PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

Robust Design & Development of In Vitro Diagnostic Medical Devices, and their accessories, is key to getting products and services to any global market.

Our highly professional and experienced IVD & medical devices team, together with our expert biostatisticians, can support you from initial concept development through to formal design and product release.
Our team members' experience spans regulators notified bodies and industry and cover the complete range of IVD products and in-house IVDs: reagents, calibrators, control materials, kits, instruments, IVD Medical Device Software, systems, specimen receptacles, products for general laboratory use specifically intended for in vitro diagnostic examinations, and accessories for IVDs.

Design & Development (D&D) Of In Vitro Diagnostic Medical Devices

How PharmaLex can help

Research and Development

- Helping you define clear device intended purposes which meet the expectations of the regulators and set the scene for formal design activities.
- Performing systematic literature searches and conducting benchmarks of similar marketed devices to help you **assess the feasibility of your technology**.
- Preparing and writing-up technical reports for proof-of-concept studies (including statistical design where needed).
- Elaborating regulatory strategies for global market entry of your device – we help you identify requirements for design and the most efficient premarket pathways, their associated costs and timelines. We help you **maximize return on investment and improve time to market** by advising the best market release sequence.
- Implementing Quality Management Systems (QMS) and processes that are tailored to your needs and effectively meet regulatory requirements to drive innovation to market.

Design Planning & Project Management

Planning is everything. Our team helps driving your design and development activities by

- **Creating quality plans** for design controls activities in line with regulations and standards,
- Helping you **stay on-track of project deliverables** and their status, participate in technical reviews and provide **quality and regulatory representation** through all project phases,
- **Define effective strategies** for verification & validation activities including, the identification and liaison with subcontractors for outsourced activities where required,
- Sharing **best documentation practices** during design reviews,
- Implementing **clear traceability methods** for design inputs through to outputs.

Design Inputs & Outputs

- In a global market context, it is essential to identify and incorporate requirements from safety and performance, and applicable consensus standards and guidelines necessary for regulatory approvals. Our team ensures your **product requirements are comprehensively and unambiguously defined** for successful market entry.
- We also provide systematic literature searches on the state-of-the-art practices, including standards that are applicable to your product requirements and technology.
- Our experts help you produce **clear and complete design outputs** that meet quality standards and facilitate transfer to manufacturing, including specifications, IFUs, labels, bill of materials, and production process flowcharts.
- If your product includes software, our hands-on IEC 62304 experts provide **tools, templates and practical advice** for implementation.

Design Verification and Validation

A quality V&V program is the key to demonstrating product safety & performance. It is also central to any premarket reviews in demonstrating adherence to regulatory requirements and ensuring continuous market access. Our team brings years of industry best practices to your V&V plans and technical documentation writing, including:

- Risk Management File creation (ISO 14971),
- V&V plans including statistical design,
- Usability files, Software V&V, Electrical Safety, stability, sterilization,
- Support for validation activities including Scientific Validity, Analytical Performance, Clinical Performance, and Performance Evaluation/Clinical Evidence evaluation.

Design Transfer Activities

- PharmaLex helps to **transfer design outputs to effective production plans**, provides appropriate statistical design and offers guidance on transfer documentation such as Control Plans, Equipment Qualification & Production Process Validation.
- Our team of experts ensure your Production Files & Device Master Records **meet regulatory requirements for successful audits**.

D&D Changes

- Design and production changes are inevitable through the product lifecycle. Our experts help you evaluate the effect of the changes to function, performance, usability, safety and applicable regulatory requirements, and **support you through the entire lifecycle** to ensure your products remain safe, effective and effectively meet regulatory requirements.

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PharmaLex Experts Involved

REGULATORY EXPERTS

Our Regulatory experts translate complex regulatory requirements into actionable plans and produce technical documentation which maximize your chances of regulatory approvals.

BIOSTATISTICIANS

Our Biostatisticians implement robust statistical plans at all phases of your design and development to demonstrate scientific outcomes and facilitate decision making.

QUALITY EXPERTS

Our Quality experts analyse and develop systems and processes which are tailored to the need of your business and efficiently align with regulatory requirements.

Product Experience

Our experience covers most IVD technologies and provides a practical view, tailored to the complexity of your device, including:

- Specimen receptacles (containers, tubes) & accessories
- Reagents, such as PBS, strips, powders, antibody, dilution buffers
- Calibrators and standards
- Control materials – positive and negative controls
- Instruments, whether portable, for laboratory-use, automated or, non-automated
- Software (IVD MDSW) – embedded and stand-alone apps
- Kits & systems, including SARS-CoV-2, DNA/RNA
- Sterile/non-sterile components
- Specimen receptacles (containers, tubes) & accessories

Contact Us

Contact us today at:
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