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Insights into Buying Cannabis Manufacturing Equipment Part I

Executive Summary

- Australia and New Zealand medicinal cannabis manufacture requires use of Good Manufacturing Practise (GMP); do not take equipment GMP readiness for granted.
- Australia and New Zealand have their own set of equipment and facility standards; overseas standards do not readily transfer.
- Local advice, support and service significantly reduces potential income loss in case of equipment breakdown.

Australia legalised medicinal cannabis in 2016. Since legalisation, the Australian industry has grown slowly, challenged by unprecedented complexity of environment. Australia has taken global leadership through highly regulating the legal framework, licensing process, and by applying stringent pharmaceutical good manufacturing practice.

This guide attempts to distil what should really matter for an Australian cannabis business, when choosing manufacturing (processing) methods and equipment:

> The establishment of a manufacturing process that is cost competitive in a global marketplace and compliant with all relevant local and international regulations.

On manufacturing methods and equipment, Australian cannabis companies are generally finding themselves “educated” by influences from Canada and the USA. The basis of such “education” is often from the practically unregulated US recreational market, which is where the industry had it's genesis.

The complexities of a technology and method “transfer” into the Australian framework and pharmaceutical GMP are often vastly underestimated, or worse, not even recognised until it is too late.

On the path to a competitive and compliant cannabis manufacturing business, decisions that have to be made formulate around, but are not limited to, notions such as:

- Production Capacity
- Manufacturing Methods and Workflow
- Equipment Importation, Certification and Validation Cost
- Equipment Service and Calibration
- Product Manufacturing Cost
- Sustainability

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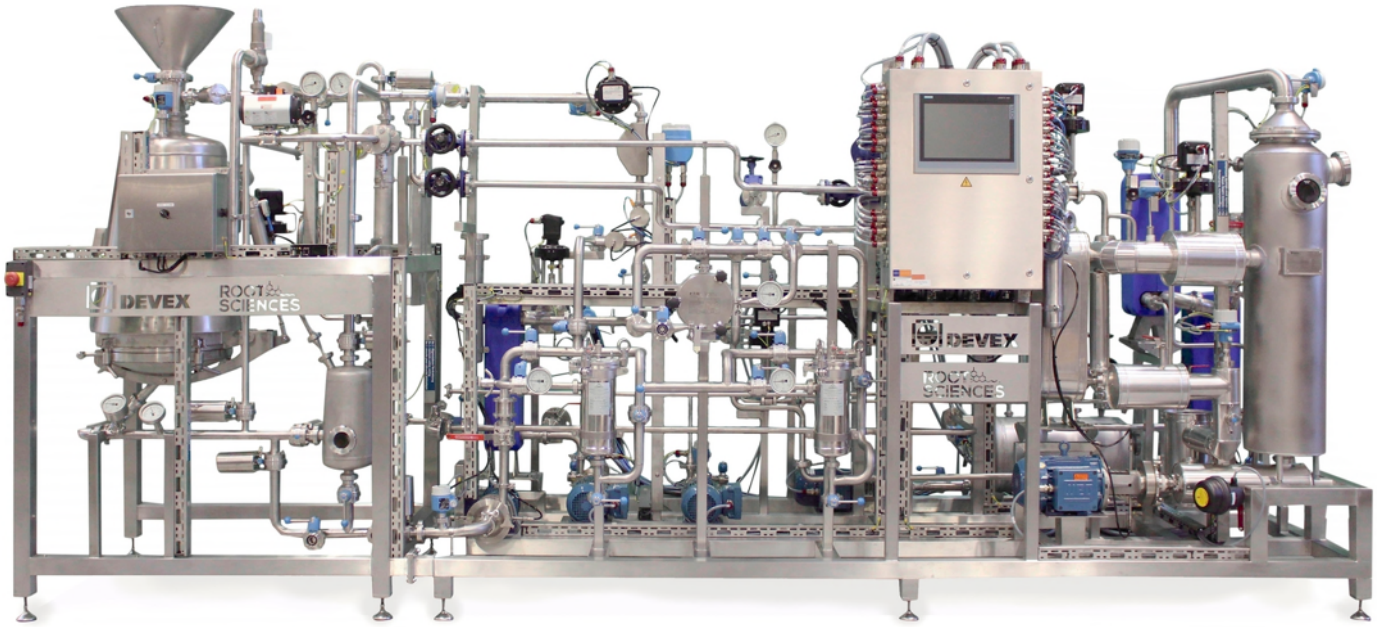
Equipment Decisions

Mainstream cannabis manufacturing started in the USA around 10 years ago. Currently, cannabis is still illegal at a federal level in the US, with states individually legalising and setting frameworks. Standards vary significantly from state to state and Canada has its own regulations entirely.

