⚠ COMPLIANCE ESSENTIAL — AUSTRALIAN LICENSED PRODUCERS 2026

Australian Cannabis LP Compliance Checklist

ODC • TGA • GMP • GACP

The complete compliance checklist for Australian Licensed Producers — covering ODC licensing, TGA manufacturing standards, GMP/GACP requirements, quarterly reporting obligations, and audit readiness.

⚠ KEY COMPLIANCE MILESTONES ⚠

Sep 2025	Quarterly	Ongoing
PIC/S GMP v17	ODC Reports Due	ODC Inspections
Now In Effect	**15th of Next Month**	**Random & Scheduled**

A$2.1B	75T+	$237K+
Projected Market by 2028	Cannabis Imported in 2024	ODC Fines Issued 2025–2026

WHAT YOU'LL FIND IN THIS CHECKLIST:

- ✓ Complete ODC licensing & permit requirements under the Narcotic Drugs Act 1967
- ✓ TGA manufacturing licence & TGO 93 quality standards
- ✓ GMP (PIC/S v17) and GACP compliance checklist
- ✓ Quarterly reporting & record-keeping obligations
- ✓ Security, traceability & audit readiness requirements
- ✓ How GrowerIQ guarantees your compliance & how to book a demo

A LETTER FROM OUR CEO

Dear fellow cannabis professional,

I wrote this checklist because I've seen what happens when Licensed Producers get compliance wrong. I've sat across the table from operators in Canada, Colombia, South Africa, and Portugal who lost months of production — or worse, their licence — because they didn't have the right systems in place when inspectors arrived.

Australia's regulatory environment is one of the most demanding I've encountered. You're not dealing with one regulator — you're answering to the ODC, the TGA, and your state Poisons authority simultaneously. The new PIC/S GMP v17 standard is now in effect. ODC inspections can happen without notice. And with **$237,000+ in fines** already issued to producers like Cannatrek and Tasmanian Botanics, the consequences of compliance gaps are very real.

I built GrowerIQ specifically for situations like this. After helping hundreds of licensed producers across more than 10 countries navigate complex multi-agency frameworks, I can tell you with certainty: **the operators who invest in compliance infrastructure early are the ones who thrive.** The ones who treat it as an afterthought are the ones who end up in enforcement proceedings.

This checklist gives you the complete picture — every ODC, TGA, and GMP requirement your operation needs to meet, laid out clearly so nothing falls through the cracks. And if you want to see how GrowerIQ can automate the hardest parts, **I'd welcome the chance to show you personally.**

ANDREW WILSON
Chief Executive Officer
GrowerIQ

Understanding Australia's Cannabis Regulatory Landscape

Australian Licensed Producers operate under **one of the most complex multi-regulator frameworks** in the global cannabis industry. Unlike single-agency markets, Australian LPs must satisfy the **ODC (federal licensing)**, **TGA (manufacturing and quality)**, and **state/territory governments (wholesale licences)** simultaneously — each with distinct requirements, reporting timelines, and inspection powers.

Who Regulates What

Authority	Jurisdiction	Key Requirements
ODC Office of Drug Control	Licensing under Narcotic Drugs Act 1967; cultivation and production permits; quarterly reporting; security oversight	Single licence + activity permits; fit & proper person test; INCB reporting
TGA Therapeutic Goods Admin	Manufacturing licences; product quality (TGO 93); GMP compliance; supply pathway approvals	PIC/S GMP v17 compliance; TGO 93 testing; stability studies; labelling
State Gov State & Territory	Wholesale licences; poisons schedule enforcement; state-specific security requirements	Wholesale licence required for export; state police coordination

> ***"The complexity of navigating ODC, TGA, and state requirements simultaneously is the number one compliance challenge for Australian LPs. One gap in any agency's requirements can halt your entire operation."***

Key Market Realities for Australian LPs in 2026

Enforcement Intensifying

$237K+ in infringement notices issued to multiple companies in 2025–2026 (Cannatrek, Cannoperations, Tasmanian Botanics, Hale Farm and others). ODC conducts at least one unannounced inspection per licensee per year.

Import Competition

77.4 tonnes imported in 2024 (~80% from Canada, from 16 countries total). Domestic LPs must demonstrate superior quality and compliance to compete.

PIC/S GMP v17 Active

The updated GMP standard took effect September 2025. All manufacturers must comply with the new PIC/S Guide PE009-17. Non-sterile cannabis producers: minimal material change.

Single Licence Reform

Since 2021, three licence types consolidated into one perpetual licence. Reduced regulatory burden but full compliance still required for each activity permit.

