**KATHLEEN HEFFERNAN, MBA**

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## PROFILE

**Over thirty years of experience in the pharmaceutical and device industry as a quality and regulatory affairs professional. Proven ability to understand and interpret regulatory issues to assess the impact on corporate decisions**.

***Core Competencies:***

- Developing and assessing regulatory strategies for multiple therapeutic areas, including dermatology, respiratory, oncology, pain management, vaccines and combination products
- IND, NDA, 505(b)(2) and ANDA processes and requirements
- Regulatory complexities regarding drug delivery systems and combination products
- OPDP requirements for drugs and devices, and promotional strategy assessment
- Due diligence for product/company acquisitions

## PROFESSIONAL EXPERIENCE

**2001 - Present** **ProPharmaCon, LLC** San Diego, CA
**Founder and Managing Partner**

Consulting practice to the pharmaceutical and device industries in the areas of regulatory affairs, business development, technical assessments, due diligence, competitive intelligence and operational management. ProPharmaCon also provides support in medical writing and CMC strategy, as well as quality systems and audits. (www.propharmacon.com)

Specific regulatory expertise includes:

- Regulatory strategic planning throughout product lifecycle.
- Assisting clients with detailed regulatory and development strategies (cost, scope, time analysis) to support their decision making, or to understand an asset for out-licensing opportunities.
- Requirements for FDA submissions (and writing), including briefing packages, INDs, NDAs [including 505(b)(2)], ANDAs, orphan drug and fast track applications.
- Promotional activities for drug, device and cosmetic products, (incl. websites, DTC advertising, sales aids, training material, etc.).
- Due diligence activities and evaluations for mergers/acquisitions.

**1992 – 2000** **Dura Pharmaceuticals, Inc.**, San Diego, CA
**Senior Director, Regulatory Affairs** (March 1999 - December 2000)
**Director, Regulatory Affairs** (July 1996 - March 1999)

- Led the regulatory department which was responsible for 12+ marketed products, development projects (including the Spiros inhalation programs), and PDMA.
- Managed the regulatory strategies, post-marketing reporting and promotional reviews for all commercialized products, including several antibiotics, inhaled nasal steroids and a line of cough/cold/allergy drugs.
- Leadership role in supporting a successful FDA PAI Inspection.
- Conducted all regulatory due diligence activities with regards to product and/or company acquisitions (with over 30 products investigated in most therapeutic areas).

**Senior Manager, Regulatory Affairs** (October 1993 – July 1996)
**Manager, Regulatory Affairs** (March 1992 – October 1993)

- Prepared and filed all drug and device regulatory submissions, including the submission and approval of a 510(k) for Aspire peak flow meter, as well as the INDs and 505(b)(2) submissions for the Spiros inhalation programs.
- Created all regulatory standard operating procedures and built systems to support a new and growing department.
- Key contact for regulatory authorities, and responsible for leading FDA meetings.

**1986 – 1992** **The Purdue Frederick Company,** Norwalk, CT
**Manager, Drug Regulatory Affairs** (November 1991 - February 1992)
**Drug Regulatory Affairs Associate** (February 1986 - November 1991)

- Coordinated and prepared all IND and NDA submissions, in the therapeutic areas of pain management, asthma and antiseptics.
- Organized submission of annual and periodic reports for all investigational and marketed drug products including reporting of adverse experiences
- Provided regulatory representation at FDA meetings.
- Represented regulatory on the promotional review committees.

**1981 – 1986** **Miles Pharmaceuticals**, West Haven, CT
**Regulatory Compliance Associate** (June 1985 - February 1986)

- Coordinated and wrote post-approval regulatory documents for marketed drug products.

**Assistant Quality Assurance Scientist** (July 1983 - June 1985)

- Performed analytical release testing on all consumer products in this division. Provided assistance in training technicians.

**Quality Assurance Lab Technician** (July 1981 - July 1983)

- Performed chemical and physical analysis on intermediate and finished products.

## EDUCATION

**Masters, Business Administration**, 1991 University of New Haven, New Haven, CT

**Bachelor of Science, Chemistry**, 1981 Fairfield University, Fairfield, CT