

CITY OF NEWTON

DOCKET REQUEST FORM

**DEADLINE NOTICE: Council Rules require items to be docketed with the Clerk of the Council NO LATER THAN 7:45 P.M. ON THE MONDAY PRIOR TO A FULL COUNCIL MEETING.**

To: Clerk of the City Council

Date: 03/21/2023

From (Docketer): Council President Susan Albright

Address: \_\_\_\_\_

Phone: \_\_\_\_\_

E-mail: \_\_\_\_\_

Additional sponsors: \_\_\_\_\_

1. Please docket the following item (it will be edited for length if necessary):

PRESIDENT ALBRIGHT reappointing Gary C. du Moulin, 24 Myerson Lane, Newton Centre, as a member of the Biosafety Committee for a term of office to expire on May 4, 2026.

2. The purpose and intended outcome of this item is:

- Fact-finding & discussion
- Appropriation, transfer,
- Expenditure, or bond authorization
- Special permit, site plan approval,
- Zone change (public hearing required)
- Ordinance change
- Resolution
- License or renewal
- Appointment confirmation
- Other: \_\_\_\_\_

3. I recommend that this item be assigned to the following committees:

- Programs & Services
- Zoning & Planning
- Public Facilities
- Finance
- Public Safety
- Land Use
- Real Property
- Special Committee
- No Opinion

4. This item should be taken up in committee:

- Immediately (Emergency only, please). Please state nature of emergency:  
\_\_\_\_\_
- As soon as possible, preferably within a month
- In due course, at discretion of Committee Chair
- When certain materials are made available, as noted in 7 & 8 on reverse
- Following public hearing

PLEASE FILL OUT BOTH SIDES

5. I estimate that consideration of this item will require approximately:

- One half hour or less
- More than one hour
- More than one meeting
- Up to one hour
- An entire meeting
- Extended deliberation by subcommittee

6. The following people should be notified and asked to attend deliberations on this item. (Please check those with whom you have already discussed the issue, especially relevant Department Heads):

City personnel

Citizens (include telephone numbers/email please)

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_
- \_\_\_\_\_

7. The following background materials and/or drafts should be obtained or prepared by the Clerk's office prior to scheduling this item for discussion:

8. I  have or  intend to provide additional materials and/or undertake the following research independently prior to scheduling the item for discussion. \*

(\*Note to docketer: Please provide any additional materials beyond the foregoing to the Clerk's office by 2 p.m. on Friday before the upcoming Committee meeting when the item is scheduled to be discussed so that Councilors have a chance to review all relevant materials before a scheduled discussion.)

Please check the following:

- 9.  I would like to discuss this item with the Chairman before any decision is made on how and when to proceed.
- 10.  I would like the Clerk's office to contact me to confirm that this item has been docketed. My daytime phone number is:
- 11.  I would like the Clerk's office to notify me when the Chairman has scheduled the item for discussion.

Thank you.

/s/Susan Albright  
Signature of person docketing the item

[Please retain a copy for your own records]

Application Form

Profile

Gary C. du Moulin
First Name Middle Initial Last Name

garydumoulin@gmail.com
Email Address

24 Myerson Lane
Home Address Suite or Apt

Newton Centre MA 02459
City State Postal Code

What Ward do you live in?

[x] Ward 8

Home: (617) 965-5690 Home: (617) 939-7809
Primary Phone Alternate Phone

Retired Vice President of Quality
Employer Operations
Job Title

Which Boards would you like to apply for?

Biosafety Committee: Submitted

Interests & Experiences

Please tell us about yourself and why you want to serve.

Why are you interested in serving on a board or commission?

For the past 30 years I have worked in the areas of cell and gene therapy (Cellcor, Sanofi-Genzyme). Prior to my industrial experience I was on the Harvard Medical school as a research scientist for 15 years. I have more than 150 publications in the areas of microbiology, epidemiology, and the regulation and quality control of living cells as a therapeutic modality. I am a graduate of Newton High School and wish to continue my service with the City of Newton.

G\_DUMOULIN\_RESUME\_2022.docx
Upload a Resume

## CURRICULUM VITAE

**NAME** Gary Carl du Moulin  
**ADDRESS** 24 Myerson Lane, Newton Centre, MA  
**DATE OF BIRTH** October 14, 1947  
**PLACE OF BIRTH** Belle Harbor, New York

### EDUCATION

1969 B.S., Norwich University, Northfield, Vermont  
1971 M.S., Northeastern University, Boston, Massachusetts  
1980 M.P.H., School of Public Health, Boston University School of Medicine, Boston, Massachusetts  
1982 Graduate, The Command and General Staff College, Ft Leavenworth, Kansas  
1984 Ph.D., Boston University School of Medicine, Division of Graduate Medical Sciences, Boston, MA (Title of Dissertation: "The Pathophysiology of Gram Negative Bacillary Sepsis: Multi-organ Responses to Bacteremic Challenge in a Rat Model of Peritonitis")

### LICENSURE AND CERTIFICATION

1973 Registered Microbiologist, American Academy of Microbiology, License #937  
1990 Director, Laboratory of Cellular Immunology and Cancer Diagnosis, U.S. Dept of Health and Human Services CLIA License No. 20-1150

- 1992 Regulatory Affairs Certified - Regulatory Affairs  
Professional Society - Certificate #562
- 2001 Tissue Bank Director, Genzyme Biosurgery  
ID No. CP097TP019, New York State Department of Health

**ACADEMIC APPOINTMENTS**

- 1976-1984 Associate in Anesthesia, Harvard Medical School,  
Boston, Massachusetts
- 1984-1985 Instructor in Anesthesia, Harvard Medical School,  
Boston, Massachusetts
- 1985-1986 Lecturer on Microbiology, Boston University School of Medicine
- 1985-1989 Assistant Professor of Anesthesia, Harvard Medical  
School, Boston, Massachusetts
- 1990.1991 Adjunct Professor of Chemical Engineering and  
Senior Research Fellow, Center for Biotechnology Engineering,  
Northeastern University, Boston, Massachusetts
- 2013-2017 Adjunct Associate Professor of Drug Regulatory Affairs  
Massachusetts College of Pharmacy and Health Sciences University  
Boston, Massachusetts

**PRINCIPAL CLINICAL AND HOSPITAL SERVICE RESPONSIBILITIES**

- 1971- 1973 Captain, U.S. Army, Chief of Microbiology, Womack  
Army Hospital, Fort Bragg, North Carolina
- 1978 - 1989 Director, Anesthesia/Respiratory Therapy Equipment  
Assessment Unit, Beth Israel Hospital, Boston, MA
- 1989 - 1993 Commanding Officer (Colonel), 399th Combat Support Hospital,  
U.S. Army Reserve
- 1993 - 1997 Chief of Staff (Colonel), 804th Medical Brigade,  
U.S. Army Reserve

