Dinesh S. Thakur

EXECUTIVE PROFILE

Innovative and results-driven leader focused on achieving exceptional results in highly competitive environments that demand continuous improvement.

- Public health activist with demonstrated track record of advocating for access to good quality, affordable medicines
- Established "Data Integrity" as a key issue of concern in the pharmaceutical and biotechnology industry. Advocate for better quality and compliance with ICH standards
- Direct experience with delivery of healthcare in the developing world
- Hands-on experience in developing national health policy and challenges with competing priorities
- Hands-on experience with issues related to pharmaceutical pricing, intellectual property and access to medicines
- Understanding of funding models for public health
- Demonstrated track record of success and proven leadership, managerial, and problem-solving skills, with experience in the pharmaceutical industry / biomedical product development / healthcare sector / drug regulatory authorities
- Experience working in a global, multicultural organization with demonstrable success in managing staff from diverse cultures and backgrounds and creating a unified team
- Demonstrated strategic capability for developing and implementing strategic plans, business plans and policies that support an organization's mission and goals
- Direct experience in working with large funding organizations to address issues of public health
- As a CEO, experience working with Boards in a changing business environment meeting the challenges of the future
- A record of success managing organizational change, delivering on objectives, setting priorities for staff while adept at balancing internal management with external presence and relationships
- Proven track record of building high quality trusting relationships through shared risk-reward scenarios, creativity and innovation across multi-cultural teams
- International entrepreneurial experience in generating and expanding business globally, structuring and managing large complex multi-year outsourcing relationships and industry thought leadership
- Experience working with US Department of Justice and US FDA Office of Criminal Investigations in identifying and prosecuting healthcare fraud
- Demonstrated expertise in regulatory compliance, cGMP implementation, pharmaceutical sourcing and pharmaceutical product quality
- Analytical thinker with a natural ability to motivate teams, implement clear business objectives, and deliver measurable results of revenue growth, improved client relations, and increased product/brand/service awareness.

PROFESSIONAL EXPERIENCE

Medassure Global Compliance Corporation, Madeira Beach, FL **Jan 2014 - Present**
Founder, Executive Chairman

Medassure (www.medassurecompliance.com) provides consulting and risk management services to the pharmaceutical and biotechnology industry focused on supply chain and manufacturing. Leveraging its

proprietary assessment framework, it enables its clients to better understand the risks in sourcing API, intermediates, excipients and finished formulations from manufacturing facilities located overseas.

- Advocated for medicine quality with US Senate HELP Committee & US House of Representatives Committee on Foreign Affairs
- Petitioner of two Public Interest Litigations in the Supreme Court of India aimed at overhauling the country's Drugs & Cosmetics Act of 1940 (available at: http://dineshthakur.com/legal-background/)
- Public speaker at industry meetings including delivering keynote addresses at Asian Development Bank, ISPE Annual Conference in US and in China, Rx-360 Annual Meeting, CHPA Annual Scientific and Regulatory Meeting, US Pharmacopeia, Access to Safe Medicines & World Congress on Public Health
- Outspoken advocate for public health in numerous newspapers and journals (links available at: http://dineshthakur.com/media/)

Sciformix Corporation, Westborough, MA **May 2007 – June 2012**
Co-Founder, CEO & President

Established Sciformix Corporation (www.sciformix.com) as a Knowledge Process Outsourcing organization and grew revenues to $6.5 million with 0.5 million EBITDA in 2011. Was on track to close FY 2012 with $10.5 million in revenue and $1.5 million EBITDA.

