Resumé

NAME: Donna D. Walczak, Ph.D.

CURRENTLY: President, Cayuga Consulting (1999 to present)
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Cayuga Consulting is a full-service Medical Writing and Clinical Research Consulting firm (www.cayugaconsult.com). Headquartered in Providence, RI, Cayuga Consulting provides contract medical writing, nonclinical writing, clinical and nonclinical development support, and development of regulatory submissions (all phases) for the Pharmaceutical, Biotechnology and Device industries.

As the President and Cayuga Consulting founder, I lead the scientific and medical writing teams, coordinate project and document planning, data review/QA, document production, and provide regulatory affairs and clinical development writing and expertise.

- Trained in biochemical pharmacology, general pharmacology, neuropharmacology, pharmacokinetics, and clinical drug development, I have authored numerous Phase 1, Phase 2, and Phase 3 CSRs for immediate-release, sustained-release, and parenteral dose forms, as well as combination drug products.
- I have experience in a wide range of therapeutic areas, including oncology, neuropharmacology, dermatology, and antibiotics.
- Protocol development for Phase 1 through Phase 3 studies is a very active area. Phase 1 trials, First Time in Human trials, PK/PD studies, Dose Escalation trials (standard 2-phase and adaptive/seamless) to determine MTD or RP2D, Combination Treatment Studies, and Phase 2 Proof of Concept studies are some of my specialties; these activities form a large part of my work, along with their corresponding Clinical Study Reports.
- In the regulatory affairs area, I have also authored numerous NDA/BLA Module 2 Summaries (nonclinical and clinical), and routinely provide peer review for Quality, Nonclinical and Clinical summary sections of regulatory submissions.
- My primary interests are in Regulatory Submissions (NDAs, BLAs, etc.) and Clinical Development (protocols, investigational drug brochures, and clinical study reports) for small-molecule pharmaceuticals, biologics, and antibody-drug conjugate products.

MEDICAL WRITING EXPERIENCE

Clinical Development Documents

- IND submission components, Annual Reports, related documents
- Clinical Protocols [First-time-in-Human (FTIH); Mass Balance Studies; PK/PD Studies; Dose Escalation/Expansion trials; Phase 1, Phase 2, and Phase 3 Studies; Observational Trials; Noninferiority Trials; Biosimilar Trials, and Postmarketing and Investigator-Initiated Studies (IIS)]
- Investigational Drug Brochures (IDB) – both new and updates
- Target Product Profiles (TPP), Summary of Product Characteristics (SmPC), Core Company Data Sheets (CCDS), and Prescribing Information/ Product Labeling in SPL Format (PI)
- Patient Safety Narratives (writing, review, and QA)
- Abstracts, posters, and presentations (planning/writing/layout/editing/printing)

- Systematic Overviews of published literature and Meta-analyses (including literature search and bibliography management)
- Patient Education Materials, Clinical Program Newsletters

Clinical Regulatory Documents

- Clinical Study Reports [Phase 1, Phase 2, Phase 3, PK/PD, Meta-analyses of Clinical Studies, ISS, ISE]
- CMC/Process Development/Analytical Methods Reports
- eCTD summary sections including Nonclinical, Biopharmaceutics, Clinical Pharmacology, Efficacy and Safety - Overviews and Summary Sections
- NDAs, BLAs, 505(b)(2), 351(k), ANDA submissions, small molecule, biologic and biosimilar INDs
- eCTD 120-Day Safety Updates
- Responses to FDA queries on NDA/BLA/other submissions and requests for information
- PMA Supplements; 510k Submissions
- Device Clinical Summaries (US/EU Safety Updates and CE Mark Summaries)
- Annotated bibliographies and literature reviews, meta-analyses of published literature
- FDA briefing books (pre-IND, End of Phase 2, pre-NDA, Advisory Panel, Special)
- Annual Reports, Safety Updates