With cannabis products remaining illegal at the federal level in the US, and, with cannabis product manufacture not controlled by the US Food and Drug Administration (FDA), “grey market” methods and equipment are dominating the US equipment landscape and, to some extent, the Canadian marketplace, where pre-existing process and equipment often has been grandfathered.



Pharmaceutical Industry Good Manufacturing Practice (GMP, PIC/S)

Cannabis manufacturing equipment made in the US and Canada traditionally does not have GMP (PIC/S) standards applied, which virtually prevents their use in a GMP environment or makes validation very challenging at best.

It is extremely difficult, time consuming and costly, to “certify and engineer GMP into equipment”, where the equipment was not designed and manufactured in line with GMP equipment standards in the first place.

Fundamental support documents such as material certificates, surface quality certificates, weld certificates or IQ/OQ documentation are very hard to produce retrospectively.

Leading North American manufacturers are making efforts to improve their products towards GMP, however, this is a process that takes years , and, unfortunately, is often misunderstood. This can lead to assertionsa of “GMP compliance” with actual equipment delivery and later validation turning out to be far more challenging than promised. Generally speaking European manufacturers are better placed due to their long standing pharmaceutical industry experience.

When purchasing equipment for use in pharmaceutical GMP it is important to follow good practice including completion of a User Requirement Specification (URS) document, which will assist your business in supplier selection.

A simple, yet very efficient way to verify whether a potential supplier is actually capable of supplying suitable equipment is, to insist on the provision of example GMP documentation for review before even engaging in the quotation or equipment selection process. Being unable to quickly supply professionally written example documents should lead to automatic disqualification of a supplier.

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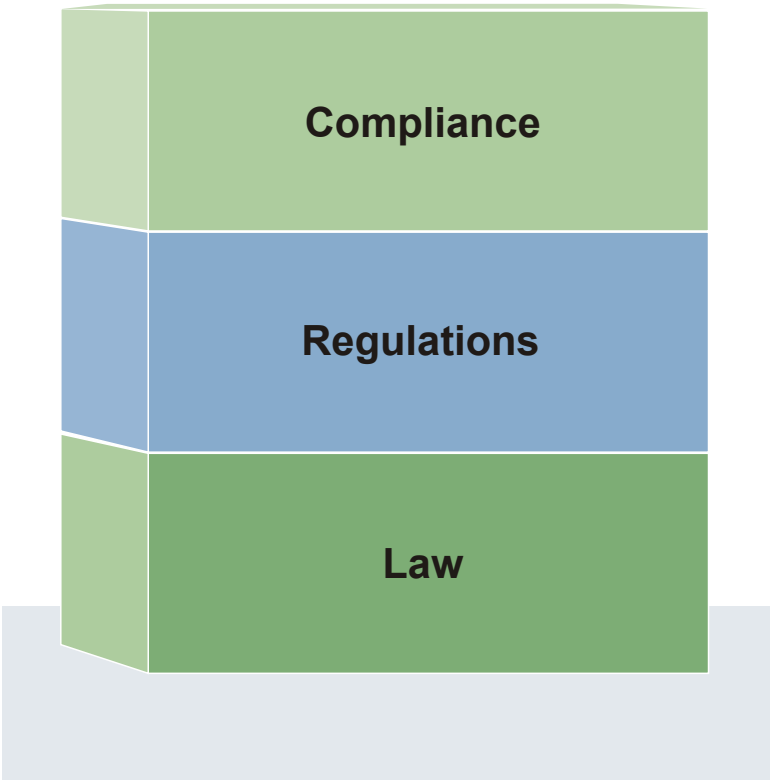
Australian / New Zealand Standard Compliance

Australian Standards, relating to equipment and facilities often vary significantly from North American (US or Canadian) standards. Most ASNZ standards are aligned with European codes, so European equipment is generally easier to certify locally.

