

Charles Harmon Pierce, MD, PhD, FCP, CPI

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Overall Experience:

20+ years administrative & educational activity in the Medical Research Industry
40+ years practice of medicine as a Family Physician (ABFP 1977-1994)
40+ years teaching, research and practice with an interest / expertise in Asthma
35+ years activity in Continuing Medical Education
35+ years in "Clinical Pharmacology" (FCP in '74)

Education:

McGill University, Department of Pharmacology and Therapeutics. Post-Doctoral year, 1971 - 1973, with Mark Nickerson, Ph.D., M.D.

University of Saskatchewan, College of Graduate Studies (Surgery), **Ph.D., 1974**
Thesis: "An Inquiry into the Nature of Circulatory Shock: Development and Use of an Experimental Model Utilizing Controlled Cardiac Tamponade." Advisors: Eric M. Nanson, M.B., Ch.B.; John R. Gutelius, M. D.; and Fred G. Inglis, M. D.

University of Saskatchewan, College of Medicine, 1965 - 1968, **M.D., 1968**

University of Minnesota, Graduate School (Pharmacology), **M.Sc., 1961**
Thesis: "Effects Upon Respiratory Function of a Meperidine Derivative Using a New Experimental Approach" Advisor: Raymond N. Bieter, M.D., Ph.D.

University of Minnesota, College of Science, Literature and Arts - **B.A., 1956**

Memberships:

Member, Association of Clinical Pharmacology Units, Elected Trustee 2007-2011

Fellow, American Coll. of Clinical Pharmacology, 1974: Elected Regent 1995 - 2000; Annual meeting chairman, September 2001; Emeritus, July 2002; Recipient of the Nathaniel T. Kwit Memorial Distinguished Service Award - 2004

Member, American Academy of Pharmaceutical Physicians (AAPP) now the Academy of Pharmaceutical Physicians and Investigators (APPI), 1997 -

Fellow, American Academy of Family Physicians, elected 1988, Member since 1979, and Life Member 2001

Member, Canadian Society for Clinical Pharmacology, 1982 -

Charter Member, American Society of Hypertension, 1986

Medical Licensure:

State Medical Board of Ohio, (8-2173) Jan 2003 - 2012

DEA Registration (BP8369818) July 2003 - Jul 2012

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Positions/Appointments:

- Medical Director, CTI Clinical Research and Consulting Services, Cincinnati, OH 2006
- Medical Monitor, Ethicon Endo-Surgery, Clinical Trial Department
- Executive Director, Medpace Clinical Pharmacology Unit, March 2006-January 2007
- President, Pierce One Consulting, Cincinnati, Ohio July 2000 to the Present
- Adj. Assoc. Professor, Department of Psychiatry, College of Medicine, University of Cincinnati. December 2005 - present
- Board of Directors, Annapolis Center for Science-Based Public Policy, Annapolis, MD
- VP, Medical Affairs, N.A., Harrison Clinical research, München, Germany, May 01-
- Adj. Professor of Pharmaceutical Sci., and Adj. Asst. Professor, University of Cincinnati, Colleges of Pharmacy and Medicine respectively. Cincinnati, Ohio, Aug, 2000 to July 2003
- Associate Director, Clinical Trials Office of the Cincinnati Children's Hospital Medical Center, Cincinnati, Ohio, Nov., 2000 – July 2003
- Sr. VP & Chief Operating Officer, Phoenix International Life Sciences (US) Inc. Cincinnati, Ohio and Neptune, New Jersey; June, 1999 - April, 2000
- Director of Medical Affairs, MDS Harris Laboratories, Lincoln, NE. April 97 - Feb, 1999
- Medical Director & Principal Investigator, L.A.B. Pharmacological Research Intl. Ltd., Vaudreuil, Québec (formerly Clinical Research division of Bio-Research Laboratories Ltd. of Senneville (Montréal), Québec); Dec. 1989 - Apr 1997
- Attending Staff, Department of Medicine and Pediatrics, Medical Center Hospital of Vermont, Burlington, Vermont, 1985 - 1989
- Active Staff, Dept. of Family Medicine, Doctors Hospital, Toronto, Ontario, and the County of Bruce General Hospital, Walkerton, Ontario 1983 -1985
- Active Member, Council of Physicians & Dentists at St. Mary's Hospital, Department of General Medicine, Montréal, 1977 - 1982
- Consulting Member (Clinical Pharmacology) Council of Physicians of the Montréal Heart Institute, Montréal, Québec, 1976 - 1982
- Assistant Professor, Department of Family Medicine, McGill University, Montréal, Québec, 1977 - 1979
- Member, Council of Physicians & Dentists of the SMBD-Jewish General Hospital, Department of Family Medicine, Montreal, Quebec 1976-79
- Assistant Professor, Department of Pharmacology, University of South Alabama College of Medicine, Mobile, Alabama, 1974 - 1976
- Active Staff, Department of Family Practice, University of South Alabama Medical Center, Mobile, Alabama, 1974 - 1976

