Maria.Gogova@altria.com

# MARIA GOGOVA MD, PHD

## SUMMARY

Extensive experience in reduced risk product development and FDA TCA regulatory pathways. Driver of impactful change through research, science-and evidence-based advocacy and leadership in tobacco harm reduction. Proven track record navigating all aspects of FDA's Premarket Tobacco Product Application (PMTA), Modified Risk Tobacco Product Application (MRTPA) and Substantial Equivalence (SE) processes, including design and execution of scientific strategies, regulatory submissions, post-market surveillance activities, regulatory compliance, and reporting.

Natural problem solver with proven capabilities managing large projects and multimillion dollar budgets, building and leading high performing internal and external cross-functional project teams, and anticipating emerging scientific and technological advances to manage business goals and lead through change.

## PROFESSIONAL ACHIEVEMENTS

**6 U.S. PATENTS GRANTED**

Available upon request

**PEER REVIEWED PUBLICATIONS**

in areas of clinical research, modeling, and population health impact (available upon request)

## SKILLS

FDA TCA regulation

Science integration

Strategic planning

Strategic communications

## WORK HISTORY

**VP & CHIEF SCIENTIFIC OFFICER, ALTRIA**

2021 – present

- Leading Altria's scientific organization of 100+ professionals by developing and executing scientific strategies for Altria's family of companies and building the scientific capabilities necessary to achieve Altria's 10-year Vision.
- Driving impactful change through strategic leadership of cross-functional teams of world class scientists (chemistry, toxicology, clinical research, behavioral science, epidemiology, and population modeling) to meet business goals while optimizing organizational performance, efficiency, quality, productivity.

- Building strategic external partnerships and participating at conferences to accelerate tobacco harm reduction.

**VP REGULATORY SCIENCES, ALTRIA**

2020- 2021

- Led the development and execution of regulatory science strategies for Altria's family of companies. Responsibilities included oversight of strategic partners, budget, and project timelines.
- Developed a scientific framework to navigate all aspects of FDA's premarket application requirements.

**MANAGING DIRECTOR REGULATORY AFFAIRS – SCIENCE STRATEGY AND ANALYSIS, ALTRIA**

2018- 2019

- Led a team of regulatory professionals and scientists to develop strategies for new and modified risk tobacco product applications that are aligned with FDA tobacco product regulations and public health standards.
- Led foundational research to provide science and evidence-based approach to product development (e.g. preclinical, clinical and behavioral assessment, survey instruments, safety assessment).
- Provided regulatory strategies and built programs to support post-authorization assessment of the population impact across different reduced risk product platforms. (pharmacovigilance).

**ASSOCIATE FELLOW - REGULATORY STRATEGY AND POSTMARKET SURVEILLANCE, ALTRIA**

20011-2018

- Led the development of our scientific framework, including clinical and behavioral programs, to support new and modified risk tobacco product applications.
- Developed a post-market surveillance infrastructure for novel tobacco products to monitor prevalence, safety, use behavior and unintended consequences.
- Provided safety oversight across all tobacco categories.
- Built Altria's safety surveillance infrastructure and SOPs, including coaching of safety staff.
- Managed scientific engagement with FDA to gain feedback on proposed evaluation framework.
- Identified and collaborated with external CROs and expert consultants (KOL) to design, conduct, evaluate and interpret human studies in support of pre-market fillings and post-market surveillance.
- Participated in writing and review of study reports and product safety reports in support of timely regulatory submission.
- Represented the company at external scientific meetings.

**SENSORY PHYSIOLOGY – SR. PRINCIPAL SCIENTIST / SR. MANAGER, ALTRIA**

2007-2011

- Established Altria's Sensory Physiology group with full budgetary control and supervision of 15 scientists.
- Conceptualized and managed all sensory research within R&D. Technical leader for human sensory and behavioral research, with focus on human sensation/perception to develop and substantiate successful solution to major sensory product deficit associated with reduced harm tobacco products.
- Built an interdisciplinary cross functional research program that included network of KOLs and state of the art laboratories.
- Product development responsibilities included identification of enabling research technologies and intellectual properties required for the development of reduced risk tobacco products.
- Co-authored several invention disclosures, three of which resulted in issuance of U.S. patents.
- Planed, developed, organized, and executed a research strategy to study respiratory irritation with focus on product related harm. The strategy was adopted by the company as one of its harm reduction programs for four consecutive years.

**CLINICAL RESEARCH MANAGER/SR. RESEARCH SCIENTIST, PHILIP MORRIS**

2002-2007

- Managed several Phase I clinical trials subcontracted to CROs, including design, protocol, SAP and ICF development.
- Monitored multiple clinical studies to assure adherence to study protocol, site specific SOPs, FDA, ICH and GCP guidelines.

**INTERNAL MEDICINE, ST ELIZABETH CANCER INSITUTE, BRATISLAVA, SLOVAKIA**

- Oncology, internal medicine physician

## EDUCATION

**POSTDOCTORAL FELLOW**

Clinical Pharmacology, University of Florida

**PH.D. CLINICAL PHARMACOLOGY**

School of Public Health, Trnava University, Slovakia

**DOCTOR OF MEDICINE**

Comenius University, Bratislava, Slovak Republic