

- We provide end-to-end support that connects global healthcare innovation with New Zealand's regulatory landscape.
- Our team has a strong working relationship with Medsafe, enabling us to manage communications between your company and the regulatory body effectively.
- We act as your local legal entity, ensuring 100% compliance while you maintain 100% control over your commercial strategy.

Unlike using a distributor as a sponsor, CARSL Consulting provides independent representation. This ensures that your proprietary dossiers and product design information remain strictly confidential and that your market access isn't tied to a single sales partner. If a distribution relationship ends, your registrations remain secure with CARSL.

Comprehensive Market Support Offered:

- **Sponsorship:** Medical Devices & Pharmaceuticals
- **WAND Listings:** Streamlined entry for all classes of Medical Devices
- **Medsafe Dossier submissions:** End-to-end management of New Medicine Applications (NMA)
- **Post-market vigilance:** 24/7 Pharmacovigilance & Device-Vigilance to protect your brand reputation
- **Changed Medicine Notifications:** Full-service management of notifications to Medsafe for post-approval changes
- **Clinical Trial Sponsorship:** Serving as the legally required New Zealand-resident sponsor for clinical research.
- **Importer of Record:** Facilitating the legal entry of goods into New Zealand for offshore manufacturers.
- **Dietary Supplement compliance:** Expert review of formulations, labelling, and therapeutic claims under the Medicines Act.
- **Regulatory Affairs:** High-level consultancy and feasibility assessments on the evolving New Zealand regulatory landscape.

 027 508 6002

 david@carsl.co.nz

 www.carsl.co.nz



David Smyth — Director & Consultant

David is known for his deep understanding of regulatory environments and his ability to navigate complex challenges in the medical field. Mentored by CARSL founder Brian Day, David is passionate about the ever-evolving medical industry, where new technologies and innovations drive change. His professionalism, business acumen, and attention to detail ensure clients get expert regulatory advice and guidance.