**PRINCIPAL INDUSTRIAL RESPONSIBILITIES**

1989-1992	Director, Quality Assurance / Quality Control, Cellcor Inc. Newton, MA
1992-1995	Vice President, Quality Assurance / Quality Control, Cellcor Inc. Newton, MA
1995-1997	Director, Quality Systems Genzyme Tissue Repair Inc., Cambridge, MA
1997- 2000	Senior Director, Quality Systems Genzyme Tissue Repair Inc., Cambridge, MA
2000- 2007	Vice President, Quality Operations Genzyme Biosurgery, Cambridge, MA
2007 – 2014	Senior Director Quality, Aseptic Controls Genzyme (A Sanofi Co), Allston, MA

**OTHER PROFESSIONAL POSITIONS**

1972-1973	Microbiologist, Venereal Disease Screening Program, North Carolina Department of Public Health
1973-1976	Research Assistant, Harvard Medical School at the Beth Israel Hospital, Boston, Massachusetts
1977-1982	Major, 323rd Medical Laboratory, U.S. Army Reserve
1980	Faculty, American Society of Anesthesiologists Regional Workshop in Hazards and Pitfalls of Anesthesia Equipment, Chicago, Illinois
1980	Faculty, New York State Society of Anesthesiologists' 34th Postgraduate Assembly on Anesthesia Technology, New York
1980	Consultant, Tuberculosis Control Division, State of Massachusetts (Epidemiologic investigation of non-tuberculous mycobacterial Disease in the State of Massachusetts)
1981	Panel Member, U.S. Environmental Protection Agency Peer Review Workshop in Microbial Contamination of Water Arlie House, Virginia
1982-1986	Lieutenant Colonel, Executive Officer, 323rd Medical Laboratory, U.S. Army Reserve
1985	National Councillor, Northeast Branch, American Society for Microbiology
1985-1986	Vice President, Northeast Branch, American Society for Microbiology

1986-1988	President, Northeast Branch, American Society for Microbiology
1986-1989	Commanding Officer, 323rd Medical Laboratory, U.S. Army Reserve
1986	Faculty, "AIDS in the Hospital, Home, and Community, Advances in Care and Challenges for 1987" Boston, MA
1987	Promoted to Colonel, Medical Service Corps, U.S. Army
1988	Faculty, "International Symposium on Nosocomial Pneumonia, Nosocomial Infection Control in Intensive Care" Freiberg, Germany
1988	Faculty, "Waterborne Disease Agents and the Immuno-compromised - A Public Health Issue?" American Public Health Association Annual Meeting, Boston, MA
1991	Faculty, International Conference on Nosocomial Infection Control in Intensive Care, Freiberg, Germany

#### AWARDS AND HONORS

1969-1971	Northeastern University Tuition Assistantship, Department of Biology, Northeastern University, Boston, MA
1970	Phi Sigma Honor Society for Biological Research, Northeastern University
1973	Army Commendation Medal
1983	Army Achievement Medal
1987	Board of Fellows, Norwich University, Northfield, VT
1989	Army Commendation Medal with Oak Leaf Cluster
1990	Army Commendation Medal with 2nd Oak Leaf Cluster
1990	Meritorious Service Medal
1992	Expert Field Medical Badge
1993	Meritorious Service Medal with Oak Leaf Cluster
1998	Meritorious Service Medal with 2nd Oak Leaf Cluster
2000	Legion of Merit

#### MAJOR COMMITTEE ASSIGNMENTS

1972-1973	Infection Control Committee, Womack Army Hospital, Fort Bragg, NC
1977-1989	Committee on Infection, Beth Israel Hospital, Boston, MA,
1979-1989	Hospital Safety Committee (chairman), Beth Israel Hospital Boston, MA

1981-1982	Committee on Quality Assurance and Risk Management, Beth Israel Hospital, Boston, MA
1991-1998	Industrial Advisory Board, Dept. of Biology, Northeastern University
1997-2000	Advisory Panel on Gene and Cell Therapies, United States Pharmacopeia, Rockville, MD
1998-2000	Editorial Board - <i>Biologics - Regulatory Affairs Focus</i>
2000-2002	Chairman, Editorial Board- <i>Regulatory Affairs Focus</i>
2000-present	Gene Therapy, Cell Therapy, and Tissue Engineering Expert Committee United States Pharmacopeia
2006-present	Chairman, Ad hoc Subcommittee on Fetal Bovine Serum, United States Pharmacopeia
2008-present	Editorial Advisory Board – <i>Regenerative Medicine</i>
2009-present	Alternate Member, Scientific and Medical Research Funding Working Group California Institute for Regenerative Medicine (CIRM)

### PROFESSIONAL SOCIETIES

1971	American Society for Microbiology
1973	American Academy of Microbiology
1977	New York Academy of Sciences
1977	Society of Armed Forces Medical Laboratory Scientists
1981	American Association for the Advancement of Science
1986	American Association of Pathologists
1989	American Society for Quality Control
1989	Regulatory Affairs Professional Society
1992	Cell Transplant Society
1992	Association of Military Surgeons of the United States
2010	Parenteral Drug Association

### TEACHING EXPERIENCE

1976-1977	Lecturer, Department of Infectious Diseases, Children's Hospital Medical Center, Boston, MA
1976-1978	Lecturer, College of Pharmacy and Allied Health Professions, Northeastern University, Boston, MA
1976-1989	Lecturer, Department of Anesthesia, Beth Israel Hospital, Boston, MA
1977-1989	Lecturer, Department of Microbiology, Boston University School of Medicine
1985-1989	Assistant Professor of Anesthesia, Harvard Medical School, Boston, Massachusetts
2000- 2003	Lecturer, Health Professions and Sciences Program, Northeastern University, Boston, MA
2013-2017	Adjunct Associate Professor of Drug Regulatory Affairs Massachusetts College of Pharmacy and Health Sciences University



**PATENTS**

Inventors: du Moulin GC, Hedley-Whyte J, Lynch SE  
 Invention: CA 1114271 - Assay of Gram-Negative Bacteria  
 Country: Canada  
 Issued: Dec 15, 1981  
 Patent owner: President and Fellows of Harvard College

