

JOHN A. BENNAN

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PROFESSIONAL EXPERIENCE

ComplianceNet, Inc. - Golden, Colorado (1995 - Present)

President

Founded ComplianceNet to offer consulting services in GLP/GMP compliance, quality assurance and regulatory affairs. Serving clients needing assistance in establishing or improving defensible compliance programs that are based upon sound scientific rationale and that match a firm's stage in product development. Specialize in writing reports that detail not only the issues identified, but also the regulatory rationale behind the concerns and recommendations for corrective action.

- Provided GMP training seminars to industry and clients on significant areas of compliance specializing in topics and current issues in pharmaceuticals and biopharmaceuticals.
- Performed client specified internal audits, detailed area compliance reviews, and mock regulatory inspections of active pharmaceutical ingredient and finished drug product manufacturers, specializing in biopharmaceuticals and aseptic processing.
- Audited and assisted in oversight of contract manufacturers, contract laboratories, and raw material suppliers on behalf of clients.
- Led reviews for single and multi-product facilities including design and qualification of process equipment, support utilities, and laboratory systems to meet Design Qualification and/or GAMP requirements
- Generated regulatory submissions including CMC sections, Investigational New Drug Applications and Drug Master Files. Assisted in meeting preparation and regulatory strategy.
- Set-up Quality Assurance, Quality Control, and Document Control departments at multiple firms including all required GMP quality systems and associated Standard Operating Procedures.
- Established Process Validation programs that include development laboratories, clinical manufacturing and through conformance lots at market scale.
- Improved, replaced, and reengineered quality systems at the request of clients including, but not limited to cell banking, raw material control, document control, internal auditing, deviation handling, product release, and plant changeover.
- Extensive management consulting in assisting firms to develop existing personnel, expand departments with experienced personnel, and in developing quality departments to work as a team with the rest of the organization.

Synergen, Inc. - Boulder, Colorado (1987 - 1995)

Employment Summary

Established and developed the Quality Assurance (QA) Programs at Synergen to support clinical and marketable manufacturing of Biopharmaceuticals emphasizing a partnership between QA and all GMP areas. Extensive experience in quality system implementation at 3 facilities, including management of the inspection preparedness program for the large scale LakeCentre manufacturing facility. Overall skills and accomplishments include:

- Responsible for hiring and development of staffing up to 22 people and budget of 3 million dollars.
- Led compliance audits of internal departments, raw material suppliers, contract laboratories, and contract manufacturers.
- Responsible for final QA release of all drug products.
- Established and improved systems for GMP Documentation, Calibration, Maintenance, Cell Banks, Exception Reports, Plant Changeovers, Materials Review Boards, Labeling and Training.
- Established quality programs for the Validation of Equipment, Computers, Processes, and Cleaning that stress the importance of ongoing multi-departmental involvement.
- Reviewed and wrote Chemistry, Manufacturing and Control sections of regulatory submissions.

Associate Director, Quality Assurance (1994 - 1995)

- Responsible for Corporate Quality Assurance.
- Direct managers of Quality Assurance, Document Control, Validation, and the Raw Materials/Microbiology Laboratory.
- Responsible for all correspondence with the British MCA inspectors until receiving agency approval.
- Directed shutdown activities of the quality department at the LakeCentre facility to ensure completion of key quality functions and document/information retrievability.
- Evaluated staffing requirements and established new plan for Quality Assurance in association with corporate downsizing.

Quality Assurance Manager (1992 - 1994)

- Managed Product Release, Facility Compliance, Analytical Compliance, Computer Validation, Automation, Contract Manufacturing Compliance, and the Raw Materials Laboratory.
- Led Synergen to a successful inspection by the British MCA of the LakeCentre manufacturing facility. Organized the inspection approach, led audits, gave training to all GMP personnel, and acted as the QA representative during the inspection.
- Hired personnel and established a QA department and quality systems at the LakeCentre facility. Actively involved with the start-up team and facility validation program.
- Assured quality standards were maintained as Synergen moved into Europe through leading audits of a contract fill and finish facility in the Netherlands, of a separate European company where product testing was performed, and of associated material suppliers.
- Developed computerized audit observations database to track corrective action follow-up.

