

## J. MICHAEL GRINDEL, Ph.D.

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**PROFILE:** Twenty-five plus years of progressively responsible experience in managing Pharmaceutical R&D domestically and internationally. Recruited, hired and trained scientists to build three new organizations. Ability to work effectively with Marketing, Manufacturing and QA to assure smooth technology transitions. Self-starter with excellent communication, leadership and team management skills.

### EXPERIENCE:

#### **EPD Pharma Solutions, LLC (2002 to present)**

**2002-present**

##### **President**

Principal Consultant in a practice that focuses on the pharmaceutical and biotechnology industries. Provide expertise in multinational human drug product development and commercialization. Evaluate internal and external technology, ongoing or proposed product development programs, project portfolios or planning processes. Develop and/or manage cost-effective, time-efficient, quality product development programs. Prepare or review nonclinical and clinical study protocols and reports, identify and manage CROs for nonclinical and manufacturing activities, prepare INDs or NDA summaries and provide training for management, staff or project development teams on project management, team leadership and external vendor management.

#### **CytRx Corporation, Norcross, GA (1997 to 2002)**

**1997-2002**

##### **Vice President, Drug Development**

Directed the Drug Development organization with responsibility for all scientific, manufacturing, preclinical, medical and regulatory issues involved in the development, registration and commercialization of the Company's products. The group included 6 Ph.Ds with a budget of \$15 MM/yr. Successfully designed and completed manufacturing scale-up of the active ingredient, final dosage form development and scale-up to commercial quantities, and an array of preclinical toxicology and drug metabolism studies. The phase III clinical program was designed, implemented and completed with data analysis for the pivotal study available within 90 days of the last patient visit. Responsible for all regulatory interactions with the FDA and obtained expedited development status for the lead drug. Responsible for planning, budgeting, and directing the scientific efforts of multiple outside contractors as well as internal staff. Responsible for hiring and developing scientific and support staff to build the organizations capabilities.

## **J. MICHAEL GRINDEL, Ph.D.**

### **Hybridon, Inc., Cambridge, MA (1994 to 1997)**

- 1994-1997**      **Vice President, Preclinical Development**  
Directed the Preclinical Development Department with responsibility for all scientific and regulatory activities in Drug Safety Evaluation, Drug Metabolism & Pharmacokinetics, Formulations Development & Manufacture, and Pharmacology Safety Evaluation. The group was comprised of 14 scientists of whom 7 had Ph.Ds with a budget of over \$8 MM/year. Designed and directed the preclinical development of five new compounds leading to four first-in-man clinical trials, three-US INDs, and one-Canadian IND. Responsible for planning, budgeting, and directing the scientific efforts of multiple outside contractors as well as internal staff.
- 1996-1997**      **Vice President, Biological Research and Pharmaceutical Collaboration**  
Directed the Biological Research Division comprised of researchers active in the areas of virology, oncology, and angiogenesis. The group included 22 scientists with 8 Ph.Ds. The group developed one clinical development candidate which entered clinical trials in 1996 and recommended two more candidate compounds for preclinical development in 1997. Responsible for managing the Company's external collaborations with Hoffman La Roche, Searle Pharmaceutical and other pharmaceutical partners.

### **Johnson & Johnson Family of Companies, New Brunswick, NJ (1976 to 1994)**

- 1988-1994**      **R. W. Johnson Pharmaceutical Research Institute**  
**Vice President, Strategic Planning (1994)**  
**Vice President, Project Planning & Management (1991 - 1994)**  
**Executive Director, Project Planning & Management (1988 - 1990)**
- 1976-1988**      **McNeil Pharmaceutical**  
**Executive Director, Quality Improvement (1985 - 1988)**  
**Executive Director, R&D Project Planning (1982 - 1985)**  
**Director, Department of Drug Metabolism (1980 - 1982)**  
**Head, Drug Metabolism Research Section (1978 - 1980)**  
**Group Leader, Drug Disposition Group (1977 - 1978)**  
**Research Scientist, Drug Disposition Group (1976 - 1977)**
- 1973-1976**      **Walter Reed Army Institute of Research, Walter Reed Army Medical Center, Washington, DC, Chief, Clinical Drug Metabolism Laboratory**  
**Commissioned Officer, US Army (1971-1976)**

**HONORS AND AWARDS:**      Johnson & Johnson Achievement Award, 1990

**EDUCATION:**      Ph.D. - Medicinal Chemistry, University of Kansas, Lawrence, KS (1973)  
B.Sc. (cum laude) - St. Benedict's College, Atchison, KS (1969)