
Helping clients
transform into an **AI
Enhanced** business



Neural Vibe

Regulatory Affairs

Who are Neural Vibe ?



Neural Vibe is a rapidly expanding consultancy specializing in helping clients transform into an AI enhanced business, with a strong focus on Strategy, Risk, Planning, Implementation, Regulatory Affairs and ISO Standards Certification.

Although we are a new company, our senior team has many years of combined experience in helping clients manage transformative change in their businesses, industries, and customer expectations.

At Neural Vibe, we help our clients identify AI technologies that offer them the greatest advantages, helping to seamlessly integrate them into their operations, services, and products. Our approach ensures strict compliance with regulatory requirements, aligning with industry best practices and international standards.

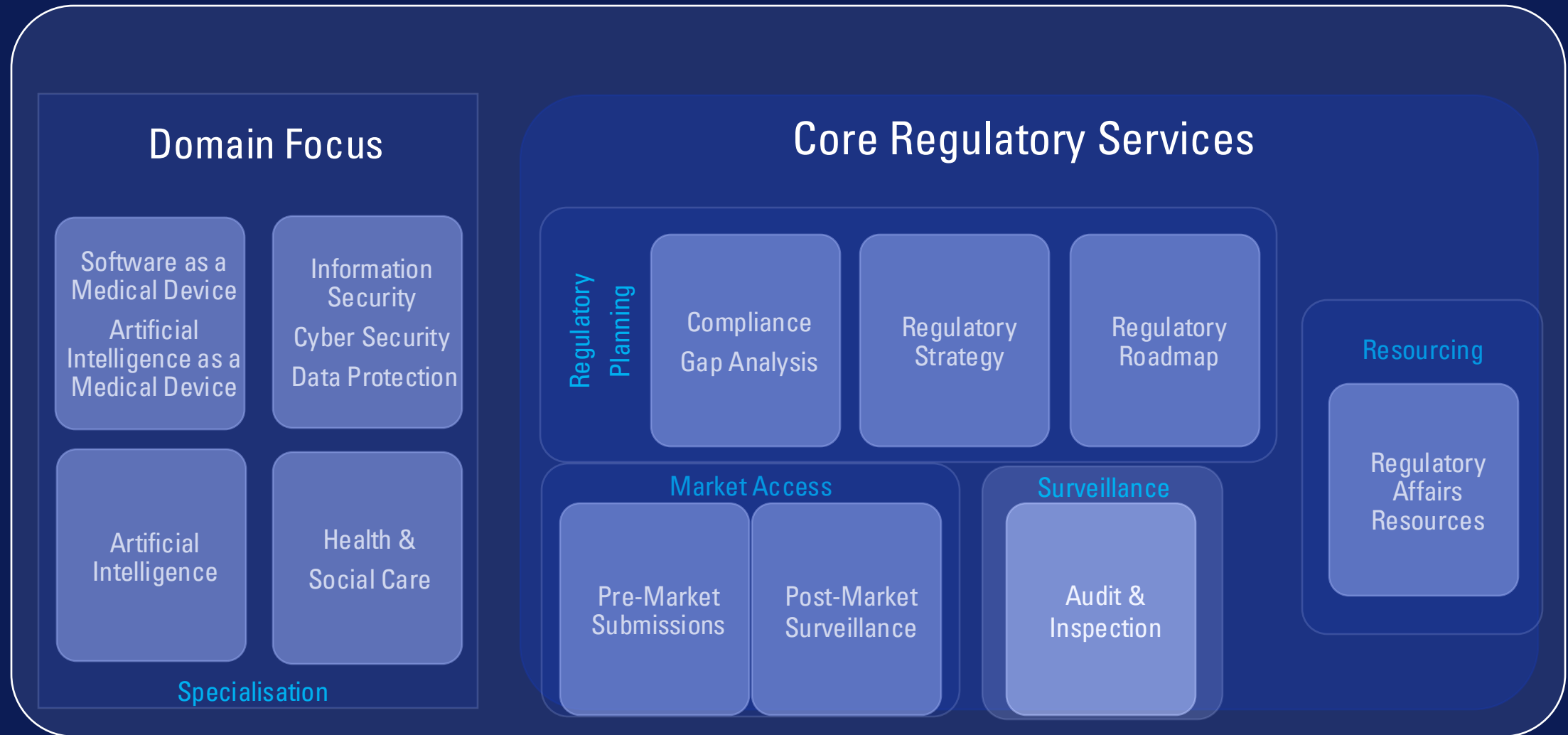
Why choose **Neural Vibe** as your Regulatory Affairs partner ?

