RAYMOND C. HEIMBUCH

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Bridgewater, NJ 08807
(908)725-4676

SUMMARY:

Proven record of working effectively to deliver validated, submission quality, clinical data, supporting tables and computer systems to summarize clinical findings. Key member of management and development teams. Functioned successfully as head of an operational department and as head of several key Information Services projects. Have a unique combination information systems technical and management skills.

AVAILABILITY and CONTACT info:

Now. Ray@HeimbuchAssoc.com 908-278-0973

PROFESSIONAL EXPERIENCE:

HEIMBUCH ASSOCIATES LLC **MAR 2008 TO PRESENT**

Independent Consultant Group

Consultant to major pharmaceutical organizations. Projects include UNIX and SAS system development of automated analysis dataset creation system, key member of global standards definition team working on CDISC compliant standards for clinical development. Mapped legacy neurological data to SDTM standard for submission to CAMD industry intitaitve. Validation of submission tables and datasets. Provide clinical programming support for Oncology and Neurology trials at major pharmaceutical companies. Key member of rapid response programming team generating adhoc support for Nuerologic Regulatory Submissions and Phase 4 oncology clinical group. Working in UNIX and Windows environment supporting SAS programming.

NOVARTIS PHARMACEUTICAL **2001 to 2008**

Biostatistics and Safety Reporting
Senior Principal Programmer

Senior member of clinical programming group, responsible for implementation and adherence to programming standards and procedures. Lead of CDISC cross-functional group to determine impact and response of CDISC standards upon Novartis procedures. Lead of development team preparing pilot CDISC submission to FDA. In support of this project developed a validated mapping application for the conversion of standard analysis datasets to CDISC compliant submission package. Represented my company on five HL7/CDISC workgroups including SDS Trial design, Protocol Representation, Define.XML, ADaM, and Bridge project. SAS development programmer for major pharmaceutical on global clinical report standardization project. Lead in re-validation project of company wide statistical reporting package. Member of large team which established new hardware, software, database, statistical, and reporting standards for all clinical research facilities of a major pharmaceutical. Responsibility included development of report specifications, SAS implementation, testing, and validation of the reports. Provided programming support of oncology clinical trials and directed the efforts of several other trial programmers as Project programmer lead of multiple compounds. Developed and maintained effective relationships with clinical, statistical and data management peers within clinical teams.

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PROFESSIONAL EXPERIENCE: (continued)

HEIMBUCH ASSOCIATES **1994 - 2001**
Independent Consultant Group

Projects include: Development of SAS macro system to generate standard clinical study summary and data listing reports for use in regulatory submissions in Europe, Great Britain, Japan, and United States. Design and manage the installation of Microsoft BackOffice software suite for pharmaceutical consultant group. Project Leader for development of innovative promotion payment program for major manufacturer of consumer candies, Validation of major pharmaceutical SAS/Oracle based Clinical system. SAS support of clinical trials for major pharmaceutical, Client Server application in support of an international Shipping concern monitoring the movement of cargo containers. Database application for International Pharmaceutical firm monitoring the work flow for major marketing events, Multimedia training program for major Pharmaceutical corp., and Strategic Market survey for Clinical Research Organization.

ANDERSEN CONSULTING **1995**
Arthur Andersen & Co., S.C.
Strategic redesign of major pharmaceutical R&D facility. Lead analyst on Information Technology Needs Assessment. Developed and presented integrated technology strategy to support regulatory submissions.

BRISTOL-MYERS SQUIBB COMPANY, BRISTOL-MYERS PRODUCTS DIVISION 1985 to 1994
Consumer Affairs Manager (1991-1994) Department Head. Negotiated incremental improvements in the cost of the function. Within one year, reduced the per call costs by 30%. Established two special purposes, outside facilities. One facility services coupon inquiries, realizing a $55,000 per year savings. The other facility generates a net profit via direct sales program.

Information Services Dept. Research and Development Area Project Manager (1987-1990)
Directed development and implementation of all computer systems in the R&D facility

Information Systems, Logistics Project Manager (1985-1987)
Developed and maintained APL systems which aided the forecasting of product demand.

ORTHO PHARMACEUTICAL CORP. 1982 to 1985
Department of Medical Statistics and Data Management Manager of Application Programming
Supervised a staff of sixteen programmers in SAS support of statistical analysis of clinical data.

SCHERING-PLOUGH CORP. 1980 to 1982
Department of Information Systems Senior Systems Analyst, Project Leader, Toxicology
Created and implemented a SAS computer system to support pre-clinical research.

YALE SCHOOL OF MEDICINE 1976 to 1980
Department of Human Genetics Research Associate
Developed SAS and PL1 statistical programs to analyze data on the genetic basis of complex human behavior such as depression and stuttering.

