Judy Magruder

Senior Program Development Consultant

Core Competencies

- POC to IND Clinical Trials
- Nonclinical CROs
- Cross-Functional Alignment
- Late Stage Research
- Registration Clinical Trials
- CMO Technology Transfer
- PAI Prep & Strategy
- Launch Planning

Professional Summary

Ms. Magruder has deep experience in early stage strategy and planning over the course of her 38-year career. She supports the key disciplines of drug development, facilitating effective program management to define, track, troubleshoot and meet business goals. She has a track record of building successful cross-functional teams and significantly impacting achievement of project goals. Her portfolio includes hands-on development of small molecules, biologics, drug-device combinations, oral dosage forms, injectables, implants, transdermal and microneedle patches.

Education

M.B.A.	Business Adminstration	Santa Clara University
B.S.	Animal Science	University of California Davis

Professional Experience

Design Space Inpharmatics, LLC **2020 – Present**
Senior Program Development Consultant

Independent Consulting **2016 - Present**

- Identified vendors and managed plans and deliverables at CMC CMOs for API synthesis, analytical vendors, finished product manufacturing and testing, packaging, equipment design/build/qualification, facilities buildout and validation,
- Developed strategic Product Development plans, Gannt charts and budgets,
- Managed cross-functional project teams to meet key program goals,
- Vendor management of nonclinical, clinical and bioanalytical CROs,
- Planning and execution of pivotal clinical registration trials,
- Program management of manufacturing for registration stability, pivotal efficacy, safety studies and validation.

Zosano Pharma **2015 - 2016**

Vice President Program Management

- Project lead on key assets in development, integrating all functions necessary for successful development of combination drug/device products through Phase 2 & 3.

Signature Therapeutics **2004 - 2015**

Vice President Operations

- Recruited and managed a complete virtual development team to move 4 late stage research assets successfully through pre-IND development and first-in-man clinical studies,
- Regulatory lead in FDA interactions that resulted in fast track reviews,
- Company lead in DEA compliance achieving successful licensure of facility and quota grants,
- Managed intellectual property portfolio and new patent filings.

Durect Corporation **1999 - 2004**

Senior Vice President Development

- Responsible for all aspects of strategic product development for drugs, devices, and drug/device combination products,
- Direct line management responsibilities for Project Management, Clinical Operations, Regulatory Affairs, Quality and Portfolio,
- Areas of focus: Detailed project planning and budgeting; Design, build-out and qualification of a Phase III / commercial ready aseptic processing plant; design and conduct of clinical studies; clinical lot manufacture; toxicology study planning / execution; regulatory filing planning, preparation and submission (Phase 1-Phase III); DEA compliance.

Vascular Therapeutics **1998 - 1999**

Director of Product Development

- Team head for preclinical assets through IND and for lead product in Phase 2 clinical trials,
- Portfolio analysis and product selection via market research and high throughput screening assays for novel targets.

Alza Corporation **1982 - 1998**

Research Scientist and Head of Program Management

- Designed and successfully launched oral, transdermal, and implantable products with over 50 US Patents,
- Managed a staff of chemists and engineers developing products and conducting novel research,
- Product Development Manager for several oral products and Head of Project Management for Implant Business Unit,
- Program manager in the quality assurance group for clinical development candidates as well as commercial production.