When purchasing equipment for use in Australia it is highly recommended you require certified compliance with the following equipment standards (selection):

- AS/NZS3000: 2018 - Australian Wiring Rules (dictates the correct colour for external wiring from device to facilities)
- AS/NZS 3112:2017 - Approval and Test Specification - Plugs and Socket-Outlets (dictates what power plugs are acceptable for use in Australia)
- AS/NZ 3100: 2017 - Approval and Test Specification - General Requirements for Electrical Equipment (electrical tests which equipment should comply with)
- AS/NZS 3820:2009 - Essential Safety Requirements for Electrical Equipment (safety equipment provisions such as fuses etc).
- AS/NZS 1210: Pressure Vessels (dictates the design requirements for a pressure vessel)
- AS/NZS 4343:2015 - Pressure vessel Equipment Hazard Levels (used to assess what risk category a pressure vessel falls under, anything above category E requires design and plant registration).
- AS/NZS 60079 - Explosive Atmospheres (series of standards which dictate which equipment can be used in explosive atmospheres, compliance to this essentially means assessment to conform with IECEx or ANZEx)



In a worst-case scenario, equipment has been purchased and imported, which then had to be modified locally at unforeseeably high cost or, which had to be returned / discarded, when it was assessed as not practical for compliance upgrade.

Often the lost opportunity cost of non-compliant equipment is far higher than the actual conversion or replacement.

Delayed market launch of many months may cause, amongst others,

- Loss of income
- Loss of investor confidence
- Loss of share value

It is worth noting that, as a Director of a local business, you may expose yourself and your business to liability if your business operates equipment that is not standard-compliant.

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Equipment Cost

Purchasing Terms

Overseas equipment suppliers will generally offer pricing with INCOTERMS EWX (ex works) or DAP (delivered at place basis) whilst a local, ANZ based equipment partner will generally supply you under DDP.

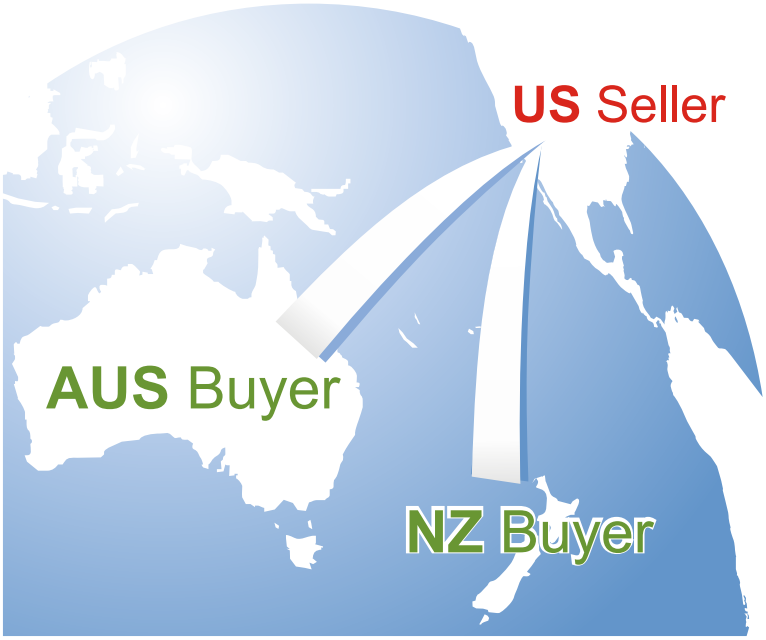
The total cost for international transport, duties, customs processing and local delivery will typically exceed 10% to 30% of the quoted price. Significant additional freight cost can occur if air freight is chosen instead of sea freight transport. Add to this the cost of ensuring local standards compliance and performing all necessary equipment certifications and registrations. This cost is often vastly underestimated, when international quotations are compared with local offers.

Incoterms

EXW

This rule places minimum responsibility on the seller, who merely has to make the goods available, suitably packaged, and at the specified place, usually the seller's factory or depot. The buyer is responsible.

- for loading the goods onto a vehicle (even though the seller may be better placed to do this)
- for all export procedures
- for onward transport and
- for all costs arising after collection of the goods



In many cross-border transactions, this rule can present practical difficulties.

Specifically, the exporter may still need to be involved in export reporting and clearance processes and cannot realistically leave these to the buyer.

Watch out for your insurance risk which starts at loading the goods at the seller!

DAP

The seller is responsible for arranging carriage and for delivering the goods, ready for unloading from the arriving means of transport, at the named place.

Risk transfers from seller to buyer when the goods are available for unloading, so unloading is at the buyer's risk.

The buyer is responsible for import clearance and any applicable local taxes or import duties. For Australia the duty is dependent on manufacturing country and type of goods – generally 5% of the purchase price.

