



Thomas Warden

SUMMARY

An experienced Regulatory Affairs consultant, with over 30 Drug Master Files written; Regulatory Affairs Certified (RAC) for ten years. Participant in many FDA inspections, including PAI inspections. Performed many GMP compliance audits, and experienced as a GMP compliance consultant for the medical device and pharmaceutical industries. Experienced in sterile and manufacturing process validations, as well as in water system design, testing and troubleshooting.

PROFESSIONAL EXPERIENCE

Pharmaceutical Consultant: 2003-Present

- Offering consulting in Regulatory Affairs and Quality to the pharmaceutical and medical device industries.
- Process development and implementation.
- Domestic and international DMF creation and management.
- US DMF representative.
- GMP audits-ICH compliance.
- CEP development and implementation.
- Quality oversight.

Executive Vice President of Operations, Natural Pharmaceuticals, Inc.: 2002-2003

- Responsible for company-wide production of the bulk pharmaceutical paclitaxel.
- Responsible for corporate oversight of Quality, Regulatory, Safety and Environmental areas.

Vice President of Regulatory Affairs and Vice President of Sales and Marketing, Natural Pharmaceuticals Inc.: 1999-2002

- Responsible for the complete corporate compliance including Regulatory, Safety and Environmental.
- Created the entire GMP compliance program for the corporation.
- Wrote Drug Master Files.
- Oversaw successful FDA inspection.
- Developed world-wide marketing and sales program.
- Secured significant raw material supplies.

Managing Director-Pharmaceuticals Division, Hauser Inc.: 1995 – 1999

- Complete pharmaceuticals business responsibility covering financial, sales, marketing, product development and related activities of a \$10M business.
- Responsible for all legal coordination and contract negotiation on both national and international levels.

Director of Regulatory, Quality and Environmental Affairs, Hauser Chemical Research Inc.: 1989 – 1995

- Coordinated drug approval with partner companies: Bristol-Myers-Squibb, American Cyanamid



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(Lederle), Wyeth (American Home Products), (Immunex) and Yew Tree Pharmaceuticals. Responsible for corporate FDA, EPA and ATF compliance.

- Prepared Drug Master Files.
- Responsible for Environmental compliance including local environmental dispute negotiation.
- Negotiated supply agreements and patent licensing with international firms.

Director of Quality Resources, Vipont Pharmaceutical Inc.: 1987-1989

- Responsible for the development and implementation of corporate Quality programs for both commercial and research levels.
- Initiated the documentation control and compliance programs.
- Initiated receiving components and testing program.
- Assisted in adverse reaction reporting.
- Direct customer service interface.
- Extensive vendor problem solving experience.

Manager of QC Bio/Chem Testing /Product Quality Control Manager and Creator of COBE Analytical Services, COBE Laboratories, Inc.: 1976-1987

- Responsible for support of all FDA inspections and submissions.
- Responsible of all GMP laboratory testing including chemistry, microbiology, cell culture, particulate counting and identification, biocompatibility testing and animal facilities.
- Responsible for 36 people.
- Water purification, testing and off-site troubleshooting.
- Supported laboratory personal with at the bench troubleshooting and experimental design.
- Formed COBE Analytical Services-contract laboratory services and medical device consulting.
- Responsible for sterilization validation-steam, ETO, dialysis machines and Gamma irradiation.

EDUCATION

University of Denver, Beaumont Center for Management Development: 1981
Certificate in Management

Masters Degree, Colorado State University: 1970-1972
Major: Biochemistry

Bachelors Degree, Colorado State University 1966-1970
Major: Chemistry

Regulatory Affairs Certified (R.A.C.) from the Regulatory Affairs Professionals Society: 1991-2001