TED FEUERBACH

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Feuerbach and Associates 1989 – Present
Senior Partner/Consultant

Over 25 years of experience in all phases of Clinical Trial SAS Programming, Big Data Analytics, Data Warehousing, Data Mining, Data Management and Clinical Trial Monitoring. Plus, five years in Medical Laboratory Technology and five years in Clinical Laboratory Information Systems.

Feuerbach and Associates Internal Projects May 2011 – 2014
Developed a Hadoop stack for Big Data analytic system development using MapReduce, Hbase (NoSQL), Hive, Pig, Scala, Maven and Apache Spark. Creating the Pharmaceutical and Biotechnology/Big Data news, opinion and jobs websites: http://www.biopharmaceutical.info and http://www.bigdatascience.info

PRA March 2014 – September 2014
Consultant
Created statistical analysis tables and listings for an ISS for Gout therapy using SAS software. Wrote software to create and merge CDISC SDTM datasets.

Cromsource Feb 2013
Consultant
Validation of CDISC SDTM datasets. Macro development.

UCB Pharma Nov 2010 – Apr 2011
Consultant Mar 2009 – Jul 2010
Developed and validated CDISC SDTM, ADaM and PK/PD (NONMEM) analysis 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. Data visualization software development.

Richmond Pharmacology Aug 2010 – Nov 2010
Consultant
Created analysis datasets for Anesthesia and Pulmonary (COPD) phase 1 clinical trials. Created data analytics tables, listings and figures for an Endocrine phase 2 study.

Merck Sep 2008 - Dec 2008
Consultant
Performed custom, ad hoc data analysis for an FDA questionnaire. Created SAS software for the generation of tables, listings, data visualization figures and CDISC ADaM compliant analysis datasets using SAS V9.

Grünenthal GmbH Sep 2007 - Sep 2008
Head of Biostatistical Programming
Managed the newly created Biostatistical Programming department after it was split from the Biostatistics department.

CV Therapeutics Nov 2004 - Jul 2007
Consultant 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. Integrated safety datasets by combining data from over forty clinical studies. Developed CRT/SDTM files using CDISC standards. Created PK/PD (NONMEM) datasets. Performed software validation. Developed software systems to automatically generate mixed media documents combining graphic, tabular and listing data on a single page. Data analytics, data visualization and data warehousing. Environment: SAS/Base, SAS/Stat and SAS/Graph, SAS/Macros, SAS/AF

Gilead Sciences May 2004 – Oct 2004
Consultant 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. Data analytics software development. 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.
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 for complex data visualization.

Novacea May 2003 – Mar 2004
Consultant
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 for data visualization. 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 May 2000 - Feb 2001
Consultant

Developing online data capture, data warehouse 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 Database. 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

15 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)
Nucynta (Tapentadol)
Doxil (Liposomal Doxorubicin)
Ranexa (Ranolazine)
CellCept (Mycophenolate Mofetil)
Lexiscan (Regadenoson)
Truvada (Emtricitabine/Tenofovir)
Cytovene (Ganciclovir Sodium)
Cimzia (certolizumab pegol)

Pending FDA/EMEA review:
CVT-510 (Tecadenoson)
Epratuzumab (monoclonal antibody)
DN-101 (Calcitriol)

THERAPEUTIC AREAS

Analgesic
Cardiology
Oncology
Neurology
Rheumatology
Pulmonary
Hepatic
Antiviral
Endocrinology
Antifungal
Immunology
Anesthesia
CNS
Renal

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, LIMS) department.

Two years in Clinical Laboratory Information Management Systems (LIMS) as a Customer Engineer developing, 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.

Clinical Laboratory Technology Program 1983
National Health Laboratories
Fairfax, Virginia

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/Work Permit: Unbefristet Niederlassungserlaubnis
US Citizen, native English speaker