

## THEODORE FEUERBACH

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CONSULTANT

1989 – Present

CV Therapeutics

Nov 2004 - Present  
Jan 2002 - May 2003

Developed software to analyze efficacy, pharmacokinetic and adverse drug reaction data for two cardiac drug (Ranolazine and Regadenoson) ISS/NDA 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 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: Windows/2000, SAS/Base, SAS/Stat and SAS/Graph, SAS/Macros, SAS/AF, HTML, Adobe Acrobat PDF, MS/Access, MS/Excel

Gilead Sciences

May 2004 – Sep 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 two anti-retroviral drug (Adefovir and Tenofovir) 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 CDROM 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. Environment: Unix, Windows/2000, SAS/Base, SAS/Stat and SAS/Graph, SAS/Macros, SAS/Connect, HTML, Adobe Acrobat PDF, MS/Access, MS/Excel, Razor, Perforce, SubVersion, TortoiseCVS

Novacea

May 2003 – March 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

May 2000 - Feb 2001

Developing data capture and statistical analysis systems for a 5,000 patient, 5 year prospective epidemiological study of coronary bypass surgery outcomes using SAS Version 8. 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.

Santen Pharmaceuticals

1999

Evaluated foreign SAS datasets for suitability for US regulatory submissions.

Environment: Windows 98, SAS/Base, SAS/Stat .

JP Research

1999

Analyzed highway safety and mortality data for litigation support.

Environment: Windows NT, SAS/Base, SAS/Stat, SAS/Graph.

ALZA

1997 - 1998

Associate Project Manager, assisting the medical surveillance department in validating an adverse event reporting system.

Environment: Windows NT, SAS/Base, Microsoft Access.

Vital Insite

1997

Developed SAS software macros to perform data smoothing, cleaning and visualization of raw data output from a non-invasive, prototype medical monitoring instrument.

Environment: Sun Solaris Unix, SAS/Base, SAS/AF, SAS/Stat and SAS/Graph.

Genentech

1995 - 1997

Developed software to analyze efficacy and adverse drug reaction data for Nutropin and Protropin recombinant human growth hormone.

Environment: Sun Solaris Unix, Informix, SAS/Base, SAS/Stat and SAS/Graph .

Roche Bioscience

1995

Performed upgrades, validation and documentation of a collection of legacy SAS software macros used in the NDA for Oral Ganciclovir.

Environment: DEC-VAX VMS, SAS/Base, SAS/Stat and SAS/Graph.

Liposome Technologies

1994

Developed software to analyze efficacy, pharmacokinetic and adverse drug reaction data for liposomal formulations of Doxorubicin (Doxil) for Kaposi's Sarcoma and for Amphotericin (Amphocil) for fungal infections associated with AIDS. Adapted the "Napoleon's Army" Graphic for the presentation of drug efficacy data.

Environment: Sun Solaris Unix, Oracle, SAS/Base, SAS/Stat and SAS/Graph.

Syntex

1993

Analyzed drug safety data in the NDA's for OTC Naprosin (Aleve) and Ketorolac.

Developed software for pharmacokinetic studies of Micophenolate.

Environment: DEC-VAX VMS, SAS/Base, SAS/Stat and SAS/Graph.

Monsanto

1990 – 1993

Developed an integrated system to analyze product stability data for recombinant Bovine Somatotropin (rBST) and automatically generate complex textual and graphical reports.

Environment: IBM-AIX Unix, IBM VM-CMS, SAS/Base, SAS/Stat, SAS/Graph, SAS/AF and SAS/FSP.

Dow Chemical Corporation

1989

Developed software to analyze data for prospective and retrospective epidemiological studies of health and environmental data.

Environment: IBM VM-CMS, SAS/Base, SAS/STAT, SAS/AF and SAS/FSP.

SENIOR SYSTEMS ANALYST

1988 - 1989

American Express Information Services Company

Omaha, NE

Project Manager of software implementation and quality assurance with management responsibility for 5 Systems Analysts.

Designed database conversion software.

Evaluated and implemented a 4th generation database and programming language.

Designed a management reporting system with 1700 user selectable report variations.

In charge of validation standards for a mainframe based medical billing system.

Theodore J. Feuerbach (p. 4)

ASSISTANT DIRECTOR OF DATA PROCESSING 1985 - 1988  
Saginaw Medical Center  
Saginaw, MI

Managed a 24hr/365day clinical laboratory information data center.  
Developed and implemented a cost accounting and income/volume system.  
Designed an anatomic pathology system.  
Created components of a CAP workload recording system.  
Developed operations automation software.  
Performed numerous mainframe hardware and system software enhancements.  
Developed on-line, real-time system and instrument interfaces.  
Redesigned and diagnostically organized the patient reporting system.

ADDITIONAL EXPERIENCE

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.

EDUCATION

BS – BIOLOGY 1982  
Radford University  
Radford, VA  
209 credits with 128 in Life Science, Computer Science, Chemistry and Math.

Advanced SAS/AF Programming Course Certificate  
SAS Institute  
San Francisco, CA 2000

MEMBERSHIPS

American Association for the Advancement of Science  
Drug Information Association  
American Microscopical Society  
Bay Area SAS Users Group  
San Diego SAS Users Group