# 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

(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