**ORIGINAL REPORTS**

1. Klick JM, du Moulin GC, Hedley-Whyte J, Teres, D, Bushnell LS, Feingold, DS: Prevention of Gram-negative bacillary pneumonia using polymyxin aerosol as prophylaxis. II. Effect on the incidence of pneumonia in seriously ill patients. *J. Clin. Invest.* 1975; 55:514-519.
2. Feeley TW, du Moulin GC, Hedley-Whyte J, Bushnell LS, Gilbert JP, Feingold DS: Aerosol polymyxin and pneumonia in seriously ill patients. *New Eng. J. Med.* 1975; 293:471-475.
3. Eichhorn JH, Bancroft ML, Laasberg LH, du Moulin GC, Saubermann AJ: Contamination of medical gas and water pipelines in a new hospital building. *Anesthesiology.* 1977; 46:286-289.
4. du Moulin GC, Saubermann AJ: The anesthesia machine and circle system are not likely to be sources of bacterial contamination. *Anesthesiology.* 1977; 47:353-358.
5. Klick JM, du Moulin GC: An oxygen analyzer as a source of Pseudomonas. *Anesthesiology.* 1978; 49:80-81.
6. du Moulin GC, Stottmeier KD: Use of cetyl-pyridinium chloride in the decontamination of water for culture of mycobacteria. *Appl. Env. Microbiol.* 1978; 36:771-773.
7. du Moulin GC, Dasse P, Miller MC, Friedland G: Staphylococcal outbreak in an intensive care unit: A narrative account of its management. *Heart and Lung.* 1979; 8:94-99.
8. du Moulin GC: Airway colonization by Flavobacterium in an intensive care unit. *J. Clin. Microbiol.* 1979;10:155-160.
9. Bancroft ML, du Moulin GC, Hedley-Whyte J: Hazards of hospital bulk oxygen delivery systems. *Anesthesiology.* 1980; 52:504-510. (reprinted In *Respiratory Care* 1981; 26:339-346.)

10. du Moulin GC, Doyle GO, MacKay J, Hedley-Whyte J: Bacterial fouling by of a hospital closed loop cooling system by *Pseudomonas* sp. *J. Clin. Microbiol.* 1981; 13:1060-1065.
11. du Moulin GC, Paterson DG, Hedley-Whyte J, Lisbon A: Aspiration of gastric bacteria in antacid - treated patients: A frequent cause of postoperative colonization of the airway. *Lancet.* 1982; 1:242-245.
12. Fleischman RW, du Moulin GC, Esber HJ, Ilievski V, Bogden AE: Nontuberculous mycobacterial infection in two Rhesus monkeys due to *Mycobacterium intracellulare* serotype 10. *J. Am. Vet. Med. Assoc.* 1982; 181:1358-1362.
13. du Moulin GC, Lynch SE, Hedley-Whyte J, Broitman SA: Detection of Gram-negative bacteremia by *Limulus* amoebocyte lysate assay: Evaluation in a rat model of peritonitis. *J. Infect. Dis.* 1985;151:148-152.
14. du Moulin GC, Paterson D, Hedley-Whyte J, Broitman SA: *E. coli* peritonitis and bacteremia cause increased blood-brain barrier permeability. *Brain Research.* 1985;340:261-268.
15. du Moulin GC, Sherman IH, Hoaglin DC, Stottmeier, KD: *Mycobacterium avium* complex: An emerging pathogen in Massachusetts. *J. Clin. Microbiol.* 1985;22: 9-12.
16. du Moulin GC, Skea, WM, Bartolini, BA: Microbiologic assessment of drinking water potability during brigade operations. *Milit. Med.* 1986;151:570-573.
17. du Moulin GC, Coleman EC, Hedley-Whyte J: Bacterial colonization and endotoxin content of a new renal dialysis water system composed of acrylonitrile butadiene styrene. *Appl. Environ. Microbiol.* 1987;53: 1322-1326.
18. Doos WG, du Moulin GC, Jordi H, Orf HW, Seder R, Skea WM: Field tests on four state-of-the-art blood chemistry analyzers in a mobile laboratory setting. *Milit. Med.* 1988;153: 81-86.
19. Pelletier PA, du Moulin GC, Stottmeier KD: Mycobacteria in public water supplies: Comparative resistance to chlorine. *Microbiol. Sci.* 1988; 5:147-148.
20. du Moulin GC, Pelletier PA, Stottmeier KD, Tsang AY, Hedley-Whyte J: Concentration of *Mycobacterium avium* by hospital hot water systems. *JAMA* 1988; 260:1599-1601.

21. du Moulin GC, Asiaf JR, Cesaro P, Prewandowski KA, Silva CV, McKeon MM, Koblitz KA: Field evaluations of the Testuria and Selecticult systems for the in vitro screening of bacteriuria. *J. Military Medical Laboratory Science*; 1991; 19:196-198.
22. Pelletier PA, Carney EM, du Moulin GC: Comparative resistance of *Mycobacterium avium* complex and other nontuberculous mycobacteria to chloramine. *Proceedings of the Annual Meeting of the American Water Works Association*. June 1991.
23. du Moulin GC, Hamilton DL, Price JE, Kosik ZJ, Liu VYS, Osband ME: Quality assurance and quality control (QA/QC) in Biocare. Autolymphocyte Therapy as a model. *Biopharm* 1990; 3:30-35.
24. du Moulin GC, Price JE, Shen YJ, Osband ME: Use of the *Limulus* amebocyte lysate assay (LAL) assay in Living Cell Therapies. *Biopharm* 1992; 5:32-37.
25. du Moulin GC, Liu V, Osband ME: Implementation of an effective program for Quality Assurance and Quality Control in Living Cell Therapies: A two year experience with Autolymphocyte Therapy. *Transplantation Proceedings* 1993; 24:2803-2808.
26. du Moulin GC, Stack J, Kruger R, Liu V: Quality Assurance/Quality Control Compliance Program: A Cellular Therapy Developer's Perspective. *Regulatory Affairs* 1993; 5:461-472.
27. du Moulin GC, Stack J, Pitkin Z, et al.: A Review of the Development and Implementation of a model QA/QC System Supporting the Multisite Delivery of a Lymphocyte Based Therapy for Renal Cell Carcinoma: A Three Year Experience. *Biotech Bioengineer* 1994; 43:693-699.
28. Hamilton D, Goodwin, J, Clarke M, du Moulin, G, et al.: Preliminary Validation of an activation assay for *ex vivo* activated T cells utilized in cancer immunotherapy. *Biotech Bioengineer* 1994; 43:700-705.
29. du Moulin GC, Pitkin Z, Shen, Y, et al.: Overview of a Quality Assurance/Quality Control Compliance Program Consistent with FDA Regulations and Policies for Somatic Cell and Gene Therapies: A Four Year Experience. *Cytotechnology* 1994 15:365-372.
30. Montecalvo MA, Forseter G, Tsang AY, du Moulin GC, Wormser GP: Colonisation of potable water with *Mycobacterium avium* complex in homes of HIV-infected patients. *Lancet* 1994; 313:1639-1640 (letter).