- Created a differentiated and science focused functional service provider with strong domain depth to attract large pharma, biotech and CROs as clients.
- Consistently delivered services in the four key areas of drug safety, biometrics, medical and regulatory writing and clinical operations to build an order book exceeding $25 million and a client portfolio of 27 customers.
- Setup and grew to a 300 FTE operation supporting clients like Pfizer, Johnson & Johnson, Glaxo-Smithkline, Amgen, Paraxel and Boehringer-Ingelheim.
- Recruited a highly competent team of functional leaders to help create a differentiated organization. Established operations in Westborough, MA, Mumbai & Pune in India and in Manila in the Philippines.
- Led the creation of a high performance, values driven, differentiated service provider which continues to attract high quality individuals to the organization.
- Raised venture capital to fund the growth of the company in December 2007.
- Managed a complex corporate structure and ensured compliance with US GAAP. Managed subsidiaries of a US C-Corp in India, Mauritius and Philippines. Knowledgeable about transfer pricing, optimizing cash flow and servicing debt.
- Setup and managed globally dispersed delivery teams focused on process and customer service improvements while building results-oriented partnerships with key decision makers.
- Effective at communicating, collaborating, influencing and mentoring within and across disciplines. Acknowledged for building and motivating high energy teams.
- Recognized for providing sound advice to clients.
- Operations at Sciformix were audited by independent consultants (Elliot Brown Consulting, UK) in addition to the MHRA and the US FDA with no major observations.

Infosys, Bridgewater, NJ **April 2006 – May 2007**
Vice-President, Healthcare and Life Sciences

Was hired to setup Infosys' Life Sciences BPO practice.

- Led pursuits for two large deals, at Bristol-Myers Squibb and at Roche for clinical and safety services; made it to the final round of selection and lost to the competition (BMS signed up with Accenture,

Roche signed up with TCS) because Infosys wasn't interested in investing in developing this competency
- Managed delivery of claims processing and revenue cycle management services to Aetna and Ameriprise Group

entityx.com, Gurgaon, India **May 2005 – April 2006**
Managing Director & CEO

As an independent consultant, helped setup offshore operations for United States Pharmacopiea at the ICICI Knowledge Park in Hyderabad, India.

- Led planning and execution of the setup, assisted in hiring of key individuals and integration of analytical and data management systems with USP in Rockville, MD.

Ranbaxy Laboratories, Gurgaon, India **June 2003 – April 2005**
Director & Global Head, Research Information & Portfolio Management

Was responsible for R&D Information Management, integration with manufacturing and commercial systems to enable effective management of product development, manufacturing and commercial operations' information. Also responsible for setup and management of project and portfolio management function within the company.

- Created a vision for IT enabled Research and Development at Ranbaxy and led its implementation.
  - Managed the implementation of systems to automate data capture from all laboratories, prepare global regulatory submissions, compliance with regulations governing IT systems from the US FDA and EMEA and integration with manufacturing systems for analytics and decision support.
  - Bought all computer systems in compliance with 21 CFR Part 11.
  - Managed optimization of business process across several sites in the US, Europe, Brazil and in India.
  - Standardized business processes across R&D and Manufacturing to enable efficient technology transfer using informatics and analytics.
  - Ranbaxy filed its first electronic aNDA (eCTD) in December 2005 with all formulation development, bioequivalence, manufacturing batch records, analytical characterization and technology transfer data collected and managed electronically.

- Conceptualized and created a portfolio and project management group focused on Ranbaxy's 1+ billion generic drug portfolio.
  - Implemented PMBOK practices for management of formulation development, bioequivalence studies and regulatory submission across the established and emerging markets.
  - Established a risk-managed portfolio prioritization process supported by analytical tools to optimize the value of the product portfolio in development.
  - Key contributor to the First-to-File strategy to maximize revenue in the US market.
  - Implemented decision support systems to allow company management to effectively project revenue objectives and commitment to investors.
  - Ran the first portfolio prioritization process leading up to a product portfolio organized by distinct geographies with high revenue products identified for launch in four distinct geographies leading to consistent quarterly projections for the company.
- Managed three key alliances in New Drug Discovery Research
  - Led the discovery program for the development of RBX-11160 with Medicines for Malaria Ventures.
  - Managed 2 discovery programs in the metabolic diseases therapeutic area with Glaxo-Smithkline and a drug delivery system alliance with Schwarz Pharma.