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Medical Practice / Clinical Experience:

- Family Practice including Emergency room (E) 1974 - Present
 - 2006 - Present, Urgent Care, Cincinnati, Ohio
 - 2003 - 2006, Cincinnati, Ohio; Montréal, Québec
 - 1990 - 1997, Montréal, Québec (part time)
 - 1985 - 1989, Burlington, Vermont
 - 1982 - 1985, Toronto, Ontario (E)
 - 1976 - 1982, Montréal, Québec (E)
 - 1974 - 1976, Mobile, Alabama (part time)
- Staff Physician, Doctors Hospital, Toronto, Ontario and County of Bruce General Hospital (Emergency Room), Walkerton, Ontario, 1982 - 1985
- Staff Physician, Family Medicine Center (1977-1979) and Emergency Room (1977-1981) at St. Mary's Hospital, Montréal, Québec
- Staff Physician, General Medical Clinic and Hertzl Family Practice Center of the SMBD-Jewish General Hospital, Montréal, Québec, 1976 - 1977
- Attending Physician and Director, Mobile County Jail Medical Department, Mobile, Alabama, 1975 -76
- Staff Physician, Veterans Administration Ambulatory Care Clinic and the University of South Alabama Medical Center, Mobile, Alabama, 1974 - 1976
- Clinical Pharmacology Hypertension Clinic, Montréal General Hospital, Montréal, Québec, 1973 - 1974
- Intern (Rotating) University Hospital, University of Saskatchewan, Saskatoon, Saskatchewan, 1968-69

Certifications:

- AAPP (APPI) Certified Physician Investigator (CPI - #15) 9 November, 2003
- SPEX examination (S21792098 / 25565) January, 2003
- Diplomat of the American Board of Family Practice, (#133881), 1977-1994
- Advanced Cardiac Life Support Instructor, 1980, 1982, 1984 (OHF #9072), 1986
- Basic Cardiac Life Support Instructor Trainer (#1076) June, 1982
- Advanced Cardiac Life Support, 1979, 1981
- Licentiate, Medical Council of Canada (LMCC), (#28642), 1969
- National Board of Medical Examiners: (#69526) Part I, 1964; Part II, 1969

Interests and Hobbies

Competitive Squash, Classical music, and Photography

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Honors:

Board of Directors, Association of Clinical Pharmacology Units, 2006 on
Nathaniel T. Kwit Distinguished Service Award for 2004 from the ACCP
Board of Directors, The Annapolis Center for Science-Based Public Policy, 2002 on
Regent of the American College of Clinical Pharmacology - elected for 1995 - 2000
Affiliate Faculty - ACLS, Ontario Heart Foundation, 1984 - 1985
Research Fellow, Canadian Heart Foundation, 1969 - 1973
Assoc. Editor, Canad. Assoc. of Medical Students and Interns Journal, 1967 - 1968
President, Students Medical Soc., U. Saskatchewan Coll. of Medicine, 1967 - 1968
Captain, Univ. of Minn. Squash Racquets B Team, League Champions, 1964 - 1965
Sigma Delta Psi - National Honorary Athletic Fraternity, elected 1957
President, Theta Delta Chi Academic Fraternity, 1955 - 1956

Medical/Professional Committees:

Member, APPI Education Committee and Publications Committee 2000 - 2005
Chair, ACCP 2001 Annual Meeting, September 2001, Tysons Corner, Virginia
Member, Academy of Medicine of Cincinnati CME committee. 2000 - 2001
Member, ACCP - ACCME Committee, 1997 to 2003
Chair, Clinical Research Seminars Committee of the AAPP 1997 - 2000
Chair, Membership Committee, ACCP, 1996 to 2000
Member, The Vermont Formulary Committee, 1987 – 1989
Member, Pharmacy & Therapeutics Committee, MCHV, Burlington, Vermont, 1986-89
Chair, Pharmacy & Therapeutics Committee, Doctors Hospital, Toronto, 1985
Member, Therapeutics and Infection Control Com., Doctors Hosp., Toronto, 1983 - 84
Chair, Pharmacology & Therapeutics Committee, St.Mary's Hosp, Montreal, 1977-82
Chair, Pharmacy & Therapeutics Committee, Univ. of So. Alabama Med Center, 1975

Community Activities:

Rotary Club of Cincinnati (Club # 17) Ohio – Sept 1999 - Present
Rotary Club of Lincoln (Club # 14) Nebraska – July 1997 - July 1999
Paul Harris Fellow, July 1999
Rotary Club of Westmount (Québec) - Jan 1990 - July 1997
Director, 1991 - 1993, 1994 – 1996, President 1996 – 1997
Rotarian of the Year for 1990 - 1991
Rotary Club of Burlington (Vermont) - July 1985 - December 1989
Board of Directors 1987 – 1989, President Elect 1989
Rotarian of the Year for 1987 - 1988
Rotary Club of Toronto Eglinton - Sept 1981 - June 1985
Rotary Club of Westmount (Québec) - Oct 1979 - Sept 1981

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Continuing Medical Education Activities:

Featured speaker - More than a dozen Webinars about the GCP of Clinical Research including Investigator Responsibility, Good Documentation Practices, and many others. Sponsors include: ComplianceOnline, CompliancePanel and FDA News, 2008, 2009

Major speaker at a Clinical Research training session at the Medimmune facility in Cambridge, England sponsored by the ECCRT, Brussels, Belgium, February 2008

Keynote Speaker, "Bringing Research to the Forefront", a Clinical Research Symposium sponsored by the Grand Rapids Education Research Center, Grand Rapids, MI, 15 Mar 2007

Advisory Board and Speaker, International Workshop on the GCP of Clinical research in Hyderabad, India, July 28 – 29 2006

Session Chair - Clinical Track of the Canadian DIA in Montréal, Québec, 25-27 Sept 2005

Advisory Board and Speaker of the International Workshop on "Fundamentals of Clinical Trails & GCP held in Hyderabad, India, August 5-6, 2005

Course Director of "The Clinical Research Puzzle II: Putting the Pieces Together" a day and a half course on GCP aimed at protecting the integrity and rights of human subjects. May 31 – June 1, 2002

Course Director of "Insuring Human Subject Safety: A Clinical Investigator's Workshop" - a One day course on the ethics and science of clinical research of the Academy of Medicine of Cincinnati. January 13, 2001

Chairman of "Asthma Therapy in the Next Decade - Hang on to Your Hats" an ACCP/CSCP joint symposium at the Royal College of Physicians and Surgeons meeting. September 23 - 27, 1998 in Toronto, Ontario

Chairman of "Changing Face of Asthma Therapy in the Next Decade" a symposium at the annual ACCP meeting. September 18 - 20, 1997 in Phoenix, Arizona

Course Director of "Advanced Cardiac Life Support" – three, two day courses sponsored by The Doctors Hospital and the Ontario Heart Foundation, Toronto, Ontario. June & November 1984 and June, 1985

Course Director of "Advanced Cardiac Life Support" – three, one and one-half day courses sponsored by the Department of General Medicine of St. Mary's Hospital and the Québec Heart Foundation, Montréal, Québec. December 1980 and April & October, 1981

Course Director of "What's new in Drug Therapy" - a CME offering at the annual meeting of the American Academy of Family Physicians, New Orleans, Louisiana. October 1980

Course Director of "G.I. Clinical Day - Practical Answers to Problems of the Upper G.I. Tract in Office Practice" - a one-day course - Hotel Bonaventure, Montréal, Québec. Sept. 1979

