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Top Skills

Regulatory Submissions
Design Control
Risk Management

Certifications

Coaching Skills for Leaders and Managers

15 Secrets Successful People Know about Time Management (getAbstract Summary)

Transitioning from Manager to Leader

Ram Charan on Coaching High Potentials

What Are Your Blind Spots? (getAbstract Summary)

Joshua R.

Associate Manager Regulatory Affairs at Johnson & Johnson
Beachwood, New Jersey, United States

Summary

- Accomplished regulatory compliance leader with 13+ years' expertise in US and international markets, specializing in Biomedical Engineering and Economics. Proficient in iterative process optimization and diverse product lifecycle management, encompassing NDA drugs, medical devices, digital products, cosmetics, and dietary supplements.
- Extensive background in FDA submissions, clinical development, digital software and hardware regulatory pathways, ensuring process excellence, compliance, and successful audit activities. Strategic focus on risk management, patient and customer value, and overall business strategy within the healthcare and pharmaceutical industry.
- Adept communicator with a keen understanding of emerging communication trends and technologies. Proven track record in media relations, demonstrating the ability to learn fast, adapt swiftly, and consistently raise the bar. Detail-oriented, proactive, efficient, and creative, with a results-oriented mindset. Comfortable making decisions with imperfect information, thriving on complex challenges, and maintaining flexibility while prioritizing core objectives.

SKILLS

Manufacturer Compliance
Quality & Compliance Systems
Clinical Trials
Human Factors Development
Health Authority Compliance & Submissions
Regulatory Policy Shaping
Digital Health
Data Science
Process Optimization
Project Management
Adobe Suite

Experience

Johnson & Johnson Innovative Medicine

Lead Regulatory Scientist

April 2024 - Present (1 year 4 months)

Johnson & Johnson

13 years 3 months

Associate Manager Regulatory Affairs

July 2017 - April 2024 (6 years 10 months)

Skillman, NJ

- Lead Regulatory Strategist supporting the Skin Health & Self Care portfolios (NTS > \$908MM).
 - o Marketed areas include acne medical devices, baby, dietary supplement, makeup and sun care.
 - o Activities include acquisition integration, GxP & quality system compliance, development (competitive & risk (CAPA) analysis, formula, innovation, labeling, product, and raw material)
 - o Developed digital labeling, environmental transparency & real-world evidence strategies
- Lead labeling process assessments and optimization for North America Regulatory
- North American lead in digital health & data science global regulatory pillar for apps (digital health/software as a medical device NTS \$430MM) & diagnostic tools
 - o Developed cross-functionally driven priorities & global apps/diagnostics portal/framework to simplify and influence business innovation decisions and health authorities' compliance standards
- Led health authority (FDA) medical device submissions collaborating with global cross-functional teams to prepare and clear new and in market risk management changes to acne Medical Devices (510(k), Device Master Records, Design History Files)
- Manage team (i.e., 5 global contractors) supporting North America Oral, Wound & Skin Health regulatory product development and lifecycle management

- North America Regulatory lead for global Consumer organization developing & implementing corporate baby product transparency program & environmental claims corporate standards
- Managed oral care Request for Designation (RFD) submission, validating clinical trial research submission strategy

Senior Regulatory Affairs Associate

August 2016 - July 2017 (1 year)

Skillman, New Jersey

- Lead Regulatory Strategist supporting the Essential Care & Medical Device portfolios (NTS > \$800MM)
 - o Marketed areas include oral care, wound care, external analgesics & acne
- Lead the Consumer Sector Medical Device development for UDI and GUDID
 - o Established Quality Procedures for labeling and submissions into Design Control Procedures
 - o Ensured compliance for over \$360MM U.S. net trade sales
 - o Shaped FDA policy through industry working group participation
 - o Successful FDA exemptions negotiation (NHRIC & product code)

Regulatory Affairs Specialist

July 2013 - August 2016 (3 years 2 months)

Skillman, New Jersey

- Lead Regulatory Strategist supporting Wound Care franchise, Club Brands and NDAs for Eye & Hair Care portfolios (NTS > \$676MM)
- Audit and Investigation Consumer Sector regulatory support
- Global regulatory lead for a conversion of product documentation systems:
 - o Performed user acceptance training
 - o Created global communication plans
 - o Optimized standard operating procedures
 - o Streamlined with other systems to help provide automated approaches and improved deliverable
- Led health authority (FDA) marketed product submissions (CBE, PAS, PADER, Annual Reports, IND discontinuation) for all Consumer IND/NDAs

Regulatory Affairs Specialist - International Documentation

February 2011 - July 2013 (2 years 6 months)

- Fulfill Global Documentation for commercializing US products in international markets:
 - o Certificate of Free Sale, Certificate of Pharmaceutical Product, Certificate of Foreign Government
 - o Legal documents related to manufacturers and entity relationships

- Perform quality control checks on products & formulas at all levels of product lifecycle
- Project lead on Global Regulatory SOP review
 - o Compiled support information for 400 SOPs in one day
- Resolved border hold issues within FDA retention guidelines
- Set up filings for National Drug Codes
- Designed and managed the North American International Documentation Request SharePoint with over 400 requests a year:
 - o Good Documentation Practices, request timing improvements, team feedback, global market rollout WebEx presentations, metrics, project timelines, design of SOP's, and visual help guides
 - o Developed global expansion Latin America SharePoint transition to full use for both Regulatory & Quality Assurance
 - o Assessed the feasibility to implement North American SharePoint design on a global level
- Champion Asia-Pacific requests for global dossier preparation for submissions to KFDA, SFDA and other local health authorities

Casino Pier Arcade

Manager / Engineer

June 2003 - September 2011 (8 years 4 months)

- oConstructed and managed new Pier Surf Store
- oAnalyzed and solved Sacoa play card system programming issues for 264 swipe systems
- oBuilt and installed hardwired play card setups and wireless access points
- oResearched and created manuals for play card system
- oTrained co-workers about system and monitored performance
- oEnsured floor attendants executed correct work procedures
- oConstructed and maintained boardwalk stands and their cash flow
- oManaged and delegated work for 12 stand employees

Rutgers University

Researcher

February 2010 - June 2011 (1 year 5 months)

"DNA Purification Via Phenol Extraction : Cell Lysis"

- oDesigning a serpentine droplet-based extraction device for DNA extraction
- oObtained lab technique and safety training including gel electrophoresis, cell culture, microfluidics, and fluorescent microscopy

oPattern Recognition Project and research paper - February 2010 - May 2010

"Microarray Data: The Complexities in Analysis"

- oProgrammed and adapted complex pattern recognition algorithms to use with a dataset of 3080 entries
- oStudied and scrutinized six methods for data analysis

Rutgers Center for Advanced Infrastructure and Transportation

Geocoder

August 2010 - December 2010 (5 months)

Self

Tutor

January 2006 - May 2010 (4 years 5 months)

Tutored all levels of Math and Science to High School students

CVS Pharmacy

Technician

September 2007 - May 2008 (9 months)

Distributed, inputted, and filled prescriptions

Analyzed patients needs and evaluated extenuating circumstances

Certified Environmental Agency

Laborer

June 2007 - September 2007 (4 months)

Acquired soil samples to check for oil saturation

Installed new oil tanks and removed old oil tanks

Education

Rutgers University

Bachelors of Science, Biomedical Engineering · (2008 - 2011)

Beijing University of Technology

Chinese Summer Business Ambassador · (2008 - 2008)

Concordia College

Bachelor of Science, Mathematics & Biology · (2006 - 2008)