By partnering with Neural Vibe, you are choosing a team with multi-domain expertise and experience including Medical Devices, Cybersecurity, Artificial Intelligence, Data Privacy and more.

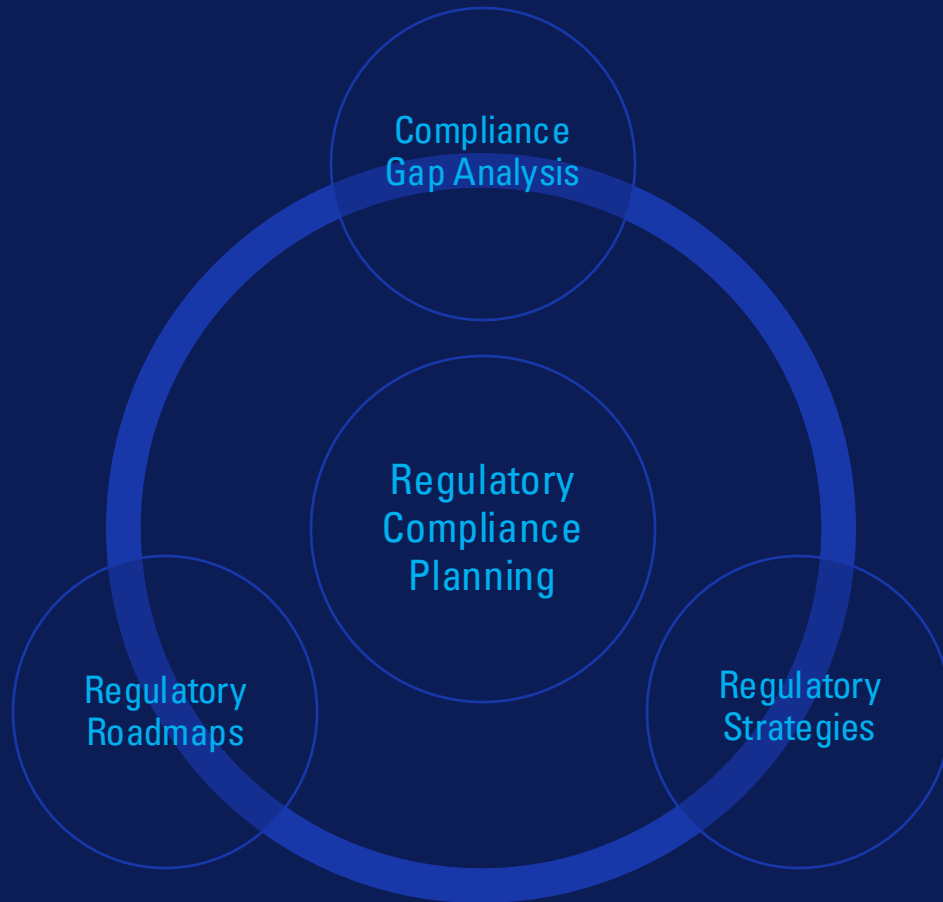
Our extensive services portfolio, including Compliance Gap Analysis, Regulatory Strategies and Roadmaps, Pre-Market Submissions, Post-Market Surveillance and Human Resource provision ensures that all your regulatory affairs needs are addressed.

Our senior team, with decades of combined experience, provides custom-made solutions that align with your business goals and compliance objectives. By choosing Neural Vibe, you benefit from our commitment to excellence, an innovative approach, and a truly global perspective, ensuring your success in navigating complex regulatory environments.

