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Navigating Tailwinds and Headwinds for Successful Market Entry into China

Widler and Schiemann

Your Partner in Strategic Drug Development

&

Customized Quality Solutions

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Key Facts:

- China represents an enormously attractive market entry opportunity for promising medicinal and device products and solutions
- China now ranks as the second largest pharmaceutical market in the world
- Huge unmet medical needs in a variety of therapeutic areas require global innovative solutions
- Dynamic patient populations and growing number of clinical sites with GCP capacity are part of a growing global development landscape
- China's National Medical Products Administration (NMPA) has made successful advances in evolving its regulatory frameworks to absorb, manage, and sustain a robust development and manufacturing market in China, and adheres to key international standards and organizations like ICH

- Similar to other global regulatory mechanisms, NMPA provides a large variety of multiple pathways in which medicinal candidates can seek accelerated review and approval in China
- Different strategies for both development candidates as well as current market products, need to be considered and implemented

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Regulatory Affairs Services from Widler & Schiemann Include:

- Regulatory intelligence and expert advice on local regulatory requirements and procedures (US, EU, China)
- Advice and execution of regulatory and submission strategy (local or global strategies)
- Health Authority interactions and Regulatory Representative (China, US and EU et al)
- Licensing, registration and maintenance (DMF, IND, CTA, NDA, ANDA, BLA submissions in China, US, EU et al)
- Post-market activities
- Regulatory operation excellence model design and implementation
- GDPR representation for non-EU based companies

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Examples of Successful Engagements of W&S Regulatory Services in China (non-exhaustive list):

- **a top 10 global biosimilar company:** multi-national regulatory intelligence and strategy, in-country regulatory affairs (including China), and global regulatory operation excellence model and post-approval regulatory tasks
- **a Europe-based pharma startup:** delivered a risk-based market access strategy including (in China) regulatory pathway, partnership selection/qualification, clinical development strategy, pricing negotiation, and high-level technology transfer roadmap
- **a US-based biotech startup:** designed a pre-approval inspection readiness program including regulatory review of critical components
- **a Japan-based biopharmaceutical company:** delivered China regulatory strategy, registration pathway, clinical development consultation, HA interaction and KOL engagement support for its novel product
- **an Israel-based biopharmaceutical company:** delivered China registration pathway, agency consultation and marketing application support
- **a China-based biotech startup:** developed TPP and Pre-IND meeting packages and proposed strategy for Health Authority interactions
- **Multiple pharma/biotech startups in the US, Europe, and China:** developed and implemented Regulatory QMS, including SOPs and training sessions
- **Multiple pharma/biotech startups in the US and Europe:** supported CTD medical writing, medical translation and eCTD conversion support in China
- **Multiple due diligence projects** for pharma/biotech companies in the US, Europe and ROW

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Why Choose Widler & Schiemann?

- Widler & Schiemann is a world renowned consulting firm in drug development
- Global regulatory experts directly employed by W&S with 15 -25 years' experience in the US, China, Europe and established local offices of W&S in EU, China and US

- Widler & Schiemann has a proven track record of helping multiple Global Clients enter China and other markets with significant milestones
- With over 20+ global partners and a combined average of 20+ years of experience from pharma/biotech, regulatory authorities and organizations as well as expertise in all GxP aspects, regulatory affairs, marketing strategy and quality, Widler & Schiemann has the expertise you need to evaluate and implement your China market entry access plan

For more information, please contact us at info@wsqms.com and be sure to visit us on our website at www.wsqms.com and on LinkedIn

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