PHARMALEX

CONFIDENCE BEYOND COMPLIANCE

Your trusted partner in IVDs

PharmaLex brings a global reputation for excellence and trust built on decades of experience in quality, regulatory affairs and strategic consulting services

ABOUT US

PharmaLex is the leading provider of specialized services for the pharma, biotech and MedTech industries.

We guide you from early strategic planning activities through product development, regulatory submission processes and post-approval / maintenance post-launch activities. Our experts use technology-enabled solutions to support you through the entire product lifecycle. We deliver exceptional results – going above and beyond the standard to deliver tailor-made solutions worldwide.

OUR EXPERTISE

PharmaLex brings a global reputation for excellence and trust built on decades of experience in quality, regulatory affairs and strategic consulting services. We are leaders in IVD global regulatory compliance.

Whether it's a multi-gene assay from a next gen sequencer, a companion diagnostic, software for automated pathology image analysis, traditional laboratory ELISA or Point of Care rapid tests, we have the global experience to support you.

- Companion diagnostics
- Genomics and proteomics
- Home use tests
- Molecular diagnostics
- Laboratory tests
- Point of care tests
- Software as a medical device
- Software in a medical device

Diagnostic Capabilities with broad range of Biomarkers

DNA

RNA

PROTEIN

CELL

TISSUE

OUR SERVICES

We support clients through a streamlined, staged process:

REVIEW	Express, objective review of your product, its international regulatory status and the body of evidence that is integral during regulatory review
POSITIONING	Assessment of optimal pathway – including market positioning and eligibility for expedited processing or exemption
FILE CREATION	Technical support in development and compilation of product technical files for all classes of IVDs
QUALITY SYSTEMS	Establishment and implementation of quality systems that support company-specific operational needs
SUBMISSIONS	Streamlined applications to regulators
SUPPORT	Real-time support to expedited regulatory reviews with effective global communications in any time zone
POST-MARKET	Technical support through the entire product lifecycle including change management, regulatory intelligence, surveillance, license holding, vigilance and recalls

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WHY CLIENTS CHOOSE US

We have our finger on the pulse of a rapidly evolving ecosystem.

We are up to speed in a fast-moving world through detailed, current understanding of the regulatory frameworks, backed by strong relationships and expertise built over decades.

pharmalex.com

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