

Applicant	
Terry Peter Combs	(617) 932-9888
terrypcombs@gmail.com	Belmont, Massachusetts, USA

1. CRO and Pharmaceutical Industry Positions	
May 2023 -Aug 2024	<p>A. Pharmaron, Woburn MA Immunogenicity Manager</p> <ol style="list-style-type: none"> Bioanalytical Principal Investigator of GLP pharm/tox studies for INDs, TMFs, and IBs. Ligand binding assay SME across CRO service lines including antibody, fusion protein, gene therapy, enzyme replacement, gene editing, and oligonucleotide therapeutic drug candidates. Assay development, validation, and sample analysis PI and regulatory lead across ELISA and MSD platforms. Small molecule potency assay development for chirality study. Frequent communication with scientists, QC, QA, directors of operation, and up to 5 direct reports for quality systems maintenance and improvements. Author of study plans and memos, development and data reports, SOPs, and QA deviations. QC reviewer of data, sample analysis reports, and sponsor audits to ensure accuracy and compliance of lab related processes. Lab maintenance, contract timeline oversight, and best practice application to increase productivity. Sales meetings participation, technical point of contact, company representation at scientific conferences. Hiring Manager: Mark J. Cameron (cameronmarkj38@yahoo.com)
Aug 2017 -Apr 2023	<p>B. Pfizer, Andover MA Senior Scientist</p> <ol style="list-style-type: none"> Pfizer bioanalytical late-stage drug candidate PK, ADA, Nab, and antigenic epitope studies. AAV therapeutics, biotherapeutics, biosimilars, and oncolytic virus drug candidates including <u>Pfizer's first gene therapy drug, approved April 2024.</u> Regular communication with QC, QA, scientists, and global product development (clinical pharmacology unit). IND/BLA data table submissions support. LBA experience with ELISA, MSD, Gyrolab, and interferometry platforms. cGxP software experience including Watson LIMS, IDBS E-Workbook, Methodical Mind, SoftMax, GDMS, Gyrolab Evaluator, JMP, Biovia WebPort, and DOE. Research instrument qualification IQ/OQ/PQ. SME support of CRO method validations and sample analysis campaigns. Data analytics experience with supervised and DNN machine learning model predictions. AAPS Bioanalytical Conference (2020), CHI Immunogenicity/Bioassay Summit (2018) invited speaker. Supervisors: Drs Gorovits (boris.gorovits@regeneron.com) and Kamerud (Jqkamerud@msn.com)
Sep 2016 -Aug 2017	<p>C. Pfizer, Andover MA Scientist (contracted)</p> <ol style="list-style-type: none"> Nonregulated adeno associated virus (AAV) capsid epitope mapping. Clinical PK validation and anti-capsid ADA development.

2. CFR 21 Compliant Experiments Signed-Off		
2023-2024	>150 hard copies	Pharmaron
2016-2023	>700 filed in IBDS E-Workbook/Watson LIMS	Pfizer
3. Regulated SOPs, Method Development/Validation and Sample Analysis Plans/Reports Authored		
2023-2024	> 15 eQCM files	Pharmaron
2016-2023	> 15 GDMS files	Pfizer

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4. Faculty Appointments	
Apr 2012- Aug 2016	<p>A. McGill University, Montreal, Canada Adjunct Professor (NIH Health Career Reentry Fellowship recipient)</p> <ol style="list-style-type: none"> Drug discovery and target validation studies. Clinical whole-body insulin clamp studies using labeled tracers and GC/MS analysis. Primary tissue culture research. Laboratoire Combs Inc. start-up launch (2014-16, Therrien-Couture-Jolicoeur), federal/provincial research tax-credits (Ernst & Young), antibody commercialization (Millipore), patent filings (USPTO). Endocrine Society Meeting (2016) and International Adiponectin Biology and Medicine Symposium (2012) invited speaker. Supervisor: Dr. Errol B. Marliss (errol.marliss@muhc.mcgill.ca)
May2004- Aug 2011	<p>B. University of North Carolina, Chapel Hill NC Tenure Track Assistant Professor (NIH Research Scientist Development Award recipient)</p> <ol style="list-style-type: none"> Clinical study director (CRTC-2645: 07-1158), clinical protocol author, IRB submission. Biomarker and drug target validation. Gene discovery studies. Course director/lecturer, student admissions, undergraduate/graduate degree supervisor. RNA and DNA sequencing, PCR, HPLC, LC/MS, UPLC TSQ MS and LCQ-Deca Ion Trap MS. Lab director, UNC faculty research program support, peer reviewer (14 journals), grant review committee (American Diabetes Association), grant reviewer (Welcome Fund). Tulane University (2011) and International Symposium Neurobiology and Neuroendocrinology of Aging (2008) invited speaker. Combs Lab Inc (2011-2016, Wyrick-Robbins). Supervisor: Dr James A. Swenberg (deceased October 5th, 2023)

