JAMES J. KOLLMAR, M.D.

Merck & Co., Inc.
351 N. Sumneytown Pike, North Wales, PA 19454

PROFESSIONAL SUMMARY: Experienced pediatrician and regulatory scientist with 10 years in vaccine development at Merck. Proven leader in global regulatory strategy, clinical safety, and regulatory submissions across vaccine and infectious disease portfolios. Strong track record of cross-functional leadership, regulatory compliance, and technical guidance for product development from early clinical stages through global registration and lifecycle management. Enterprise-wide leader overseeing Merck Research Laboratories (MRL) transformational Generative Artificial Intelligence (AI) initiatives.

CORE COMPETENCIES

- Regulatory Strategy & Policy
- Clinical Safety & Pharmacovigilance
- Clinical Trial Development
- Global Regulatory Submissions
- Cross-functional Leadership & Team Management
- Generative AI Process Optimization & Regulatory Authoring
- Risk Assessment & Compliance
- Regulatory Intelligence & Labeling Strategy
- Stakeholder Engagement & External Affairs

PROFESSIONAL EXPERIENCE

2022-Present	Scientific Assoc. Vice President, Global Regulatory Affairs & Clinical Safety, MRL, Vaccines and Infectious Diseases, Merck & Co., Inc.
2021-2022	Executive Director, Global Regulatory Affairs & Clinical Safety, MRL, Vaccines and Infectious Diseases, Merck & Co., Inc.
2020-2021	Distinguished Scientist, Global Regulatory Affairs & Clinical Safety, MRL, Vaccines and Infectious Diseases, Merck & Co., Inc.
2018-2020	Senior Director, Global Regulatory Affairs & Clinical Safety, MRL, Vaccines and Infectious Diseases, Merck & Co., Inc.
2015-2018	Director, Global Regulatory Affairs & Clinical Safety, MRL, Vaccines and Infectious Diseases, Merck & Co., Inc.

- Provide leadership and strategic direction for global regulatory affairs and clinical safety activities across early and late-stage development programs for vaccines and infectious disease portfolios.

- Develop and implement regulatory strategies for new market approvals, license maintenance, and lifecycle management.
- Oversee and mentor global regulatory leaders; review and approve regulatory strategies and submissions for assigned products.
- Cross-functional subject matter expert on drug development, providing technical and professional leadership for project teams.
- Participate in regulatory risk assessments and company-level decision-making to ensure compliance with global regulations and guidance.
- Expert for regulatory strategy, clinical safety interpretations, and regulatory interactions with health authorities.

1997-2015 Physician, Owner, Horsham Pediatric Associates, PC., Horsham, PA

- Managed a busy pediatric practice delivering comprehensive primary care for infants, children, and adolescents.
- Oversaw clinical operations, staff management, patient care coordination, and quality improvement initiatives.
- Maintained high standards of clinical care, patient communication, and medical record documentation.
- Provided vaccination counseling and preventive care services in line with public health guidance.

EDUCATION

1990-1994 M.D., Temple University School of Medicine, Philadelphia, PA
1986-1990 B.S., Biology, Cum Laude, University of Scranton, Scranton, PA

POSTGRADUATE TRAINING

1994-1997 Internship & Residency, Children's Hospital of Pittsburgh, Pittsburgh, PA

LICENSURE & CERTIFICATIONS

1996-Present Medical Physician and Surgeon, Commonwealth of Pennsylvania
1997-Present American Board of Pediatrics, Board Certified, Pediatrics
2019-2022 Regulatory Excellence Leadership Academy, McKinsey & Company
2021 Advanced Course on Vaccinology (ADVAC), Annecy, France

PROFESSIONAL MEMBERSHIPS

1994-Present Fellow American Academy of Pediatrics
2016-Present Member BIO Pediatric Specialty Committee (BIO)
2017-Present Member Infectious Diseases Society of America (IDSA)