Let Neural Vibe manage your **Regulatory Affairs**



Regulatory Affairs services designed just for you

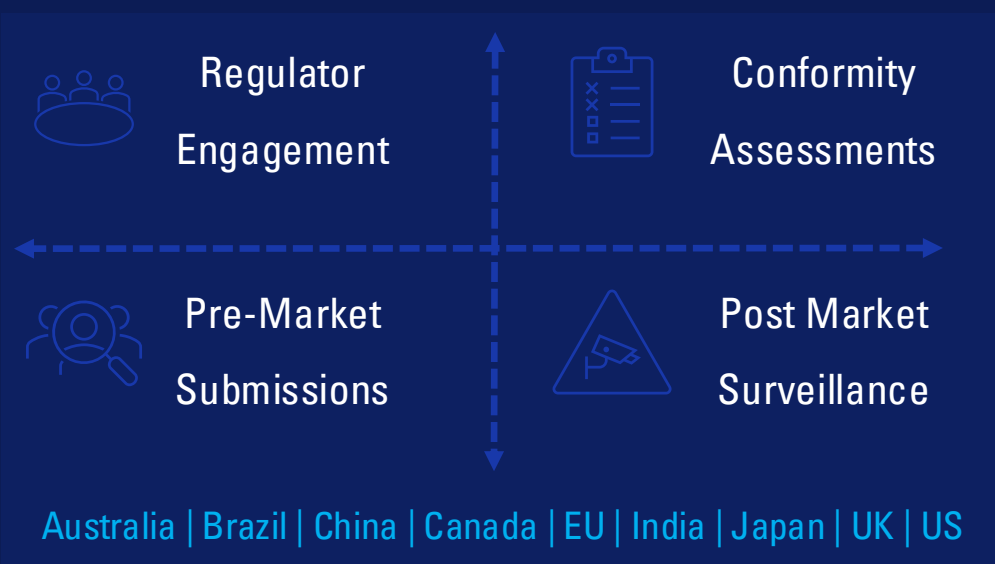


At Neural Vibe, we deliver comprehensive and dependable regulatory planning services tailored to your specific needs. Our expertise spans across three critical areas:

- 1. Compliance Gap Analysis:** We identify gaps in your current compliance framework, ensuring you understand the necessary regulatory standards that apply to your business.
- 2. Regulatory Roadmaps:** Our detailed roadmaps provide a clear and structured path to achieving full regulatory compliance, guiding your business through each step of the process with precision and clarity.
- 3. Regulatory Strategies:** We develop robust multi-market regulatory strategies that align with your business objectives, enabling you to operate in diverse regulatory environments effectively to capitalize on market opportunities.

By choosing Neural Vibe, you benefit from our extensive experience, industry knowledge, and commitment to excellence. We ensure your regulatory planning is compliant and strategically aligned with your growth and innovation goals. Trust Neural Vibe for reliable, expert guidance in regulatory affairs, helping you achieve sustained success in a competitive market.