State/Territory Differences: Unlike the US or Canada where cannabis is regulated at the state/provincial level, Australia's primary LP framework is **federal** (ODC + TGA). However, each state/territory has its own Poisons/Drugs legislation requiring **additional authorisations** for possession, manufacture, and supply of S4/S8 substances. Requirements vary — NSW (Poisons & Therapeutic Goods Reg 2008), Victoria (Drugs, Poisons & Controlled Substances Act), and Queensland (Medicines & Poisons Act 2019) each have distinct wholesale licence forms, fees, and compliance requirements. Always verify your state's specific obligations.

Checklist 1: ODC Licensing & Permits NARCOTIC DRUGS ACT 1967

The Office of Drug Control (ODC) administers licensing under the Narcotic Drugs Act 1967. All items below are mandatory requirements for Licensed Producers.

Single Licence Requirements

- [ ] **Obtain a Medicinal Cannabis Single Licence** from the ODC — authorises cultivation, production, or both under one licence. Commercial licences are perpetual (no renewal); research-only licences remain time-limited
- [ ] **Apply for activity-specific permits** for each site — cultivation, production, and/or manufacture permits required separately per location
- [ ] **Pass the Fit and Proper Person test** (Sections 8A & 8B) for all licensees, individuals, and corporate business associates — criminal history checks and financial probity assessments mandatory
- [ ] **Demonstrate supply chain viability** — cultivators must prove they will supply to a licensed producer or manufacturer; unprocessed raw cannabis export is prohibited (GMP-processed dried flower, extracts, and finished products may be exported)
- [ ] **Ensure single-crop compliance** — only cannabis on licensed sites (per Single Convention on Narcotic Drugs 1961); mixed crops are not permitted

Quarterly Reporting Obligations MANDATORY

- [ ] **Submit quarterly reports using the ODC Cannabis Reporting Template** — monthly breakdowns of cultivation, production, manufacture, use, and stock levels
- [ ] **Reports are cumulative** — each quarterly report covers January through end of that quarter. Q4 must include a full annual reconciliation
- [ ] **Submit by the 15th of the following month:** Q1 (Jan–Mar) due 15 Apr; Q2 (Jan–Jun) due 15 Jul; Q3 (Jan–Sep) due 15 Oct; Q4 (Jan–Dec) due 15 Jan
- [ ] **Submit separate reports for each permitted site** — multi-site operations require individual reports per location

⚠ **Warning:** Non-submission, late submission, or false/misleading information may result in compliance action including infringement notices, licence conditions, or licence cancellation. The ODC reports to the International Narcotic Control Board (INCB) — your data feeds Australia's international treaty obligations.

Export Requirements

- [ ] **Obtain appropriate state/territory authorisations** for all activities conducted in your jurisdiction (manufacturing, possession, supply of S4/S8 substances) — requirements vary by state
- [ ] **Exportable products:** finished ARTG-listed medicines, cannabis extracts (including non-final dosage forms), and GMP-processed dose-standardised dried flower. Unprocessed raw cannabis may NOT be exported
- [ ] **Secure export permits from the ODC** and verify import country requirements before shipment

Checklist 2: TGA Manufacturing & Quality Standards TGO 93

The TGA enforces manufacturing licences and the TGO 93 quality standard. These requirements apply in addition to (not instead of) ODC licensing.

Manufacturing Licence

- [ ] **Obtain a TGA Licence to Manufacture Therapeutic Goods** if manufacturing cannabis products domestically — this is separate from the ODC licence
- [ ] **Comply with PIC/S Guide to GMP version 17 (PE009-17)** — effective since 1 September 2025 for all medicine manufacturing
- [ ] **Cultivation exemption:** Growing, cutting, and drying cannabis may be done without GMP if material is used as starting material for a GMP-licensed facility. First crude extraction may also qualify

TGO 93 Quality Requirements MANDATORY TESTING

- [ ] **Cannabinoid content accuracy** — actual THC/CBD quantities must fall within the specified range of the stated label quantity
- [ ] **Aflatoxin testing:** B1 not more than 2 µg/kg; total aflatoxins not more than 4 µg/kg
- [ ] **Foreign matter:** Not more than 2.0% by weight
- [ ] **Heavy metals testing** — arsenic, cadmium, lead, mercury within TGO 93 limits
- [ ] **Ochratoxin A, pesticide residues, and total ash** (not more than 20.0%) within specified limits
- [ ] **Analytical method validation** must comply with ICH Q2(R1) — specificity, precision, accuracy, linearity, range, LOD/LOQ, robustness

Stability & Expiry

- [ ] **Conduct stability studies following ICH Q1 principles** — expiry dates must be based on stability data in the actual marketed packaging
- [ ] **Maintain ongoing stability programme** for all marketed products with documented protocols and results