EDUCATION:

YALE UNIVERSITY 1973
M. Phil. in Physical Anthropology

UNIVERSITY OF CALIFORNIA AT DAVIS 1970
B.S. in Genetics

T*wenty-two statistical publications in scientific journals on Physical Anthropology, Human Genetics, Anatomy, and Archaeology.*

Technical Expertise:

Computer Systems/Operating Systems

Windows XP , Windows NT, AIX, HPUX, LINUX, VMS, OS/2, MVS, TSO, CMS

Database Environments

Oracle, SQL Server, Fox Pro, Paradox, Clipper, DB2

Computer Languages

SAS, REXX, APL, Forth, Motorola 6809 Assembler

Software Packages

SAS V8.2, NT Server, Exchange Server, Proxy Server, Crystal Reports, Relational Reportwriter, FoxPro for Windows, Authorware, Corel Draw, Paradox for Windows, Quattro Pro, WordPerfect, AskSam, DB2, Ingress, Oracle

Design Concepts

Structured Analysis and Design, Relational Database Design, Object oriented Analysis and design.

Projects:

Consult with Global pharmaceutical firm on CDSIC based global standards for CRFs, data structures, reporting and programming standards.

Develop project standard SAS data edit checks for oncology project in a UNIX based environment. Provide support to data management team for database lock on key oncology trials.

Develop and design a UNIX based SAS system for automated production of analysis datasets.

Provide programming support for rapid response programming team. Turn around clinical requests for analyses as part of integrated team of statisticians and programmers.

Direct the retrospective validation of standard tables and listings system. Coordinate definition and execution of validation plan, working closely with Quality Assurance representatives and Departmental management to establish validation of a production system.

Provide trial support for major pharmaceutical oncology group.

Manage programming group developing CDISC SDTM mapping system. Design and implement SAS based architecture acting as lead programmer and directing the efforts of two additional programmers.

Participate as team member in the development of a validated global standard tables and listings system. SAS based macro system with standard data structures and multiple tables and listings defined.

Design and implement the construction of a NT network for a small pharmaceutical consultant group. Installed and configured network of 10 personal computers using Ethernet. Installed Microsoft BackOffice for Small Business Server. To provide additional functionality in support of group functions such as Calendar and shared Contact lists upgraded to Exchange Server 5.5. Wrote VBASIC scripts to support enhanced functions in Contacts. Maintained the intranet site for shared resources within the consultant group.

Projects (cont'd):

Project Leader for innovative new promotion payment system for major consumer candy manufacturer. Member of team comprised of business managers and technical managers whose task is the creation of new performance oriented reimbursement program for customers of major candy manufacturer. If successful, the program will dramatically redefine the relationship between manufacturer and customer in the tobacco/candy arena. Technical aspects of the system are SAS based data warehouse technology with data being supplied by customers, being scrubbed by members of the team, and being converted into business intelligence suitable for use by the sales organization. Led the Pilot project as technical manager, determining the policy, process and procedures necessary to validate the successful accomplishment of the business requirements of the program.

Validation of SAS/Oracle Clinical system. Major pharmaceutical firm international development effort. Designed, wrote and executed test scripts necessary for the validation and qualification of the new system. SAS components utilized in testing were VAX based SAS version 6, PC-SAS version 6.11.

SAS programming support of clinical trials for major pharmaceutical. Developed and executed SAS macros to generate data listings and analysis reports.

Fox Pro for Windows - World-wide Shipping application, tracking current position of Cargo containers. Develop screens, reports, optimize performance on LAN and WAN. SQL Server conversion of FoxPro application to use of a SQL Server under Windows NT.

Authorware by MacroMedia - Multimedia instruction in Regulatory Affairs for major pharmaceutical. Develop interactive instruction package using 486 based stations.

REXX coordination of multiple Amiga computer applications with real-time exchange of data between successive approximations of values and graphic representation of relationships.

REXX - Develop REXX programs to append data collected at a remote call center to the existing Consumer Affairs database. Read ASCII, comma delimited data, parsed it and constructed new records compatible with prior system.

Relational Reportwriter - developed reports to summarized information being collected by Consumer Affairs call center. Reportwriter is general purpose report package developed to access Xbase databases.

SAS - Decision support using graphics and base statistics capabilities of PC - SAS.

REXX interface to Canadian Call center transferring ASCII files of collected consumer information to Xbase database.

APL under MVS support of Logistics Dept.. System to support the forecasting function incorporating data from warehouse shipments to forecast and schedule production requirements.

Management and guidance of SAS programming in support of Clinical trials. Convert statisticians requirements into SAS datasets. SAS on DEC environment.

Design and implement SAS programs on MVS system to support Pre-Clinical Toxicology research. Extensive SAS manipulation of data collected on PDP-10 and transferred to IBM system.

SAS programs to support research in Human Genetics. Extensive manipulation of SAS datasets to clean data for incorporation into Maximum Likelihood estimation programs.

PL1 programs to record and analyze family pedigrees.

APL programs to evaluate Maximum Likelihood of familial patterns in pedigrees.