

Clifford S. Mintz, PhD
153 Dorchester Road
Windsor, NJ 08547
(608) 426-4530 (608) 203-7078 (mobile)
E-mail: cmintz@comcast.net

SUMMARY OF QUALIFICATIONS

Seasoned biopharmaceutical executive and scientist with expertise in drug discovery/development, API manufacture, drug delivery, regulatory compliance and biomanufacturing. Industry professional with a strong background in pharmaceutical and biopharmaceutical management consulting, intellectual property assessment and patent prosecution, strategic planning, corporate business development, and regulatory affairs.

PROFESSIONAL EXPERIENCE

Complete Health Vizion, Ewing, NJ

2006-present

Scientific Director

Provided scientific and strategic support for various several brands in the areas of transplantation, immunology, women's health and osteoporosis
Developed strategic and tactical plans for publication planning
Participated in key message development and gap analyses
Member of account teams who visited and serviced clients

Prescriptions for Strategy, Axis Healthcare, Newton, PA

2004-2006

Strategic Planning and Medical Communications

Medical communications consultant/writer who created medical marketing/ lifecycle management presentations and proposals for biotech and pharmaceutical clients
Identified new clients seeking strategic planning and brand lifecycle management
Provided strategic business and scientific solutions for drug development and brand lifecycle management for clients
Crafted and participated in numerous pitches with clients to develop new business

BioInsights, Inc., East Windsor, NJ

1998-2004

Founder and Principal Management Consultant

Provided drug development and business assistance, intellectual property assessment and scientific and regulatory direction to private and public biopharmaceutical companies including *Millennium Pharmaceuticals, ImunnoVaccine Technologies, Inc., Clinysis, Inc., API, Inc., HybriVax, Inc., DE Miles & Company, Alchemia, Pty., Prolong Pharmaceuticals, Grant Life Sciences (GLIF.OB), Canyon Pharmaceuticals and Proleon Therapeutics*
Co-founder, Prolong Pharmaceuticals, a privately held Company specializing in drug delivery and protein PEGylation of new and off-patent biologics
Developed and assembled business plans, created fund raising presentations, and advised companies on fund raising strategies

Advised corporate clients on business strategies, managed intellectual property portfolios, identified potential business partners, and closed several IP/licensing deals
Performed scientific due diligence for venture firms and intellectual property assessment for corporate mergers and acquisitions
Worked with academic and corporate clients to develop workforce development and biomanufacturing training programs
Provided recruiting and staffing services and placed CEOs, management and technical personnel into jobs at pharmaceutical and biotechnology companies

Long Term Consulting Assignments

Proleon Therapeutics, San Diego, CA (2005)

Provided, strategic, scientific and regulatory guidance for the development of a sustained release formulation of a human growth hormone product
Participated in business development activities
Performed due diligence on prospective corporate partners

Katan Associates, NY, New York (2004-2005)

Performed industry intelligence and business/financial due diligence for clients in the areas of HPV, HIV/AIDS and HepC viral diagnostic product development and viral/ oncology vaccine development
Performed business due diligence and financial analyses of biotechnology start up companies
Evaluated M & A opportunities for corporate clients and venture capital groups
Participated in business development activities and patent portfolio management for a variety of start up companies and corporate clients
Managed deal flow and identified capital resources for several start up biopharmaceutical companies

Alchemia, Pty. Brisbane, Queensland, Australia (2001-2003)

Created and provided scientific and business direction for a pre-clinical antibacterial drug development program
Reviewed MIC, toxicology and ADME data on lead antibacterial candidates to support regulatory filings
Established business and scientific relationships with antibacterial development specialists and industry thought leader
Performed due diligence on potential corporate business partners

Middlesex County College, Edison, NJ 1996-1998
Chairman of Biology Department

Managed day to day operations of a Biology Department that consisted of 15 full time faculty members, 20 adjunct instructors, three full time staff members and several student assistants
Responsibilities included grant writing, budget preparation, performance evaluations, conflict resolution, staffing decisions, and laboratory research

Transcell Technologies, Monmouth Junction, NJ 1994-1996

Project Director Antibiotic Discovery

Managed and oversaw personnel involved with antibiotic drug discovery and development
Identified bacterial targets and developed assays for high throughput screening of carbohydrate and glycopeptide libraries for antibacterial activity
Cloned and over expressed bacterial proteins for use as targets in high throughput screens to identify lead anti-infective compounds
Conducted MIC assays to assess antimicrobial activity of lead compounds
Devised and executed experiments to measure transport of plasmid DNA into eukaryotic cells

Department of Microbiology and Immunology, Univ. of Miami

1987-1994

School of Medicine, Miami, FL

Assistant Professor (tenure-track)