31. Slaviv, JD, du Moulin GC, Borden, S, Tabaroni, R, DeProspero, D: Hospital Integrated Lanes Training (HILT): Brigade Directed Implementation of a Medical Lanes Training Program During Annual Training. *Milit. Med.* 1994;159:704-708.
32. du Moulin GC, Haggerty N, Parker WA, Humphrey JC, Tabaroni RF, Slaviv JD: Experiences with Extended Duration Medical Laboratory Support in Deployable Medical Systems. *Milit. Med.* 1996; 161: 521-525.
33. Pitkin, Z, Chhugani P, Chenette A, Shen Y, du Moulin GC: Validation of an Automated Method of Endotoxin Testing for Use in the end product testing of *ex vivo* Activated T-lymphocytes used in a Somatic Cell Therapy. *Biotech and Bioengineer.* 1996;50:541-547.
34. Morohashi M, du Moulin GC, Barone L, Mayer GL: A Case Report on Industrialization of Autologous Chondrocyte Implantation in the United States. *Biopharmacology.* 1997 ;23:568-571.
35. Mayhew T, Williams GR, Senica MA, Kuniholm G, du Moulin GC: Validation of a Quality Assurance Program for Autologous Cultured Chondrocyte Implantation. *Tissue Engineering* 1998; 4:325-334.
36. du Moulin, GC and Morohashi, M: Development of a regulatory strategy for the cellular therapies: An American perspective. *Materials Science and Engineering* 2000; C13:15-17.
37. du Moulin, GC: Some final thoughts. *Regulatory Affairs Focus* 2002; 7:40.
38. du Moulin GC, Entstrasser, CA, Kielpinski GL: Challenges of quality assurance and product release in patient specific technologies. *Regulatory Affairs Focus* 2004; 9:40-42.
39. Kielpinski G, Prinzi S, Duguid J, Price, du Moulin G: Validation of an automated sterility test method for release of autologous cultured chondrocytes for implantation. *Cytotherapy* 2005: 7:531-541.
40. Duguid J, du Moulin G: Automated rapid microbiological methods for the biopharmaceutical industry : Selection, validation and implementation for an autologous cell therapy product. *Am. Pharm Rev.* 2009: 12(3):74-77.
41. Duguid J, Kielpinski G, Seymour B, du Moulin G: Risk assessment for a rapid mycoplasma test optimized for cell therapy products. *Am Pharm Rev.* 2009: 12:100-104.

42. du Moulin GC: Considerations for performing virtual quality audits on manufacturers of gene therapy viral vectors: An auditor's perspective during the COVID-19 public health emergency. *Cell & Gene Therapy Insights*. 2021;7(2):199-210.

43. du Moulin GC: Raw and starting materials for cell and gene therapies. *Cell and Gene Therapy Insights*. 2021; 8(2), 211-217. (DOI:10.18609/cgti.2022.031.

## REVIEWS

1. du Moulin GC, Hedley-Whyte J: A plea for moderation in anesthesia standards. *AORN Journal*. 1977; 25:1025-1028.

2. du Moulin GC, O'Brien AP: Pulmonary tuberculosis in surgical patients. *Survey of Anesthesiology*. 1978; 22:590-591.

3. du Moulin GC, Hedley-Whyte J: Bacterial interactions between anesthesiologists, their patients, and equipment. *Anesthesiology*. 1982; 57:37-41.

4. Hedley-Whyte J, du Moulin GC: The environment of endotracheal tubes in the colonization of the upper airway and development of pneumonia. *Proc. Workshop on Tracheal Tubes*, HFK 310, Bureau of Medical Devices (RC Shupak and TC Deas, eds.), Silver Spring, Department of Health and Human Services. 1982; 91-102.

5. du Moulin GC, Hedley-Whyte J: The stomach as a bacterial reservoir; clinical significance. *Int. Med. for the Specialist*. 1982; 3:47-55.

6. du Moulin GC, Hedley-Whyte J: Hospital-associated viral infection and the anesthesiologist. *Anesthesiology*. 1982; 59:51-65.

7. Bancroft ML, du Moulin GC: Re-evaluating the role of respiratory care equipment and practices in the prevention of nosocomial pneumonia. *Resp. Care*. 1983; 28:165-168.

8. du Moulin GC, Paterson D: The clinical relevance of post mortem microbiologic examination: A review. *Human Pathol*. 1985;16: 539-548.

9. du Moulin GC, Stottmeier KD: Waterborne mycobacteria: An increasing threat to health. *ASM News* 1986;52: 525-529.

10. du Moulin GC, Love W: The value of autopsy microbiology. *Clin. Microbiol. Newsl*. 1988; 10:165-167.

11. du Moulin GC: Minimizing the potential for nosocomial pneumonia: Architectural, engineering, and environmental considerations for the intensive care unit. *Eur. J. Clin. Microbiol.* 1989; 8:69-74.
12. du Moulin GC: Tracheobronchial colonization. *Klin. Wochenschr.* 1991; (Suppl XXVII) 69:6-11.
13. Janoschek R, du Moulin GC: Ultraviolet Disinfection in Biotechnology: Myth vs. Practice. *Biopharm* 1994; 7: 24-31.
14. Ostrowski S, du Moulin GC: Achieving Compliance in Validation and Metrology for Gene and Cell Therapy. *Biopharm* 1995; 8:20-28.
15. Kielpinski G, Kehinde O, Kaplan B, Bonn T, Buxton D, Wescott M., Arangio A, Duguid J, Thyne, C, du Moulin, GC: Quality Control for *ex vivo* Cell Therapy. *Biopharm* 1997; 10:34-40.
16. Omstead D, Baird L, Christenson L, du Moulin G, Tubo R, Maxted D, Davis J, Gentile F: Voluntary Guidance for the Development of Tissue-Engineered Products. *Tissue Engineering* 1998; 4:239-266.
17. du Moulin GC: The potential and challenges of tissue engineering activities in the United States. International Technology Research Institute Workshop on Tissue Engineering Research in the United States. June, 2000.
18. Sentissi A, du Moulin GC: Quality systems for xenotransplantation products. *Regulatory Affairs Focus*, 2000; 35-40 (June).
19. du Moulin GC: The challenges and future of cell therapy and tissue regeneration. *Symposium Proceedings, BioJapan 2000*, 337-346.
20. du Moulin, GC: Cell therapy and tissue engineering: An overview. *Bioprocessing Journal* 2003;2:17-21.
21. Denoya CD, Colgan ST, du Moulin GC: Alternative microbiological methods in the pharmaceutical industry. The need for a new microbiology curriculum. *American Pharmaceutical Review* 2006; 9:10-18.
22. Duguid J, Balkovic, E, du Moulin GC: Rapid Microbiological Methods: Where are they now? *American Pharmaceutical Review* 2011; 13:18-25.

