MARGUERITE KOLB

Statement of Qualification for Election to EDA's Mediation Board

I am submitting my Curriculum Vitae (CV) and this statement as a testament to my qualifications for holding a position on the EDA's Mediation Board.

Throughout my life I have always been the person my family and friends turn to when they needed advice in resolving issues. They understood that I would listen to what they were saying and what they thought was the issue. I would ask the questions that would get to the core issue taking into consideration all the parties involved, their thoughts and feelings, and work with them on developing a peaceful and cooperative solution. While taking part in these conversations, I would take my own personal opinions and feelings out of the equation. This is a skill that I feel is vital in a mediator.

Working in the corporate world in global companies I see the need for mediation every day. Through the various positions that I have held I have had the opportunity to discuss and resolve issues that involved several different departments within the company. In order to create effective resolutions that are satisfactory to all the parties involved research has to occur to ensure that all the facts were present, that the formal regulations and policies are being interpreted correctly, that the issue is clearly defined and that all parties, including the mediators, understand all aspects of the issue. My work involves disseminating the government regulatory agency regulations, policies and guidelines, making sure that all departments within the company understand them and are correctly implementing them and answering and resolving any issues that occur from misunderstandings. I feel this work has greatly assisted me in developing my collaboration and mediation skills.

Thank you for your consideration.

Marguerite Kolb

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EXPERIENCE

AUGUST 2017 – PRESENT

PRINCIPLE, CLINICAL DATA STANDARDS, SUBMISSIONS & REGULATORY INTELLIGENCE, JANSSEN PHARMACUETICALS

- Provide significant expertise in data submission requirements and strategies and leads and participates in highly complex cross-functional initiatives involving clinical data standards, departmental processes, training and support related to regulatory submissions and submission standards.
- Support and influence the company's strategy by fully engaging in industry and Regulatory Authority discussions related to data submissions, interpreting the regulations, requirements and guidance's and ensuring the company is aligned to all regulatory requirements.
- Coordinate the internal review and interpretation of newly released or updated Regulatory Authority and industry guidance documentation related to data and data submission.
- Represented the company at external working groups and conferences connecting with the Regulatory Authorities, such as the FDA, PMDA, CFDA, EMEA, focusing on information sharing of data standard requirements and evolution in the industry.
- Assisted in the testing and implementation of new and updated externally developed software tool for clinical trial data validation.

AUGUST 2016 – AUGUST 2017

SDTM EXPERT, JANSSEN PHARMACUETICALS

- Took on an active role in defining and maintaining the company's data submission processes: made decisions on need, changes, updates to these processes and ensured policies, SOPs and job aids are in place and up to date.
- Provided guidance to various company department staff related to data submission activities. Produced training materials and provided training when needed.
- Actively developed documentation and processes regarding the content of Study Data Tabulation Model (SDTM) data standards, ensured standards documentation is available to departments.

JULY 2003 – AUGUST 2016

PROGRAMMING MANAGER, JANSSEN PHARMACUETICALS

- Coordinated programming activities for multiple clinical trials or a specific indication for a product.
- Assisted with analysis planning; Developed project plans including time frames and staffing estimates.
- Assisted with project specific training and supported performance reviews.
- Reviewed and approved program specification documents and validation plans.
- Represented the Clinical Research Programming Department in clinical team meetings and other interdisciplinary settings.
- Developed and documented programs to create analysis datasets summarizing key clinical trial data.
- Trained new personnel in departmental procedures and tools.
- Performed and documented quality control checks for programs.
- Participated in the development of SAS programming SOPs, guidelines and training materials.
- Assisted in the testing and implementation of new and updated internally and externally developed software as well as new SAS releases.

AUGUST 2002 – JULY 2003

SAS CLINICAL TRAILS PROGRAMMER, EDP CONTRACT SERVICES

- Provided coding, testing and implementation support for SAS programs used for pharmaceutical clinical research.
- Developed and documented programs to produce datasets, tables, listings, graphs and reports used to analyses and summarize clinical trial results.
- Performed and documented quality control checks for programs.

FEBRUARY 2001 – AUGUST 2002

PROGRAMMER/WEBSITE DEVELOPER/LANGUAGE TRANSLATION PROGRAM MANAGER, ELECTRONIC COMMERCE CODE MANAGEMENT ASSOCIATION

- Responsible for the creation, development, installation and testing of new programs, features, enhancements and updates to the company's website utilizing HTML, Perl, PHP, CGI, MySQL, FTP, and Emacs.
- Creation of databases for Language Translation project. Developed processes for storing, updating and maintaining language translation databases.
- Maintenance of Visual Basic searcher program.
- Provide technical support worldwide for website users and staff via technical papers, manuals, presentations, telephone and e-mail.
- Implemented the automation of processes previously performed manually.

1988 – 1999

CLINICAL SAS PROGRAMMER ANALYST (1990 TO 1999)
COMPUTER OPERATOR (1988 TO 1990), COVANCE , INC.

- Provided analysis, design, coding, testing and implementation support for SAS programs used for pharmaceutical clinical research. Created tables, listings, graphs, and diagnostics to identify data errors, and create data transfer files in client specified formats.

- Developed documentation to support user interface, customized applications and system changes.
- Acted as key point of contact for technical questions regarding in-house developed Laboratory System.
- Worked closely with internal users/clients to develop and enhance new or existing systems.
- Originally hired to support the programming and data management environment. Coded and input data; handled console operations.

Achievements:
Received special recognition for early completion of Takeda project.
Finished Integrated Safety Summary for submission to FDA ahead of scheduled completion date.
Received Team Award as member of Proctor & Gamble Risedronate Team.

1983 – 1987

LEAD TERMINAL OPERATOR/TECHNICAL SPECIALIST, FIREMAN'S FUND INSURANCE

- Provide technical and hardware support for all system users.
- Assisted with network upgrade, including cabling coax from system to system.
- Managed all print functions, distributing batch reports and sorting output from previous day.
- Assumed responsibility for policy amendments during 4-month absence of coworker, while continuing responsibilities as Senior Homeowner Entry.
- Initially hired in a data entry role, coding and entering homeowner's policies

EDUCATION

NOVEMBER 2010

CONTINUING EDUCATION, CDISC
Define XML

DECEMBER 2002

CONTINUING EDUCATION, NORTHAMPTON COUNTY AREA COMMUNITY COLLEGE
Dreamweaver on-line course

DECEMBER 2001

DIPLOMA IN COMPUTER PROGRAMMING, THE CHUBB INSTITUTE

1990-1993

CONTINUING EDUCATION, THE SAS INSTITUTE

SAS Macro, SAS Graph, SAS Stat, SAS Report Writer

DECEMBER 1989

CONTINUING EDUCATION, MERCER COMMUNITY COLLEGE

Introduction to SAS, BASE SAS

JUNE 1983

ASSOCIATES DEGREE IN COMPUTER SCIENCE, WIDENER UNIVERSITY