PHARMALEX

REGULATORY SUBMISSIONS FOR TOBACCO/VAPE PRODUCTS

PharmaLex offers regulatory compliance services that address the new FDA requirements that have been implemented to govern the tobacco and vape industry. Our regulatory compliance experts have over twenty-five years of experience in supporting clients to fulfill their FDA requirements and reporting obligations to maintain regulatory compliance.

Our teams bring together knowledge, skill and expertise ensuring accuracy, accountability and responsiveness for the successful preparation, compilation and delivery of regulatory submissions.

A PHARMALEX SOLUTION THAT MEETS YOUR EVOLVING NEEDS

Prepare submissions materials for the Premarket Tobacco Product Application (PMTA)

- Guide you through the regulatory requirements to ensure compliance with new requirements and establish the best possible way to pursue for PMTA.
- Act as US Agent to the FDA and communication representative on behalf of clients based inside or outside of the United States.

Electronic submissions processing/publishing and submission

- Author and/or submit your PMTA in electronic format (eTTD) via the Center for Tobacco Products Portal or FDA Electronic Gateway (ESG)
- Act as a designated user for your Center for Tobacco Products Portal once your Industry Account Manager (IAM) created a user account.
- Submit your establishment registration and product listings online using the tobacco registration and listing module in FDA Unified Registration and Listing System (FURLS).
- Electronic submission of ingredient listings for tobacco products.

95% client continuation rate

Over 1500 submissions annually in electronic format

Regular interactions with major global Regulatory bodies

Proven track record with 6,000 successfully completed projects

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

DELIVERING SUCCESS WITH CONFIDENCE

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

"Since our founding in 1994, every single one of our clients is our top priority! We lead where others follow. We help clients to go beyond compliance, to capitalize on greater efficiencies, streamline complexity and to deliver true business value.

Ask us how we can make your job easier – over 600 customers are glad they did."

Dr. Thomas Dobmeyer, CEO

PharmaLex is one of the largest specialized providers of **Development Consulting, Regulatory Affairs, Quality Management & Compliance and Pharmacovigilance, Epidemiology & Risk Management** worldwide. Our global teams of experts can take you through early strategic planning activities and non-clinical requirements to clinical development, through regulatory submission processes and finally guide you to market approval and product maintenance post-launch activities.

PharmaLex supplies the widest range of **highly-skilled leading experts**. Our experienced teams span **all geographies** to expedite product developments and provide **access to much needed resources**.

Stay **one step ahead** of essential requirements needed by health agencies worldwide. Our knowledge accelerates your business success...

Knowledge. Accelerated.

CONTACT US

ADAIR TURNER, MS, RAC
Dir. Regulatory Operations North America
adair.turner@pharmalex.com

TIMM PAULI
Head of Regulatory Operations
timm.pauli@pharmalex.com

1000+
SUBJECT MATTER EXPERTS
WORLDWIDE

25+ YEARS
OF INDUSTRY EXPERIENCE

9/10
TOP PHARMACEUTICAL
COMPANIES ARE
OUR SATISFIED CLIENTS

40+ NATIONALITIES
ON STAFF, INCLUDING FORMER
FDA AND EMA EXPERTS

50+%
OF OUR PROJECTS
ARE GLOBAL