## BOOKS AND MONOGRAPHS

1. du Moulin GC, Lynch SE, Hedley-Whyte J, Broitman SA: The detection of Gram-negative bacteria in the blood of septic rats by a *Limulus* amebocyte lysate assay. In SW Watson, J Levin, TJ Novitsky (eds.), Detection of Bacterial Endotoxins with the *Limulus* Amebocyte Lysate Test, Alan R. Liss, Inc., New York. Prog. Clin. Biol. Res. 1987; 231:349-356.
2. du Moulin GC: Minimizing the potential for infection in the hospitalized burned patient: Architectural, engineering, and environmental considerations. In Acute Management of Burn Trauma, JAJ Martyn (ed.), W.B. Saunders Company, Philadelphia, 1990.
3. du Moulin GC, Mayhew T, Kielpinski G, Citron M, Surgenor T: The Application of Good Manufacturing Practices (GMP) to the Expansion of Human Cell Populations for Cell and Tissue Therapy. in Animal Cell Technology: Basic and Applied Aspects (*Proceedings of the 8th Annual Meeting of the Japanese Association of Animal Cell Technology*). ed. Funatsu K, Shirai Y, Matsushita T, Kluwer Academic Publishers, Dordrecht, 8:19-23, 1997.
4. Schaeffer S, Stone BB, Wolfrum J, and du Moulin GC: "Ex vivo Autologous Cell Therapies" in Biopharmaceutical Process Validation ed. Sofer G, and Zabriskie, D.W., Marcel Dekker Inc. New York, 2000.
5. Expert Committee for Gene Therapy, Cell Therapy and Tissue Engineering. "<1046> Cell and Gene Therapy Products" (General Information Chapter).in United States Pharmacopeia-National Formulary 26, Rockville MD, US Pharmacopeial Convention, pp2257-2285, 2002.
6. du Moulin GC: "Adventitious Agents and Chemical Toxicity" in Methods of Tissue Engineering, ed. Atala, A and Lanza, R. Academic Press, San Diego, 2002.
7. du Moulin GC, Entstrasser CA, Kielpinski G: "Quality control in producing cells for tissue engineering". In Tissue Engineering in Musculoskeletal Clinical Practice. American Association of Orthopaedic Surgeons. Rosemont, IL, 2004.
8. Expert Committee for Gene Therapy, Cell Therapy and Tissue Engineering. "<1043> Ancillary Materials for Cell, Gene and Tissue Engineered Products" (General Information Chapter).in United States Pharmacopeia-National Formulary 29, Rockville MD, US Pharmacopeial Convention, pp.2814-2821, 2006.

9. du Moulin GC, Kielpinski G, Prinzi S, Duguid J, and Price A: "Detection of microbial contaminants for cell therapy products: Validation of an automated microbial detection system" in Encyclopedia of Rapid Microbiological Methods, ed. Miller M., Parenteral Drug Association, Bethesda, MD, pp273-290, 2005.
10. Expert Committee for Gene Therapy, Cell Therapy and Tissue Engineering. "<1024> Bovine Serum" (General Information Chapter). *Pharmacoepial Forum* 35(3) 629-647, 2009.
11. du Moulin GC: "Approaches to validation for cellular therapy products. In Cellular Therapy: Principles, Methods, and Regulations. Ed. Areman EM and Loper K. American Association of Blood Banks. Bethesda, MD, 2009.
12. Expert Committee for Gene Therapy, Cell Therapy and Tissue Engineering. "<90> Fetal Bovine Serum – Quality Attributes and Functionality Tests. *Pharmacoepial Forum* 35(5) 1219-1224, 2009.
13. Houck T and du Moulin GC: "Approaches to validation for cellular therapy products. In Cellular Therapy: Principles, Methods, and Regulations. (2<sup>nd</sup> edition) Ed. Areman EM and Loper K. American Association of Blood Banks. Bethesda, MD, 2016.
14. Duguid J, Khuu H, and du Moulin GC: "Assessing cellular therapy products for microbial contaminants". In Cellular Therapy: Principles, Methods, and Regulations. (2<sup>nd</sup> edition) Ed. Areman EM and Loper K. American Association of Blood Banks. Bethesda, MD, 2016.
15. USP, Modern Microbiological Methods Expert Panel. The development of compendial rapid sterility tests (Stimuli to the Revision Process). *Pharmacoepial Forum*, Vol 43 (5), 2017.
16. du Moulin GC: Regenerative Medicine Advanced Therapies: Phase Appropriate Good Manufacturing Practices. In Phase Appropriate Good Manufacturing Practices for Biological Processes. Ed. Deeks T, Parenteral Drug Association, Bethesda, MD, pp 341-397, 2018.
17. Balkovic E and GC du Moulin: Competency based training approach for microbial identifications. In Microbiological Identifications: Vol 2, Ed. Reber D. and Griffin M, Parenteral Drug Association, Bethesda, MD, pp 457-492, 2018.



## ABSTRACTS

1. Klick JM, du Moulin GC, Hedley-Whyte J, Teres D, Bushnell LS, Feingold DS: Prevention of Gram-negative bacillary pneumonia with polymyxin B aerosol. *Crit. Care Med.* 1975; 3:38.
2. du Moulin GC, Lynch SE, Hedley-Whyte J: Utilization of the *Limulus* amebocyte lysate assay in the rapid diagnosis of Gram-negative bacteremia. *Fed. Proc.* 1978; 37:319.
3. du Moulin GC, Friedland G, Indorato K, Stottmeier KD: Contamination of mycobacterial specimens with a waterborne strain of *Mycobacterium avium*. *Abstr. 78th Ann. Meeting Am. Soc. Microbiol., Washington, D.C.* 1978; p.206.
4. du Moulin GC: Lower respiratory tract colonization of seriously ill patients by a waterborne strain of Flavobacterium. *Abstr. 78th Ann. Meeting Am. Soc. Microbiol. Washington, D.C.* 1978; p.285.
5. Dasse P, Boyle C, du Moulin GC, Stottmeier KD, Friedland G: Pseudoepidemic traced to contamination of clinical specimens by waterborne atypical mycobacteria. *Abstr. Assoc. for Practitioners in Inf. Control, 1979 APIC Journal.* 1979; 7:29-30.
6. du Moulin GC, Lynch SE, Bousquet FB III, Hedley-Whyte J: Inability to reproduce bacteremia in rats paralyzed and ventilated with nitrous oxide and oxygen. *Fed. Proc.* 1979; 38:1002.
7. du Moulin GC, Lynch SE, Chien, N, Hedley-Whyte J: Gram-negative bacteremia and the *Limulus* amebocyte lysate assay (LAL). *Fed. Proc.* 1980; 39:1178.
8. du Moulin GC, Doyle GO, MacKay J, Hedley-Whyte J: Biofouling by *Pseudomonas fluorescens* of a hospital closed loop cooling system. *Abstr. 80th Ann. Meeting Am. Soc. Microbiol., Washington, DC.* 1980; p. 179 (N94).
9. du Moulin, GC, Sherman IH, Stottmeier KD: *Mycobacterium intracellulare*; an emerging pathogen in Massachusetts. *Abstr. 81st Ann. Meeting, Am. Soc. Microbiology, Washington, DC.* 1981; p.269 (C43).
10. Somersille CS, du Moulin GC, Hedley-Whyte J: *E. coli* peritonitis after C3 depletion: sensitive assay of chemotactic behavior based on species differences. *Fed. Proc.* 1982; 41:325.