DDP (typically quoted by your local provider)

The seller is responsible for arranging carriage and delivering the goods at the named place, cleared for import and all applicable taxes (e.g. GST) and duties paid.

Risk transfers from seller to buyer when the goods are made available to the buyer, ready for unloading from the arriving means of transport.

This rule places the maximum obligation on the seller and is the only rule, that requires the seller to take responsibility for import clearance and payment of taxes and/or import duty.

These last requirements can be highly problematic for overseas sellers. In Australia and New Zealand, import clearance procedures are complex and bureaucratic, and so, are best left to a partner with local knowledge and experience.

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Installation, Start-up and Training

For high value or complex equipment installation, start-up and training should be included in your overall purchase price.

Overseas sellers will often work with flat rates, that are highly inflated to simplify their quotation process. These flat rates will include substantial travel time and obviously international travel cost.

Naturally a local supplier will be able to offer this service at much lower cost because travel distances and times are shorter.

Overseas supplier offers are capped at a maximum time allowance.

If there are any delays during the installation caused by the buyer, the supplier will generally charge for additional engineer time and travel cost. For longer delays the supplier may have to abandon the site visit, which may incur significant additional return travel charges – especially from overseas.

You would expect a local partner to be far more flexible.

Commissioning, GMP document execution

As part of GMP requirements it is commonly expected that part of the support documentation is completed onsite during installation and commissioning of the equipment. Depending on equipment type, manufacturer, buyer URS and agreement terms this generally includes at minimum a Site Acceptance Test (SAT) and often Operation Qualification (OQ).

It is also common practice to perform local calibration (and certification) of all process relevant machine sensors to ensure traceability to National Association of Testing Authorities (NATA) standards or similar.

Specialised equipment is needed, that is difficult or expensive to ship internationally and often not available locally for rent.

A local equipment provider with experience in GMP will be well setup to perform such tasks, generally saving the buyer substantial time thus cost in attempting to perform these tasks themselves.

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Warranty and Ongoing Support

Purchasing equipment from overseas generally means, that you are left without local warranty and ongoing support.

Overseas suppliers will often reduce service team travel and cost by using sales or warranty terms, that involve part supply only. You are left with the responsibility to assist with problem identification and repairs. For specialist equipment, the necessary skills and tooling may not easily be available locally and training your own team, as well as maintaining their training levels, is time consuming and costly.

For on-site warranty support an overseas supplier will always attempt a remote fix first in order to avoid the cost of international engineer travel.

Where overseas suppliers provide in-person support, there will be substantial delays with onsite support, given time zone challenges, response times and international travel. It is not unusual for overseas engineers to require between one and two weeks before they can arrive onsite, often at substantial cost.

On top goes the logistical challenge of getting spare parts to site in time for an engineer to arrive. Where initial remote diagnosis was not correct, or a problem cannot be fixed with parts on hand, then further delays are caused by the need to import more parts from the equipment factory.

For scheduled preventative maintenance and support a lot of these delays may be prevented, however, the cost of international travel will always weigh heavy when compared to local service.

What is more significant than engineer travel and part shipping cost, is the loss of business revenue, when your production equipment is non-operational for an extended period of time.

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Equipment Reliability and Downtime Cost

In the Australian cannabis industry it is not uncommon for daily production profits to be in excess of $ 50,000. Consider you have one breakdown, that takes an overseas engineer ten days to attend to (due to international travel), that a local engineer can do in two.

These eight days would cost your business $ 400,000.

Consider the potential cost to your business of purchasing equipment, that is not of appropriate quality thus reliability.

Supplier Selection

The Australian cannabis industry ought to look at what our well established and internationally recognised pharma industry is doing.

These companies are very aware of equipment downtime cost, so they are undertaking huge efforts to manage risk, by (at minimum)

- Defining their requirements in form of URS documents, which form the basis of any equipment purchase
- Verify supplier equipment through
  - Supplier background checks
  - Supplier factory inspections
  - User reference checks
  - Example GMP document inspection
  - Supplier Quality Management System inspection
  - Engineering and built plan review
  - Support capability checks
- Determining and placing breakdown prevention and remediation plans including
  - Critical spare part stock
  - Guaranteed onsite response time support agreements
  - Establishment of preventative maintenance agreements

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Sydney Australia Pty Ltd
Unit 1, 12 Chaplin Drive
Lane Cove NSW 2066
Phone: 1800 023 467
cannabis@scitek.com.au
www.medicinalcannabisproduction.com.au

Author
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Tobias Schappeler
tobias@scitek.com.au