Course Director of "Consultations in Hypertension" - a one-day workshop at St. Mary's Hospital, Montréal, Québec. February 1978

Course Director of "Pulmonary Disease in Office Practice" Second in a series on Practical Answers to problems in Primary Care, a one and one-half day course at the SMBD-Jewish General Hospital, Montréal, Québec. November 1977

Course Director of "Rational Use of Antibiotics" and "Practical Management of Hypertension," two, AMA regional CME courses, Marquette, Michigan. Aug 1977 and Cardiovascular Drug Therapy - An Update". A one day AMA regional CME course, Birmingham, Alabama. Feb 1977

Course Director of "The Use of Antibiotics" - first in a series on Practical Answers to Problems in Primary Care. A one-day course at the SMBD-Jewish General Hospital, Montréal, Québec. May 1977

Course Director of "Drug Therapy I" - a two day continuing medical education course in Drug Therapy with topics in Basic Pharmacology, current Antihypertensive therapy, Cardiac Pharmacology and current problems and controversies in drug therapy, Mobile, AL. Feb., 1976

Selected Invited Presentations

- “Working with IRBs and Regulators to prepare for Clinical Trial Audits” and Clinical Track moderator at the 4th Annual FDA Inspections Summit, 21-23 October 2009, Bethesda, MD
- “Clinical Research Training including 21 CFR 11, 56, Investigator obligations at the ECCRT Course, Cambridge, England, 22 February 2008
- “PI Responsibility -The Scary Reality” at the Spectrum Health course on “Bringing Research to the Forefront, Keynote speaker and Advisor, Grand Rapids, MI, 15 March 2007
- “Research Subject Safety”, “What is the Informed Consent Process”, “Why is Adverse Event reporting so essential” and other topics at an International Workshop entitled “Complying with Regulatory and Sponsor Requirements in New and Generic Drug Development” in Hyderabad, India, 28-29 July, 2006
- “Human Research Subject Safety – Legal and ethical aspects” at the “Outsourcing and Offshoring of Clinical Trials” conference in Boston, MA 22-23 May, 2006
- “The Role of Academia in the Drug Development Process” in the Clinical Track of the Canadian DIA meeting in Montréal, Québec, September 25-27, 2005
- “Responsibility: The key to Uncompromised Data” at the International Workshop entitled “Fundamentals of Clinical Trial & GCP” in Hyderabad, India 5-6 Aug 05
- “Principal Investigator Responsibilities - The Scary Reality” at the DIA meeting in Ottawa, Ontario, Canada, November 7-9 2004
- “How Compliance with GCP and the Regulations Protects Human Research Subjects” A Pharmaceutical Education Associates Seminar, Philadelphia, June 25, 2004
- “Clinical Trail Design and Execution”, A workshop in the Pharmaceutical Risk Management course, Philadelphia, Dec 8-9 2003
- “The Importance of Adverse Event Reporting in Clinical Research” in the “Hot Topics” series of the University of Cincinnati, College of Medicine
- “ P.I. Responsibilities - The Reality” at the University of Cincinnati Clinical Research professional certificate program - 22 October 2003, 2004, 26 October 2005
- “The GCP’s of Clinical Research”, A 5 hour UC, CCHMC course for Neonatologists at the CCHMC 30 May, 2003
- “Changing Face of Clinical Research” (23 April) & “The Clinical Investigators Responsibilities: The Reality” (8 May) at the “Hot Topics” series of the University of Cincinnati, College of Medicine
- “Health Needs in Kathmandu, Nepal - a World Away”, Cincinnati Children’s Hospital Medical Center, International Child Health Seminar, 21 February 2003
- “The Changing Face of Clinical Research”, University of Cincinnati HemeOnc Grand Rounds, Cincinnati, Ohio, 7 February, 2003
- “Investigators Responsibilities in Clinical Research” in the University of Cincinnati Clinical Research Professional certificate Program - 30 October 2002
- “What patients need to know to manage their asthma”, At the Queen Elizabeth Hospital, Bridgetown, Barbados - 5 April, 2002
- “Update on the management of Asthma” - 2002, At the Patan Hospital and at the Nepal Medical College, Kathmandu, Nepal - 8 March, 2002
- “Clinical research through the eyes of the Ophthalmologist”, at the AGAH-ACCP meeting, Garmisch-Partenkirchen, Germany - 27 January 2002

