

PVAC/PMG-MAN Consultative Meeting to strengthen PMG-MAN's Technical and Digital Capacity

Meeting Details

S/N	Date	11 th -12 th September 2025
1	Time	9:00 AM-5:00 PM daily
2	Venue	Amber Residence, 16 Esugbayi Street, GRA Ikeja, Lagos
3	Participating Organizations	PVAC, PMG-MAN, InSight Health Consulting, Empower Swiss, Infinity Health

Meeting Objectives

The consultative meeting was designed to:

1. Review PMG-MAN's technical capacity needs across regulatory and operational domains.
2. Co-develop short- and medium-term capacity development plans, including relevant training modules.
3. Assess PMG-MAN's current digital infrastructure and identify opportunities for automation and interoperability with regulatory agencies.
4. Present prototype technology solutions and agree on detailed implementation plans for pilot deployment.
5. Agree on clear next steps for strengthening PMG-MAN's technical and digital systems.

Workshop Activity

Day 1 – (September 11, 2025)

1. Opening Session

The workshop began with a welcome by Dr Muhammad Balarabe (PVAC), who outlined the purpose of the meeting and stressed the importance of strengthening the capacity of the association. Mr Bolaji Akala (InSight Health Consulting) presented the workshop objectives, setting the tone for a collaborative process focused on technical and digital capacity development for PMG-MAN.

2. Technical Presentations

The first part of the day featured presentations from technical partners and PMG-MAN representatives. These provided an overview of current challenges, opportunities, and proposed strategies.

a. Technical Capacity Assessment – Sakhile Dube (Empower Swiss)

Sakhile presented Empower Swiss's approach to assessing PMG-MAN's role in Galvanising the Industry and driving national pharmaceutical self-sufficiency. The presentation emphasized:

- A mandate to build institutional capacity and develop workforce competencies in regulatory affairs, manufacturing, and supply chains.
- Use of a 10-pillar framework to assess organizational, technical, and individual capacity.
- Planned activities over the two-day workshop, including mapping current strengths, conducting gap analysis, and identifying priority needs.
- The goal of producing actionable recommendations, a roadmap for strengthening PMG-MAN, and a feasibility study for establishing a Pharmaceutical Training Academy

b. Digital Systems and Infrastructure – Irene Nwaukwa (Infinity Health)

Irene discussed digital solutions to support PMG-MAN's regulatory and operational work, which include a document compliance engine (DCE). The goal was to establish DCE as the compliance backbone for Nigerian manufacturers by equipping PMG-MAN members with tools that standardize documentation, reduce compliance burdens, and enhance competitiveness.

Key points included:

- Development of digital tools that integrate regulatory compliance, monitoring, and reporting functions.
- Opportunities for automation and improved data sharing across manufacturers and regulatory agencies.
- Proposed pilot implementation to test the system before wider rollout.
- The importance of aligning digital tools with Nigeria's broader health system infrastructure to ensure interoperability and sustainability.

These sessions gave participants a shared understanding of the technical and digital aspects of governance, laying the foundation for group discussions.

c. PMG-MAN Operational Landscape – Frank (PMG-MAN)

Frank's presentation summarized PMG-MAN's current operating environment. He highlighted the association's role as the umbrella body for pharmaceutical manufacturers, the opportunities for growth in local production, and the barriers posed by regulatory and capacity constraints.

3. Group Sessions

Participants were divided into two groups to examine specific themes:

• Group 1: Technical Capacity Needs

This group, consisting of 9 participants, reviewed institutional and technical gaps through tailored questions from the consultant in regulatory readiness and needs, training needs, current regulatory gaps and resource requirements

- **Group 2: Digital Infrastructure Assessment**

This group, consisting of 11 participants, analyzed PMG-MAN's digital systems, identified bottlenecks, and proposed solutions for automation, interoperability, and data sharing.

Each group presented their findings in plenary, leading to an interactive discussion. Participants agreed that both technical and digital strengthening must proceed in parallel for PMG-MAN to meet its objectives.

4. Closing of Day 1.

The session ended with a recap of agreed action points and a preview of Day 2, which would focus on reviewing group deliverables and finalizing next steps. The meeting ended at 5:00 PM.

Day 2 - (September 12, 2025)

1. Opening and Review of Day 1

The second day began with a recap of key discussions and outcomes from Day 1, facilitated by Mubarak Ahmed from InSight Health Consulting. The review ensured participants had a shared understanding of the group work and provided an opportunity to clarify outstanding issues before moving into Day 2 activities.

2. Joint Review of Group Deliverables

Participants reconvened in plenary to review the outputs from both technical and digital working groups. Each group presented its draft recommendations, followed by open discussion and refinement.

a. Group 1: Technical Capacity Gaps and Mitigation – Empower Swiss

Empower Swiss facilitated a structured gap analysis across PMG-MAN's operations. Key themes included:

- **Financial constraints:** Limited access to affordable financing, highlighting the need for tax incentives, grants, and low-interest loans.
- **Data and information management:** Weak in-house data systems, limited interoperability, and a lack of ICT expertise. Recommendations included appointing a dedicated data analyst, ICT training, and licensing compliance support.
- **Regulatory hurdles:** Duplicated regulatory processes and high compliance costs. Suggested actions included streamlining registration, expanding NAFDAC capacity, and supporting bioequivalence (BA/BE) studies.
- **Supply chain and infrastructure:** Challenges with inputs, power, and logistics. Emphasis on capacity building in supply chain management.
- **Human resources:** Shortages of skilled technical staff and ICT specialists, with calls for training and professional standards.
- **Technology and innovation:** Gaps in the adoption of digital and advanced tools. Proposed solutions included training in digital platforms and innovation adoption.

