CAPABILITY OVERVIEW

GHULAM MURTAZA, MRCPharm

Regulatory Affairs · Product Lifecycle · Licensing Strategy

GPhC-Registered Pharmacist · Regulatory Strategy & Programme Leadership

GPhC-Registered Pharmacist
Reg. No. 2084661

MRCPharm – Royal College of Pharmacy
Reg. No. 1091612

Final Medical Signatory
ABPI / PMCPA

20+ years across UK & EU medicinal product lifecycle

Setting the licensing direction, building the roadmap and delivering the dossier — so medicines reach the patients who need them, compliantly and on time.

REGULATORY STRATEGY & PROGRAMME LEADERSHIP

- Developed board-approved post-Brexit UK licensing & product-portfolio strategies — piloted in the UK and built to scale across 18+ MRP territories
- Six simultaneous licensing projects led & delivered
- National conversions, duplicate licences & PLGB/PLNI splits (completed successfully)
- 3/3 New paediatric indications extension (UK approval — 100% success rate)
- Cross-functional coordination — regulatory, clinical, QC/QA, production, stability & PV

eCTD DOSSIERS COMPILATION & SUBMISSIONS

- 20+ eCTD submissions supported (MHRA & EU agencies)
- Module 1 authored in full — eAF, SmPCs, PILs, expert statements, ERAs, annexes
- eCTD compilation, lifecycle & validation (ICH M4/M8); submissions & regulator responses (RFI)
- MAAs, variations & renewals — incl. Type II new-indications
- Reclassification pathways & roadmaps (POM→P/GSL); duplicate licences & national conversions

REGULATORY MEDICAL WRITING & CMC

- Clinical & Non-Clinical Overviews and Summaries (2.4–2.7)
- Benefit-risk assessments & literature-based Modules 4 & 5
- Systematic literature reviews (PubMed, Embase, Cochrane)
- Clinical Expert (Module 1.4.3) — clinical overview addendum, paediatric indications
- Module 3 (CMC) coordination — API, drug product, QOS & stability

PRODUCT INFORMATION & LIFECYCLE

- SmPC, PIL, labelling & artwork across UK & EU (MRP & National)
- Master/daughter PIL strategy across 11 EU markets
- PIL user testing — readability & bridging (25 participants)
- Multi-market name, packaging & PIL change coordination
- Safety wording & RMP alignment; regulatory intelligence

TRACK RECORD

20+
eCTD Submissions Delivered
Initial Applications, Variations
& Renewals (MHRA & EU Agencies)

3/3
Indications Extension Dossiers
Authored, Defended & Approved
100% Regulatory Success Rate

18+
Market Access, Licensing
Strategies & Regulatory Roadmaps
(National & MRP Procedures)

20+ yrs
Cross-Functional Delivery Across
Regulatory, QC, QA, PV, Medical
& Commercial (UK, EU & Gulf)

OPEN TO NEW OPPORTUNITIES

Senior regulatory strategy, programme leadership and end-to-end dossier delivery. Open to permanent and interim roles, and to contract — direct or via specialist consultancies. Remote, hybrid or on-site.

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