

## Regulatory & Compliance

The New to R&D Grant aims to increase your long-term R&D capabilities by supporting capability development activities that involve either:

- increasing the R&D-related human capital expertise within the business organisation via training, coaching, or advisory, OR
- setting up systems, processes or operations that enable R&D to be undertaken more efficiently and effectively.

**Developing capability in Regulatory & Compliance** will help you to better understand the regulatory market landscape early in your R&D/product development and how that will inform your R&D activities and final product. Regulatory compliance is likely to impact and potentially pivot your R&D. Not considering regulation and compliance early in your R&D process risks incurring time delays and cost overruns that could result in market failure.

### **Do you know all the regulatory and compliance requirements for each market you intend to enter, and the associated costs and times for approvals?**

It is important to consider regulatory requirements as early as possible in your R&D project to help you to avoid costly loop backs as a result of regulatory hurdles and roadblocks that could appear late in development. Different markets have different requirements, so it's important to do your due diligence and draw on in-market expertise and knowledge. Having clear information will help ensure you have adequate time and budget to launch successfully.

The regulatory landscape is a complex, dynamic and challenging area that is very market, sector and product specific, and is a critical capability that businesses need to master. Understanding the legal and regulatory framework in each export market is especially important given there is no harmonisation in regulation across markets. It's important to get advice and support to meet the rules and regulations in relevant markets.

### **Key activities can include:**

- Identifying your intended geographic market(s)
- Learning by doing, through engaging a relevant regulatory expert to help with:
  - Identifying the regulatory bodies/authorities in those markets
  - Understanding each authority's regulatory/compliance standards for your intended new product
  - Understanding each authority's R&D regulatory/compliance requirements for new R&D certification
  - Establishing mandated processes, systems and reporting
  - Obtaining relevant accreditation/certification
  - Attending relevant conferences and symposiums.

### **Potential risks of not addressing regulatory issues include:**

- Your product can't be sold in a particular market
- Your product results in legal action against you
- You need to retrospectively meet compliance standards
- Your R&D process doesn't meet mandated regulations, resulting in costly time delays and rework

## Potential Capability Partners and Useful Resources

Below you'll find some potential capability development courses and providers plus some useful resources. If you know of suitable providers through your networks or have existing working relationships with providers, please feel free to discuss using them with your Funding Engagement Specialist. We make every reasonable effort to keep this information current and accurate, as a starting point to help you build capability within your business, however it is provided for your convenience only and should be taken as neither an exhaustive list of providers nor as an endorsement of those organisations represented. Callaghan Innovation does not accept responsibility for the quality, content, delivery, or outcomes of providers, and does not accept liability for any loss or damage which may directly or indirectly result from any advice, opinion, information, representation or omission, whether negligent or otherwise of the providers listed here.

## Capability Development

Provider	Programme Title or Description	Services	Link
AAPS	Pharmaceutical / Regulatory Affairs Certificates	Online courses	<a href="#">click here</a>
Building Performance	NZ building regulatory system courses	Online courses	<a href="#">click here</a>
Callaghan Innovation	World-class problem-solving expertise and R&D facilities	Expert advice	<a href="#">click here</a>
Compliance Online	Comprehensive Courses	Online courses	<a href="#">click here</a>
NZQA - Te Pukenga	New Zealand Certificate in Regulatory Practice (Level 5) with strands in Audit, Inspection, and Investigation	Course/qualification	<a href="#">click here</a>
Udemy	Introduction to Regulatory Compliance	Online Course	<a href="#">click here</a>

## Topic Resources

Title/Provider	Description	Link
HealthTech Activator: Understanding the regulatory landscape.	Collection of resources on regulatory pathways for health-related products. Includes information about regulations in New Zealand, Australia, USA, UK, and Europe, plus events, news, and articles.	<a href="#">click here</a>
IANZ - International Accreditation New Zealand	Programmes, training, accreditation, and other resources. IANZ accredits companies to global standards of competence set by the International Organisation for Standards (ISO). This includes testing laboratories, inspection bodies, building consent authorities and medical imaging providers.	<a href="#">click here</a>



Ministry for Primary Industries: Export	Exporting requirements for food and beverages, timber and wood products, animals, ACVMs, and other products.	<a href="#">click here</a>
Open Textbook Library	[PDF Textbook] Quality Assurance & Regulatory Affairs for the Biosciences.	<a href="#">click here</a>
Product360 by Callaghan Innovation	Product360 is a collection of resources that set out the commercialisation landscape with the purpose of helping you to identify areas that may need to be resolved in order to achieve product success.	<a href="#">click here</a>
SGS New Zealand	Testing, inspection and certification for a wide range of industries and product types. Also provides training and consultancy.	<a href="#">click here</a>
Upwork   The World's Work Marketplace	Talent Marketplace specialising in Development & IT, AI Services, Design & Creative, Sales & Marketing, Admin & Customer Support, Writing & Translation, Finance & Accounting, HR & Training, Legal, Engineering & Architecture.	<a href="#">click here</a>