- **Market access and patronage:** Weak government patronage, delayed payments, and limited access to regional markets. Recommendations included pooled procurement, stronger local content policies, and proactive engagement with purchasers.

b. **Group 2: Digital Capacity Gaps and Implementation Roadmap - Infinity Health**

Infinity Health presented a digital readiness assessment and proposed an implementation roadmap. Key highlights included:

- **Digital gaps:** Issues with the generation of quality modules, data privacy, validation of technical modules, and inadequate ICT capacity within PMG-MAN.
- **Mitigation strategies:**
- **Generation of quality modules:** Add CTD library features, add repository for living document and SOPs; conduct training.
- **Data Privacy:** Integration of Google Drive/Dropbox, etc, to individualise data management. Add an admin dashboard for analytics only; Implement DNCR and ISO standards to the data infrastructure.
- **Validation of technical modules:** PMG-MAN cohort to review module rubric and test, and at completion, run a PMG-MAN validation study.
- **Poor ICT Knowledge and Capacity:** Conduct training

Implementation plan: Structured in phases with clear timelines covering assessment, pilot deployment, user training, and nationwide rollout
Through this process, participants discussed the most urgent gaps and practical steps for addressing them.

3. Consolidation of Action Plans

Building on the group deliverables, the plenary developed a consolidated set of action points. These included:

- A comprehensive report on PMG-MAN's insitutional and technical capacity.
- A draft framework for strengthening technical capacity through structured training, regulatory support, and resource mobilization.
- A follow-up meeting with the regulatory committee of PMG-MAN to get further inputs on the digital solution.
- Agreement to pilot proposed digital solutions in selected organizations before wider rollout.
- Commitments from PVAC, PMG-MAN, and partners to coordinate technical assistance and monitor progress.
- A need for Infinity to secure the buy-in of NAFDAC for inter-operability of both Infinity and NAFDAC's platforms.

4. Closing Session

The meeting closed with reflections from PVAC, represented by Mr Muhammad Balarabe, and PMG-MAN, represented by Mr Abbas Sambo. Both leaders stressed the importance of sustaining collaboration beyond the workshop and turning discussions into practical actions. They expressed satisfaction with the smooth coordination of the workshop and

the quality of the outcomes. A vote of thanks was given to all participating organizations for their active contributions. The meeting ended at 3:25 P

Appendix I

Participants and Attendance

Participant Overview

The meeting brought together **20 participants** drawn from government, industry, technical consulting, and project management. The mix of participants ensured representation of decision-makers and technical expertise needed for meaningful capacity development planning.

Organizational Representation

- **Presidential Initiative on Healthcare Value Chain (PVAC):** Mr Muhammad Balarabe (Representative)
- **Pharmaceutical Manufacturers Group - Manufacturers Association of Nigeria (PMG-MAN):** Thirteen members representing pharmaceutical companies and industry perspectives, including two interns (please see the table below).
- **Technical Consulting Partners:** Empower Swiss (2 representatives, regulatory capacity); Infinity Health (1 representative, digital systems)
- **Project Management and Facilitation:** InSight Health Consulting (3 team members)

Attendance Summary

- **Total participants:** 20
- **Organizations represented:** Five primary organizations, (PVAC, PMG-MAN, IHC, Empower Swiss, Infinity Health) with multiple pharmaceutical companies represented through PMG-MAN.
- **Stakeholder categories:** Government/policy (PVAC), industry (PMG-MAN), technical consultants (Empower Swiss, Infinity Health), and project management (InSight Health Consulting)

Detailed Attendance List

S/N	Name of participant	Organization
1	Adekoh Abraham O	SAM PHARMACEUTICAL LTD
2	Igwebuike Chukwuemeka J.	SKA Pharma
3	Karo Otuorimuo	CODIX GROUP
4	Sakhile Dube Mwedzi	EMPOWER
5	Muhammad Balarabe	PVAC
6	Sunday Agamah	EMZOR
7	Collette Okenchi	EMZOR
8	Raphael Ajayi	FIDSON
9	Irene Nwaakwa	INFINITY HEALTH
10	Frank Mnonmeh	FMUMAN
11	Egbelagu Sarah	FMUMAN
12	Mbaneme N. Ariike	MAY & BAKER
13	Ngozi Osuji	DAILY NEED IND.
14	Abbas Sambo	SWIPHA
15	Omoba Josiah. O	EMPOWER
16	Enyi Okafor Adaora	PMG-MAN
17	Akande Olusola	PMG-MAN
18	Tosin Adeniyi	IHC
19	Mubarak Ahmed	IHC
20	Bolaji Akala	IHC

Appendix II Pictures