

SAVIOURS PHARMA CONSULTANCY LIMITED

Pharmaceutical Consultancy for Medicinal Products

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Final Medical Signatory

ABPI / PMCPA

20+ years across UK, EU & Gulf markets

Helping medicines reach the patients who need them — safely, compliantly and in a commercially viable way — from regulatory strategy through to market delivery.

REGULATORY AFFAIRS & PRODUCT LIFECYCLE

- Regulatory strategy, licensing roadmaps & post-Brexit UK pathways (PLGB/PLNI)
- eCTD dossiers (Modules 1–5), ICH M4/M8 — publishing, validation & submission
- MAAs, variations (incl. Type II new indications), renewals & reclassification (POM→P/GSL)
- SmPC, PIL & labelling lifecycle; PIL user testing (readability & bridging)
- Regulatory medical writing & Clinical Expert (Module 1.4.3): Clinical Overviews, Summaries & benefit-risk

MEDICAL INFORMATION, SIGNATORY & ABPI COMPLIANCE

- Final Medical Signatory (ABPI Code Clause 8) — certification & examination governance
- Medical, Legal & Regulatory (MLR) review — Veeva & Vodor workflows
- Medical information scientific service (HMR 281(2) / Clause 4.1) — enquiry handling for patients, carers, HCPs, HCOs, MI units & regulators
- ABPI Code governance, SOP frameworks, transparency & disclosure
- Compliant content creation, medical education & representative training

PHARMACOVIGILANCE & SAFETY GOVERNANCE

- Affiliate PV frameworks co-developed with UK QPPV — 18+ markets
- UK PSMF, EU PSMF, annexes to GVP Module II, PV SOPs, SDEAs & NCP support
- Risk Management Plans for branded & generic licences
- PV audits (planning to CAPA), inspection readiness & PV/MI interface
- QPPV oversight support, MHRA Submissions Portal (SPS) & Windsor Framework Cat 1/2 awareness

MARKET ACCESS & CROSS-BORDER EXPANSION

- UK market access: DHSC pricing (VPAG & statutory), Drug Tariff, NHSBSA & brand-equalisation economics
- Four-nations formularies (NICE, SMC/SIGN, AWMMSG, HSC, ICBs); dm+d & C&D; NHS CMU tenders
- Wholesaler, buying-group & tender strategy across the four UK nations
- Bi-directional market entry: UK/EU ↔ Gulf (SFDA, NUPCO, GCC-DR; Vision 2030)
- Portfolio growth strategy & phased licensing programmes (board level)

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)

500+

Medical Information enquiries handled —
patients, carers, HCPs, MI units & regulators

200+

Print & digital content created & MLR-reviewed
with website, email, design & commercial teams

100+

Promotional & non-promotional assets certified
(digital & print) — Final Signatory (ABPI/PMCPA)

ENGAGE DIRECTLY WITH THE CONSULTANT

A founder-led practice — senior-level delivery with no hand-offs to juniors. Available for contract, interim, fractional & subcontract assignments, direct or via specialist consultancies. Remote, hybrid or on-site — UK, EU & Gulf.

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