Established an ongoing investigative research program concerned with the molecular genetics of lipopolysaccharide biosynthesis and assembly by *Legionella pneumophila*
Initiated and conducted research on chromosomal gene transfer in *L. pneumophila*
Identified and characterized *L. pneumophila* conjugative plasmids
Designed and initiated studies on genomic identification of *L. pneumophila* and *M. tuberculosis* by pulsed field gel electrophoresis

EDUCATION

B. S. *Cornell University*, Ithaca, New York
Majors: Microbiology/Animal Science

M. S. *University of Wisconsin*, Madison, Wisconsin
Major: Bacteriology

Ph. D. *University of Wisconsin*, Madison, Wisconsin
Major: Bacteriology/Medical Microbiology

Postdoctoral Training *College of Physicians and Surgeons, Columbia University*, New York, NY; Genetics of *Legionella pneumophila*: Howard Shuman, Ph.D., (1984-1987)
Oregon Health Sciences University, Portland, Oregon
Pathogenesis of *Neisseria gonorrhoeae*: Stephen A. Morse, Ph.D., (1982-1984)

PROFESSIONAL ACTIVITIES

Management Consultant, Seeley Thermos Company, 1979; *Florida Department of Health and Rehabilitative Services*, 1991-1994; *PathCon Laboratories* for the genomic identification of *L. pneumophila*, 1992-present; *Millennium Pharmaceuticals, Inc.* 1997; *Newark School District*, 1997-present; *HybriVax, Inc.*, 2000- 2001; *API, Inc.*, 2000-present; *DE Miles & Co*, 2001-present; *ImmunoVaccine Technology, Inc.*, 2001-2002; *Alchemia, Pty. Ltd*, 2001- 2003, *Prolong Pharmaceuticals* 2002-present, *Grant Life Sciences (GLIF.OB)*, 2004-2005; and *Canyon Pharmaceuticals*, 2004; and *Proleon Therapeutics*, 2005.

Free Lance Science Writer, focusing on follow-on biologics, biomanufacturing, workforce development and biotechnology training and education.

Conference Organizer and Chair “*Manufacturing Off-Patent Proteins: Navigating the Regulatory and Technical Challenges*”, La Jolla, CA, 2004, “*Generic Biopharmaceutical Global Summit*”, Reston, VA, 2003; “*Bringing Follow-On Biologics to Market*”, Zurich, Switzerland, 2006

Organizer, Society for Industrial Microbiology, Marcel Faber Education Symposium, Minneapolis, MN, 2001

Invited Business Reviewer for the National Institutes of Standard and Technology (NIST), 2002-present

Adjunct Assistant Professor, Georgetown University School of Medicine Biotechnology Master Degree Program

Program Director and Instructor, SUNY-Stonybrook Biotechnology Master’s Degree program

Ad hoc Reviewer, Journal of Applied and Environmental Microbiology, 1978-1980; Bioassays, 1987-1988; Regional Immunology, 1992-present; Canadian Journal of Microbiology, 1994

Invited Instructor, National Medical School Review, 1990-1991

Invited Reviewer, Environmental Protection Agency, 1992

Lecturer, Food and Drug Administration trainees, University of Wisconsin-Madison, 1979-1981

AWARDS AND HONORS

American Society for Microbiology Foundation Lecturer, 1998-2000

Visiting Scholar, Borstel Research Institute, Borstel Germany, 1998

MacArthur Foundation Postdoctoral Fellow, 1986-1987

NIH Postdoctoral Trainee, 1984-1986

INVITED LECTURES

1. Georgetown University Medical Center, Biotechnology Master’s Degree Program, Washington, D.C., 2002- present
2. Society for Industrial Microbiology, Marcel Faber Symposium, Minneapolis, MN, 2003
3. Raritan Valley Community College, Science Symposium Series, Bridgewater, NJ 2002
4. Department of Pharmaceutical Sciences, Rutgers University, New Brunswick, NJ 2001
5. The Symposium on Biotechnology Education, Boston Museum of Science, Boston, MA 1999
6. Forschungszentrum Borstel, Zentrum fur Experimentelle Biologie und Biowissenschaften, Borstel Germany, 1998
7. Institut fur Medizinische Mikrobiologie und Hygiene, University of Dresden, Dresden, Germany 1998
8. Insitut fur Medizinische Mikrobiologie, University of Wuerzburg, Wuerzburg, Germany 1998
9. Department of Microbiology, The Technical University of Denmark, Lyngby, Denmark 1998

10. International Symposium on GFP (biotechnology education sessions), New Brunswick, NJ 1997
11. Department of Molecular Biology, "Career Paths", Princeton University, Princeton, NJ 1997
12. Department of Biology, Vassar College, Poughkeepsie, NY. 1992
13. Department of Microbiology, University of Florida, Gainesville, FL. 1989
14. Departments of Pathobiology and Medical Microbiology, University of Wisconsin, Madison, WI. 1988

