

GRx+Biosims 2026 | OPQ Keynote

CONFIDENCE IN EVERY DOSE

How quality, innovation, and resilience sustain access to affordable medicines

QUALITY | INNOVATION | RESILIENCE

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FDA | CDER | Office of Pharmaceutical Quality

Start with the patient promise

Every patient assumes the next dose will be:

SAFE — No preventable harm

EFFECTIVE — Performs as intended

AVAILABLE — There when needed

Quality is the bridge between approval and sustained access.



Access at national scale

Generics and biosimilars are a public-health engine.

90%
of U.S. prescriptions filled by generic and biosimilar medicines

$467B
saved in 2024 for patients and the healthcare system

12%
of prescription drug spending

The scale is impressive. The responsibility is even larger.

High volume + tight economics + complex supply chains = a quality challenge that must be managed intentionally.

Quality is not a point-in-time event

Quality lives across the product, process, facility, and supply chain.



No single tool assures quality. A complementary system does.

Three shifts for the next era

To sustain access, pharmaceutical quality must become:

01 **PREDICTIVE** — See risk earlier. Act before failure.

02 **AGILE** — Change responsibly without interrupting supply.

03 **RESILIENT** — Recover, adapt, and keep patients supplied.

Quality must move at the speed of science — and the discipline of public health.

Shift 1: from reactive compliance to predictive quality

The highest-value quality signal is the one we act on before patients feel it.



Predictive quality turns scattered information into actionable foresight.

Ask earlier: “What signal tells us this system is beginning to drift?”

Shift 2: design lifecycle agility into products and facilities

A resilient supply chain is not one that never changes.

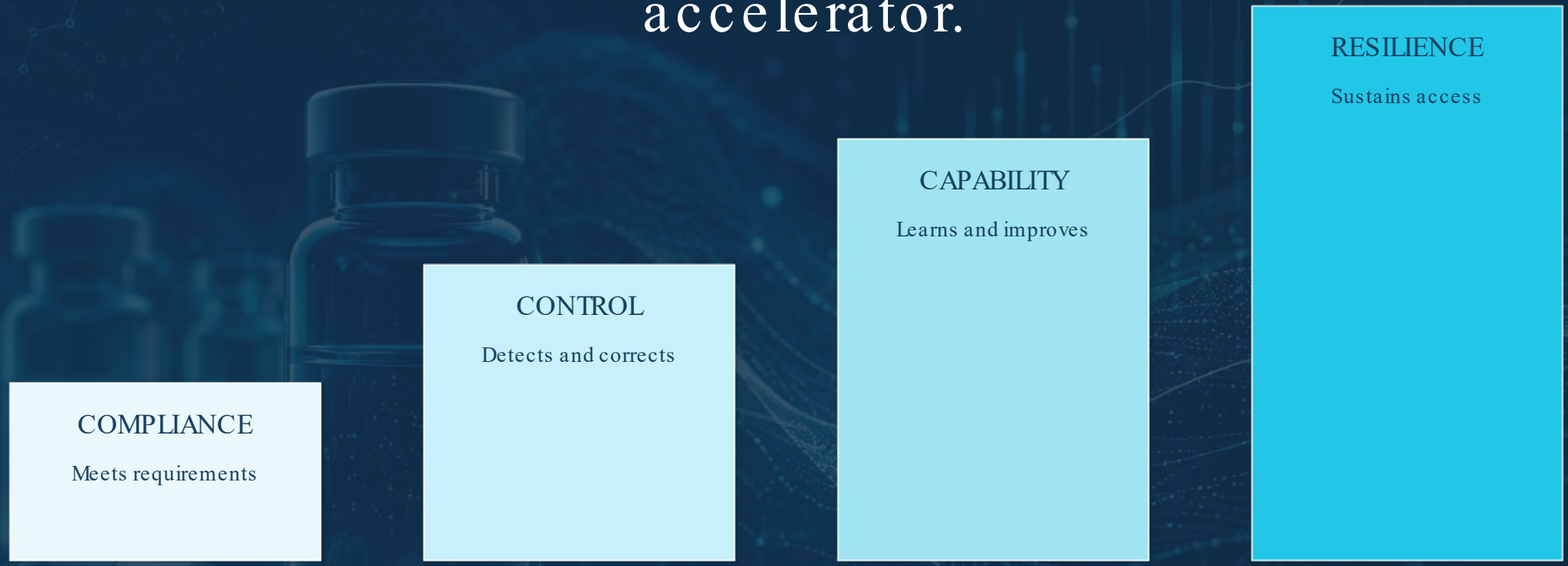
It is one that can change responsibly, transparently, and without interrupting patient access.

- Deeper product/process understanding
- Comparability before change is urgent
- Current lifecycle knowledge
- Complete, decision-ready PAC packages



Shift 3: make quality maturity a business capability

CGMP compliance is the floor. Quality maturity is the accelerator.



Executive leadership should know quality risk as clearly as it knows financial risk.

AI, automation, modeling, and advanced analytics are tools —not substitutes for accountability.

ENABLER

Technology is powerful when it strengthens judgment

The test of technology in quality:

- Does it improve understanding?
- Does it reveal risk earlier?
- Does it support explainable decisions?
- Does it protect data integrity?
- Does it improve patient outcomes?

Innovation earns trust when it is transparent, validated, and connected to a clear control strategy.

What OPQ brings to the table

Our role is to integrate evidence so quality decisions are consistent, science-based, and patient-focused.



Assessment
Can product be made reliably?

Research
What science moves us forward?

ONE QUALITY VOICE

Inspection
Is the facility capable?

Policy
What standards enable consistency?

Surveillance
What is happening in the market?

A shared compact for confidence and access

FDA and industry have distinct roles — and a shared public-health outcome.

FDA continues to pursue

- Consistency and clarity
- Science- and risk-based decisions
- Efficient communication
- Integration across quality functions
- Support for useful innovation

Industry commits to

- Complete, decision-ready submissions
- Facility readiness
- Timely disclosure of meaningful risks
- Current lifecycle knowledge
- Investment in quality capability

The common measure is simple: patients can trust the medicine and get it when they need it.

What I ask of this community

Build quality systems worthy of the scale of the mission.

01 Know your process deeply

02 Treat data as a strategic asset

03 Plan for change before it becomes urgent

04 Make quality risk visible to executives

05 Compete on reliability, not just cost

The best quality system is not the one that produces the most records. It is the one that produces the most confidence.

The future of affordable medicines will not be secured by approval alone.

It will be secured by capable processes, reliable facilities, learning quality systems, and supply chains prepared to adapt.

Confidence in every dose.

Thank you.