Bristol-Myers Squibb Company, Princeton, NJ **August 1993 – June 2003**
Last Position Held: Director, Discovery Informatics

Joined BMS as a process engineer in the Analytical Development group supporting manufacturing of NCEs and biomolecules. Rapidly promoted to Associate Director within 6 years of joining.

- Led a team of 50+ IT professionals supported by external contractors in collaboration with scientific leads in a process redesign and automation engagement across drug discovery
    - Managed $20 million capitalized portfolio of projects focused on streamlining data management in lead optimization and pre-clinical development
    - Conceptualized, developed and implemented two key capabilities, Protocol Manager and Assay Manager to complement the Drug Discovery Decision Support System SMART-IDEA
    - Reduced key cycle times for lead optimization and progression to First-in-Man studies consistent with progressive industry benchmarks
    - Protocol Manager and Assay Manager led to higher success rate leading to First-in-Man studies of pre-clinical leads because of better characterization and optimization
- Built and operated automated systems to sample and analyze process development and commercial supplies.
    - Successfully established a Center of Excellence for Laboratory Automation and was recognized as a Pioneer in Laboratory Robotics at ISLAR 1997
    - Setup an information management group to collect and analyze data from high-throughput screening, secondary lead characterization and pre-clinical development
    - Automated data management for BMS compound library consisting of over 2 million unique chemical moieties leading to faster identification of lead chemical structures
    - Automation of data management led to a four fold increase in throughput for combinatorial chemistry using standardized chemical scaffolds to synthesize new libraries
- Built and operated laboratory automation systems to continually monitor protein expression and yields from CHO cell lines for CTLA4Ig (Erbitux) and gp30.
    - Helped improve yields by 20% using on-line sampling and implementation of process analytical technologies.

Employment history:

Director, Discovery Informatics	June 2000 – June 2003
Associate Director, Discovery Informatics	June 1999 – June 2000
Group Leader, Pharmaceutical Development	April 1997 – June 1999
Senior Project Manager, Pharmaceutical Development	May 1996 – April 1997
Manager, Systems & Automation	January 1995 – May 1996
Process Engineer	August 1993 – January 1995

Genetics Institute, Cambridge, MA **May 1992 – August 1993**
Research Associate

Was responsible for the design and implementation of High throughput robotic screening assays in support of small molecule drug discovery.

NOTABLE RECOGNITIONS

- Recipient of Joe A. Callaway Award for Civic Justice for Civic Courage from Shafeek Nader Trust in 2014
- Recipient of the Cliff Robertson Sentinel Award from the Association of Certified Fraud Examiners for choosing truth over self in June 2014

- Recepient of the Champion of Justice award from the Trial Lawyers Association of Washington, DC in March 2014
- Recepient of the Whistleblower of the Year award from Taxpayers Against Fraud in October 2013
- Whisleblower in the largest case against a generic manufacturer. Helped the US DOJ prosecute Ranabxy Laboratories where the company pleaded guilty to seven counts of felony and agreed to pay penalties of $500 million for selling adulterated drugs in the US
- Recepient of Pioneer in Laboratory Robotics ward from the International Society for Laboratory Automation & Robotics in 1997

EDUCATION

1996	M. S., Computer Engineering* (credits remaining) Syracuse University, Syracuse, NY 13221
1992	M. S., Chemical Engineering University of New Hampshire, Durham, N. H., 03824
1990	B. Tech., Chemical Engineering Osmania University, Hyderabad, India.

* Did not graduate from the Master's program. Completed 18 out of the 30 credits required.

Contact Information:

US:
15208 Gulf Blvd, Apt 503
Madeira Beach, FL 33708
+1 (508) 733-9063

India:
SW-4, World Spa West, Sector 30/41
Gurgaon, Haryana, 122 001
+91 (981) 840-2188

Blog: www.dineshthakur.com
Email: dinesh.thakur@gmail.com
Twitter: d_s_thakur
LinkedIn: https://www.linkedin.com/in/dinesh-thakur-056b89/