Regulatory Planning you can rely on

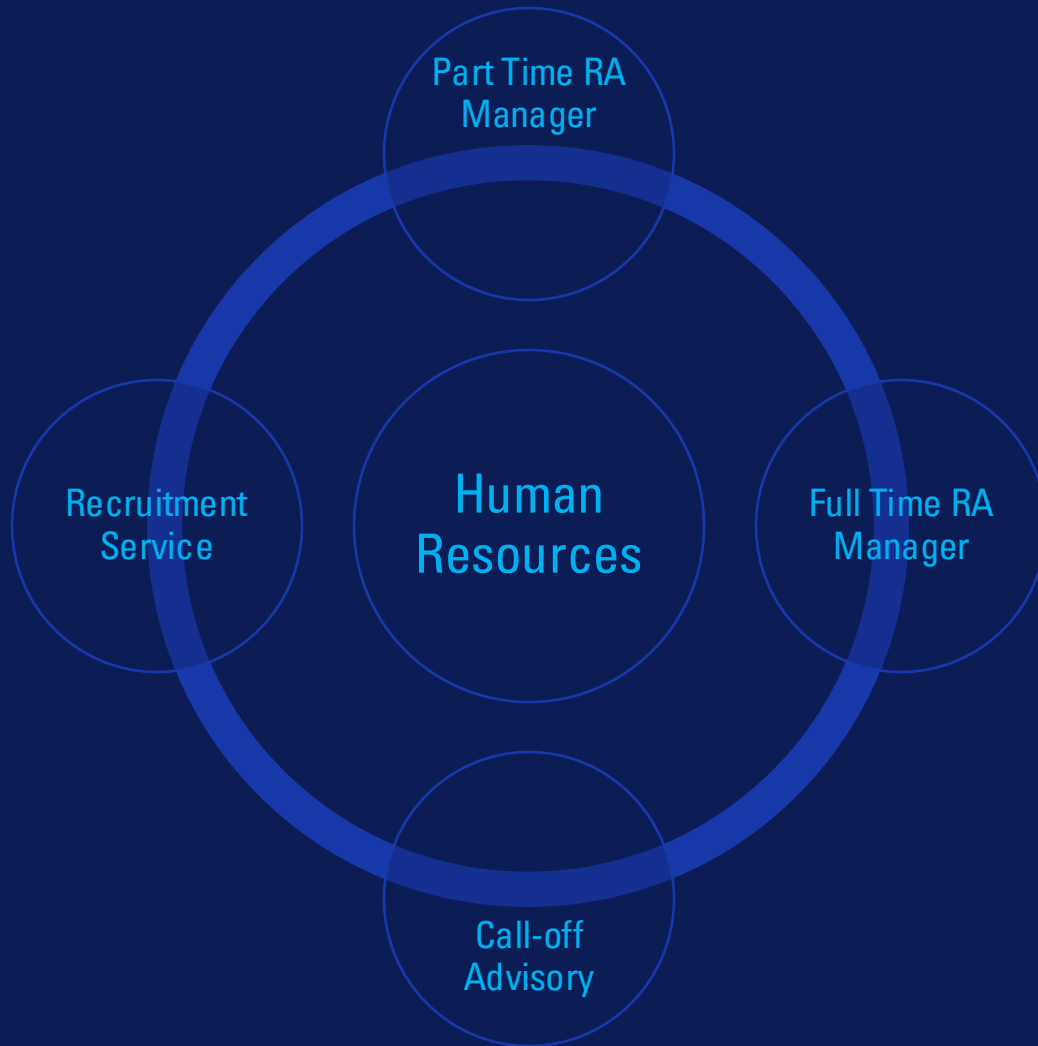


Neural Vibe helps clients **access highly regulated markets** with a strong focus on emerging Artificial Intelligence regulations, laws and guidelines, supporting their Market Access requirements. Our expertise covers major global markets including Australia, Brazil, China, Canada, the EU, India, Japan, the UK, and the US.

For example, the EU has recently implemented the comprehensive AI Act, which sets stringent requirements for **transparency**, **risk management**, and **accountability** for AI systems. In the US, AI regulation is advancing through executive orders and federal agency guidelines aimed at ensuring safe and trustworthy AI deployment. In Canada, the Artificial Intelligence and Data Act (AIDA) is being proposed, which aims to regulate high-impact AI systems and ensure responsible AI practices. Australia, Brazil, and other countries are also developing specific regulations to address high-risk AI applications.

We leverage our understanding of regulatory requirements to provide practical support that ensures compliance and market access. Our services include conducting compliance gap analysis, developing regulatory roadmaps, and managing pre-market submissions and post-market surveillance. By staying current with regulatory developments, we help clients mitigate risks and capitalize on opportunities.

