

The image features the Sanofi logo, which consists of the word "sanofi" in a bold, lowercase, sans-serif font. The first dot of the "s" and the dot above the "i" are colored purple. The logo is centered on a white background. Three thick, curved purple lines sweep across the background, starting from the left and curving towards the right, creating a dynamic, modern feel.

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Quality transformation in Biomanufacturing

*Leveraging AI to enhance
decision-making and
operational excellence*



Maité Durrenbach
Chief Quality Officer

Agenda

- 01** Introduction
- 02** Sanofi's digital transformation journey
- 03** Quality roadmap to leverage Artificial Intelligence
- 04** Deep dive in 3 use cases



At Sanofi, we are *modernizing* our organization and building an *Immunology Powerhouse*

Pharma launches



First and only therapy to delay onset of Stage 3 Type 1 diabetes

Specialty Care GBU



Leader in immunology (Atopic dermatitis and Asthma) & upcoming indications

Vaccines GBU



Targeting all infants against RSV in their first season

Manufacturing & Supply *Today*



29,000 Employees
globally

39 Manufacturing Sites
across the world

2.1 billion Units
produced annually

€8.6bn Investment
by 2030

Global Quality Vision – Take the Lead for **2030**

We will build *predictive quality ecosystem* that anticipates and prevents issues before they occur, *enabling real-time compliance monitoring* across all entities



AI-driven quality management, predicting issues before they arise, automating routine processes, converting data into actionable insights, and enabling *swift decision-making and risk prevention*.



Robust quality processes, highly standardized, leveraging hubs capabilities, supported by *strong internal expertise*.

Industry-leading **validation approaches** driving *manufacturing process robustness* while facilitating self-correcting operations.



Smart QC Ops : Set the industry standard for the *Quality Control of the future*, leveraging automation and robotics, Process Analytical Technology (PAT), real time monitoring and parametric release.



Real-Time Compliance Monitoring to ensure all time readiness for submission, launches & inspections for our Sites and strategic CMOs

A network of experts using Science-based approach to influence regulatory frameworks and build collaborative partnerships with authorities and industry associations

Skills, Culture & Mindset

Empowered employees with the *right skills*, fostering a ***culture where quality is everyone's responsibility*** and *critical thinking* is embedded in every decision *across the organization*.

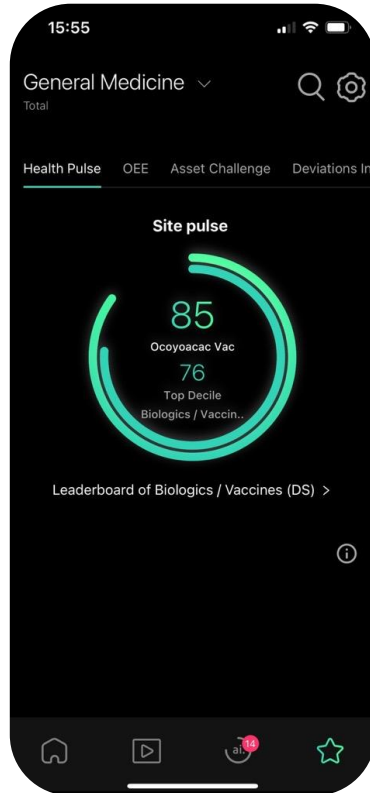
Our ambition is to become the first pharma company powered by *AI at-scale*

3 types of AI

Expert AI : apply massive computing power to solve complex problems

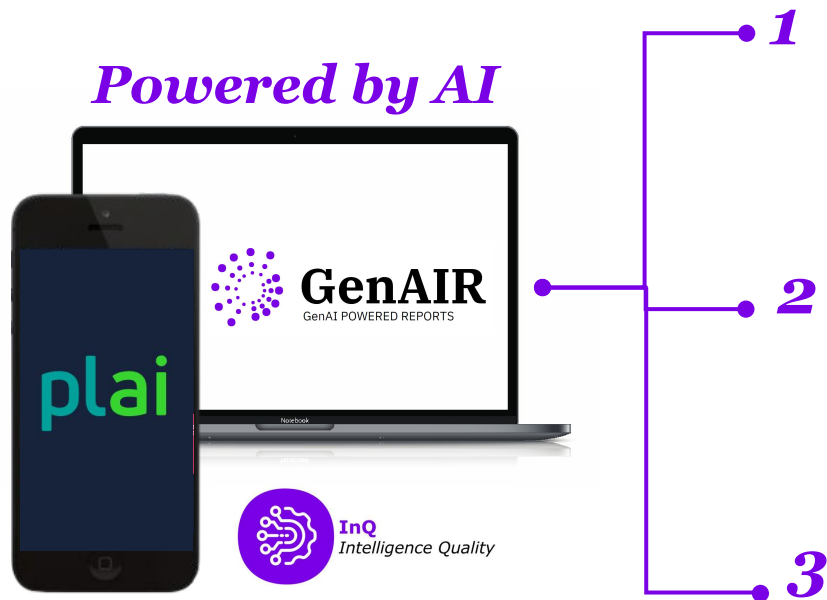
Gen AI: streamline processes, improve productivity

