PHARMALEX

RADIOPHARMA-EXPERTISE @PHARMALEX

Radiopharma-Expertise @PharmaLex

Radiopharmaceuticals in diagnostics and therapy form a special product group with specific regulatory requirements in terms of production, distribution and radiation protection. Necessary safety precautions and often very short half-lives pose special challenges for the business and require a different conceptual approach compared to „conventional" medicinal products.
Not only the special requirements for premises and equipment need to be considered, but also the staff, including the Qualified Person for radiopharmaceuticals and the Responsible Person for Radioprotection, needs additional special know-how and qualifications.

A PharmaLex solution that meets your evolving needs

- Consultancy, gap analyses and operational support on radiopharmaceutical development, regulatory affairs, quality control, manufacturing, quality assurance, distribution
- GxP-Pharmaceutical Quality Systems for radiopharmaceuticals: Design, implementation, optimization, maintenance
- Qualified Person operations for radiopharmaceuticals (AMG § 15 Abs. 3a Nr. 5)
- Expertise in radiation protection (PET-cyclotron and radiopharmacy)
- Consultancy & project management for the design and implementation of manufacturing premises / QC-laboratories
- Technology transfer
- Qualification and validation (premises, equipment, manufacturing processes, analytical methods)
- Quality Risk Management
- Audits, Inspection Support
- Management of outsourced activities
- Staff trainings

GxP experts with 20+ years of experience

Strategic consultancy & operational support

QP Services Radiopharma Radioprotection

Experienced GMP / GDP-auditors

InnoPHLEX

DISCOVERY / NON-CLINICAL

CLINICAL DEVELOPMENT

MARKETING AUTHORIZATION / APPROVAL

PRODUCT MAINTENANCE

SourcePHLEX

DELIVERING SUCCESS WITH CONFIDENCE

PHARMALEX IS A LEADING PROVIDER OF SPECIALIZED SERVICES FOR THE PHARMA, BIOTECH AND MEDICAL DEVICE INDUSTRIES

We guide you from early strategic planning activities and non-clinical requirements through clinical 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.

The PharmaLex Group now has over **1300** employees, with **38** offices in **21** countries and more than **600** satisfied clients worldwide.

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

Knowledge. Accelerated.

KNOWLEDGE.
ACCELERATED.
confidence *beyond* compliance

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STRATEGY & CONSULTING REGULATORY AFFAIRS PHARMACOVIGILANCE QUALITY MEDICAL AFFAIRS

1300+
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