Regulatory Affairs and
Pharmacovigilance/Quality
Capabilities for.....

GLORAMP Pharma Consulting Ltd, UK/EU

gloramp
PHARMA CONSULTING LTD

About us

- GLORAMP Pharma was started with the sole purpose of serving healthcare industry with Quality and Compassion
- Our experience, knowledge, scalable solutions, and consultative attitude will ensure exceptional customer service and satisfaction
- Our Values: Transparency, Accountability and Trust (TAT)

GLORAMP's ORGANOGRAM

Ramprasad K
Founder & Principal Consultant

Tarangini P
Project Manager

Suresh K
Sr Consultant (UK)

Sangeetha G
Sr Consultant (EU)

Priyanjali K
Jr Consultant (EU)

Divija G
Jr Consultant (UK)

Qualifications

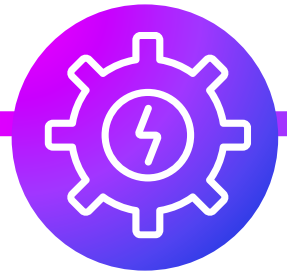
- Pharma Graduates or PG: RA/PV experience of >5 years
- Medically qualified with minimal experience of >5 years
- GMP QPs and QPPVs/Deputy QPPVs experience of >5 years

Team Management

- Dedicated Team for each RA/PV and QA activity
- Experienced Project Manager for better traction
- Oversight of Operations In-charge &/or GMP QPs / QPPVs
- Quality oriented processes

PV Global Operations – ‘Hub & Spoke Model’

Our services



Regulatory Affairs

- RA strategy Development
- New MA filings
- Agency meetings with BoH
- Compilation of MA/Submission File
- eCTD publishing
- Response to RFIs
- Life-cycle management and Licence Maintenance
- Gap Analysis/Due diligence

Core PV services

- Drug Safety
- 24/7 QPPV-UK & EU along with local QP support
- Hosting Safety Database
- PSMF
- SDEA
- Medical Information
- RMP/PSURs/Signal Management
- xEVMPD

Quality Assurance

- QP sign-off / batch release
- Audit & Inspection consultation
- Gap Analysis and CAPA execution
- SOP/WI/Guide
- Training & development

Ad hoc Services

- Act as UK/EU “Virtual” Regulatory and PV department
- Contract laboratory services via Partners
- Import and Storage / Distribution (MIA/WDA) services via Partners
- BA/BE and Formulation studies via Partners

Experience: Global footprint

Territories

- USA
- LATAM
- EU, UK
- APAC
- GCC
- ROW

Major Therapeutic Areas & Products

- Oncology
- Anti-infectives
- CNS
- Biologics/Biosimilars/Vaccines
- Small molecules
- Medical Device

KPIs & Compliance

- ICSR Submissions compliance **>99%**
- Aggregate report compliance **>99%**
- Quality score **> 98%**
- Internal & client TAT **> 99%**
- MI follow-ups compliance **> 98%**

Exposure

- Over 5 clients in CT & PMS
- Handling >50 INN
- Small to large pharma clients
- End to End PV services

Regulatory Affairs services..

- Registration Strategy Development
  - Expedited submissions and approvals
  - Secured approval through timely responses to RFI
  - EU/UK and USA and GCC/RoW Markets
- Agency Meetings with Boards of Health
  - Lead meetings and agree strategies for submission, auditing, and approval
  - Liaise with Auditing Bodies for Medical Devices
- Compilation of MA / Submission File
  - Preparation of submission documents
  - eCTD and NeeS publishing
  - Gap Analyses and Remediation
- Lead and Assist with Requests for Information (RFI) and Agency Audits
- Licence Maintenance / Life-Cycle Management

Regulatory Affairs services..

GLORAMP Pharma supports pharmaceutical and Medical Device manufacturers with EU/UK, USA and RoW registration

- Key Stages:
  - Review of current Registration File with a view to UK/EU filing
  - Lead and assist with the Remediation of deficiencies for UK/EU filing
  - Prepare / update current Registration in eCTD documents for UK/EU filing
  - Meet EMA / BoH to confirm registration strategy – Abridged Applications, DCP, MRP, CP, etc.
  - Submit Marketing Authorisation to EMA / EU/UK agency
  - Host and manage agency pre-approval inspection
  - Respond to Agency questions and Requests for Information (RFI)
  - Obtain approval and begin marketing

- **GLORAMP Pharma** has previously supported a number of clients through this process

Pharmacovigilance
(QPPV & Deputy QPPV services)