Quality Assurance Supervisor (1991 - 1992)

- Supervised Product Release, Auditing, Facility Compliance, Analytical Compliance, Contract Manufacturing Compliance, and the Raw Materials/Water Laboratory.
- Established a Quality Assurance Program and quality systems at the Synergen Delaware facility.

Quality Assurance/Quality Control Coordinator (1989 - 1991)

- Established the Quality Assurance Program for clinical manufacturing at Synergen including a system for Raw Material Control.
- Supervised the Raw Materials Testing Laboratory and incorporated the chemical and microbiological testing of plant water systems.

Research Associate (1987 - 1989)

- Performed Quality Control testing in support of protein manufacturing including HPLC, UV spectrophotometry, SDS-PAGE and Western Blots.
- Method development for reverse-phase and ion exchange chromatography, silver staining and quantitative coomassie staining of SDS-PAGE gels.
- Tested all raw materials used in clinical manufacturing. Wrote all applicable SOP's, sampling procedures, test methods, and specifications.

Westinghouse Idaho Nuclear Co., INEL, Idaho (1986 - 1987)**Chemist**

- Performed chemical instrumental analysis of nuclear process streams using: ICP, HPIC, GC, X-Ray Diffraction, AA, Ion Selective Electrodes and Potentiometric Titrations.
- Repaired and maintained all laboratory instrumentation.
- Acted as supervisor of the Remote Analytical Laboratory in the absence of the shift supervisor.
- Trained analysts and new chemists on new or updated methods and instrumentation.

Cord Laboratories (Geneva Generics), Broomfield, Colorado (1985 - 1986)

Chemist

- Performed qualitative and quantitative chemical and instrumental analysis of raw materials, bulk pharmaceuticals, tablets and capsules using: HPLC, UV-Vis, IR, GC, and Potentiometric titrations according to in-house and USP methods.
- Developed HPLC, colorimetric and titrimetric analytical methods for quantitation of drug substance in assay or dissolution tests.

EDUCATION

Master's of Business Administration
University of Colorado at Denver, Colorado

B.S. in Chemistry, ACS Certified Degree
Northern Arizona University, Flagstaff, Arizona

PROFESSIONAL AFFILIATIONS

PDA, An International Association for Pharmaceutical Science and Technology

International Society for Pharmaceutical Engineering (ISPE)

American Society for Quality (ASQ)

PRESENTATIONS AND COURSES

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| 3/04 | Process Specific Design Qualification (DQ) for Multi-Product Facilities, 2004 PDA SciTech Summit, Orlando |
| 10/03 | Meeting Design Qualification Requirements: Practical and Compliant Approaches, ISPE Local Chapter Meeting, Boulder |
| 4/03 | Compliance and Regulatory Issues for Biopharmaceutical Contract Manufacturing, PharmaNet Seminars, Orlando |
| 1/03 | Compliance for Process Validation for Biopharmaceutical API Manufacturing, Nice, France (2 day course) |
| 9/99 - Present | GMP Compliance for Biopharmaceutical API Manufacturing (3 day course) |
| 10/97, 10/98 | Evaluating Raw Materials for the Development of Biopharmaceutical Products: Clinical to Market, University of Wisconsin, Madison (2.5 day course) |
| 10/97 | Quality Systems for Good Manufacturing Practices (Pharmaceuticals), SQA Annual Meeting, Seattle |
| 11/96 | GMP Considerations in Early Stage Clinical Production of Biopharmaceuticals, PDA Annual Meeting, Philadelphia |

PUBLICATIONS

Bennan, J., et. al., "Evaluation of Extractables from Product-Contact Surfaces," BioPharm 15(12), 22-34, (December 2002).