Nonclinical Development Documents

- Pharmacodynamic, Pharmacokinetic, PK/PD, ADME, Analytical Methods Development, Mass Balance Reports
- Editing and summarizing Toxicology Reports
- Reports in molecular medicine, antibody-drug conjugates, tumor models, stability, receptor specificity/selectivity, among others
- Nonclinical sections of Investigational Drug Brochures (IDB)
- Nonclinical Sections of Summary of Product Characteristics (SmPC), Core Company Data Sheets (CCDS), and Prescribing Information/ Product Labeling in SPL Format (PI)
- Nonclinical abstracts, posters, and presentations (planning/writing/layout/editing/printing)

REGULATORY SUBMISSIONS AND POSTMARKETING EXPERIENCE – Therapeutic Areas

Indications in alphabetic order include:

- antianxiety agents, antidepressants, antipsychotics, ADHD, other psychiatric indications
- antibiotics and anti-infectives, antiviral agents, RNAi and micro RNAs (influenza, HIV, RSV, hepatitis B and C, tuberculosis, MRSA, pseudomonas)
- cardiovascular indications: hypertension, congestive heart failure, antiplatelet drugs (GP IIb/IIIa inhibitors, thrombolytics, $P2Y_{12}$ inhibitors), human thrombopoietin (TPO) agonists, antiarrythmics
- dermatologic drugs (atopic dermatitis, CB2 agonist, psoriasis, calcipotriene analogs, retinoids)
- injectable lipolytics, injectable bulking agents (hyaluronic acid derivatives)
- metabolic disorders: diabetes (Type 1 and Type 2), hyperlipidemia (microsomal triglyceride transfer protein (MTP) inhibitors)

- monoclonal antibody therapeutics/recombinant fusion proteins (rheumatoid arthritis, oncology, bone mineral metabolism,)
- musculoskeletal disorders (Duchenne muscular dystrophy)
- neurological disorders (epilepsy/complex partial seizures; Alzheimer's disease, Parkinson's disease; multiple sclerosis; schizophrenia, others)
- oncology (hematologic and solid tumors, proteasome inhibitors, antimetabolites, halichondrin B analog, Aurora A kinase inhibitors, Auristatin A derivatives, angiogenesis inhibitors, thalidomide derivatives, stomatologic preparations)
- pain and pain syndromes (opioids and opioid analogs, conotoxins, acute pain, chronic pain, opioid antagonists)
- renal disease and related disorders (bisphosphonates and bone metabolism, lanthanides, erythropoetin analogs, lanthanides and dialysis, vesicoureteral reflux, urinary incontinence)

EDUCATION

1986-1988 **Postdoctoral Fellowship** in Clinical Research and Drug Development, Burroughs Wellcome Co., the School of Medicine, University of North Carolina, Chapel Hill, NC, and Duke University, Durham NC

1977-1983 **Doctor of Philosophy**, Department of Pharmacology, University of Toronto, Toronto, Ontario, Canada

1976-1977 **Master of Science (Virology)**, Department of Natural Sciences, Roswell Park Memorial Institute, Graduate Division, State University of New York at Buffalo, Buffalo, NY

1972-1976 **Bachelor of Science**, Health-Related Sciences, Department of Biochemical Pharmacology, School of Pharmacy, State University of New York at Buffalo, Buffalo, NY

GRADUATE AND POSTGRADUATE TRAINING

Basic Sciences: inorganic and organic chemistry, general biochemistry, protein chemistry, physical chemistry, medicinal and natural product chemistry, structure-activity relationships, receptor pharmacology, analytical biochemistry, pharmacokinetics, drug metabolism, intermediary metabolism and disease.

Pharmacology/Pharmacokinetics/ Physiology/Toxicology: principles of chemotherapy, principles of pharmacology, advanced pharmacology, basic and advanced pharmacokinetics, pharmacokinetic modeling, metabolism in mass balance studies, behavioral pharmacology, intermediary metabolism and antimetabolite pharmacology, pathophysiology and disease processes, general physiology, immunology, virology, and principles of toxicology.

