MedNova Lifesciences

PRACTICAL SELF-ASSESSMENT GUIDE

NAFDAC QPPV Compliance Checklist for Marketing Authorization Holders

Is your company compliant with NAFDAC's pharmacovigilance requirements?

Every Marketing Authorization Holder (MAH) with products on the Nigerian market should periodically review its pharmacovigilance system against current NAFDAC expectations — including the QPPV guidelines effective October 2024, which require a resident, permanently available Qualified Person for Pharmacovigilance.

Use this checklist as a practical self-assessment. Work through each section honestly; the scoring guide at the end tells you what your answers mean.

Disclaimer: This checklist is provided for informational purposes only and should not be considered legal or regulatory advice.

1 Organization & Governance

- [ ] A Qualified Person for Pharmacovigilance (QPPV) has been formally appointed.
- [ ] The QPPV resides and operates in Nigeria, as required.
- [ ] A deputy or documented backup arrangement is in place.
- [ ] Roles and responsibilities are clearly documented.
- [ ] The QPPV has sufficient authority to oversee pharmacovigilance activities.

2 Pharmacovigilance System

- [ ] A documented Pharmacovigilance System is maintained.
- [ ] Current Pharmacovigilance SOPs are available.
- [ ] Staff receive regular pharmacovigilance training.
- [ ] Training records are maintained.

- [ ] A quality management process exists for pharmacovigilance activities.

3 Adverse Event Management

- [ ] Procedures exist for receiving adverse event reports.
- [ ] Healthcare professionals know how to report safety information.
- [ ] Patients have clear reporting channels.
- [ ] Individual Case Safety Reports (ICSRs) are processed within required timelines.
- [ ] Serious adverse events are escalated appropriately.

4 Aggregate Safety Reporting

- [ ] PSUR/PBRER schedules are maintained.
- [ ] Aggregate reports are submitted on time.
- [ ] Benefit-risk evaluations are documented.
- [ ] Supporting safety data are retained.

5 Signal Detection & Risk Management

- [ ] Signal detection activities are performed regularly.
- [ ] Safety trends are documented.
- [ ] Emerging risks are investigated.
- [ ] Corrective actions are documented where required.

6 Literature Surveillance

- [ ] Medical literature is reviewed routinely.
- [ ] Relevant safety findings are assessed.
- [ ] Literature review activities are documented.

7 Documentation & Inspection Readiness

- [ ] Pharmacovigilance records are complete and readily available.
- [ ] Document retention procedures are in place.
- [ ] Inspection readiness files are maintained.
- [ ] Previous inspection findings have been addressed.

8 Business Continuity

- [ ] Business continuity procedures exist for pharmacovigilance activities.
- [ ] Backup personnel can perform critical PV functions.
- [ ] Emergency contact procedures are documented.

9 Vendor Oversight

- [ ] Third-party pharmacovigilance providers are governed by written agreements.
- [ ] Responsibilities are clearly allocated.
- [ ] Vendor performance is reviewed periodically.

10 Management Review

- [ ] Senior management receives periodic pharmacovigilance updates.
- [ ] Compliance risks are reviewed.
- [ ] CAPAs are tracked to completion.
- [ ] Resources remain adequate to support pharmacovigilance obligations.

✓ Quick Self-Assessment

Mostly “Yes”	Your pharmacovigilance system appears to be well established. Continue periodic reviews to maintain compliance.
Several “No” answers	Your organization may benefit from an independent pharmacovigilance gap assessment to identify areas requiring improvement.

+ How MedNova Lifesciences Can Help

MedNova Lifesciences supports pharmaceutical, biotechnology, medical device, nutraceutical, and healthcare companies with:

- Outsourced Local QPPV services
- Local Safety Officer (LSO) support
- Local Contact Person for Pharmacovigilance
- Pharmacovigilance system setup
- Individual Case Safety Report (ICSR) management
- PSUR/PBRER preparation and submission
- Signal detection and benefit-risk evaluation
- Literature surveillance
- Pharmacovigilance SOP development
- Staff training
- Inspection readiness and regulatory support
- Product lifecycle pharmacovigilance

Request a Complimentary Pharmacovigilance Gap Assessment

If you would like MedNova Lifesciences to review your current pharmacovigilance arrangements against Nigerian regulatory expectations, we would be pleased to arrange a confidential, no-obligation consultation.

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