

## Regulatory and Compliance

**Developing capability in this area** will help you to better understand the regulatory market landscape early in your research and development (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?**

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. It is important to consider regulatory requirements as early as possible in your R&D project. This ensures you avoid costly loop backs as a result of regulatory hurdles and roadblocks that could appear late in development.

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 recommend them as capability development partners and let us know [here](#) so that we can add them to this resource page to benefit others. We make every reasonable effort to keep this

information current and accurate as a starting point for your capability development plan. 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.

You also have an opportunity to speak directly with a Callaghan Innovation Business Innovation Advisor who can help put you on the capability development path that best suits you and your current R&D needs.

## Capability Development



[www.aaps.ca](http://www.aaps.ca)

### Pharmaceutical | Regulatory Affairs | Online Course | AAPS

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[www.udemy.com](http://www.udemy.com)

### Introduction to Regulatory Compliance

Regulatory Compliance Requirements of Companies, Institutions, Businesses and Organizations

**AAPS Regulatory Affairs 101**  
Essentials of Regulatory Affairs for Pharmaceutical Scientists eLearning Series

[www.pathlms.com](http://www.pathlms.com)

### Regulatory Affairs 101 | AAPS

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## BUILDING PERFORMANCE

[learning.building.govt.nz](http://learning.building.govt.nz)

### Building Performance: All courses

English (en) Māori - Tainui (mi\_tn)  
Māori Te Reo (mi)

[www.nzqa.govt.nz](http://www.nzqa.govt.nz)

### Qualification Overview

Subject Area Society and Culture " Justice and Law Enforcement " Justice and Law Enforcement not elsewhere classified Strategic Purpose Statement The purpose of this qualification is to provide people who work in frontline operational regulatory roles w...

**w** [waset.org](http://waset.org)



### Science Conferences in 2023

science Conferences in 2023 is an indexed listing of upcoming meetings, seminars, congresses, workshops, programs, continuing CME courses, trainings, summits, and weekly, annual or monthly symposiums. science Conferences in 2023 lists relevant events fo...

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## Topic Resources



Charting your path to product success

Product360 | CallaghanInnovation

[www.product360.nz](http://www.product360.nz)

### Product360 by Callaghan Innovation - Validate your path to success

A set of New Zealand's best resources to help you plan your product development.



[hta.callaghaninnovation.govt.nz](http://hta.callaghaninnovation.govt.nz)

### Regulatory Pathway | HealthTech Activator


It's essential that healthtech innovators understand the regulatory environment of their potential markets and develop a pathway to meet regulatory requirements in conjunction with their product development and other strategies.



[www.mpi.govt.nz](http://www.mpi.govt.nz)

### Export | NZ Government

Find out how to export goods from New Zealand to other countries. Check the exporting requirements for food and beverages, timber and wood products, animals, ACVMs, and other products.



### Quality Assurance & Regulatory Affairs for the Biosciences - Open Textbook Library


This 125-page course textbook, entitled Quality Assurance & Regulatory Affairs for the Biosciences, was created by Jack O'Grady, M.S., professor at Austin Community College. This textbook accompanies the course BITC 1340: Quality Assurance for t...



[www.ianz.govt.nz](http://www.ianz.govt.nz)

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### How work should work

Browse talent by category

<b>Development &amp; IT</b> 4.85/5 1853 skills	<b>Design &amp; Creative</b> 4.91/5 968 skills	<b>Sales &amp; Marketing</b> 4.77/5 392 skills	<b>Writing &amp; Translation</b> 4.52/5 505 skills
<b>Admin &amp; Customer Support</b> 4.77/5 508 skills	<b>Finance &amp; Accounting</b> 4.79/5 214 skills	<b>Engineering &amp; Architecture</b> 4.55/5 659 skills	<b>Legal</b> 4.65/5 133 skills

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