Clinical Drug Development: principles of drug development; basic, intermediate and advanced CRA training; basic, intermediate and advanced regulatory affairs training; intermediate and advanced medical writing; biostatistics; and indication-specific training in various therapeutic areas. Additional continuing medical education classes are listed below.

Personnel and Project Management: principles and techniques of project management, equal opportunity issues and personnel management practices, targeted interviewing techniques, personnel assessment, principles of education and training, principles and practices in effective leadership, total quality management.

Summary of Regulatory Writing Experience by Therapeutic Area - Updated 4Q2016	
Therapeutic Area	**Details – Regulatory Submissions, Nonclinical Writing, and Medical Writing**
Cardiovascular	▪ 2 FDA briefing documents [Lead Writer] ▪ 2 CSRs, 4 protocols [Primary Author] ▪ 4 Investigational Drug Brochures [Primary Author] ▪ 3 protocols for QT-interval Safety Studies for various drug product submissions [Primary Author] ▪ 2 Comprehensive literature searches and summarization in support of regulatory submissions [Primary Author] ▪ Patient Safety Narratives for large Cardiovascular Device study
Central Nervous System	▪ 4 NDAs (2 pre-CTD), 2 505(b)(2) submission [Lead Writer and Project Manager] ▪ 3 Product Labels/SPL [Primary Clinical Author] ▪ 3 IND and 4 Investigator Brochure development [one IB had 135 Nonclinical Reports summarized] [Lead Writer and Project Manager] ▪ 11 CSRs (3 Phase 1, the rest Phase 2 and Phase 3) [Lead Writer and Project Manager] ▪ 9 protocols (4 Phase 1, 3 Phase 2, 2 Phase 3) [Lead Writer and Project Manager] ▪ 6 IBs [Lead Writer and Project Manager] ▪ 7 FDA briefing documents, 2 product Clinical Trial Registry Summaries (1 product) ▪ 1 Patient Safety Narratives (for NDA, 1 product, >400) [Lead Writer and Project Manager] ▪ Product Safety Update Reports; numerous posters and manuscripts [Lead Writer and Project Manager] ▪ 2 Product Marketing/Launch Support [Develop, Review and QA marketing plans, training materials, and launch materials] ▪ 3 products Package Inserts/Patient Information Leaflets (SPL format) ▪ 2 Company Core Data Sheets (CCDS) ▪ 2 SmPCs revised and updated
Dermatology	▪ 2 Product Safety Update Reports (1 psoriasis product), ▪ 2 Annual Reports for topical antifungal therapy (1 product) [Lead Writer and Project Manager] ▪ 1 Annual Report and 2 protocols for Atopic Dermatitis [Lead Writer] ▪ 1 CSR for Psoriasis (small-molecule systemic therapy) ▪ Quality review of eCTD Summary Sections (Module 2, acne, US and EU Rx-to-OTC submissions) ▪ IND Submission for atopic dermatitis (Summary of Nonclinical Pharmacology, Investigational Drug Brochure, Toxicology Tabulated Summaries, General Investigational Plan, Previous Human Experience, assembly and QA of paper IND submission).
Diabetes/Metabolism	▪ 3 CTDs (3 different products) [Lead Writer and Project Manager] ▪ Patient Safety Narratives (2 products, >200) [Lead Writer and Project Manager] ▪ Periodic Safety Update Reports (2 products), 4 Annual Reports (3 products) [Lead Writer and Project Manager] ▪ 2 Product Labels/Package Inserts [Primary Clinical Author] ▪ 2 CSRs (diabetes) [Lead Writer and Project Manager] ▪ 3 protocols (1 Phase 1 in hyperlipidemia, 2 Phase 3 in diabetes) [Lead Writer and Project Manager] ▪ 2 FDA briefing documents (diabetes, obesity) [Lead Writer and Project Manager] ▪ 3 slide kit updates [Primary Author]
Immunology	▪ 3 Annual Reports [Lead Writer] ▪ 3 CSRs (1 Phase 2 and 2 Phase 3) ▪ 1 Patient Safety Narratives (for NDA, 1 product, >450) [Lead Writer and Project