Supply Pathways

- [ ] **Determine your supply pathway:** Special Access Scheme (SAS), Authorised Prescriber Scheme (APS), or clinical trials — no Schedule 3 (Pharmacist Only) low-dose CBD products have been listed on the ARTG to date
- [ ] **Ensure all product labelling** meets TGA requirements including cannabinoid content, warnings, storage conditions, and batch identification

Checklist 3: GMP, GACP & Security Compliance PIC/S GMP v17

GMP Requirements (Manufacturers)

- [ ] **Implement full GMP documentation system:** batch records, equipment calibration logs, environmental monitoring data, personnel training records
- [ ] **Establish deviation and CAPA (Corrective & Preventive Action) system** — all deviations must be documented, investigated, and resolved with root cause analysis
- [ ] **Maintain supplier qualification records** — all raw materials and starting materials must come from qualified suppliers with documented quality agreements
- [ ] **Implement change control procedures** for any modifications to processes, equipment, materials, or facilities
- [ ] **Conduct annual GMP self-inspections** and document findings with corrective action plans

GACP Requirements (Cultivators)

- [ ] **Comply with WHO GACP guidelines, TGO 93, and PIC/S GMP Annex 7** (Manufacture of Herbal Medicinal Products) for all field-level operations
- [ ] **Document seed/propagation material quality,** growing conditions, harvest timing, post-harvest handling, and environmental controls
- [ ] **Maintain personnel training records** for all cultivation staff with documented competency assessments
- [ ] **Record all fertiliser, pest management, and agricultural inputs** — fully traceable to each batch harvested

Security Requirements ODC MANDATORY

- [ ] **Install CCTV maintained at all times with IT backup** covering all cannabis areas, entry/exit points, and perimeters
- [ ] **Implement intruder-resistant facility design** to prevent unauthorised entry and removal of cannabis — per ODC security guidelines
- [ ] **Maintain security overlay plans** showing all CCTV cameras, reed switches, motion sensors, and access control points
- [ ] **Record all access events** at internal and external perimeters — including transportation movements with documented chain of custody
- [ ] **Maintain close relationship with local law enforcement** — ODC coordinates with police agencies for site security verification

Inspection powers: Under the Narcotic Drugs Act 1967 (activating the Regulatory Powers Act 2014 framework), ODC authorised inspectors can enter licensed premises **without consent and without notice**. At least one unannounced inspection per licensee per 12-month period. Your facility must be audit-ready at all times.

Checklist 4: Traceability & Record-Keeping INCB OBLIGATION

Under the Single Convention on Narcotic Drugs 1961, Australia must report to the INCB on all cannabis quantities at each stage of the supply chain. This obligation flows down to individual licence holders.

Seed-to-Sale Traceability

- [ ] **Track every cannabis plant from seed/clone to final product** with unique batch identifiers at each stage
- [ ] **Record all stage transitions:** propagation → vegetative → flowering → harvest → drying → curing → processing → finished product/destruction
- [ ] **Document weight at each stage** with timestamp and operator attribution — required for ODC quarterly reporting and yield reconciliation
- [ ] **Maintain room-to-room movement records** with timestamps for every transfer within the facility

Documentation & Audit Trail

- [ ] **Maintain complete audit trail for every activity** — user attribution, precise timestamps, and edit/deletion history for all records
- [ ] **Implement digital signatures** for all critical compliance documents (batch records, SOPs, deviation reports, CAPA sign-offs)
- [ ] **Document all destructions** with witnesses, weights, methods, and reasons — destruction records must reconcile with quarterly reports
- [ ] **Retain all records for the period required** by the Narcotic Drugs Act and TGA — records must be retrievable for inspections at any time

QA/QC & Laboratory Testing

- [ ] **Establish partnerships with accredited laboratories** for cannabinoid profiling, contaminant testing, and microbiology per TGO 93
- [ ] **Implement sample tracking system** — link every sample to its source batch with chain of custody documentation
- [ ] **Maintain Certificates of Analysis (CoAs)** for every batch released — must include all TGO 93 parameters with pass/fail determinations

Recall Readiness

- [ ] **Implement a documented recall procedure** that can trace any finished product back to its source materials within hours
- [ ] **Conduct mock recall exercises** at least annually to test the speed and completeness of your traceability system

How GrowerIQ Guarantees Compliance for Australian LPs

Every checklist item in this guide maps directly to a GrowerIQ feature. Here's how the platform ensures you never fall out of compliance — across every regulatory body that oversees your operation.

☑ ODC Quarterly Reporting

GrowerIQ automatically tracks all cultivation, production, and stock data in the format ODC requires. Cumulative quarterly reports generate with one click — no spreadsheets, no manual reconciliation, no missed deadlines.

