pbaker@liveoakqa.com

Peter E. Baker

Education

2007 – 2010 San Francisco State University San Francisco, CA

M.S. / Chemistry

1998 - 2002 Point Loma Nazarene University San Diego, CA

B.S. / Chemistry-Biology

Professional Experience

November 2021 - Present

Live Oak Quality Assurance

President – Austin, TX

- Providing unique GXP solutions to clients around the world focusing on data integrity and data governance
- Industry and regulatory training in critical thinking, quality culture, and data governance

March 2019 – November 2021

Green Mountain Quality Assurance

Vice President – Austin, TX

- Provided pharmaceutical consulting services to industry and regulator clients around the world, including training, mock inspection, and quality systems development
- Provided specialized quality systems development and training in the area of data integrity and data governance
- Provided training and expert consulting services to senior management teams and regulators around the world in the area of current regulatory expectations for GXP compliance, cultural excellence, data governance, quality metrics, leading quality indicators, and continuous process monitoring using advanced big data analytics

February 2018 – March 2019

U.S. Food and Drug Administration - Office of International Programs

International Relations Specialist – Santiago, Chile

- Responsible for regulatory systems strengthening activities in the Latin America region working with international regulatory organizations such as the International Council on Harmonization (ICH), the Pharmaceutical Inspectorate Cooperation Scheme (PIC/s), among others
- Worked to establish clear communication pathways between FDA and regulatory agencies in the region to share information on drug shortages, inspection/review best practices, import operations, and other areas of common interest
- Served as embassy country head coordinating FDA regulation, outreach and education programs in South America related to foods, drugs and medical devices

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Professional Experience (cont.)

February 2015 – February 2018

U.S. Food and Drug Administration - Office of International Programs

Assistant Country Director (Drugs) – Beijing, China

- Performed more than 60 high risk CGMP inspections of human drug manufacturers, resulting in regulatory actions including import alert, warning letters, regulatory meetings, and voluntary recalls of APIs and drug products distributed to the US market
- Worked with the Chinese FDA to help develop a robust regulatory system through training, education and collaboration

September 2012 – February 2015

U.S. Food and Drug Administration - Office of International Programs

Assistant Country Director (Drugs) – New Delhi, India

- Performed high risk cGMP inspections of human drug manufacturers throughout India and the surrounding region
- Conducted a variety of training and development exercises for manufacturers and foreign regulators
- Performed joint GMP manufacturing inspections with a variety of foreign regulatory bodies
- Conducted joint investigations alongside local and regional investigation teams to facilitate harmonized regulatory actions

January 2008 – September 2012

U.S. Food and Drug Administration - Office of Regulatory Affairs

Consumer Safety Officer – San Francisco, CA

- Performed pharmaceutical cGMP inspections of domestic and foreign drug manufacturers, control laboratories, device manufacturers, clinical research organizations, and other FDA regulated businesses

January 2005 – August 2007

Guidant Corporation / Abbott Vascular

Quality Engineer – Temecula, CA

- Performed regular cGMP and GLP audits both internally and at contract facilities and laboratories to ensure global compliance with device and drug regulations
- Worked as a Quality Assurance Engineer focusing on global regulatory compliance, primarily US and EU regulations for a combination product (drug eluding stent)

January 2004 – June 2004

Guangxi University of Science and Technology

Associate Professor – Liuzhou, China

- Helped develop a university English department to fit the needs of China's growing economy
- Taught Oral English and Western Culture classes to Chinese engineering students

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Professional Experience (cont.)

September 2003 – January 2003

LGF Ag-Tech Co. China

Consultant-Chemical – Zhanjiang, China

- Worked closely with both Chinese engineers and scientists as a chemical engineering consultant
- Learned how to solve problems without the ability to fully communicate in the same language

August 2002 – August 2003

Cardinal Health

Chemist – San Diego, CA

- Worked in GMP/GLP environment
- Conducted laboratory methods development and validation
- Was the primary chemist involved in WFI water system validation for a new sterile drug manufacturing facility

Notable Achievements

- The Patrick J. Pouzar Award – FDA Investigator of the Year 2013
    - Investigator of the year award received due to a significant number of FDA regulatory actions taken including product recalls and import bans based on inspections where breaches in data integrity were uncovered which affected a wide variety of products in US distribution
- 2016 FDA Human Capital Investment Award
    - Human Capital Investment Award received based on data-integrity-driven collaborative initiatives with the Chinese Regulatory Authorities, including training and capacity building