11. du Moulin GC, Merrill A, Sherman IH, Stottmeier KD: *M. avium-intracellulare* in Massachusetts. *Abstr. 82nd Ann. Meeting, Am. Soc. Microbiology*, Washington, DC. 1982; p.305 (C202).
12. du Moulin GC, Laasberg LH, Lynch SE, Hedley-Whyte J: Effect of naloxone and morphine on plasma leu and met enkephalin in rats with *E. coli* peritonitis. *Fed. Proc.* 1982; 42:301.
13. du Moulin GC, Jaciow D, Teres D, Stottmeier KD: Significance of respiratory isolates of *Mycobacterium avium-intracellulare* (MAIC). *Abstr. 23rd Interscience Conference on Antimicrobial Agents and Chemotherapy*. Am. Soc. Microbiology, Washington DC. 1983; p.278 (1048).
14. du Moulin GC, Paterson D, Hedley-Whyte J: *E.coli* peritonitis is a cause of increased blood-brain barrier permeability. *Fed. Proc.* 1984; 43:381.
15. du Moulin GC, Lynch SE, Hedley-Whyte J, Broitman SA: Reticuloendothelial clearance of radiolabeled *E. coli* in experimental peritonitis and bacteremia. *Abstr. 85th Ann. Meeting, Am. Soc. Microbiology*, Washington, DC. 1985; p.29 (B66).
16. du Moulin GC, Coleman EC, Hedley-Whyte J: Bacterial colonization and endotoxin content in a new renal dialysis water composed of acrylonitrile butadiene styrene (ABS). *Fed. Proc.* 1986; 45:639.
17. du Moulin GC, Skea WM, Bartolini BA: Microbiologic assessment of drinking water potability during brigade operations. *Abstr. 11th Ann. Meeting, Soc. Armed Forces Med. Lab. Scientists.* 1986; 15:18.
18. du Moulin GC, Coleman EC, Tsang AY, Stottmeier KD: Contamination of drinking water supplies with *Mycobacterium avium* complex (MAC). *Abstr. 26th Intersci. Conf. Antimicrobial Agents and Chemotherapy*, New Orleans, LA. 1986; p.297 (1101).
19. Pelletier PA, Gates SG, Carney EM, du Moulin GC: Comparative resistance of waterborne mycobacteria to chlorine. *Abstr. 87th Ann. Meeting Am. Soc. Microbiol.*, Atlanta, GA, 1987; p. 250 (N33).
20. Johnston LC, du Moulin GC: Microbial impact to public drinking water supplies by nonmigratory Canada geese. *Abstr. 87th Ann. Meeting, Am. Soc. Microbiol.*, Atlanta GA, 1987; p.249 (N29).
21. De Girolami PC, Tsang AY, du Moulin GC, Rose R, Sisson G, Stottmeier KD: Serovars of *Mycobacterium avium* complex isolated from patients with AIDS. *Abstr. 87th Ann. Meeting Am. Soc. Microbiol.*, Atlanta, GA, 1987; p.128 (V12).

22. Gates SG, du Moulin GC, Hindman B, Hedley-Whyte J: Survival of bacteria in anesthesia breathing circuits. *Fed. Proc.* 1987; 46:1303 (5755).
23. du Moulin GC, Skea WM: Contamination of a lake by sewage effluent caused by increased military activity. *Abstr. 12th Ann. Meeting, Soc. Armed Forces Med. Lab. Scientists.* 1987; 16:18.
24. Doos WG, Orf HW, Seder RH, Jordi H, Skea WM, du Moulin GC: Field trials of four chemistry analyzers. I. Mobile medical laboratory deployment. *Abstr. 12th Ann Meeting, Soc. Armed Forces Med. Lab. Scientists.* 1987; 16:15.
25. Orf HW, Seder RH, Doos WG, Jordi H, Skea WM, du Moulin GC: Field trials of four chemistry analyzers. II. Quantitative evaluation. *Abstr. 12th Ann. Meeting Soc. Armed Forces Med. Lab. Scientists* 1987; 16:21.
26. Seder RH, Doos WG, Orf HW, Jordi H, Skea WM, du Moulin GC: Field trials of four chemistry analyzers. III. Qualitative evaluation. *Abstr. 12th Ann. Meeting, Soc. Armed Forces Med. Lab. Scientists.* 1987; 16:22.
27. Pelletier PA, du Moulin GC: Comparative resistance of waterborne mycobacteria to chloramine. *Abstr. 88th Ann. Meeting, Am. Soc. Microbiol.* 1988; p.256 (N-71).
28. Pelletier PA, du Moulin GC, Stottmeier KD: Prevalence of mycobacteria in a renal dialysis water system. *Abstr. 88th Ann. Meeting, Am. Soc. Microbiol.* 1988; p. 413 (L-12).
29. George DM, du Moulin GC, Carney EM: Comparative evaluation of a renal dialysis ultrapure water system using epifluorescence microscopy, R2A media, millipore SPC samplers, and LAL assay. *Abstr. 88th Annual meeting, Am. Soc. Microbiol.* 1988; p.413 (L-15).
30. Love W, MacHarrie D, Patton J, du Moulin GC: Assessment of the civilian contract training program for medical laboratory technicians in army reserve units. *Abstr. 13th Ann. Meeting, Soc. Armed Forces Med. Lab. Scientists.* 1988; 17:21.
31. Hindman B, Johnston L, du Moulin GC, Hedley-Whyte J: Transmission of bacterial aerosols from anesthesia machines. *Fed. Proc.* 1988; 2A1397 (Abstr. 6398).
32. du Moulin GC, Stottmeier KD, Pelletier PA, Hedley-Whyte J: Waterborne *Mycobacterium avium* is amplified by growth in hospital hot water systems. *Proc. International Congress Infect Dis.* 1988; p.197 (Abstr. 226).