PROFESSIONAL AFFILIATIONS

American Society for Microbiology
 American Association for the Advancement of Science
 Biotechnology Council of New Jersey

PUBLICATIONS

Scientific Papers

1. **Mintz, C.S.**, and R.H. Deibel. 1983. The effect of lipopolysaccharide mutations on the pathogenesis of experimental *Salmonella* gastroenteritis. *Infect. Immun.* **40**: 236-244.
2. **Mintz, C.S.**, D. O. Cliver and R.H. Deibel. 1983. The attachment of *Salmonella* to mammalian cells in vitro. *Can. J. Microbiol.* **29**: 1731-1735.
3. Morse, S.A., **C. S. Mintz**, S. K. Sarafian, L. Bartenstein, M. Bertram and M. A. Apicella. 1983. The effect of dilution rate on lipopolysaccharide and serum resistance of *Neisseria gonorrhoeae* grown in continuous culture. *Infect. Immun.* **41**: 74-82.
4. **Mintz, C.S.**, M. A. Apicella and S.A. Morse. 1984. Electrophoretic and serological characterization of the lipopolysaccharides produced by *Neisseria gonorrhoeae*. *J. Infect. Dis.* **149**: 544-552.
5. Roberts, M., **C.S. Mintz** and S.A. Morse. 1986. Characterization of *Haemophilus parainfluenzae* strains with low molecular weight or ladder-like lipopolysaccharides. *J. Gen. Microbiol.* **132**: 611-616.
6. **Mintz, C.S.** and H. A. Shuman. 1987. Transposition of bacteriophage Mu in the Legionnaire's disease bacterium. *Proc. Natl. Acad. Sci.* **84**: 4655-4659.
7. **Mintz, C.S.**, J. Chen and H.A. Shuman. 1988. Isolation and characterization of auxotrophic mutants of *Legionella pneumophila* that fail to multiply in human monocytes. *Infect. Immun.* **56**:1449-1455.
8. **Mintz, C.S.**, and H. A. Shuman. 1988. Genetics of *Legionella pneumophila*. *Microbiol. Sci.* **5**:292-295.

9. **Mintz, C.S.**, B. S. Fields and C.H. Zou. 1992. Isolation and characterization of a conjugative plasmid of *Legionella pneumophila*, *J. Gen. Microbiol.* **138**:1379-1386.
10. **Mintz, C.S.** and C.H. Zou. 1992. Isolation and characterization of a lipopolysaccharide mutant of *Legionella pneumophila* FEMS Microbiol. Lett. **93**:249-254.
11. **Mintz, C. S.**, D.R. Schultz, P.A. Arnold and W. Johnson. 1992. *Legionella pneumophila* lipopolysaccharide activates the classical complement pathway. *Infect. Immun.* **60**:2769-2776.
12. **Mintz, C.S.** and C.H. Zou. 1992. Chromosome mobilization of *Legionella pneumophila* with RK2::Mu and Tn₅-Mob. *Can. J. Microbiol.* **38**:664-671.
13. **Mintz, C.S.**, R. D. Miller and T. Malek. 1993. *Legionella pneumophila* protease inactivates IL-2 and cleaves CD4 on human T cells. *Infect. Immun.* **61**: 3416-3421.
14. Hlady, W.G., R.C. Mullen, **C.S. Mintz**, B.G. Shelton, R. S. Hopkins, G. L. Daikos. 1993. In: outbreak of Legionnaires' disease linked to a decorative fountain by molecular epidemiology. *Am. J. Epidemiol.* **138**:555-562.
15. **Mintz, C.S.**, D. R. Schultz, P.A. Arnold and W. Johnson. 1995. Antibody-independent binding of complement component C1q by *Legionella pneumophila*. *Infect. Immun.* **68**:4939-4943.
16. Zou, Y. H. Knirel, J. H. Helbig, U. Zaehring and **C.S. Mintz**. 1999. Molecular analysis of a locus involved with lipopolysaccharide biosynthesis by *Legionella pneumophila* serogroup 1. *J. Bacteriol.* **181**:4137-4141.
17. **Mintz, C.S.** 1999. Gene transfer in *Legionella pneumophila*. *Microbes and Infect.* **1**:1203-1209.
17. Fisher, H.E., and **C.S. Mintz**, 2000. Shedding light on biotechnology education: the use of the Green Fluorescent Protein as an educational tool. *J. Indust. Microbiol. & Biotech* **24**:323-326.

Freelance Publications

1. **Mintz, C. S.**, 2004. How to Prevent Workforce Shortages in the US Biotechnology Industry. *Bioprocess Int'l.* **2**:16-23.
2. **Mintz, C. S.**, 2004. Transcending the Transition from Academia to Industry. *Science Next Wave* (www.nextwave.sciencemag.org)
3. Yakatan, S. and **C. S. Mintz**. 2005. Does a Biogeneric Market Really Exist? *BioExecutive* **1**:54-59.

