

TED FEUERBACH

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Feuerbach and Associates
Senior Partner/Consultant

1989 – Present

Over twenty years of experience in all phases of Clinical Trial SAS Programming.

UCB Pharma
Consultant

Mar 2009 – Jul 2010

Developed and validated CDISC SDTM, ADaM and PK/PD (NONMEM) datasets, tables, listings and graphs using SAS, SAS/Graph and macros for Systemic Lupus Erythematosus (SLE), Rheumatoid Arthritis and Crohn's disease clinical trials with SAS V9.2

Merck
Consultant

Sep 2008 - Dec 2008

Performed custom, ad hoc data analysis for an FDA questionnaire. Created tables, listings, figures and CDISC ADaM compliant analysis datasets using SAS V9.

Grünenthal GmbH
Head of Biostatistical Programming

Sep 2007 - Sep 2008

Managed the newly created Biostatistical Programming department after it was split from the Biostatistics department.

CV Therapeutics
Consultant

Nov 2004 - Jul 2007
Jan 2002 - May 2003

Developed software to analyze efficacy, pharmacokinetic and adverse drug reaction data for three cardiac drug ISS/NDA/MAA submissions. Created ECG, Echocardiogram and SPECT image data analysis and reporting software. Generated integrated safety datasets by combining data from over forty clinical studies. Developed CRT/SDTM files using CDISC standards. Performed software validation. Developed software systems to automatically generate mixed media documents combining graphic, tabular and listing data on a single page. Environment: SAS/Base, SAS/Stat and SAS/Graph, SAS/Macros, SAS/AF

Gilead Sciences
Consultant

May 2004 – Oct 2004
Feb 2001 – Jan 2002

Installed and evaluated four software version control systems on Unix and Win/2000 for CFR 21 Part 11 and GCP compliance. Wrote SAS macros to track the utilization of standard macros. Standardized the biometrics C-Shell user environment. Designed standard macros using SAS/Connect to permit submission of SAS jobs across platforms. Updated and documented existing standard SAS macros and Unix shell scripts. Developed software to analyze efficacy, pharmacokinetic and adverse drug reaction data for three anti-retroviral drug ISS/NDA and MAA submissions.

Gilead Sciences (Continued)

Evaluated, recommended and configured a complete Unix server upgrade for the Biometrics department. Created electronic regulatory submissions. Performed software validation. Created cross-referenced HTML based CD-ROM products to deliver mixed media documents in a user friendly fashion. Developed software systems to automatically create mixed media documents combining graphic, tabular and listing data on a single page using SAS/Graph.

Novacea
Consultant

May 2003 – Mar 2004

Developed software to analyze efficacy, safety and adverse drug reaction data (AE/ADR) for an Oncology drug (DN101) Safety Board submission. Created Oncology data analysis and reporting software. Developed CRT files using CDISC standards. Performed software validation. Developed software systems to automatically generate complex mixed media documents combining graphic, tabular and listing data on a single page. Created programs to convert text files to RTF format and to automatically create user friendly, web based HTML access to multilevel report directories. Evaluated Unix servers. Environment: Unix, Windows/XP, SAS/Base, SAS/Stat and SAS/Graph, SAS/AF SAS/Macros, HTML, Adobe Acrobat PDF, MS/Access, MS/Excel

Ischemia Research and Education Foundation
Consultant

May 2000 - Feb 2001

Developing online data capture and statistical analysis systems for a 5,000 patient, 5 year prospective epidemiological study of coronary bypass surgery outcomes using SAS. Linking SAS applications to Oracle Clinical. Data Mining. Environment: HP-UX Unix, Windows NT, Oracle Clinical, HTML, SAS/Base, SAS/Stat, SAS/AF and SAS/FSP.

OTHER PREVIOUS CLIENT COMPANIES

Genentech
ALZA
Liposome Technologies
Monsanto
JP Research
Sequus

Roche
Vital Insite
Syntex
Santen Pharmaceuticals
American Express
Dow Chemical

CLINICAL TRIAL PARTICIPATION

14 FDA drug approvals:

Viread (Tenofovir Disoproxil Fumerate)
Hepsera (Adefovir Dipivoxil)
Aleve (Naproxen Sodium)
Nutropin LQ (Human Growth Hormone)
Posilac (Bovine Somatotropin)
Amphocil (Liposomal Amphotericin)
Toradol (Ketorolac Tromethamine)

Doxil (Liposomal Doxorubicin)
Ranexa (Ranolazine)
CellCept (Mycophenolate Mofetil)
Lexiscan (Regadenoson)
Truvada (Emtricitabine/Tenofovir)
Cytovene (Ganciclovir Sodium)
Nucynta (Tapentadol)

Pending FDA/EMEA review:

CVT-510 (Tecadenoson)

Epratuzumab (monoclonal antibody)

DN-101 (Calcitriol)

Cimzia (certolizumab pegol)

THERAPEUTIC AREAS

Analgesic

Cardiology

Oncology

Neurology

Rheumatology

Antiviral

Endocrinology

Antifungal

Immunology

ADDITIONAL EXPERIENCE

Feuerbach and Associates is developing a web based electronic data capture/electronic (E-CRF) system for clinical trials.

Three years as Associate Director of Data Processing in a major medical center, managing the Laboratory Information System (LIS) department.

Two years in clinical laboratory information systems as a Customer Engineer customizing, testing and performing on-site training.

Five years experience in Medical Laboratory Technology in both commercial and hospital laboratories. Expert in laboratory data analysis and cleaning.

EDUCATION

BS – BIOLOGY

1982

Radford University

Radford, VA

209 credit hours with 128 in Life Science, Computer Science, Chemistry and Math.

Advanced SAS/AF Programming Course Certificate

SAS Institute

San Francisco, CA

2000

MEMBERSHIPS

Pharmaceutical Users Software Exchange (PhUSE)

The Churchill Club

The Commonwealth Club

Drug Information Association

American Microscopical Society

PERSONAL INFORMATION

Permanent German Residence Permit: Unbefristet Niederlassungserlaubnis

US Citizen, native English speaker

Age: 56