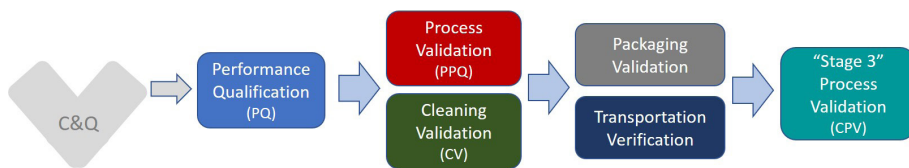


## VALIDATION SERVICES

PharmaLex offers full support along the **Validation Lifecycle (VLC)** for your New Product Introductions and Technology Transfer projects. Our Validation Professionals are not only **validation** experts, but **process** experts. And by this we mean experts in all types of manufacturing processes for all types of dosage forms.



### OUR PROMISE:

PHARMALEX WILL PARTNER WITH YOUR TECHNICAL SERVICE AND PROCESS ENGINEERING DEPARTMENTS TO CREATE A LARGER WINNING TEAM AND EXCEED YOUR EXPECTATIONS

PharmaLex will support your goals by delivering **VALIDATION** Services in the following areas:

#### ► Performance Qualification (PQ)

- Process Capability Studies
- Sterilization Qualification
  - Autoclaves and SIP
  - Isolator Decontamination
  - Depyrogenation & E-Beam Tunnels

#### ► Process Validation (PPQ)

- Drug Substance (DS)
  - Biotechnology
  - Small Molecules
- Drug Product (DP)
  - Parenterals
  - Oral Solids
  - Liquids, Creams & Ointments
- Medical Device & Combination Products

#### ► Cleaning Validation (CV)

#### ► Packaging and Transportation Validation

#### ► Continued Process Verification (CPV)



9 out of 10 top pharma companies are our valued clients



1000+ validation master plans and testing protocols successfully executed



20+ years of experience in validation of all types of pharmaceutical processes



Proven track record designing and executing validation strategies during New Product Introductions

InnoPHLEX  
DISCOVERY /  
NON-CLINICAL

CLINICAL  
DEVELOPMENT

APPROVAL /  
AUTHORIZATION

SourcePHLEX  
PRODUCT  
MAINTENANCE

# 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.

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

**Knowledge. Accelerated.**



KNOWLEDGE.  
ACCELERATED.  
*confidence beyond compliance*

## CONTACT US



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@PharmaLexGLOBAL



STRATEGY & CONSULTING **REGULATORY AFFAIRS** PHARMACOVIGILANCE **QUALITY** MEDICAL AFFAIRS



### GLOBAL COVERAGE

WITH SUBJECT MATTER EXPERTS  
WORLDWIDE INCLUDING FORMER  
HEALTH AUTHORITY / AGENCY  
EXPERTS

### 25+ YEARS

OF INDUSTRY EXPERIENCE





### 9/10

TOP PHARMACEUTICAL  
COMPANIES ARE  
OUR SATISFIED CLIENTS





### COMMITTED TO ENVIRONMENTAL CHANGE

### 50+%

OF OUR PROJECTS  
ARE GLOBAL

