

## BARRY J. RENAUD

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Phone: +1-760-724-1696  
Fax: +1-509-278-8955  
E-mail: barry\_renaud@qasinc.com

### **PROFESSIONAL EXPERIENCE:**

October 1995 to Present:

#### **PRESIDENT QUALITY ASSURANCE SYSTEMS, INC.**

30848 Villa Toscana  
Bonsall, CA 92003-6216

February 1990 to September 1995: Proprietor, Quality Assurance Systems

Perform Good Clinical Practice (GCP) & Computer System Validation Documentation Auditing – Provide GCP, Regulatory & Safety Surveillance Consulting – Write and Review Clinical Operations and Quality Assurance SOPs – Perform GCP and Audit Training services for the biotechnology, medical device and pharmaceutical industries. Manage & Direct Monitoring and Retrospective Data Collection projects. Have supplied expert and discovery witness services & testimony to corporate and outside legal counsels. Have served as an Application Integrity Policy auditor. Have performed the following types of audits and assessments for over 50 clients:

- Clinical Trial Center
- Clinical Research Process\*
- Adverse Event Reporting and Safety Surveillance Systems\*
- Inspection Readiness Assessments\*
- CRO & Core Lab (Imaging, IVRS, etc.) Audits & Assessments\*
- Clinical & Specialty Laboratory Audits & Assessments\*
- Computer System Validation Documentation
- Database
- New Drug Application
- Pre-Market Approval
- Clinical Study Report

\* Including the auditing of computer system validation documentation that was integral to the assessed processes.

Have instructed more than 100 GCP and auditor training seminars and have presented at conferences on GCP topics.

**DIRECTOR, QUALITY ASSURANCE**

March 1989 to February 1990

**McGraw-Hill Clinical Research International**

New York, NY

Reported to the President of this third party research company and started, organized and developed its QA Department. Duties included QA and QC consulting to the pharmaceutical industry as well as internal SOP development and implementation, contract review, regulatory oversight, auditing, training, and FDA liaison services.

**MANAGER, QUALITY ASSURANCE**

May 1986 through February 1989

**Boehringer Ingelheim Pharmaceuticals, Inc.**

Ridgefield, CT 06877

Reported to the Director, Drug Regulatory Affairs and started, organized and developed the Clinical QA function for this major pharmaceutical company. Duties included the development and implementation of SOP's and position descriptions and process audits of internal document management, data QC, and Drug Safety operations. Conducted and supervised internal and on-site audits and provided regulatory review for all clinical trial protocols, training to monitors and auditors, and served as the company's liaison to the FDA's Division of Scientific Investigations.

**CLINICAL RESEARCH ASSOCIATE**

January 1983 through April 1986

**Boehringer Ingelheim Pharmaceuticals, Inc.**

Ridgefield, CT 06877

Based in Chicago, IL. Performed regional monitoring services for all research products. Excellent performance rating. Promoted to start Clinical QA program.

**DISTRICT SALES MANAGER**

January 1980 through December 1982

**Boehringer Ingelheim Pharmaceuticals, Inc.**

Ridgefield, CT 06877

Based in Chicago, IL. Managed a District Pharmaceutical Sales team of 10 sales representatives.

**HOSPITAL SALES REPRESENTATIVE**

June 1977 through December 1979

**Boehringer Ingelheim Pharmaceuticals, Inc.**

Ridgefield, CT 06877

Based in Milwaukee, WI. Specialty pharmaceutical sales to academic and government hospitals and medical centers.

**PHARMACEUTICAL SALES REPRESENTATIVE**

April 1974 through May 1977

**Boehringer Ingelheim Pharmaceuticals, Inc.**

Ridgefield, CT 06877

October 1972 through March 1974

**Ayerst Laboratories**, A Division of American Home Products, Inc.

New York, NY

Based in Lansing, MI. Pharmaceutical sales to physicians, pharmacies, hospitals and medical centers.

**SECONDARY SCHOOL TEACHER**

September 1969 through June 1971

**Detroit Public Schools**

Detroit, MI

Based in Detroit, MI. Taught junior high school science and mathematics.

**HOSPITAL ATTENDANT**

June 1967 through September 1972

**Wayne County General Hospital**

Eloise, MI

Assisted nursing staff in providing patient care (Mixed full and part time position).

**EDUCATION:**

Bachelor of Science (Biology), 1969

Wayne State University, Detroit, MI

Forty post-graduate quarter credits in business, 1970 – 1972

Wayne State University, Detroit, MI

**MEMBERSHIPS:**

- Drug Information Association
- Society of Quality Assurance
- Association of Clinical Research Professionals

**SEMINAR INSTRUCTION:**

- Instruct an average of 18 public and in-house seminars per year. The titles of past and present seminars are listed below:
- Auditing & Assessing Clinical Systems
- Auditing Techniques for Clinical Research Professionals
- FDA Inspections
- Preparing for an FDA-GCP Inspection
- Good Clinical Practice
- FDA Bioresearch Monitoring Program
- Monitoring Like an Auditor

**CONFERENCES/WORKSHOPS:**

- Served as chairperson, speaker and seminar provider for Barnett International's Audits and Inspections Conference. One conference each year 1995 – 1998.
- Presented "Preparing for and FDA GCP Audit" presentation at 1997-ACRP annual meeting.
- Presented "Data Trend Analysis" presentation at 1997-ACRP annual meeting.
- Presented "Data Trend Analysis" presentation at May 2, 2000-DIA GCP Workshop.
- Presented "Data Trend Analysis as a Fraud Detection Tool at December 1, 2000 Barnett Conference on Fraud in Clinical Research
- Presented "Automated Data Trend Analysis" at DIA Electronic Clinical Trial Workshop on December 12, 2000
- Presented "Auditing Techniques for Detecting Fraud in an E-trial Environment" at Barnett International's Conference on Fraud & Misconduct in Clinical Research, October 25, 2001