ELIZABETH WIMMER, MISM

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SUMMARY

Total of 22 years of pharmaceutical development experience:

- Clinical Program/Project Management
- Medical Writing (Protocol, Final Clinical Study Reports, Investigator's Brochures, etc.)
- In-House Clinical Research Associate (CRA)
- Regulatory support for IND, IMPD, and Orphan Drug programs, Trial Master Files
- Auditing
- Design and implementation of systems compliant with 21CFR and/or Sarbanes-Oxley for pharmaceutical and financial companies
- Computer Systems Validation
- Computer Systems Project Management
- Quality Control
- Quality Assurance
- Pharmaceutical Development Project Management

THERAPEUTIC EXPERTISE

Adult

- Oncology: Relapsed/Refractory Multiple Myeloma, Bladder Cancer, Head and Neck Cancer, Glioblastoma, Breast Cancer, Immune Thrombocytopenia
- Cardiovascular: Pulmonary Atrial Hypertension
- Immunology: Hereditary Angioedema, Allergic Rhinitis, Rheumatoid Arthritis

Pediatric

- Autism, ADHD

COMPUTER EXPERIENCE

- Programming Languages: Microsoft .NET / Visual Basic 6 / Visual Basic for Applications, ColdFusion, HTML, SQL
- Computer Technologies: Active Directory, ActiveX, ADAM, ADO, COM, Cryptography, LDAP, Sharepoint, M-Files
- Development Technologies: Ant, Bugzilla, Concurrent Versions System, Confluence, CruiseControl, Eclipse, InstallShield, JIRA, VMWare
- Development Methodologies: Agile, Continuous Integration, Scrum, Test-Driven Development
- Electronic Data Capture: OpenClinica, DataTrak, MedNet, Inform, HP Digital Pen/Forms Automation, BioClinica, Proprietary system, and fax-based system
- Compassoft Enterprise (Enterprise spreadsheet discovery, analysis, and risk management)

EDUCATION

KELLER GRADUATE SCHOOL OF MANAGEMENT, KANSAS CITY, MO 2006

Masters in Information Systems Management

UNIVERSITY OF KANSAS, LAWRENCE, KS 1993

Bachelor of Arts in Microbiology

Independent Contractor **2006 – 2016**
Consultant

Responsibilities include executive-level Clinical Operations Program/Project Management, Medical Writing, In-House CRA, Auditing, SOP Development, QC Review, and Data Management Services.

- Program/Project Management services include budget design and negotiations, CMC oversight, clinical protocol development, CRF design, CRA and vendor management, site selection, recruitment/enrollment support, conducting team meetings, training, acting as liaison between site, CRAs, and sponsor, troubleshooting and resolution of site/sponsor issues, and proactive monitoring of study progress to ensure both regulatory and sponsor expectations are met.
- In-House CRA services include printing and distribution of CRFs and associated study materials to sites, inventory shipping, management, and tracking, and maintaining custom on-line study management portal, collection, review, tracking, and storage of Site Master File and Trial Master File documents (ICH and DIA models), with secure hardcopy and electronic storage
- Auditing services include vendor and clinical site qualification and GMP/GLP/GCP audits
- Medical Writing services include IND/IMPD amendments, annual reports, Investigator's Brochures, protocols, study-related materials, and final reports.
- Regulatory services include creation, editing, updating, and filing support for IND, IMPD, and Orphan Drug programs with US and foreign regulatory agencies.
- Data Management services include design and programming of VB/VBA-based software systems for data consolidation/transformation and generating reports.

Selection of Representative Clinical Projects

Phase	Indication	Number of Sites	Number of Subjects
III	Autism	30	200
II	Immune Thrombocytopenia (EU)	5	30
II	Immune Thrombocytopenia (US)	3	36
Ib	Rheumatoid Arthritis	7	54
III	Autism	18	170
I/II	Glioblastoma – Investigator-held IND	4	120
II	Pulmonary Atrial Hypertension (2 studies)	3	15
I/II	Bladder Cancer – Investigator-held IND	16	60
I/II	Head and Neck Cancer – Investigator-held IND	4	80
I	Relapsed/Refractory Multiple Myeloma – Investigator held IND	4	40
III	ADHD	15	140
IIb	Relapsed Refractory Multiple Myeloma	35	250
II	Refractory Multiple Myeloma	25	120
III	Hereditary Angioedema	4	16
I	Relapsed/Refractory Multiple Myeloma	10	100
1b	Relapsed/Refractory Multiple Myeloma with varying degrees of renal function	5	75
1b/II	Relapsed Solid Tumors and Multiple Myeloma	5	75
N/A	Continuation Multiple Myeloma for subjects responding to therapy	50	250
II	Perennial Allergic Rhinitis (Cat Chamber exposure)	3	180
Ib	Breast Cancer (vaccine, 2 studies)	2	300

COMPASSOFT, INC. **2005-2008**
Senior Director
Integration of software systems with Compassoft's Enterprise-level application framework for financial spreadsheet discovery and analysis. Responsible for product deployment and support, development of new features and technologies, meeting with clients to address business needs, integration with third-party software systems, and implementation of agile development processes.

WIMMER SYSTEMS, INC. **1999-2005**

Consultant

Responsibilities included management of legal and financial aspects of business, customer service, web server maintenance, marketing, life-cycle systems development, programming, documentation, and software validation. Developed and implemented web-based scientific reporting system for pharmaceutical contract research organization using Cold Fusion and Microsoft Access. Primary developer for industry-leading software system, providing Microsoft Excel compliance with FDA 21 CFR 11 regulations for electronic records and electronic signatures, using VB6 and VBA. Developed VBA-based microbiological data analysis program in conjunction with Hewitt Bioassays. Highly sought after consultant on 21 CFR 11 and computer validation topics. Company acquired by Compassoft, Inc. in 2005.

OREAD LABORATORIES **1996-1999**

Project Manager, Microbiology 1998-1999

Project Manager and senior technical expert in pharmaceutical microbiology for contract drug development. Responsibilities included business development, project management, report writing, microbiology research and consulting, and development and validation of microbiological methods in a GXP environment. Additional responsibilities included ensuring compliance with FDA requirements, consulting on formulations development work, and maintenance of computerized laboratory systems. Expertise in aseptic technique, barrier isolation technology, vapor hydrogen peroxide sterilization, USP compendial microbiological methods, and environmental monitoring. Developed, validated, and implemented Laboratory Information Management System using VBA, Microsoft Excel, and Microsoft Access

Quality Assurance Auditor, GLP/cGMP Quality Assurance 1996-1998

Responsible for performing data, report, and systems audits in support of drug development projects (IND/NDA/ANDA). Audits included areas such as animal studies, chemical synthesis, analytical chemistry, bioanalytical chemistry, microbiology, validation, facility, and sub-contractor audits. Served as liaison for ANDA program. Developed, validated, and implemented multi-user audit tracking system using VBA and Microsoft Access, time-entry interface system for in-house database, and interface systems for PeopleSoft implementation.

BOEHRINGER INGELHEIM VETMEDICA **1994-1996**

Supervisor, Microbiological Quality Control

Responsibilities included direct management of Quality Control laboratory operations and personnel performing microbiological testing in a cGMP production environment. Technical expert in pharmaceutical microbiology and environmental monitoring. Provided technical consulting to manufacturing on microbiological issues. Responsible for the development and validation of microbiological methods under FDA, USDA, and EU requirements, microbiological cleaning validation program, production line environmental monitoring program, and implementation of barrier isolation technology.