REEMA J. MEHTA, PHARM. D., M.P.H.

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DRUG SAFETY & GLOBAL RISK MANAGEMENT

Global & U.S. Risk Management and Pharmacovigilance Expert / FDA Regulatory Strategy & Execution

Incisive, proactive, and highly analytical pharmaceutical risk management executive with 15+ years of combined FDA and industry leadership experience in drug safety policy, pharmacovigilance, and review of NDA and BLA submissions. Strategic and visionary leader able to communicate big picture strategies through strong organizational culture in regional and global markets.

CORE QUALIFICATIONS

Member, FDA Leadership	Global, EU, & US Risk Management/REMS	Pharmacoepidemiology
Communication & Diplomacy	FDA Organizational Processes & Issues	Program Management
Leadership & Team Building	Pharmacovigilance Expert	Accomplished Spokesperson

CAREER HIGHLIGHTS

- Established Pfizer's first integrated business solution for process and lifecycle management of risk management programs, from development to implementation.
- Established Agency processes for developing and implementing single shared REMS programs that involved the integration and coordination of multiple companies and drug products.
- FDA lead creating an internal standardized REMS processes and template that resulted in documentation of best practices, improved internal clearance processes, and reduced reviewer inconsistencies
- Provided leadership for the development and/or implementation of several REMS programs, including but not limited to, Extended-Release/Long-Acting Opioid Analgesic REMS, Transmucosal Immediate Release REMS, and iPledge REMS
- Developed J&J's first standard operating procedure (SOP) and standard working practices (SWP), including decision-making processes, using Six Sigma Process Excellence methodology for initiating and implementing risk management plans for drugs that receive US or ex-US approval, which allowed for a proactive and comprehensive approach for periodic evaluation of safety data.

PROFESSIONAL EXPERIENCE

PFIZER, INC, Peapack, NJ — 2016 – Present

SENIOR DIRECTOR, HEAD OF RISK MANAGEMENT CENTER OF EXCELLENCE

Provide global leadership in delivering innovative and strategic risk management excellence, regulatory compliance, effectiveness evaluation, and operational excellence for Pfizer's portfolio of drug products with risk management programs. Establish external relationships related to risk management science/research, including influencing legislation and other industry experts.

- Supervise, coach, and direct multidisciplinary teams comprised of risk management product leads, including pharmacists, nurses, and epidemiologists to develop high quality deliverables.
- Provide strategic support to product teams for risk assessment and risk mitigation approaches, including additional pharmacovigilance activities (e.g., PASS, targeted questionnaires) and additional risk minimization activities.
- Serve as the business process owner for Pfizer's risk management processes and subject matter expert supporting regulatory inspections.
- Participate on projects to support external working groups (e.g., NAVITAS, ICH, IMI) for issues related to risk management, patient preferences, and benefit risk frameworks.

UNITED STATES FOOD & DRUG ADMINISTRATION, Silver Spring, MD — 2010 – 2016

DEPUTY DIRECTOR, CENTER FOR DRUG EVALUATION & RESEARCH / OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY / OFFICE OF MEDICATION ERROR PREVENTION AND RISK MANAGEMENT / DIVISION OF RISK MANAGEMENT (JUN 2014 – PRESENT)

Provide leadership to the Division through effective management, technical direction, strategic planning, supervisory oversight, and subject matter expertise for NDAs and BLAs involving a risk evaluation and mitigation strategies (REMS) policies and initiatives.

- Supervise, coach, and direct multidisciplinary teams comprised of risk management and health communication analysts, including pharmacists, physicians, nurses, and health educators to develop high quality deliverables.

- Established Agency process for developing and implementing single shared REMS for NDA products with approved generics and the approval of the first generic to market.
- FDA lead for the creation of an internal standardized REMS template based on best practices
- Serve as FDA official and representative at internal and external meetings on REMS, including the CDER International Forum, meetings with ex-US Health Regulators (e.g., European Medicines Agency), meetings with federal partners, and meetings with external trade associations.

TEAM LEADER, CENTER FOR DRUG EVALUATION & RESEARCH / OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY / OFFICE OF MEDICATION ERROR PREVENTION AND RISK MANAGEMENT / DIVISION OF RISK MANAGEMENT (JUN 2012 – JUN 2014)
Led a team and oversaw the review of all NDAs and BLAs submitted to the Division of Pulmonary, Allergy, and Rheumatology Products, Division of Dermatology and Dental Products, Division of Gastroenterology and Inborn Errors Products, Division of Anesthesia, Analgesia, and Addiction Products, Division of Psychiatry Products, Division of Cardiovascular and Renal Products, and Division of Neurology Products.

