

MICHAEL D. KAUFER

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PROFESSIONAL SUMMARY

A collaborative, enthusiastic quality systems professional with more than ten years experience in the pharmaceutical/biopharm industry. Knowledgeable in auditing, raw material and component specification development, consent decree remediation, cGMP training, quality control for clinical and manufacturing operations.

AREAS OF EXPERTISE

Quality System Management	cGMP Training	Technical Writing
Materials Management	Quality Audits	SOP Development
Deviation/OOS Investigations	Corrective Action Plans	Quality Control

PROFESSIONAL EXPERIENCE

ECVS, Inc. / CGMP-Solutions, Inc.

2002 – present

Quality System Management activities, in-house training and on-line training to biopharmaceutical companies in the Mid-Atlantic/Mid-West area.

- Auditing of Quality Systems, Production Processes and Products, including PAIs.
- Customized training in cGMPs.
- Assist the development and/or maintenance of functional areas such as materials management, operations, quality and validation.
- Technical writing and communications with federal health agencies.
- Preparation of SOPs
- Perform Compliance/Quality Investigations and Audits of contract manufacturers

Temple University

2001 - present

College of Pharmacy/QARA Program & Fox School of Business
Adjunct Professor

- Teach graduate courses in Quality Auditing
- Teach undergraduate courses in Management Sciences /Operations Management

Wyeth Laboratories

2001 – 2002

QA Manager – Incoming Raw Materials/Clinical Release

Managed a team of six responsible for the timely review and release of clinical trial materials; started-up a department responsible for the timely review and release of components, packaging and labeling for approved and clinical products.

- Released components and processing aids for NDA and IND products.
- Wrote and implemented SOPs for procurement; review and release; control of TSE/BSE-risk.
- Reviewed/approved OOS investigations; investigated and wrote reports for clinical trial components; reviewed and approved manufacturing deviation investigations.
- Developed training program prototype meeting Consent Decree requirements.
- Lead audits of warehouse and WIP areas in focused factories.

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Watson Laboratories, Inc.

2000 – 2001

QA Manager – Manufacturing

Managed a QA Department responsible for manufacturing inspection, packaging inspection, retention sample program, and deviation system. \$2.1 million annual budget and staff of 50.

- Developed and launched a new deviation investigation system; wrote new SOP and trained 140+ employees in QA, QC, Tech Services and Manufacturing/Packaging; lead effort to complete 110 late investigations from previous system in six months.
- Developed more efficient sampling and inspection procedures resulting in more efficient labor usage, fewer deviations and increased confidence in inspection results.
- Evaluated facility and equipment change controls, documentation and qualification reports (air-handling system upgrades, design qualification of isolator system and general facility repairs).

Merck & Co., Inc.

1996 – 2000

Senior Process Analyst

Reviewed batch records, resolved atypical/OOS situation, assembled and reported metrics for department efficiency while adhering to planned schedule.

- Managed review and release activities for twelve different product families, including solid and liquid dosage forms.
- Wrote and implemented SOPs for deviation investigations, cGMP documentation and sampling.
- Controlled non-conforming product through use of MRP software.

Lead Quality Auditor

- Scheduled, prepared, led and reported approximately ~50 internal and external audits of manufacturing, packaging, internal QA/QC operations, laboratories and key packaging suppliers.
- Managed CAPA (corrective action/preventative action) program, which included reviewing for effectiveness, assembling and maintaining documentation, and assembling metrics and reports.
- Performed OOS investigations and maintained archives.
- Represented QA on manufacturing upgrade projects, including facility and equipment change controls, documentation and qualification reports (liquid dosage form facility and equipment, solvent granulating facility, WFI systems, and chemical-sampling booths).

Various temporary and contract positions:

1991 - 1995

**Research Associate
Clinical Packaging Supervisor
Quality Engineer**

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EDUCATION

MS Quality Assurance & Regulatory Affairs, Temple University, 2002

MBA Operations Management, Temple University, 1998

BA Political Science, Hebrew University, Jerusalem, 1988

Continuing Education/Personal Development:

- FDA/PQRI: A Drug Quality System for the 21st Century 2003
- Value Added Auditing, 2002
- Certified Quality Manager, 2001
- PDA/FDA: Global Harmonization: Challenges and Opportunities for Compliance, 2000
- Industrial Pharmacy, 1999
- Certified Quality Engineer, ASQ, 1998
- Certified Quality Auditor, ASQ, 1996
- Statistical Process Control, ASQ, 1994

PUBLIC PRESENTATIONS

“Containment, Control and Elimination of BSE/TSE Risk in Pharmaceutical Production” delivered at ASQ Harrisburg Section 0503, February 12, 2003 with Michael Rorick.

“A Case Study in Lab Compliance” delivered at *Complying with Laboratory cGMP Requirements*, sponsored by the FDA and ASQ, November 20, 1997.