5. University Course Lectures		
2014	2 (>100 students)	McGill University
2004-2011	156 (>700 students)	University of North Carolina
6. Project Management		
2014-2016	Start-Up Corporation (Canada)	Laboratoire Combs
2011-2016	Start-Up Corporation	Combs Lab
2012-2016	4 faculty, students, lab staff	McGill University
2004-2011	61 faculty, students, lab staff	University of North Carolina
7. Student Research Supervision		
2004-2011	31 MD, PhD, MSc, BSc	University of North Carolina
8. Drug-Development Initiatives		
2015	US Patent (antigenic epitopes)	9,102,719
2013	US Patent (gene target)	8,530,174
2012	Antibodies Commercial License Agreements	EMD Millipore
2011	Human Protein Sequence	DAA34786
2010	Murine Protein Sequence	ADC34694
2010	Murine mRNA Sequence	FJ977045
2010	Murine Gene Sequence	BK007093

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9. Post-Doctoral Training	
Jul 1997 -May 2004	<p>Albert Einstein College of Medicine (Yeshiva University), Bronx NY Postdoctoral Fellow (NIH National Research Service Award recipient)</p> <ol style="list-style-type: none"> 1. Pharmacodynamics, drug target and biomarker research. 2. Murine gene modifications (transgenics, inducible and congenic knockouts), colony management, in vivo tracer studies, cell culture. Bioanalytical method development and sample analysis. 3. MD/PhD, postgraduate, graduate, and undergraduate student training. 4. UNC Chapel Hill, UNC Charlotte, Rutgers University, University of Minnesota, GSK Canadian Working Group on Insulin Resistance, McGill University (2004), University of Puerto Rico, Vanderbilt University, Uniformed Services University of the Health Sciences (2003), European Thyroid Association (2002) invited speaker. US National Institutes of Health National Research Service Award (2002) and Canadian Diabetes Association Postdoctoral Fellowship (2000). 5. Supervisor : Dr Philipp E. Scherer (philipp.scherer@utsouthwestern.edu)

10. University Education		
1997	PhD (Physiology): Estrogen Action and Aging Dr. James F. Nelson (nelsonj@uthscsa.edu)	University of Texas Health Science Center at San Antonio
1989	BSc (Chemistry)	Concordia University

11. Honors and Awards		
2020	Invited Speaker	AAPS Bioanalytical Conference
2018	Invited Speaker	CHI Immunogenicity & Bioassay Summit
2016	Career Reentry Fellowship	National Institutes of Health (NIDDK)
2009	National Meeting Sessions Chair	American Diabetes Association
2010	Research Grant Review Committee	American Diabetes Association
2006	Research Scientist Development Award (DK075573)	National Institutes of Health (NIDDK)
2005	Grant Reviewer	Wellcome Trust
2003	Travel Grant	Endocrine Society
2002	National Research Service Award (DK061228)	National Institutes of Health (NIDDK)
2000	Post-Doctoral Fellowship	Canadian Diabetes Association
1995	Graduate School Student Representative	Board of Regents, University of Texas System
1993	Awarded Poster with Dr. Shyamala G. Harris	Society for Neuroscience

12. 42 Peer-Reviewed Publications	
9 corresponding authorships, 7 with clinical arms, 61 co-authors, >12,000 citations	
2017 Journal of the Endocrine Society 26:861	
2015 Journal of Clinical Endocrinology and Metabolism 100:E1065	
2014 Reviews of Endocrine and Metabolic Disorders 15:137	
2013 Pediatric Exercise Science 25:238, 2013	
2012 Growth Hormone and IGF Research 22:87	
2012 Human Molecular Genetics 21:463	
2011 American Journal of Respiratory Cell and Molecular Biology 45:340	

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2010 American Journal of Pathology 177:1936
2010 Gerontology 56:404
2009 Hepatology 50:592
2009 Experimental Gerontology 44:26
2008 Biochimica Biophysica Acta, 1781:352
2008 Endocrinology 149:1581
2007 Journal of Biological Chemistry 282:350
2007 Obesity 15:1419
2007 Diabetes, Obesity and Metabolism 9:246
2007 Chemical Biological Interactions 166:170
2005 Journal of Biological Chemistry 280:24085
2005 Nature Medicine 11:797-803
2005 American Journal of Physiology 288:1317-1331
2005 Journal of Biological Chemistry 280:4617-4626
2004 Journal of Biological Chemistry 279:12152-62
2004 Endocrinology 145:367-383
2003 American Journal of Physiology 285:E1151
2003 Oncogene 22:6408
2003 American Journal Physiology 28:C222-35
2003 American Journal of Pathology 162:C2059
2003 Journal of Biological Chemistry 278: 9073
2003 Diabetes 52:268-276
2003 Canadian Journal of Diabetes 27:433
2002 Journal of Biological Chemistry 277:8635
2002 Trends in Endocrinology and Metabolism 13:84
2002 Journal of Acquired Immune Deficiency Syndromes 31:514
2002 Endocrinology 143:998
2001 Journal of Clinical Investigation 108:1875
2001 Nature Medicine 7:947
2001 Diabetes 50:1149
1999 Biochemistry Journal 344:313
1999 Biochemistry Journal 342:321
1999 Diabetes 48:128
1992 Endocrinology 130:1923
1992 Mechanisms of Ageing Development 65:137