- Provided leadership and strategic thinking to develop internal and external policy regarding risk management and REMS.
- Represented FDA at internal and external meetings on REMS, including FDA Medical Policy Council, FDA REMS Oversight Committee, CDER International Forum, and APhA
- Collaborated with other federal agencies, such as the Drug Enforcement Agency (DEA), Substance Abuse and Mental Health Services Administration (SAMHSA), Veteran's Affairs (VA), and Department of Defense (DOD) to develop REMS that comply with existing systems.

SENIOR RISK MANAGEMENT ANALYST, CENTER FOR DRUG EVALUATION & RESEARCH / OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY / OFFICE OF MEDICATION ERROR PREVENTION AND RISK MANAGEMENT / DIVISION OF RISK MANAGEMENT (JAN 2012 – MAY 2012)
Lead risk management reviewer for several notable REMS programs, including but not limited to programs for isotretinoin, thalidomide, and lenalidomide.

- Participated in strategic work group to identify or update processes external stakeholder outreach to improve collaboration with stakeholders on REMS programs
- Core team member for FDA initiative to develop FDA smartphone application for adverse event collection and pharmacovigilance
- Developed and implemented new employee subject matter expert orientation training process within DRISK, including the development of a reference handbook, mentoring program, and on-boarding tools for supervisors

RISK MANAGEMENT ANALYST, CENTER FOR DRUG EVALUATION & RESEARCH / OFFICE OF SURVEILLANCE AND EPIDEMIOLOGY / OFFICE OF MEDICATION ERROR PREVENTION AND RISK MANAGEMENT / DIVISION OF RISK MANAGEMENT (SEP 2010 – JAN 2012)
Reviewed NDAs and BLAs, including proposed REMS submissions, submitted to the Division of Pulmonary, Allergy, and Rheumatology Products, Division of Dermatology and Dental Products, Division of Gastroenterology and Inborn Errors Products, and Division of Neurology Products.

- Established standardized language for the healthcare prescribing information regarding REMS for products with elements to assure safe use
- Represented the Agency at a Drug Safety and Risk Management Advisory Committee meeting for iPledge regarding recommendations for standardizing REMS.

RUTGERS UNIVERSITY, SCHOOL OF HEALTH RELATED PROFESSIONS, Newark, NJ Jan 2014 – May 2015

ADJUNCT ASSISTANT PROFESSOR
Taught "Multiple Analyses for Clinical Trials"; an online, web-based course in the Masters of Health Systems curriculum directed to multidisciplinary health professional students.

JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH AND DEVELOPMENT, LLC, Raritan/Titusville, NJ 2003 – 2010

DIRECTOR, MEDICAL PHARMACOVIGILANCE (2008 – 2010)
Lead safety expert for assigned oncology products, including data mining and signal detection for clinical trial and post-marketing safety data, and developing risk mitigation options for identified and potential safety signals.

- Team lead on cross-functional task force regarding policies for development and implementation of risk management plans for Johnson & Johnson's prescription medications
- Cross-functional team member, liaising with Regulatory Affairs, Medical Affairs, Marketing, Legal, and other team members to determine benefit risk profile for key oncology products

ASSOCIATE DIRECTOR, BENEFIT RISK MANAGEMENT (2004 – 2008)

Responsible for development and implementation of global risk management plans, preparation of ad hoc clinical reviews of available post-marketing safety data, and providing recommendations for core data sheet updates, as appropriate.

- Developed J&J's first SOP and SWP using Six Sigma Process Excellence methodology for initiating and implementing risk management plans for drugs
- Developed and implemented a matrix educational training curriculum for therapeutic areas, including teaching modules in pharmacovigilance theory and guidance, medicine, pharmacology, and pharmacokinetics to allow seamless transition into department

POSTDOCTORAL FELLOW, BENEFIT RISK MANAGEMENT (2003 – 2004)

Prior tenures included:

ADJUNCT PROFESSOR, UNIVERSITY OF FLORIDA, COLLEGE OF PHARMACY, Gainesville, FL / New Brunswick, NJ

