

## Virginia (Ginny) Fleming

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**Objective:** To produce clear, accurate, well-written technical documents for medical, pharmaceutical, biotech, and international health applications

### **Key Experience and Skills:**

- Extensive professional experience in medical writing in the pharmaceutical industry in the US and Europe.
- Excellent writing and editing skills. Very thorough.
- Strong analytical and project management skills.

### **Education:**

BS, Molecular Biology

MS, Mathematics/Computer Science

### **Professional Experience:**

Impax Laboratories, Hayward, CA

Contract Medical Writer 2016-present

Write and edit clinical study reports and other regulatory documents in support of the development of treatments for Parkinson's disease.

Eiger Biopharmaceuticals, Palo Alto, CA

Contract Medical Writer 2015-present

Write and edit clinical study protocols and investigator brochures for orphan disease treatments.

Bristol-Myers Squibb, Redwood City, CA

Contract Scientific Writer 2015-present

Edit pre-IND nonclinical reports of monoclonal antibody drug candidates.

InterMune Inc, Brisbane, CA

Contract Medical Writer 2013–2015

Wrote and edited IND safety summaries, patient safety narratives, and statistical analysis plans for NDA resubmission of pirfenidone (treatment for idiopathic pulmonary fibrosis). Wrote orphan drug designation application, white paper, and clinical study reports for pirfenidone as treatment for systemic sclerosis.

Gilead Sciences Inc, Foster City, CA

Contract Medical Writer 2004–2014

Wrote and edited clinical study reports, investigator brochures, and clinical summaries regarding HIV, hepatitis, and cardiovascular treatments. Substantively edited technical reports documenting manufacturing processes, stability testing, and process optimization.

**Professional Experience, continued**

Jazz Pharmaceuticals Inc, Palo Alto, CA

Contract Medical Writer 2010–2015, also 2008, 2004

Wrote, edited, and QC'd clinical study reports, study protocols, and patient safety narratives (neurology/psychiatry therapeutic area). Summarized clinical literature.

PATH, South San Francisco, CA

Contract Medical Writer 2013–2014

Wrote and edited clinical study protocols and investigator brochures regarding diarrheal disease treatments for this international nonprofit organization.

Achaogen Inc, South San Francisco, CA

Contract Medical Writer 2011–2013

Wrote and edited clinical study protocols, investigator brochures, annual reports, and IND summaries in support of antibiotic drug development.

Alexza Pharmaceuticals, Mountain View, CA

Contract Medical Writer 2009–2011

Wrote and edited clinical study reports and clinical summaries regarding *Staccato* drug-device combination products (loxapine and zaleplon) for systemic delivery by inhalation. Managed documents through review process and integrated reviewer comments.

ALZA Corporation, Mountain View, CA

Contract Medical Writer 1997–2005

Wrote and edited clinical study reports, technical reports, investigator brochures, NDA and IND summaries, publications, validation and quality plans, and encyclopedia chapters on drug delivery technologies. Administered publication clearance process; wrote and edited book chapters, journal articles, abstracts, and presentations.

Additional pharmaceutical clients:

Pharmacyclics, Inc, Sunnyvale, CA, 2012–2013

Protein Design Labs, Fremont, CA (now PDL Biopharma), 2001–2007

PowderJect Technologies, Fremont, CA, 2001

Inhale Therapeutic Systems, Inc, San Carlos, CA (now Nektar Therapeutics), 2000

Fujisawa GmbH, Munich, Germany, 1999-2002

Syntex Laboratories, Palo Alto, CA 1983-1986

Hewlett-Packard Company, Cupertino, CA & Plexus, a Division of BancTec, Sunnyvale, CA  
Software engineering, technical support, and supervisory positions 1988–1996

**Therapeutic Areas:** Pulmonology, oncology, diarrheal diseases, urology, ADHD, pediatrics, rheumatology, ob/gyn, allergy, psychiatry, antivirals (HIV/HBV/HCV/HDV), antibiotics, drug delivery systems, pain management

**Professional Organizations:** American Medical Writers Association (earned "Core Curriculum" certificate); Board of Editors in the Life Sciences (earned "Editor in the Life Sciences" certificate); Drug Information Association