REGPAK'S RA/PV/QA EXPERTISE

Full Service Regulatory Affairs, Pharmacovigilance & Quality Assurance Consultancy

Mission, Vision and Values

Established in 2008, RegPak has always strived for success by delivering quality services

Mission

- Our mission is to deliver value added, reliable and cost-effective services to our customers, through our varied expertise.

Vision

- Aiming for long-term partnership with our customers based on shared beliefs and goals for synergetic growth.

Values

- Quality, Customer service, Integrity, Teamwork, Commitment, Accountability, Personal Growth, Initiative, On-time delivery.

Our Team

- **Parminder Kaur, M.Sc., PGDBM:** Founder and RA, PV & QA expert with more than 19+ years of industry experience
  - ❖ *Received Sikh Businesswomen of the Year award in 2014*
- 1 Medical Doctor on-board for medical expertise
- 5 RA and 4 PV consultants
- 1 Medical Device & Health/Food Supplement Consultant
- 2 Consultant QPs responsible for QP Release
- Huge network of professionals to provide in-country support, as needed for RA/PV activities

RegPak's Services

Our Expertise

- Regulatory Affairs
- Pharmacovigilance
- Medical Writing
- Quality Assurance
- EU Batch Testing & Release
- Assistance with Parallel Import/ Warehousing/Importation
- Corporate Training

Regulatory Affairs Expertise

Regulatory Strategy and submission:

-Biologicals (Incl. Biosimilars), Gene Therapy, Small Molecules, Controlled DS, Generics

Marketing Authorisation/MA Transfer/ Maintenance:

-Human and veterinary medicinal products

- MAA procedures- National, CP, MRP, DCP
  - *Various modules for MAA & Licence Maintenance incl. variations*
- CTA applications (incl. VHP procedure) + substantial amendments
- Orphan Drug Designation
  - *Todate obtained designation for Fabry's Disease, Scarring post Glaucoma Filteration Surgery, Huntington's Disease, Acute Myeloid Leukemia, Factor VIII and Fredrich's Atexia*
- Early access to unapproved medicinal products
- CE Marking Technical file for medical devices

-Nutraceutical / Food Supplement/Herbal Approvals

-Health cosmetics

Scope of Services in Regulatory Affairs

Scientific Advice:

- EMA: Scientific Advice & ITF Briefing Meeting, Pre-Submission Meeting
- Member State Scientific Advice
- FDA: Pre-IND, EOP2, Pre-BLA

Regulatory Dossier-Compilation and Maintenance:

- Compilation and evaluation
- Completeness and Gap Analysis
- Preparation of submission in CTD/eCTD/NeeS format
- Support in creating Module 1-5 for all procedures according to National/EU/US requirements
- Liaison with authorities
- DCP slots blocking and management
- Transforming/ creation of eCTD format
- Variations-CMC and Safety
- Renewals of MAs
- Sunset clause monitoring and solving (EU)

Labelling Management

Label Compliance:

- Serialisation assistance to meet with Falsified Medicines Directive requirements
- Patient Information Leaflet (PIL), Summary of Product Characteristics (SPC), Packaging Material (Mock-Ups)
- Harmonisation of texts according to:
  - European QRD format
  - Local requirements
  - EU reference product (generics)
- Mock-up creation
- Translation of texts to all languages
- Braille requirements
- Readability testing/Bridging report preparation

Clinical Trial Labelling:

- Review and approve clinical trial labels
- Arranging and/or updating import license for shipment of clinical supplies
- Establishing and updating Product Specification File

Pharmacovigilance Services

Pharmacovigilance monitoring of the products 24/7/365:

- Services for receipt of adverse events signals
- Dedicated database (PV Net & Extedo)
- Literature search service
- Safety studies /clinical trials support

Complex PV Services:

- QPPV, Deputy QPPV Services
- Creation and run of the PhV system according to current EU requirements
- Electronic submission of ADRs/AEs to EMA/NA (MedDRA, EudraVigilance / IDMP)
- Electronic submission of product information to EMA database (XEVMPD)
- Risk Management Plan (RMP), Periodic Safety Updates (PSUR/PBRER), Pharmacovigilance System Master File (PSMF)
- Establishing in-house PV systems incl. SOP/Policy writing
- Pharmacovigilance training

