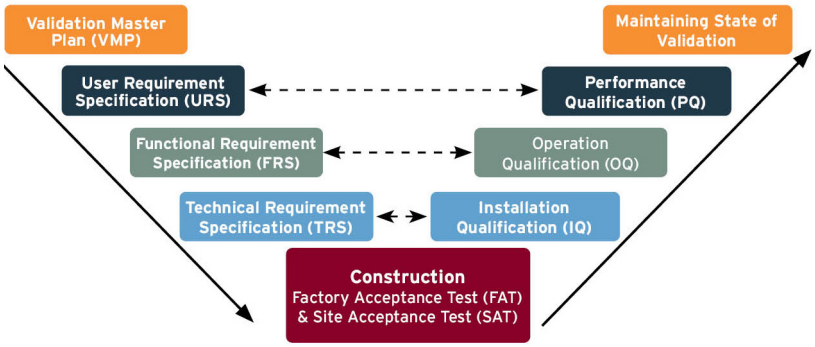
PHARMALEX

COMMISSIONING AND QUALIFICATION (C&Q)

PharmaLex offers full support along the **Commissioning, Qualification and Validation Lifecycle (VLC)** for your new or modified facilities, equipment, and systems. Our Commissioning & Qualification (C&Q) professionals are experienced in each deliverable from the C&Q portion of the VLC; i.e. the V-Model, as established by ASTM E2500 and ISPE's GAMP 5.



OUR PROMISE:

PHARMALEX WILL PARTNER WITH YOUR ENGINEERING DEPARTMENT AND CONSTRUCTION FIRMS TO CREATE A LARGER WINNING TEAM AND EXCEED YOUR EXPECTATIONS

PharmaLex will be your perfect partner, that's our promise. We will support your goals by delivering C&Q Services in the following areas:

- **Facilities Commissioning and Qualification**
- **Qualification of Utilities and Critical Systems**
- **Equipment Commissioning and Qualification (I/OQ)**
  - Manufacturing Equipment
  - Inspection and Packaging Equipment
  - Laboratory Equipment
- **Thermal Studies**
  - Warehouses
  - Controlled Temperature Chambers (CTC)
  - Transportation Qualification (TQ)
- **Computerized Systems and Software Validation**

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 commissioning & qualification of equipment and facilities

Proven track record implementing leverage approaches to C & Q for new and modified facilities and equipment

InnoPHLEX
DISCOVERY / NON-CLINICAL
CLINICAL DEVELOPMENT
APPROVAL / AUTHORIZATION
SourcePHLEX
PRODUCT MAINTENANCE

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

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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