



**Michael McCracken**

## **QUALIFICATIONS**

Detail-oriented, problem solving veteran of 30 years in Procter & Gamble's consumer products and pharmaceutical businesses. Background in analytical chemistry (Ph.D.), analytical testing, biopharmaceutics, project management, clinical data management, clinical operations and alliance management. Outstanding management and leadership skills. Proven ability to work across diverse organizational interfaces. Excellent oral and written communications.

## **PROFESSIONAL EXPERIENCE**

*Bench Analytical Chemist, Human & Environmental Safety @ P&G* 1978-1982

- Analytical support for perfume inhalation toxicology program, including test compound characterization, GC method development and automation of data gathering
- Analytical support for neurotoxicology and electro-physiology programs
- Development of microcomputer-based image analysis for analytical measurements of animal testing
- Author/co-author of thirteen outside publications and presentations covering this work

*Bench Analytical Chemist, Pharma Discovery @ P&G* 1982-1990

- Characterization of excipients, drug substances, and dose formulation using HPLC, GC, NMR, IR and mass spectroscopy using novel as well as USP and NF methodologies
- Analysis of drug substance and mediators in saliva and nasal washes using HPLC and GC
- Development and implementation of the Perkin Elmer Analytical LIMS consisting of a chromatographic data system and an analytical laboratory information system
- Author/co-author of twelve outside publications and presentations covering this work

*Section Head OTC Tech. Dev., Biopharmaceutics/Clinical Supplies @ P&G* 1990-1993

- Led a group of ten staff responsible for the formulation, drug delivery, drug transport/absorption/pharmacokinetics and clinical supplies aspects for the technology organization

*Project Manager OTC Product Development @ P&G* 1993-1995

- Led a multi-disciplined team in the development of two cholesterol lowering projects leading to the out-licensing of one of the products
- Co-led, with an Information Technology partner, a multidisciplinary team in the development of a global health care product development library which was the precursor to a regulatory document management system



## **Michael McCracken**

*Section Head OTC Clinical Data Management and Clinical Operations @ P&G*

1995-2004

- Responsible for the management of nine clinical data managers who managed ~60 clinical studies each year in support of GI, respiratory, and oral care OTC claims; consistently increased throughput and exceeded quality expectations
- Led the development of a global fax/imaging system for the automated workflow associated with case report forms from clinical studies; applied to both Rx and OTC globally
- Led the OTC clinical data management team (3 staff and ~30 contractors) over a two year period in support of the FDA submission to switch omeprazole to OTC (Prilosec); largest clinical studies ever managed by clinical data management in the Pharma or OTC sides of the P&G business
- Led the in-house development of electronic case report data entry at OTC clinical sites on PCs
- Managed five clinical research associates responsible for the clinical execution of oral care studies
- Encouraged first web-based data entry clinical study at P&G; conducted by an OTC data manager
- Co-author of two outside presentations on web-based clinical data entry

*Alliance Manager for Pharma Cardiac New Drug Dev. @ P&G*

2004-2006

- Managed the alliance between P&G Pharma and Alexion Pharmaceutical during the phase III clinical development of a novel therapeutic; responsible for the alignment of the clinical execution plans across the alliance and escalation of issues to the senior alliance leadership team when needed
- Developed the concept of “dashboard metrics” on the critical metrics across the alliance which led to a focus on real issues and not perceived problems

*Section Head Project Management & Planning Pharma New Drug Dev. @ P&G*

2006-2008

- Assumed section head responsibility for a group of twelve staff which was dysfunctional; two of the senior members would not meet with the other members or the previous section head. By taking the time to understand the reasons (lack of appreciation of the two individuals’ opinions/thoughts) and by personally valuing their input in the decisions which I made as the manager, the two individuals rejoined the group after three months.
- I worked with the group to mold a cohesive group resulting in increased output (2x), all members able to contribute to their best ability and an environment where the senior members of the group could mentor the junior members. I was recognized by senior management for this accomplishment with one of the few stock option awards made at my level in 2007.

### **EDUCATION**

- Knox College, Galesburg, IL., B.A., Chemistry, Phi Beta Kappa, 1973
- University of Illinois, Champaign, IL., M.S., Analytical Chemistry, 1975; Ph.D., 1978

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**OTHER AFFILIATIONS**

- Certified alliance manager through Association of Strategic Alliance Professionals
- Adjunct chemistry professor at Cincinnati Christian University for four years
- Currently secretary of Buckeye United Fly Fishers

**References:** available on request