☑ Digital Master Batch Records

One-click generation of GMP-ready batch records with complete seed-to-sale lineage, multi-tier traceability (current, parent, grandparent), room movement cards, deviation reports, CAPA tracking, and document appendices. Print-ready for auditors.

☑ Deviation & CAPA Management

Structured deviation reporting with classification, root cause analysis, impact assessment, and full CAPA lifecycle tracking. Every action is assigned, tracked, and signed off — exactly what GMP inspectors look for.

☑ Complete Audit Trail

40+ activity types tracked with user attribution, precise timestamps, and edit history. Every action is logged permanently — from planting to processing to destruction. Fully satisfies ODC, TGA, and INCB traceability requirements.

☑ QA/QC & Lab Integration

Sample creation, lab result recording, test result sign-offs with digital signatures. Sanitation activity tracking for GMP hygiene protocols. All linked to source batches for complete TGO 93 compliance documentation.

☑ AI Report Builder

Query 55+ data tables in plain English — no IT dependencies. Generate compliance reports, audit summaries, and investigative queries instantly. Full audit trail of every query run. Perfect for pre-inspection preparation.

☑ Recall Management

Complete product lineage tracking from seed to final product. If a recall is needed, trace any batch to all related source materials and downstream products instantly — meeting TGA recall requirements.

☑ Digital Signatures & SOPs

Secure digital signatures with timestamp capture for batch records, SOPs, deviation reports, and CAPA sign-offs. Activity-linked and user-attributed — built for GMP and TGA audit requirements.

> ***"One software that can be used from cultivation all the way through to distribution. The software is user-friendly, making it easy for our team to adapt." — Rebel J., Shared Services Manager***

Checklist 5: Priority Actions — What to Do Now

🚨 Immediate Actions

- [ ] **Conduct a compliance gap analysis** — compare your current operations against every ODC, TGA, and GMP requirement in this checklist
- [ ] **Implement a seed-to-sale tracking platform** — **paper-based systems will not survive an ODC inspection**; digital traceability is essential
- [ ] **Review your ODC quarterly reporting process** — next deadline is approaching; ensure your data is accurate and cumulative
- [ ] **Verify PIC/S GMP v17 compliance** — the new standard is now in effect; review Annex 1 changes if applicable to your operation

⚠ Near-Term — Next 90 Days

- [ ] **Establish or update your deviation/CAPA system** — GMP inspectors will ask to see active CAPA records and resolution timelines
- [ ] **Audit your security infrastructure** — CCTV, access controls, and security overlays must match ODC guidelines
- [ ] **Conduct a mock recall exercise** to validate traceability completeness and response time
- [ ] **Train all staff on compliance protocols** — SOPs, inspection procedures, deviation reporting, and emergency response

✓ Strategic Action: Secure Compliance with GrowerIQ

- [ ] **Implement GrowerIQ for complete Australian LP compliance** — the only seed-to-sale platform with proven multi-regulator compliance experience across 10+ countries. ODC reporting automation, GMP-ready batch records, deviation/CAPA management, and full traceability from seed to export.

- [ ] **BOOK YOUR FREE DEMO WITH GROWERIQ**
  Visit **groweriq.ca/book-a-demo** and see how Australian LPs are achieving audit-ready compliance with the platform that guarantees regulatory continuity.

Is Your Operation Audit-Ready?

ODC inspectors can arrive without notice. GrowerIQ has already ensured compliance for regulated producers across 10+ countries and 6 continents. See the platform in action.

BOOK YOUR FREE DEMO

groweriq.ca/book-a-demo

- ✓ **ODC Compliant:** Automated quarterly reporting in ODC format
- ✓ **GMP Built-In:** Deviations, CAPAs, and digital signatures
- ✓ **Recall Ready:** Instant seed-to-product lineage tracing
- ✓ **TGA Ready:** TGO 93 documentation and batch records
- ✓ **Audit-Proof:** Complete traceability with 40+ activity types
- ✓ **10+ Countries:** Proven in every major regulated market

The Seed-to-Sale Platform That Guarantees Compliance
for Australian Licensed Producers.
Traceability. Compliance. Uninterrupted Production.

A$2.1B	PIC/S v17	10+
Market by 2028	Now In Effect	Countries Served

Don’t wait for an ODC inspection to find your gaps.
Achieve audit-ready compliance today.

BOOK YOUR FREE DEMO

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10+	6	ODC	24/7
Countries Served	Continents	Inspection Ready	Audit Trail

Sources: ODC, TGA, Narcotic Drugs Act 1967, PIC/S GMP PE009-17, TGO 93, Single Convention on Narcotic Drugs 1961, NSW Health, Vic DHHS, Qld Health.