Summary of Regulatory Writing Experience by Therapeutic Area - Updated 4Q2016	
Therapeutic Area	**Details – Regulatory Submissions, Nonclinical Writing, and Medical Writing**
	Manager] ▪ 2 protocols, numerous posters and manuscripts [Primary Author]
Musculoskeletal	▪ 3 CSRs (1 Phase 2 and 1 phase 3) ▪ 1 Investigator's Brochure (Duchenne Muscular Dystrophy)
Oncology	▪ 3 CTDs, 2 CTD Supplements [Lead Writer and Project Manager] ▪ 4 FDA briefing documents (pre-NDA and Advisory Panel) [Lead Writer and Project Manager] ▪ 2 products, Package Inserts/Patient Information Leaflet (SPL format) ▪ 6 CSRs (3 Phase 1, 2 Phase 2-3, 1 Phase 3) [Lead Writer and Project Manager] ▪ 1 Systematic Overview of the literature [Lead Writer and Project Manager] ▪ 12 protocols (6 Phase 1 dose-escalation, 6 Phase 2-3 safety and efficacy) [Lead Writer and Project Manager] ▪ 4 IBs [Lead Writer and Project Manager] ▪ 3 Structured Product label, 1 Patient leaflet [Primary Author] ▪ 2 slide kit updates, numerous posters and manuscripts [Primary Author] ▪ 3 IND Nonclinical Summaries, 7 Nonclinical Reports [pharmacology, toxicology], 8 mAb development reports, QA audit of 18 Nonclinical and Molecular Medicine reports
Respiratory	▪ 5 CSRs (Phase 2/Phase 3) [Lead Writer and Project Manager] ▪ 4 protocols (2 Phase 1, 2 Phase 3) [Lead Writer and Project Manager] ▪ 2 manuscripts/posters [Primary Author]
Urology	▪ 1 PMA, 1 PMA supplement [Lead Writer and Project Manager] ▪ 1 Systematic Overview of the literature for injectable bulking agents [Lead Writer and Project Manager] ▪ 3 Annual Reports (1 product), 2 Product Safety Update Reports [Lead Writer]
Virology, general	▪ 2 FDA briefing documents (2 products) [Lead Writer and Project Manager] ▪ 1 Practice Guideline [Lead Writer and Project Manager] ▪ 2 protocols (Phase 2) ▪ 3 manuscripts (postsubmission data mining) [Primary Author] ▪ 1 Product Label/Package Insert [Primary Clinical Author] ▪ 1 Marketing/Launch Support (Develop, Review and QA marketing plans, training materials, and launch materials) [Lead Writer and Project Manager]
Virology, HIV	▪ 1 FDA briefing document [Lead Writer] ▪ 3 manuscripts [Lead Writer and Project Manager] ▪ 2 Systematic Overviews of literature/Meta-analyses [Lead Writer and Project Manager] ▪ 2 protocols (Phase 3) [Primary Author]
Infectious Disease	▪ 2 FDA briefing document [Lead Writer] ▪ 5 NDAs for antibiotics (MRSA/ABSSSI/cSSTI) including clinical summary sections, quality summary sections, and nonclinical written and tabulated summary sections ▪ 1 NDA for MDR-TB including clinical summary sections, quality summary sections
Women's Health	▪ 2 Osteoporosis Observational Trial protocols [Lead Writer and Project Manager] ▪ 2 osteoporosis CSRs [Primary Author] ▪ 1 product Safety Narratives (osteoporosis NDA, >300) [Primary Author] ▪ 2 Product Safety Update Reports (1 product) [Primary Author] ▪ 2 osteoporosis manuscripts [Primary Author] ▪ 1 infertility training manual for nurses [Primary Author]
Other Therapeutic Areas	▪ 1 IND for injectable lipolysis product (2 protocols, CMC/Quality section) [Lead Writer and Project Manager] ▪ 14 Clinical Summaries (updates for EU CE Mark registration, 3 orthopedic products)