4. **Mintz, C. S.**, 2005. Outsourcing Biomanufacturing. *Contract Services Europe*. **4**:26-31.
5. **Mintz, C. S.** 2005. Managing Bio-outsourcing Relationships. *BioExecutive* June, 2005:46-49.
6. **Mintz, C. S.**, 2006. Developing and Managing Successful Bio-Outsourcing Relationships. D & MD Publications.

Books and Chapters

1. Norrod, E. P., **C.S. Mintz** and C.W. Sokolik. 1985. Induction by growth medium of changes in gonococcal lipopolysaccharide, pp. 395-399. In: Gary K. Schoolnik (ed.), the pathogenic neisseriae. American Society for Microbiology, Washington, DC.
2. **Mintz, C.S.** and C. H. Zou. 1993. Isolation of a *Legionella pneumophila* mutant that produces antigenically-altered lipopolysaccharide. pp. 83-85. In: J.M. Barbaree, R.F. Breiman, and A. P. Dufour (eds.) *Legionella: Current Status and Emerging Perspectives*. American Society for Microbiology, Washington, DC.
3. H. E. Fisher and **C.S. Mintz**, 1999. Use of the green fluorescent protein to teach undergraduate courses in biotechnology and microbiology, pp. 451-453 in: A Roda, M Pazzagli, L J Kricka and P E Stanley (eds.) "Bioluminescence and Chemiluminescence: Perspectives for the 21st Century. John Wiley Press, London, England.

Abstracts

1. **Mintz, C.S.**, M. A. Apicella and S.A. Morse. 1983. Electrophoretic and serological analysis of gonococcal lipopolysaccharide. Abs. Ann. Mtng. Soc. Microbiol. p. 33.
2. **Mintz, C.S.**, M. A. Apicella, C. Chen and S.A. Morse. 1983. Further electrophoretic and serological analysis of gonococcal lipopolysaccharide. Abs. Int. Soc. STD Res.-V., p. 41.
3. Morse, S.A., **C.S. Mintz**, S. K. Sarafian and M.A. Apicella. 1983. The effect of dilution rate on lipopolysaccharide and serum resistance of *Neisseria gonorrhoeae* grown in continuous culture. Abs. Int. Soc. STD Res.-V., p. 42.
4. **Mintz, C.S.**, S. K. Sarafian, M.A. Apicella and S.A. Morse. 1984. Growth phase-dependent serum resistance of *Neisseria gonorrhoeae*. Abs. Ann. Mtng. Amer. Soc. Microbiol., p. 47.
5. **Mintz, C.S.**, J. Chen, C. O'Brien and H.A. Shuman. 1986. Isolation of auxotrophic mutants of *Legionella pneumophila*. Abs. Ann. Mtng. Amer. Soc. Microbiol., p. 68.
6. **Mintz, C.S.** 1989. Chromosome transfer in *Legionella pneumophila*. Abs. Ann. Mtng. Amer. Soc. Microbiol., p. 90.

7. **Mintz, C.S.**, P I. Arnold and D. R. Schultz. 1990. Classical pathway activation in normal human serum by cell wall components of *Legionella pneumophila*. *Complement and Inflammation* 7:125.
8. **Mintz, C.S.**, and C.H. Zou. 1991. Conjugal transfer of a cryptic plasmid of *Legionella pneumophila*. *Abs. Ann. Mtng. Amer. Soc. Microbiol.*, p. 107.
9. **Mintz, C.S.** and C. H. Zou. 1992. Isolation and characterization of a lipopolysaccharide mutant of *Legionella pneumophila*. *Abs. 1992 Inter. Symp. On Legionella.* p. 12.
10. **Mintz, C.S.** and K. Eddy. 1992. Molecular cloning of five tryptophan genes from *Legionella pneumophila*. *Abs. Ann. Mtng. Amer. Soc. Microbiol.*, p. 101.
11. **Mintz, C.S.** and C.H. Zou. 1993. Molecular cloning of a locus involved with expression and biosynthesis of *Legionella pneumophila* lipopolysaccharide. *Abs. Ann. Mtng. Amer. Soc. Microbiol.*, p.89.
12. **Mintz, C.S.**, D. Davis, D. Gonzalez, and W. W. Ward. 1997. Development of a Biotechnology Laboratory Curriculum using a Novel Green Fluorescent Protein. *Abs. Ann. Mtng. Amer. Soc. Microbiol.*, p.590.
13. E. Fisher and **C.S. Mintz**, 1998. Use of the green fluorescent protein to teach undergraduate courses in biotechnology and microbiology, *J. Biolum. And Chemilum.* **13**:256.