QUICK REFERENCE GUIDE

PHARMALEX
CONFIDENCE BEYOND COMPLIANCE

TECHNICAL HELPDESK

SERVICE BENEFITS:

Our clients find this service to be of value where:

EXPERT OPINION / ADVICE
is required to support decision making in the organisation

AN ISSUE ARISES
that is outside of day-to-day operations and, therefore, expert opinion on the best path forward is required

WHEN EVALUATING
a decision / course of action against industry best practice.

WHEN LOOKING FOR ACCESS
to a team of international consultants, including a number of former EU and US Regulators, with expertise across the entire product lifecycle ensuring that the broad regulatory perspective is factored into the detailed consideration of your queryv

WHAT IS IT?

The Technical Helpdesk is a service solution that provides your team with quick and easy access to the breadth and depth of expertise of our Consultant team giving you the confidence that an SME is available to respond to your GxP queries as they arise, without having to go through the proposal/procurement process for individual/smaller queries.

QUALITY MANAGEMENT AND COMPLIANCE ADVICE – WHEN YOU NEED IT

The Helpdesk team provides answers to a wide range of technical queries covering all areas including but not limited to;

- **Good Manufacturing Practice (GMP)**
- **Good Distribution Practice (GDP)**
- **Good Pharmacovigilance Practice (GVP)**
- **Good Clinical Practices (GLP)**
- **Medical Device Regulations**
- **Marketing Authorisation Holder (MAH) compliance**
- **Promotion and Advertising**
- **Current Best Practice – various topics**
- **Interpretation of Legislation**
- **Opinion on specific scenarios**
- **Review of Investigation Reports, Draft QTAs, etc.**
- **Batch specific quality queries**
- **Quality Risk Management (QRM)**
- **Computer System Validation (CSV)**

QUICK AND EASY ACCESS TO EXPERTISE

A SIMPLE, QUICK AND EASY USER PROCESS:

1. **Query received via email or phone**
2. **Client defines scope and contexton**
3. **Time required is estimated – typically response within three working days**
4. **Review by SME**
5. **PharmaLex confirms timeline for response to client**
6. **Peer review of response completed prior to submission to client**
7. **Can also cover technical telecon with a SME**

FOR A PROPOSAL OR MORE INFORMATION, PLEASE CONTACT
CONTACT@PHARMALEX.COM

WHO WE ARE:

PharmaLex is a leading provider of specialized services for the pharma, biotech and medical device industries. We guide our clients from early strategic planning activities and non-clinical requirements through clinical development, regulatory submission processes and post-approval/maintenance post-launch activities. We deliver exceptional results - going above and beyond the standard to deliver tailor-made solutions worldwide. The PharmaLex Group has over 1000 employees, with 33 offices in 21 countries and more than 600 satisfied clients worldwide.

pharmalex.com

ABOUT PHARMALEX

25+ YEARS
OF INDUSTRY EXPERIENCE

OVER 50%
OF OUR PROJECTS ARE GLOBAL

100% COVERAGE
OF ALL PRODUCT CATEGORIES INCLUDING MEDICINAL PRODUCTS, MEDICAL DEVICES, CONSUMER HEALTH AND VETERINARY

40+
HEALTH AUTHORITY MEETINGS PER YEAR WITH EMA/FDA/PMDA

95%
OF OUR PROJECTS PASSED SUCCESSFULLY THROUGH DEVELOPMENT PHASE WITHOUT MAJOR FINDINGS