33. du Moulin GC, Stottmeier KD, Pelletier PA: Health effects of mycobacteria in public water supplies. *Abstr. 116th Ann. Meeting, Am. Public Health Association.* 1988; p.118 (Abstr. 2034).
34. Duray PH, du Moulin GC, Boucher L, Splitz A: The cultivation of *Borrelia* in a mobile field laboratory. *Abstr. 14th Ann. Meeting Soc. Armed Forces Med. Lab. Scientists.* 1989;18:4.
35. du Moulin GC, Calhoun BH, Fisher SL, Duray PH: The field medical laboratory configured to investigate the epidemiology of Lyme borreliosis. Operational concepts and concerns. *Abstr. 14th Ann. Meeting Soc. Armed Forces Med. Lab. Scientists.* 1989;18:3.
36. du Moulin GC, Hamilton DL, Price JE, Osband ME: Quality assurance/quality control (QA/QC) issues in adoptive immunotherapy. *Abstr. Proc. 4th Ann. Conf. on Clinical Immunology* 1989. (Abstr #9).
37. Price JE, Shen YJ, du Moulin GC, Osband ME: Safe processing of autologous lymphocytes for therapeutic use: Use of the *Limulus* amoebocyte lysate test for endotoxin testing. *Abstr. 90th Ann Meeting, Am Soc. Microbiol.* 1990.
38. Chow A, du Moulin GC: Demonstration of *in vitro* antimicrobial activity of *Schisandra chinensis* against strains of *Mycobacterium avium* isolated from environmental water sources and patients with AIDS. *Abstr. Proc. International Cong Infect. Disease.* 1990,pg 38 (abstract 527)
39. Koblitz KA, Arpin JA, Boulanger CD, du Moulin GC: Evaluation of a cold water procedure to clean and sanitize eating and kitchen utensils in a tactical field environment. *Abstr. Proc. 15th Ann. Meeting Soc. Armed Forces Med. Lab. Scientists.* 1990; 19:55 (P-15).
40. Wormser G, Forseter G, Montecalvo MA, Tsang AY, du Moulin GC: Recovery of *Mycobacterium avium* complex (MAC) from the home tap water of HIV-infected patients in New York State. *31st Interscience Conference on Antimicrobial Agents and Chemotherapy.* 1991,pg 38 (abstract 240).
41. du Moulin GC, Hamilton D, Oommen S, Osband ME: Development of an effective diagnostic laboratory program to support the adoptive immunotherapy of cancer. *Fed Proc* 1992; 6:2886.
42. du Moulin GC, Cyr C, Chew-Darke J, Pitkin Z, Stack J, Osband ME, Torres B: Intrinsic contamination by *Bacillus* in blood culture media: Implications for Quality Control in adoptive immunotherapy. *Proc 1992 Ann Meeting Am Soc Microbiol.*1992; 436 (C-95).

43. Eylath A, du Moulin GC, Cyr C, Pitkin Z, Shen Y, Liu V, Osband ME: Validation of the Isolator "Isostat" Microbial System for sterility testing of cells in adoptive immunotherapy. *Proc. 1992 Ann. Meeting Am. Soc. Microbiol.* 1992; 428 (C-48).
44. Borden S, du Moulin GC, Foehr D: Beyond Regional Training Sites: DEPMEDS training for Army medical personnel is enhanced when RTS equipment training is augmented at unit level by integration of the DOD DEPMEDS Clinical Treatment Policies and Data Base. *Soc Armed Forces Med Lab Scientists Proceed.* 1992; 21:50 (DS-8).
45. du Moulin GC, Hamilton D, Oommen, C. Osband ME: Development of an effective diagnostic laboratory program to support the adoptive immunotherapy of cancer. *Cell Transplantation* 1992; 1:107 (16).
46. du Moulin GC, Liu V, Eylath A, Cyr C, Pitkin Z, Shen YJ, Osband ME: Testing of living cells for sterility and endotoxin prior to patient infusion. *Cell Transplantation* 1992; 1:107 (17).
47. Ross SD, Liu V, du Moulin G, Osband ME: Challenges in performing clinical trials using living cell therapies. *Cell Transplantation* 1992; 1: 233 (256).
48. du Moulin GC, Borden S, Foehr D, Sullivan J, Paul C, DePriest O, Chabior L, Petrangelo J, Andrade L, Allison D, Martinez-Dickerson S: Hospital Integrated Lane Training (HILT): Review of initial implementation for a combat support hospital (CSH) during annual training. *J Milit. Med. Lab. Sci.* (22, 1993).
49. Borden S, Foehr D, du Moulin GC: Hospital Integrated Lane Training (HILT). *J. Milit. Med. Lab Sci.* (22, 1993).
50. du Moulin GC, Liu V, Chew-Darke J, Conti E, Cyr C, Peart J, Pitkin Z, Shen Y, Stack J, Hamilton D, Davies B, White A, and Osband ME: Implementation of an effective program for quality assurance and quality control in living cell therapies. A 2 year experience with autolympocyte therapy. *Proc. Amer Chem Soc* (Abstract #120, 1993).
51. Clarke MB, du Moulin GC, Gaines D, Liu V: Validation of sterility testing media used in the autolympocyte therapy of cancer: Application of Quanti-Cult System. *Proc 1993 Meeting Am Soc Microbiol* (Q276, 1993).
52. Miesowicz F, du Moulin GC, Liu V, Hamilton D, Davies B, Pitkin Z, Stack J, Chew-Darke J, and Osband ME: Development and Implementation of Delivery and Quality Control System for Cellular Therapies: Experience in 500 Patients. *Cell Transplantation* 1994:3:S53.

53. Cyr C, Pitkin Z, Shen Y, du Moulin GC: Evaluation of an Automated Method of Endotoxin Testing for Use in the End Product Testing of *ex vivo* Activated T-Lymphocytes Used in the Adoptive Immunotherapy of Cancer. *Proceedings of the Cell Transplant Society*:1994, 3:238 (108).
54. Pitkin Z, Cyr C, Shen Y, Perkins R, du Moulin GC. Quality Control Sterility Testing Program for *ex vivo* Activated Lymphocytes: Recovery of *Propionibacterium acnes* (*P. acnes*) From Apheresis Cell Product (ACP). *Proceedings of the Cell Transplant Society* :1994, 3:222 (46).
55. Pitkin Z, Chhugani P, Shen Y, Chennette A, du Moulin GC: Validation of an automated method of endotoxin testing for use in the end product testing of *ex vivo* activated T lymphocytes used in the adoptive immunotherapy of cancer. *Proc 1995 Am Soc Microbiol.* (1995).
56. du Moulin GC, Mayhew T, Kielpinski G, Citron M, and Surgenor T: The application of Good Manufacturing Practices (GMP) to the Expansion of Human Cell Populations for Cell and Tissue Therapy. *Proc. Eighth Annual Meeting of the Japanese Association for Animal Cell Technology* (1995).
57. Mayhew T, du Moulin GC, Williams R, Garcia R, Entstrasser C, Peart J: Quality Assurance for Cells Manipulated *ex vivo* for Autologous Transplantation. *Proceedings of the 1996 Annual Meeting of the American Association of Tissue Banks.* (1996).
58. du Moulin GC : Aspects of Quality Control/Quality Assurance for Cell and Tissue Based Therapies. *Proceedings of the 1st Annual Meeting, Process Development and Production Issues for Cellular Therapy and Tissue Engineering - The Williamsburg BioProcessing Foundation* (1996).
59. Buxton D, Thyne C, Kielpinski G, Hendricks A, Buonopane M, Deshield N, and du Moulin GC: Initial Evaluation of the Difco ESP System for Use in Sterility Testing of *ex vivo* Cultured Autologous Chondrocytes for Transplantation. *Proceedings of the 97th General Meeting of the American Society for Microbiology* (1997).
60. Buxton D, Kielpinski G, Hendricks A, Deshield N, Prinzi S, Galvez G, Lessor J, Antohi M, Araneda M, Buonopane M, and du Moulin GC: Evaluation of Media in USP Sterility Testing of *ex vivo* Cultured Autologous Chondrocytes and Keratinocytes for Transplantation. *Proceedings of the 97th General Meeting of the American Society for Microbiology* (1997).
61. Buxton D, Kielpinski G, Hendricks A, Deshield N Buonopane M, Prinzi S, Galvez G, Lessor J, Antohi M, Araneda M, Kehinde O, Thyne C, Hall A, and du Moulin GC: Management of Microbial Colonization of *ex vivo* Cultured

Autologous Keratinocytes for Transplantation. *Proceedings of the 97th General Meeting of the American Society for Microbiology (1997)*.