At Neural Vibe we manage your **Market Access**

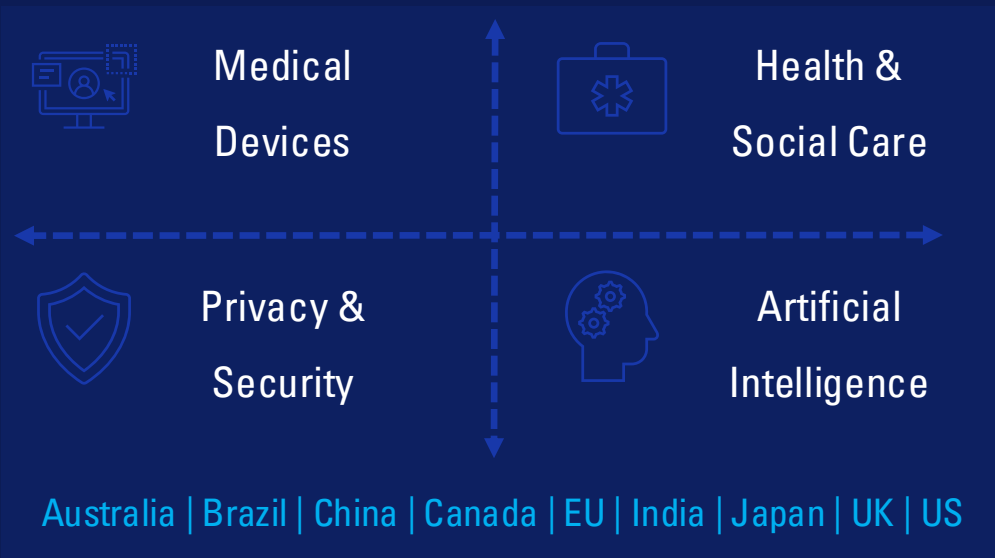


At Neural Vibe, we offer **flexible Human Resourcing solutions** to meet your regulatory affairs needs. We provide call-off, part-time, and full-time regulatory affairs resources to fill immediate gaps in your team. Whether you need experts for a specific project or ongoing support, we have the right professionals to ensure your compliance and regulatory success.

For clients looking to build a permanent regulatory affairs team, we can run recruitment exercises to find the best candidates for your organization. Our comprehensive recruitment services ensure that you find the right talent to meet your long-term regulatory needs.

At Neural Vibe, we provide the Human Resourcing support you need to maintain compliance, achieve your goals, and ensure operational excellence.

We have the **Human Resources** you need



Neural Vibe offers specialized regulatory affairs services across domains including **Security, Healthcare, Medical Devices, Artificial Intelligence** and more. Our in-house experts, supported by an extensive network of independent specialists, deliver precise and effective regulatory strategies tailored to your business needs.

We apply our domain and geographical market-specific knowledge to address your regulatory challenges in diverse markets, including Australia, Brazil, China, Canada, the EU, India, Japan, the UK, and the US.

This expertise is integrated into all our core services, which include Compliance Gap Analysis, Regulatory Strategy, Regulatory Roadmap, Pre-Market Submissions, Conformity Assessments, Post-Market Surveillance, Regulator Engagement, Audit & Inspection and Regulatory Affairs Resourcing.

Partnering with Neural Vibe means gaining access to **a wealth of expertise and a global perspective**. We work closely with you to identify and implement the right solutions, helping you navigate complex regulatory environments with confidence and ease. Trust Neural Vibe to be your dedicated partner in achieving regulatory success.

We have the **Domain Specialists** you need



At Neural Vibe, we offer Surveillance Support services to ensure your ongoing compliance and operational excellence. We conduct internal audits to assess and enhance your internal controls and compliance with relevant standards. Preparing for external audits can be daunting, so our expert team provides support with documentation preparation, responding to auditor queries, and implementing corrective actions to ensure a successful audit outcome.

Staying current with regulatory requirements is crucial, and we help you manage and streamline your regulatory reporting obligations, ensuring timely and accurate submissions. Additionally, we implement continuous monitoring to maintain compliance with evolving regulations, conducting regular reviews and utilizing real-time monitoring systems. We also develop and execute corrective and preventive action plans to address non-compliances and prevent future occurrences.

At Neural Vibe, we provide the Surveillance Support you can rely on to maintain compliance, reduce risks, and achieve operational excellence.

Surveillance Support you can rely on



Neural Vibe

Access all our service
overviews [here](#)

Thank You

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