Medical / Regulatory Writing Services

- Clinical Development Plans (CDP)
- Clinical Study Protocol (CSP)
- Investigators Brochure (IB)
- Paediatric Investigational Plans (PIP)
- Orphan Drug Applications
- Company Core Data Sheet (CCDS)
- Target Product Profile (TPP)
- Environmental Risk Assessment (ERA)
- Toxicology Risk Assessment
- Prevalence & Epidemiology Report
- Risk Management Plan (RMP)
- Periodic Safety Updates (PSUR/PBRER)
- Pharmacovigilance System Master File (PSMF)
- Risk Evaluation and Mitigation Strategy (REMS)
- Investigational Medicinal Product Dossier (IMPD)
- Site Master File (SMF)

Batch Release

Batch Testing & Release:

- Batch testing and release
- Warehouse facility prior to batch being released
- Importation within EU

QP Declaration:

- GMP declaration
- Biologicals, Controlled Drugs, Ethical Pharma and Generics
- Audit Support for manufacturing sites for EU GMP

RegPak's Experince with Biosimilars

- ***Parminder Kaur appointed as a regulatory advisor for biosmilars pathway by JFDA***
- ***Recently awarded 2 major projects with Abdi Ibrahm, Turkey as well as Reliance Life Sciences for regulatory gap assessment and fulfilment of gaps for US, EU & MENA***
- EU representative for Biosidus, Argentina for biosimilar registration in Ukraine; Transfer from old MAH to Biosidus whereby RegPak shall be holding the MAA
- mAbxience Spain & (pharmADN, Argentina)-Lead global filing strategy for Rituximab; Dossier preparation for global launch: Managed scale-up variations globally (EU, APAC, MENA, LATAM)
- MSD, Netherlands: Provided strategic input to the development plan for BS mAb and arranged scientific advice meetings with Netherlands and Belgium authorities

RegPak's Experince with Biosimilars

- Gap assessment and fulfillment of biosimilars for Reliance Biosciences Ltd., India for US & EU Filings (Long term project)
- Gap assessment, Response to Questions, and training on biosimilar matters for Abdi Ibrahim (Long term project)
- Biosidus Argentina with advise on regulatory pathway for Ukraine
- Cipla Biotech-Gap assessment of dossier and fulfilment of gaps plus establishment of regulatory operations in India (Goa site)
- Bharat Serums, India: Provided development pathway for the EU approval (r-FSH)
- Bilthoven Biologicals, Netherlands (Poonawala Gp.) : Gap assessment of EPO dossier, fulfillment of gaps; scientific advice meetings with Netherlands regulatory agency
- Dr. Reddy's: Assistance with response to questions for Biosmilar submission
- OctoPlus, Netherlands: Established EU regulatory pathway for biosmilar/biobetter product registration for interferon alpha
- Julphar Pharmaceuticals, UAE: Strategic input for the registration of biosimilar insulin in EU

Clients Served Thus Far….

RegPak has served many clients worldwide and many more to come…

- Abdi Ibrahim, Turkey
- AOP Orphan, Austria
- Apotex, Netherlands
- Besins Healthcare, Belgium
- Bharat Serums, India
- Bilthoven Biologicals, Netherlands (Cyrus Poonawala Company)
- Biosidus, Argentina
- Cipla BioTec, India
- Clintox, India
- CSL Behring, Germany
- Dr. Reddy's, India
- Glenmark Pharmaceutical Ltd. U.K.
- Kemin Pharma, Belgium
- Lloyd Labs, Philippines
- Lundbeck, Denmark
- mAbxience S.A., Spain
- MSD, Netherlands
- Merus Labs, Netherlands
- Meriyana Biotech, Taiwan
- MyTomorrows, Netherlands
- Promedior, Inc. U.S.A.
- Rada Pharma, Russia
- Reliance Lifesciences Ltd.
- uniQure B.V., Netherlands
- Unimark Remedies, India

Questions or Business Enquiries

FOUNDER & RA/PV CONSULTANT

Parminder Kaur
parminder@regpakbiopharma.com
+31 (0) 629 07 5858