62. Mayhew T, Williams GR, Lang K, Senica M, Voelksen R, Entstrasser C, du Moulin GC: Quality Assurance for Cells and Tissues Cultured *ex vivo* for Autologous Transplantation. *1st Annual Smith and Nephew International Symposium - Advances in Tissue Engineering and Biomaterials*, University of York, England, (S5) 1997.
63. du Moulin GC, Mayhew T, McCormack S, Kielpinski G, R Voelksen: Development of a Quality Assurance Program for Autologous Chondrocyte Implantation Based Upon the Commission of the European Communities (EEC) "Guide to Good Manufacturing Practice for Medicinal Products". *Proceedings of the 7th Annual Meeting of the European Tissue Repair Society*, Cologne, Germany 1997.
64. du Moulin GC, Mayhew T, Williams R, Mc Cormack S, Senica M, Kuniholm G, Nowowieski P, Voelksen R: Evaluation of a Quality Assurance Program for Autologous Chondrocyte Implantation. *Proceedings of the 2nd European Tissue Repair Society Consensus Meeting* Freiberg, Germany 1997.
65. Wolfe L, and du Moulin G: Manufacturing and Quality Systems for Autologous Cultured Chondrocytes. *Proceedings of the Annual Meeting of the American Chemical Society*, Boston, 1998.
66. Macchi M, Bonn T, Wolfrum J, Roth M, Arangio A, Larson E, Fairweather B, Apostol G, Zheng R, DeFranzo B, du Moulin G, and Kielpinski G: Use of a Modified Biological Reactivity Test as a Lot Release Assay for Autologous Cultured Chondrocytes: An Alternative to the General Safety Test. *Proceedings of the Annual Meeting of the Parenteral Drug Association*, Washington, DC, 1998.
67. Peterson L, Surgenor T, Cummings J, du Moulin GC: Carticel Cell Therapy: From Research to the Market. *Abstr. 219<sup>th</sup> Meeting of the American Chemical Society*, San Francisco, CA, 2000.
68. du Moulin GC, Barone L, Resink M, Entstrasser C, Kielpinski G, Mc Cormack S: A Quality Assurance/Quality Control compliance program for autologous chondrocyte implantation: A 4,000 patient experience. *Abstrs. of the 3<sup>rd</sup> Annual Meeting*, International Cartilage Repair Society, Gothenberg, Sweden, 2000.
69. du Moulin GC, Entstrasser C, Kielpinski G, Barone L, McCormack S: A Quality Assurance/Quality Control compliance program for autologous chondrocyte implantation: A 3,600 patient experience. *Abstr. of the International Workshop on Bio-integrated Materials and Tissue Engineering*, Tsukuba, Japan, 2000.
70. du Moulin GC: Biologics (In Focus Department), *Regulatory Affairs Focus* (pg 2), June, 2000.

71. du Moulin GC: Quality Systems for autologous chondrocyte implantation: A 5,000 patient experience with Carticel. *Proceedings of the 2<sup>nd</sup> Symposium of Recent Advances in Cartilage Repair and Tissue Engineering*. Portoroz, Slovenia, 2001.
72. du Moulin GC: Lessons learned in the scale-up of quality systems for a cell therapy: An 8,000 patient experience with autologous chondrocyte implantation. *Proceedings of the Standardization of Quality Control of Cell and Gene Therapy Products*. European Directorate for the Quality of Medicines, Strasbourg, France, 2003.
73. Kielpinski G, Prinzi S, Duguid J, Price A, and G du Moulin. Automated sterility testing: An alternative approach to compendial sterility testing of cell therapy products. *Proceedings of the International Society for Cell Therapy Annual Meeting*. Phoenix, AZ 2003.
74. Kielpinski G, Bonn T, Maria M, LaForest R, Schutz B, Lessor J, Duguid J, and G du Moulin. Use of a polymerase Chain Reaction (PCR) mycoplasma assay as a drug product component release test for a cell therapy cancer vaccine product. *Proceedings of the 10th International Society for Cell Therapy Annual Meeting*, Dublin, Ireland 2004.
75. Prinzi S, Duguid J, Kielpinski G, Araneda M, Galvez G, Ostrovskaya T, du Moulin G. Automated Rapid Microbial Detection for an autologous cell therapy: A twelve month review of sterility testing data. *Proceedings of the 2006 AAPS Annual Meeting and Exposition*, San Antonio Texas, 2006.
75. du Moulin GC, Prinzi S, Kielpinski G, Araneda M, Galvez, Ostrovskaya T, Duguid J. Automated rapid microbiological detection for the pharmaceutical industry. Experience with validation and implementation for an autologous cell therapy product. *New Microbiology Chapter of the European Pharmacopeia*. European Directorate for the Quality of Medicines, Strasbourg, France, 2006.
76. Duguid J, Prinzi S, Kielpinski G, Galvez G, Ostrovskaya T, du Moulin G. Automated rapid microbial detection for an autologous cell therapy: A twelve month review of sterility testing data. *Proceedings of the 13<sup>th</sup> Annual International Society for Cell Therapy*, Sydney Australia, 2007.
77. Duguid J, Kielpinski G, du Moulin G, Seymour B. Application of a risk based approach to optimize a rapid mycoplasma test for cell therapy and tissue-engineered products. *Proceedings of the American Association of Pharmaceutical Scientists*, 2008.



78. Kielpinski GL, Parker A, Dethlefsen S, O'Brien C, Wicks J, Dono D, du Moulin G, Skrabut EM. Compatibility of anti-infective agents with cultured epidermal autografts: An in vitro assessment of cytotoxicity. *Proceedings of the 42<sup>nd</sup> Annual Meeting of the American Burn Assn*, 2010.

79. Balkovic E and du Moulin GC. Biocide effectiveness for the elimination of *Acinetobacter baumannii* from work surfaces in biopharmaceutical manufacturing. *Proceedings of the 114th General Meeting of the American Society for Microbiology* (2014).