Summary of Regulatory Writing Experience by Therapeutic Area - Updated 4Q2016	
Therapeutic Area	**Details – Regulatory Submissions, Nonclinical Writing, and Medical Writing**
	[Lead Writer and Project Manager] ▪ 2 Product Safety Update Reports (1 product, lipid-lowering agent) ▪ 2 protocols for blood substitutes (oxygen carriers) [Lead Writer and Project Manager] ▪ 1 IB for lipid-lowering product (nonstatin) [Primary Author]

CONTINUING EDUCATION (Topic and Year)

2006 Webinars and Conferences

- Structured Product Language and New Package Insert Requirements (2006, 2008)
- CDISC Standards and Application to Submission Data (2007, 2008)
- Comparative Review Practices: US and Canada (2008)
- Adaptive Trial Design (2007, 2009)
- Avoiding Statistical Errors in Clinical Trials (2006)
- New Regulations for Global Clinical Trials (2008)
- Exploratory IND Studies and Microdosing (2007, 2008)
- New Requirements for ISE, ISS in CTD Submissions (2008, 2009)
- Pre-IDE Meetings: Purpose, Approach and Structure (2009)
- Design and Conduct of Patient Registries and Observational Trials (2010)
- Methods in Signal Detection and Data Mining (2010)
- Optimizing Structure and Format of Analysis Datasets (2010)
- Medical Device Directive and Active Implantable MDD Clinical Requirement Changes (2010)
- Membrane Transporters in Drug Development (2010)
- Trends in FDA Warning Letters (2010)

2011 - 2015 Webinars and Conferences

- US and International Labeling Requirements Compared and Contrasted (2011)
- Adaptive Trial Design in Oncology (2011)
- Formulation Issues Using Cyclodextrins (2011)
- Development of Antibody-Drug Conjugates in Nonclinical Development (2011)
- Patient Reported Outcomes and Safety Surveillance (2012)
- Update on Adaptive Design Trials and FDA Guidance (2012)
- Content Comparisons: IMPD/EU CTS versus the US FDA IND Submission (2012)
- Bone Health in Cancer Care: NCCN Task Force Review (2013)
- Development of Company Core Safety Data Sheets (2014)
- Quick Tips for a Successful FDA Submission (2014)
- Avoiding Statistical Errors in Clinical Trials - Preparing for FDA Review (2015)
- FDA Regulations on Cosmetics: Impact of the Proposed Personal Care Products Safety Act (2015)
- Benefit-Risk Analysis for Medical Products (2015)
- Web-Based Software for Literature Review: A Product Demonstration (2015)
- Enriched Clinical Trial Design from Retrospective to Prospective Study Designs: Leveraging Clinical, Administrative, and Patient Reported Data for Clinically Meaningful Research (2015)

2016 Webinars and Conferences

- How FDA Reviewers Learn and Do Their Jobs: A Survey of Resources and Reviewer Requirements (2015)
- Achieving Operational Excellence in Prospective Observational Research (2016)
- Maximizing the Likelihood of First-Cycle Approval of ANDAs (2016)
- Genomic Approaches to Model the Immune Landscape of Human Tumors for Cancer Immunotherapy (2016)
- Clinical Trial Transparency: What you need to know about European Medicines Agency Policy 0070 091416 (2016)
- How to Use PRO Pain Scales Consistently and Effectively (2016)
- Clinical Trial Quality by Design Factors Critical to Quality (2016)

