

tranScrip Regulatory Affairs for Human Medicines

Place your regulatory approval in safe hands

tranScrip is a leading contract drug development organisation providing strategic expertise and operational support across the entire lifecycle of medicines, medical devices and combination products.

Our Experts



- We are a multi-skilled team of proven experts in regulatory affairs. We excel as a regulatory team alone or alongside our our colleagues within the tranScrip team as a multifunctional delivery team
- We provide strategic input & operational delivery for medicinal products over the entire product lifecycle with experience in mitigating against costly delays each step of the way
- Our certified ISO 9001:2015 Quality System underpins a quality culture providing consistency of project deliverables & oversight of your medicines path to commercialisation



Our Support, Your Deliverable

- Development, licensing & product lifecycle strategy
- Due diligence, gap analysis, technical reviews & consulting
- Planning, driving & leading your agency dialogue & meetings
- Writing, publishing & managing all your agency submissions
- Strategising, development & operational execution of your clinical trials
- Planning, care & management of your product lifecycle needs
- Ensuring your regulatory & quality systems compliance

Our Clients are at the core of everything we do.

Planning, understanding regulatory demands and embracing new regulatory initiatives are essential for optimal drug development programs. Our regulatory experts work independently or alongside our other tranScrip colleagues to provide our clients with efficient support. We deliver timely approvals and support the ever-ongoing development needs of your product throughout its entire lifecycle.

Pre-Clinical Development

CMC RA, Pre-IND meetings, ITF, ATMP classification, prepare & submit IND/CTA, apply for SME Status

P1 Clinical Development

Input to TPP & target product label, agency dialogue, evaluate & apply for Orphan/Fast-Track/ ILAP, ATMP certification, oversight of CTs

tranScrip Regulatory

Commercialisation

Lifecycle

Post-authorisation commitments, post

marketing studies, post-

approval product changes,

agency inspections, life-

cycle maintenance, line

extensions

NDA/MAA submission, procedure management, agency questions, responses & meetings, pre-approval inspections ROW submissions

Development

Oversight of CTs, FDA EoP2 Meetings/SA/PA, SPA for P3 Protocol, Further label development, PSP/ PIP

P2 Clinical

P3 Clinical Development

Pre-NDA/BLA/Pre-MAA meetings, Build and publish global dossier, finalise core data sheet & target product label



"The service and delivery from these consultants is first class. I wouldn't change a thing."

- Regulatory Director, European SME

"Thanks to all again for performing such excellent work & in such a professional manner."

- Associate Director of Regulatory Affairs,
US based speciality pharmaceutical company

Our Value to your projects

- Benefit from tranScrip's significant collective expertise in drug development and study delivery
- De-risk the pathway to smooth the way to commercial success
- Gain rapid access to a highly adaptable, skilled, cross-functional team when you need it
- Maintain consistency along the development journey using an extended team on your side
- Optimise your internal FTE resources, and reduce overheads, internal processes and administrative need





For more info, visit us at: transcrip-group.com

Or drop us an email: Info@transcrip-group.com