.R., Coles, V., Hecht, S., Radcliffe, G., Sherman, M.E., (1998). The stability of estrogen and progesterone receptor expression on breast carcinoma cells stored as PreservCyt suspensions and as ThinPrep slides. *Cancer Cytopath.* 84, pp.355-360.

Sompuram, S., Kodela, V., Ramanathan, H., Wescott, C., Radcliffe, G., Bogen SA (2002) Synthetic peptides identified from phage-displayed combinatorial libraries as immunodiagnostic assay surrogate quality-control targets. *Clin Chem* 48: pp.410-420.

Sompuram, S.R., Kodela, V., Zhang, K., Ramanathan, H., Radcliffe, G., Falb, P. and S.A. Bogen, (2002). A novel quality control slide for quantitative immunohistochemistry testing. *J. Histochem. Cytochem.* 50 (11):1425-1433, 2002.

Andrews, J.M. and Radcliffe, G.E., (2003). Lessons learned in transferring medical device manufacturing. *RAPS Focus*, January 2003, pp.35-36.