Snackable AI (plai) : help us make better everyday decisions





Ai




With strong focus on digitization & data cleaning, we built our Quality roadmap to leverage *Artificial Intelligence*



Trending and Reports Generation

- Deviation trending and clustering 
- GenAI Product Quality Review / report drafting 
- Drafting of HA Q&A and CTD variations (LLM)

Predictive Quality Ecosystem & Analytics

- Quality Maturity Index 
- Quality Risk Exposure 
- Deviations and TP Audits prompt  Concierge
- Predictive product Stabilities (AKM)
- Continuous Process verification (Sentinel)

Agentic & Intelligent Automation

- Insights companion (Newton)
- Extended Reports automation (Doc Factory)

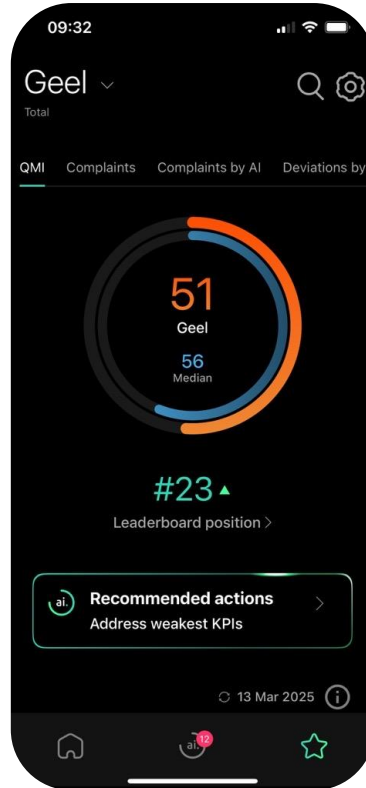
With our Quality Maturity Index in PLAI, *trend prediction is available to everyone, enabling proactive decision making*

QMI
2.0

6 Categories

Covering Quality Processes through
30 KPIs for Sanofi M&S sites

- Audit & Risk
- Stakeholder & Personnel
- Operations, equipment and supply chain
- Lab and specific compliance
- Documentation compliance
- Quality system



Cell Phone



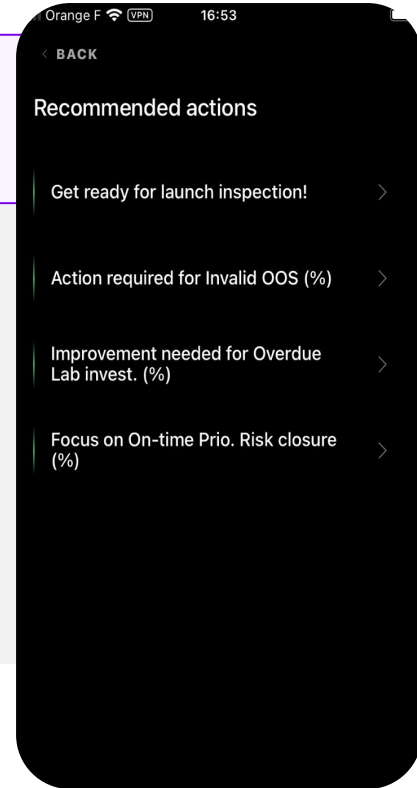
Computer

Overall score

Median score (archetype)

Position within network

Recommended actions



With GenAIR, we will significantly *remove low value added burden*, helping QA teams to refocus on insights

From... highly manual, admin-heavy report drafting activities

To... GenAI-automated technical reports

3,500

PQRs written each year
(mandated by Reg. Authorities)

50+

Different data sources used

130hr

Time spent per PQR, highly manual
and admin heavy task



~70% Data retrieval automated



25 manufacturing sites using GenAir



PQR writers re-focused on insights
and continuous improvements



50% Efficiency (+80% expected in
2026)



Conclusions translated into English

Deviation/CAPA *Process Optimized*

*6 specific Prompts
to improve & accelerate key steps of Deviation/CAPA process*

5W2H initial summary

Structures deviation information into clear 5W2H format

Investigation steps synthesis

Supports on problem investigation & solving (GPS3 methodology)

Root cause suggestion

Creates RC / CAPA& EC suggestions for a deviations based on user information.

CAPA/ EC suggestion

Deviation summary and conclusion

Creates a structured and justified final conclusion and risk assessment.

Executive Summary

Creates one-page summary for a deviation required from HA inspector

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Artificial intelligence is not a substitute for human intelligence; it's an amplifier of human potential

Fei-Fei Li

Thank
you

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