2017 Webinars and Conferences

- Technical Communication Basics (2017)
- 21st Century Cures Act Review [FDANews] (2017)
- Argumentation and Persuasion for Regulatory Professionals [RAPS] (2017)
- Growth Curve Modeling for Patient-Reported Outcomes Research [DIA] (2017)
- FDA's New Final Rule for Electronic Drug Registration and Listing: What's Changing? What's Not? [DIA] (2017)
- Developing PRO Instruments in Clinical Trials: Issues, Considerations, and Solutions [DIA Statistics Community] (2017)
- Virtual Program: Understand the New EU Medical Device and IVD Regulations (RAPS) (2017)
- FDA's New Final Rule for Electronic Drug Registration and Listing (DIA) (2017)
- 21st Century Cures Act – How will it affect you? (FDANews) (2017)
- Case Study - Bringing Agility and Automation to New Drug Application (NDA) Development (RAPS) (2017)
- Parkinson's Disease: The Search for Biomarkers (The Scientist) (2017)
- The Clinical Trial of the Future is Here - Now: Understand how technology is transforming clinical development (RAPS) (2017)
- Microbiome-Centric Human Health: A Call for Systems Biology (The Scientist) (2017)
- Microbiome-Centric Human Health: A Call for Systems Biology (DIA) (2017)
- Conduct Audit-Ready Literature Reviews for Your CERs: A Systematic Method (RAPS) (2017)
- Navigating the Regulatory Complexities of Orphan Drugs: Know the Unwritten Rules of Designations and What's Next (DIA) (2017)
- Cancer Stem Cells: Getting to the Root of Cancer (The Scientist) (2017)
- Statistician's Contributions to Enabling Biomarkers in Labels for Regulatory-Approved Precision Medicine (DIA) (2017)

PREVIOUS AND CURRENT EMPLOYMENT

Dates	Employer	Title and Duties
1999 - Current	Cayuga Consulting Providence, RI	President Lead Sr. Medical Writer
2000 - 2015	Clinical Research Management, Inc., Agawam, MA	VP, Clinical Research
1998 – 1999	Ergo Science Corporation Charlestown, MA	▪ Director, Clinical Research and Regulatory Affairs ▪ Ergoset (Cycloset) Diabetes Program ▪ Ergoset (Cycloset) Obesity Program ▪ PDT Oncology Program
1996-1998	Amgen Colorado, Inc. Boulder, CO	Associate Manager, Clinical Affairs ▪ Clinical Manager for Infergen® Hepatitis C Program ▪ Clinical Manager for Infergen® Oncology Program ▪ Interim Team Leader, Clinical Studies Management Team ▪ Associate Manager for Clinical Training and Development
1991-1996	Solvay Pharmaceuticals Marietta, GA	▪ Senior Clinical Research Scientist (1996), Clinical Operations Phase I Group ▪ Senior Clinical Research Scientist (1992-1995) CNS Therapeutic Area ▪ Senior Clinical Research Associate (1991), CNS Therapeutic Area
1990-1991	Environmental Protection Agency, Research Triangle Park (RTP), NC and National Institute of Environmental Health Sciences RTP, NC	▪ Research Toxicologist Neurotoxicology Division ▪ Visiting Scientist, Laboratory of Molecular and Integrative Neurosciences (cross-appointment)
1990-1991	Independent Consultant, Research Triangle Park, NC	Clinical Drug Development (Phase 1-3)
1988-1990	Cato Research, Ltd., Durham, NC	Senior Clinical Research Scientist
1988-1988	Merrell Dow Research Institute, Cincinnati, OH	Senior Research Pharmacologist II, Research Coordination Section
1986-1988	Burroughs Wellcome Co., Research Triangle Park, NC	Clinical Pharmacology Research Fellow, Neuropharmacology Section, Department of Clinical Neurosciences
1987-2005	US Army Independent Ready Reserve	MOS: Biochemist; reserve rank: Lieutenant
1983-1986	Walter Reed Army Institute of Research, Washington, DC	Principal Investigator, Neurochemistry and Neuroendocrinology Branch, Division of Neuropsychiatry, Rank: Captain, United States Army Medical Service Corps.