Contact

www.linkedin.com/in/dianeshoda (LinkedIn)

Top Skills

Regulatory Affairs
Cross-functional Team Leadership
Creative Problem Solving

Publications

Dynamic Dossier in the Cloud: A Sociotechnical Architecture for a Real-Time and Metrics-Based Data Tracking System with Gene and Cell Therapies as a Case Study

XATP: Framework for eXtended ATP Authentication, Enhanced Verification, and Saleable Returns Documentation

Adaptive Licensing: Taking the Next Step in the Evolution of Drug Approval

Genetic Engineering of Metabolic Pathways Applied to the Production of Phenylalanine

Diane Shoda

Senior Advisor
Las Vegas, Nevada, United States

Summary

* Building consensus amongst regulators & key stakeholders for development pathways
* Leading cross-functional initiatives spanning clinical, safety, clinical supply, data management, project management and quality

Experience

Greyscaling LLC
CEO
February 2019 - Present (5 years 7 months)
www.greyscaling.com
Regulatory Consulting for Drug Development

LedgerDomain
Senior Advisor
February 2019 - Present (5 years 7 months)
LedgerDomain is an enterprise blockchain company working to bring fast, personalized, and secure transactions to the pharmaceutical supply chain. Their technology drives powerful mobile applications and executive dashboards that help deliver the right medications to the patients who need them.

Unlearn.AI
Clinical/Regulatory Consultant
March 2018 - Present (6 years 6 months)
San Francisco, California, United States
Unlearn.AI leverages AI-generated prognostic digital twins to enable smaller, more efficient pivotal clinical trials.

Massachusetts Institute of Technology
Senior Advisor, MIT Center for Biomedical Innovation, NEWDIGS
February 2019 - December 2020 (1 year 11 months)
Greater Boston Area

Pfizer

32 years

Sr. Director/Director Worldwide Regulatory

June 2011 - February 2019 (7 years 9 months)

Global Regulatory Lead Lyrica.

Responsible for developing and executing regulatory strategies for Lyrica, Pfizer's top selling medicine. Leads regulatory subteam covering US, EU, Emerging Markets, Japan and Canada. Successes include:

-Developed and executed creative regulatory strategy for pediatric epilepsy program valued over $1B.

-Multiple 1st cycle Approvals for new indications (spinal cord injury, pediatric epilepsy) and controlled release formulation.

-Gained agreement with ex-US health authority on a regulatory path forward to submit an application with a study that failed its primary endpoint.

Director, Worldwide Regulatory

June 2004 - May 2011 (7 years)

Global Regulatory Lead for Detrol LA, Toviaz, Viagra, Neurontin

-Managed all regulatory aspects including lifecycle strategy, global advertising & promotion review, and compliance. Successes include overcoming multiple regulatory hurdles that led to industry's first virtual clinical trial

US Regulatory Lead for Cox-2s

-Responsibilities included product defense and evaluating licensing opportunities

Director, Team Leader, Transition Management

2003 - May 2004 (1 year)

Served on cross-divisional informatics board that oversaw a $200M budget and retired/consolidated 54 IT systems as part of the Pfizer/Pharmacia Integration.

Led Clinical Supply Chain Integration leading to a Service Level Agreement resulting in improved planning and on-time performance for both the supply chain and clinical operations.

Director, Clinical Data Operations

1997 - 2003 (6 years)

Managed Clinical Data Operations process re-engineering projects through the deployment of new technology and related procedures. Successes include

-Clearing backlog of closing out over 2500 studies utilizing CROs. Closed out more studies in 3 years than in the previous 10.
-Established quality standards and processes that reduced Quality Assurance observations for clinical study reports by 60%.

Manager, Technical Coordination, Clinical & Scientific Affairs
1993 - 1997 (4 years)

Oversaw development of Standard Operating Procedures (SOPs). Created more than 30 SOPs covering monitoring, data management, safety reporting and regulatory submission

Senior Project Administrator/Project Administrator
1989 - 1993 (4 years)

Developed and maintained clinical project plans. Responsibilities included negotiating timelines and resources.

Project Coordinator, Formerly Warner Lambert
January 1988 - December 1988 (1 year)

OTC projects

Clinical Project Administrator, Formerly Wyeth-Ayerst
1987 - 1988 (1 year)

Biotechnica International
Bioprocess Engineer
1985 - 1987 (2 years)

Education

Massachusetts Institute of Technology
BS, Chemical Engineering (X) · (1981 - 1985)