BARBARA W. UNGER

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GMP AUDITING and DATA INTEGRITY ASSESSMENTS

Demonstrated expertise in GMP auditing and associated remediation for both traditional small molecule drugs and biotechnology products including evaluations of data governance and data integrity. Audit experience includes leadership of the Amgen Inc. Corporate Audit group responsible for API, drug substance, Quality Systems, and computer systems, and auditing in the consultancy area for both Don Hill & Associates and Unger Consulting Inc. Deep understanding of history and intent of CDER, CBER, and EMA GMP requirements. Ability to interpret requirements and impact of potential changes and trends. Able to quickly identify and analyze new GMP enforcement requirements and trends and communicate impact to relevant functional areas and senior management to set priorities, initiate policy changes and identify advocacy opportunities. Developed and implemented comprehensive GMP Regulatory Intelligence program within Fortune 500 pharmaceutical company.

Areas of expertise:

- GMP Regulatory Intelligence
- GMP Enforcement & Trends
- GMP Inspection Readiness Evaluations
- GMP Auditing
- Advocacy Strategies
- Data Management / Data Integrity Assessments
- GMP Training
- Policy Issues & Interpretation

SELECTED ACCOMPLISHMENTS

- Data management / data integrity assessments
  - Served as interim data integrity officer for small US based CMO. Developed plan for data governance program. (2016)
  - Audited Global Pharmaceutical Company sites for data integrity concerns; wrote reports and co-authored final report summarizing status of all twenty-plus sites along with suggestions for remediation (2015)
- Led Corporate GMP audit group focused on API, drug substance, computer systems and Quality Systems.
- GMP consultant to pharmaceutical industry with emphasis on biotechnology products.
- Developed, implemented and maintained comprehensive GMP Regulatory Intelligence program within Amgen Inc. for eight years, including surveillance, analysis and communication of new or revised legislation, regulations, guidance and GMP inspection trends for major regulatory jurisdictions.
- Founding chairperson and 5-year leadership of Rx-360 working group for GMP/GDP Intelligence Reporting.
- Led GMP Intelligence subgroup of the Midwest Discussion Group 2010-2014.

PROFESSIONAL EXPERIENCE

UNGER CONSULTING, Inc., Newbury Park CA **2014 – present**

- Provide GMP auditing and consulting services to the pharmaceutical and biotechnology industry, with a focus on data integrity assessments

- Editor-in-Chief for weekly GMP Newsletter published by FDAzilla
- Currently co-lead of the Rx-360 Data Integrity Working Group

AMGEN Inc., Thousand Oaks, CA **2004—2014**

Director, External Quality, 2009-2014

Director, Corporate Quality Compliance, 2006-2009

Developed, implemented and maintained a comprehensive GMP Intelligence program for 8 years. Included surveillance, analysis and communication of new or revised legislation, regulations, guidance and GMP inspection trends for major regulatory jurisdictions.

- Published bimonthly newsletter with readership of >1000 Amgen staff.
- Special data collection and analysis for Quality Senior Vice President.
- Led or participated in industry trade group efforts to influence regulatory authority policy decisions.
- Founding Chairperson of the Monitoring and Reporting work stream of Rx-360 Supply Chain Trade Organization (2009 – 2014).
- Chairperson of the GMP-Intelligence Subgroup of the Midwest Discussion Group (2010-2014).

Associate Director, Corporate Quality Compliance, **2004-2006**

Led group of up to six auditors responsible for internal audits of Active Pharmaceutical Ingredients (API) manufacturers, both Amgen owned and contract manufacturers located outside the US. Audited Corporate Quality Systems. Scheduled, coordinated and conducted audits, wrote reports, assigned criticality, followed up corrective actions, developed and communicated metrics / issues to management.

DON HILL & ASSOCIATES Inc. **2001-2004**

Consultant to Biologics and Pharmaceutical industries regarding CGMP Compliance, Quality Programs and CMC aspects of Regulatory Affairs.

Principal Consultant

- Assisted mid and large cap pharmaceutical clients in development and implementation of Quality System GMP improvements.
- Performed mock inspections as preparation for regulatory agency inspections, developed gap analysis and prioritized remediation activities.
- Assisted clients responding to FDA 483 inspection observations and warning letters.

ELI LILLY AND COMPANY, Indianapolis, IN. **1994-2001**

Associate Regulatory Consultant, Quality Unit, **2000-2001**

Developed and implemented project management plan to prepare both company owned and contract manufacturing sites for pre-approval inspection (PAI) for a novel recombinant protein product.

Associate Regulatory Consultant, Regulatory Affairs, CMC **1996-2000**

Senior Regulatory Representative, Regulatory Affairs, CMC **1994-1996**

Responsible for global CM&C and facility regulatory issues for selected biotechnology pharmaceuticals. Developed regulatory plan and strategy relative to CM&C and facility issues ensuring that regulatory issues align with other areas within the project team. Served as technical mentor to new department members assigned to biotechnology products.

- Coordinated, wrote and edited CM&C sections of regulatory submissions such as IND's, IND amendments, CTX, annual reports and BLAs or NDAs for the development phase project teams. Additionally, coordinated interaction with FDA reviewers as needed to resolve issues

- Provided due diligence assessment of potential joint business ventures for Business Development group, provided input on structure of contractual agreements for joint ventures.

EDUCATION

B.S., Chemistry major, Microbiology minor, University of Illinois, Urbana, Illinois.

SELECTED INVITED PRESENTATIONS

- Rx-360 Annual Conference, November 3-4, 2016, *invited*. *Tracking Data Integrity Issues Across the Globe*
- SoCal PDA Chapter's 6th Annual Industry Summit Expo, October 6, 2016. *Form 483 Trends in Data Integrity and Documentation*
- PDA Southern California Chapter, May 10, 2012, *Data Integrity Including Electronic Records: Still an Issue to the Industry*
- Puerto Rico Pharmaceutical Quality Association / U of WI School of Pharmacy, January 2012, *Data Integrity Including Electronic Records: Still an Issue to the Industry*
- *InformEx Webinar presented in Conjunction with Rx-360, Enforcement for FY2015 Including Data Integrity Focus* December 3, 2015

DATA MANAGEMENT / DATA INTEGRITY TRAINING

- **Electronic Data and Computerized Systems Compliance**; Taught by Monica Cahilly of Green Mountain Quality Assurance LLC in 3Q2010
- **Computerized Systems Validation & Audits of Computerized Systems;** Taught by Monica Cahilly of Green Mountain Quality Assurance LLC in 3Q2010
- **Reviewing Electronic Data & Audit Trails;** Monica Cahilly of Green Mountain Quality Assurance LLC webinar December 16, 2015
- **Data Integrity Assurance & Investigations of Electronic Data and Computerized Systems: current perspectives for U.S. FDA compliance**; Monica Cahilly of Green Mountain Quality Assurance LLC, February 22-23, 2016
- **Advanced Data Integrity / Train-the-Trainer;** Monica Cahilly of Green Mountain Quality Assurance LLC, February 24-25, 2016