PHARMACIST, TARGET PHARMACY, South Brunswick, NJ

PHARMACIST, MANDELL'S PHARMACY, New Brunswick, NJ

PHARMACIST, CVS PHARMACY, Plainfield, NJ

EDUCATION / CREDENTIALS

MASTER OF PUBLIC HEALTH, JOHNS HOPKINS BLOOMBERG SCHOOL OF PUBLIC HEALTH, Baltimore, MD

DOCTOR OF PHARMACY, RUTGERS UNIVERSITY ERNEST MARIO SCHOOL OF PHARMACY, Piscataway, NJ

BACHELOR OF SCIENCE, PHARMACY, RUTGERS UNIVERSITY ERNEST MARIO SCHOOL OF PHARMACY, Piscataway, NJ

PRECEPTOR FOR A CHANGE – LEADERSHIP CERTIFICATION, US FOOD & DRUG ADMINISTRATION, CENTER FOR DRUG EVALUATION & RESEARCH, Silver Spring, MD

PROCESS EXCELLENCE – GREEN BELT CERTIFICATION, JOHNSON & JOHNSON RESEARCH AND DEVELOPMENT, LLC, Titusville, NJ

PROFESSIONAL AFFILIATIONS AND ACTIVITIES

Alumni Member, **ALPHA ZETA OMEGA PHARMACEUTICAL FRATERNITY**

Fellow Member, **AMERICAN SOCIETY OF HEALTH-SYSTEM PHARMACISTS**

Fellow Member, **AMERICAN PHARMACEUTICAL ASSOCIATION**

Fellow Member, **DRUG INFORMATION ASSOCIATION**

Fellow Member, **INTERNATIONAL SOCIETY FOR PHARMACOEPIDEMIOLOGY**

Presentations:

- Concerns Establishing Single Shared ETASU REMS, Waivers and Generic Blocking. Panel Discussion. 11th Risk Evaluation and Mitigation Strategies Summit, Arlington, VA, January 2019.
- Co-Chair. 11th Risk Evaluation and Mitigation Strategies Summit, Arlington, VA, January 2019.
- Case Study: Tikosyn® (dofetilide) Risk Evaluation and Mitigation Strategy Elimination. 2nd Annual Risk Management and Pharmacovigilance America Summit, Boston, MA, October 2017.
- Explore the Implications of the FDA's Application of Statutory Factors in Determining When a REMS is Necessary. Panel Discussion. 9th Risk Evaluation and Mitigation Strategies Summit, Arlington, VA, January 2017.
- Engaging the Customer: Health Care Providers. Topic Presentation. DIA Pharmacovigilance and Risk Management Strategies, Washington, DC, January 2017.
- Risk Management for Prescription Drugs and Biologics. Topic Presentation. CDER Forum for International Drug Regulatory Authorities, College Park, MD, April & October 2011, October 2012.
- Risk Management for Prescription Drugs and Biologics. Continuing Education Presentation. NIH Pharmacotherapy Frontiers Symposium, Bethesda, MD, April 2012.

- Integrating REMS into Healthcare Delivery Systems: Challenges and Approaches, Topic Presentation, Drug Safety and Risk Management Advisory Committee Meeting, Silver Spring, MD, December 2011.
- Using Risk Evaluation and Mitigation Strategies to Improve Quality of Care and Patient Safety. Topic Presentation. 71st International Congress of FIP, Hyderabad, India, September 2011.
- Labeling and RMPs: CCDS, SmPC, USPI, Medication Guides. Lecture. Benefit-Risk Management of Healthcare Products, Temple University, November 2009.
- Application of Public Health Methodology. Lecture. Environment and Public Health, University of Rhode Island, Providence, RI, October 2008.
- Interpretation of Epidemiological Data. Lecture. Environment and Public Health, University of Rhode Island, Providence, RI, September 2008.
- Primer on Epidemiology. Lecture. Environment and Public Health, University of Rhode Island, Providence, RI, September 2008.
- Lessons Learned in the Design and Implementation of Opioid RMPs. Topic Presentation. Food and Drug Administration, Rockville, MD, June 2007.

Publications:

- Mehta, Reema. An Evaluation of the Impact of REMS on spontaneous reporting for marketed products. Johns Hopkins University, December 2009. (Capstone)
- Mehta, Reema. Analysis of the Impact of Media Reports on the Magnitude of Spontaneous Reporting by Health Care Professionals and non-Health Care Professionals. American Society of Health-System Pharmacists, December 2007. (Poster)
- Mehta, Reema. Risk Management Plan Contributions to Submissions. Johnson & Johnson, Benefit Risk Management, September 2006. (Article)
- Chen, Amy, Mehta, Reema, et al. Analysis of the Frequency and Trends in Postmarketing Reports Between Healthcare Professionals and Consumers During a Prescription to Over-the Counter Switch. American Society of Health-System Pharmacists, December 2004. (Poster)
- Mehta, Reema. Recommendations for Healthcare Professionals Traveling from the United States to China. Johnson & Johnson, Benefit Risk Management, April 2004. (Review)