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Publications:

- Pierce, C.H.; McHugh, R.B.; and Bieter, R.N. A new experimental approach for evaluation of the effects of narcotic analgesics upon respiratory function. *Journal of the Minnesota Academy of Science* 32:117-120, 1965.
- Bloch, J.H.; Pierce, C.H.; Manax, W.G.; and Lillehei, R.C. Treatment of experimental cardiogenic shock, *Surgery* 58:197-214, 1965.
- Bloch, J.H.; Pierce, C.H.; Manax, W.G.; Lyons, G.W.; and Lillehei, R.C. Experimental cardiogenic shock: effects of low molecular weight dextran. *Arch. Surgery* 91:77-85, 1965.
- Pierce, C.H. and Wright, H.N. Accidental poisoning in children: epidemiology and prevention. *Journal of Minnesota Academy of Science* 33:44-48, 1965.
- Bloch, J.H.; Pierce, C.H. and Lillehei, R.C. Adrenergic Blocking agents in the treatment of shock. *Annual Rev. Medicine* 17:483-508, 1966.
- Bloch, J.H.; Dietzman, R.H.; Pierce, C.H. and Lillehei, R.C. Theories of the production of shock: A review of their relevance to clinical practice. *British Journal of Anaesthesiology* 38:234-249, 1966.
- Pierce, C.H. The enigma of shock. *Canadian Medical Association Journal* 103:621-623, 1970.
- Pierce, C.H.; Briggs, B.T. and Gutelius, J.R. Methylprednisolone and phenoxybenzamine and experimental shock: cardiovascular dynamics and platelet function, *Shock in Low- and High-Flow states*. B.K. Forsher, International Congress Series No. 247, Amsterdam (1972).
- Pierce, C.H. Les mecanismes d'action d'un agent corticosteroidique synthetique dans le choc experimental. *L'Union Medicale du Canada* 102:2473-2480, 1973.
- Pierce, C.H.; Oshiro, G.; Briggs, B.T.; Kay, W.W. and Gutelius, J.R. Mechanisms of the effectiveness of a synthetic corticosteroid like agent (Methylprednisolone) in controlled hypoperfusion induced shock. *Steroids and Shock*, T. Glen, Editor, Univ. Park Press, 1974.
- Pierce, C.H. Guidelines for the Management of Hypertension - 1976. Report of the Alabama Advisory and Coordinating Council on Hypertension. May, 1976.
- Pierce, C.H. Comments on the Management of Hypertension - 1976. *Journal of the Medical Association of Alabama*, pages 23-26. July and August, 1976.
- Daniel, A.; Pierce, C.H.; MacLean, L.D. and Shizgal, H. Lactate metabolism during canine shock from hemorrhage, cardiac tamponade or endotoxin. *Surgery, Gynecology and Obstetrics* 143:581-586, 1976.
- Pierce, C.H. Practical Aspects of Presenting Information to Practicing Physicians. *Journal of Clinical Pharmacology* 21:262-264, 1981.
- Pierce, C.H. An Approach to Drug Interactions. *Consultant*, 22(12):138-143, December, 1982.

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Publications (continued)

Pierce, C.H. When we should be measuring plasma concentrations of drugs. *Consultant*, 25(5): 174-183 May, 1984.

Pierce, C.H. How calcium antagonists interact with Cardiac Glycosides. *Consultant*, 26(9): 82-89 September, 1986

Pierce, C.H. Asthma Therapy from the Practice perspective: Changes in the Wind. *Journal of Clinical Pharmacology*, 39(3): 223-229, March 1999

Pierce, C.H. Human subject safety; *GCPj* 8(3), 9, March 2001

Pierce, C.H. Are new drugs really riskier?; *GCPj*, 9(7):6, July, 2002

Pierce, C.H., Walson, P. Where are the Pediatric Investigators?; *GCPj*, 9(8): Aug, 2002

Pierce, C. H. The American Academy of Pharmaceutical Physicians is...; *Clinical Researcher*,; 4(5): 34-36, May, 2004

Perce, C. H. Certification: A Smart Move for Investigators. *GCPj*, 11(9), 19-22, September 2004