ICSR Safety Mailbox handling

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Local affiliate

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Triaging

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End to end Case processing

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Quality Review

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Medical Review

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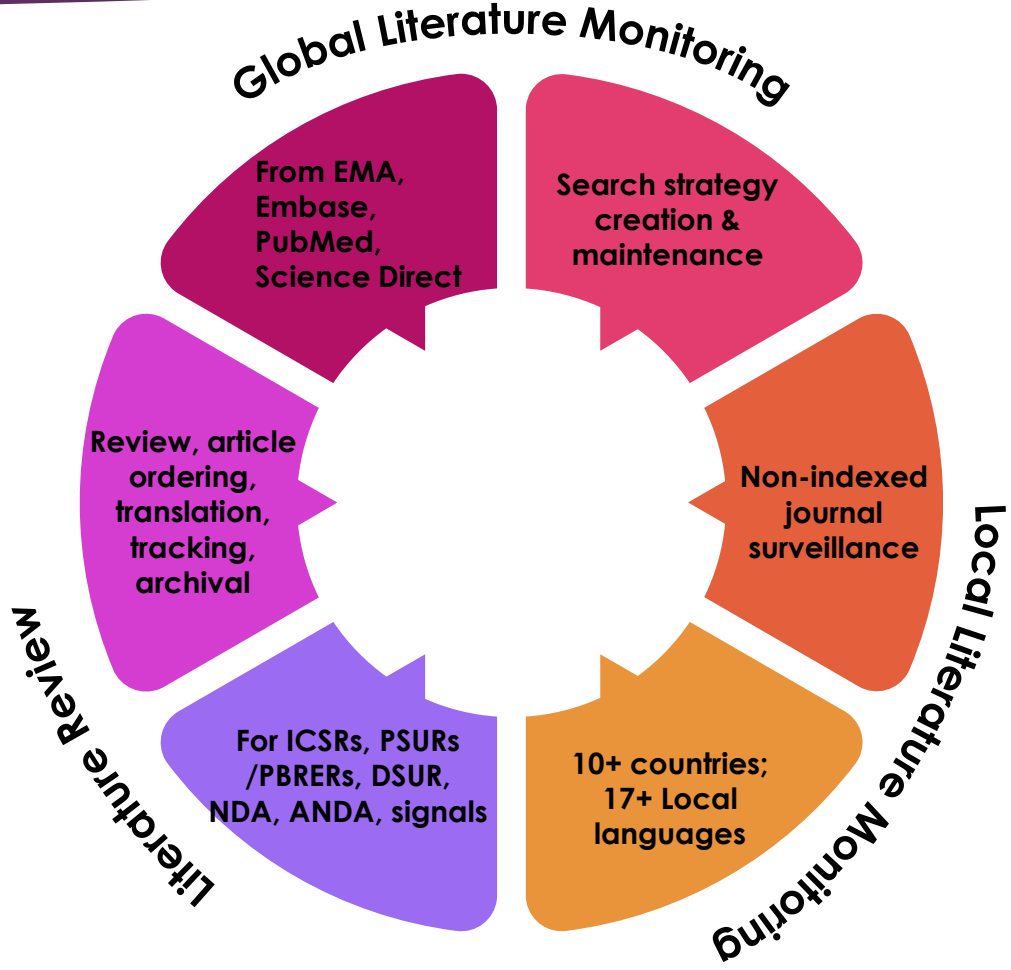
ICSR submissions

End to End Literature Surveillance..

- 5+ years of overall Avg. experience
- Team of HCPs & physicians
- 70 % team with >3 years of core literature experience

- 25+ active ingredients covered
- 20,000+ abstracts screened

- 05 global clients
- Annual volumes for our top 3 literature Clients volume: 8k



Signal Management Expertise

DRUG-EVENT PAIRS EVALUATIONs ANNUALLY

25+
MOLECULES MANAGED

5
GLOBAL PHARMA CLIENTS

5+
AVERAGE YEARS OF EXPERIENCE OF TEAM MEMBERS

- Across all therapeutic areas; meeting global requirements
- Post-marketing & molecule under clinical trials covered
- Safety review meeting; QPPV/expert review & oversight
- Screening of Regulatory sites to identify signals
- Adherence to Good Documentation and Archival practices
- Centralized tracking system for Signal Management Lifecycle. Audit trail maintained

Quality Assurance and Technical services..

GLORAMP Pharma offers full Importation and Wholesaler Dealer services via Partners

- Product importation from non-EU and EU countries
- Local contact address for offshore manufacturers
- Ensure secure, controlled storage of GMP pharmaceutical products
- Shipping and distribution within the EU/UK

GLORAMP Pharma offers Technical support via Partners

- Research & Development (Formulation)
- BA/BE Studies (CRO)
- Nitrosamines impurities Evaluation
- Elemental Impurities Risk Assessment
- Contract manufacturing and QC testing support
- Full release testing
- QP sign-off / batch release
- Stability storage (temperature and humidity controls) and stability-indicating tests

Project Execution & Governance

Kick off/Planning

- Project reward, MSA sign off
- Deploying a project manager
- Team finalization and setting up expectations
- Preparation of SDEAs, TA, etc.
- Training and (SOPs, Job Aids, etc.)
- Finalization of regulatory and literature monitoring strategy
- Scheduling calendars for various activities

Execution (Real-Time Deliverables)

- Compilation of MAs/Submission files
- ICSRs collection and processing, submissions
- Weekly Literature monitoring
- Regulatory communications
- Response to RFIs
- Query and follow ups with reporters

Value Added Services

- GMP QP support
- Preparation of batch release documents
- QPPV/LRP support
- PSMF authoring and maintenance
- Signal detection and authoring of aggregate reports and RMPs
- Periodic QA audits

Project Governance

- Communication channel through Principal Consultant
- Determining tangible KPIs
- Regular connect with technical teams

Why GLORAMP?

FULL-SPECTRUM OFFERINGS

- Global presence covering all territories
- One-stop solution for RA/PV and QA services including MIA/WDA services via Partners
- Good track record with regulatory inspection and client audits
- Cost-effective & scalable solutions for small to large projects
- Monthly compliance report for client oversight
- Compliance with US, EU & UK data regulations (including HIPPA, GDPR, DPA, etc.)

THANK YOU…