GRx+BIOSIMS 2026 | THE GENERICS & BIOSIMILARS CONFERENCE

Scaling U.S.-Based Generic Drug Manufacturing

From Policy Signals to Practical Adoption

Mayank Nagar, MS, MBA
Vice President & Head, Strategic Alliance Management & Tech Services
Dr. Reddy's Laboratories

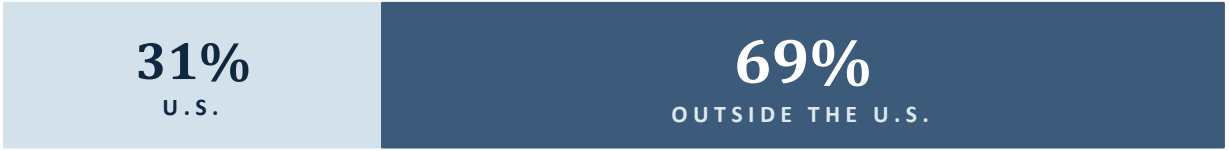
MONDAY, NOVEMBER 2, 2026
3:45 p.m. – 4:45 p.m.
Bethesda North Marriott, Rockville, MD

U.S. generic supply chains remain highly dependent on global manufacturing

The dependence is more pronounced upstream, where domestic API production remains limited.

GENERIC DRUG PRODUCT

Finished dosage forms supplied to the U.S.



FDA manufacturing-location estimate, 2025

ACTIVE INGREDIENTS

API volume used in U.S. prescription medicines



USP Medicine Supply Map analysis, published 2026

Translating policy momentum into sustainable U.S. capacity will require coordinated attention to economics, infrastructure, and capabilities

ECONOMICS | INFRASTRUCTURE | CAPABILITIES

Sustainable U.S. scale-up must address the economics that shaped global manufacturing

U.S. scale-up must protect the generic value proposition while building new capacity and capabilities.

THE ECONOMIC CONTEXT

~30 -50% Gap

Offshore cost of manufacture is roughly 30-50 % of the U.S. cost, depending on drug / dosage forms

GENERIC SUCCESS NEEDS ALL THREE



Match the reference product; meet CQAs

Compete on affordability and price erosion

Reach market early to capture economics

WHAT U.S. SCALE-UP REQUIRES

1. **CAPITAL**
   Facilities, equipment, compliant digital systems
2. **LEAD TIME**
   New infrastructure takes years to build, qualify and approve
3. **TALENT**
   Engineering, operations, quality and regulatory skills

ROUTE 1 | BUILD NEW FACILITIES

30–40+ months

A multi-year commitment, not a near-term supply response. Illustrative planning horizon. Varies by technology platforms

ROUTE 2 | ACTIVATE EXISTING U.S. CAPACITY

Unutilized U.S. facilities can be put to work immediately

PORTFOLIO LOGIC

Complex | **Shortage** | **Biosimilars** | **Conventional**

Regulatory acceleration opens the door. Durable economics can sustain manufacturing at home.

FDA policy can cut time-to-market; complementary levers can strengthen the long-term business case.

REGULATORY FOUNDATION **FDA: earlier facility engagement + priority review for qualifying domestically manufactured generics**

COMPLEMENTARY LEVERS TO CONVERT MOMENTUM INTO CAPACITY

01 **DOMESTIC BONUS EXCLUSIVITY**
Time-limited commercial advantage for qualifying U.S.-made generics.

02 **CAPITAL + TAX INCENTIVES**
Grants, investment tax credits, accelerated depreciation and low-cost financing.

03 **BANKABLE DEMAND**
Multi-year purchase commitments, minimum volumes and strategic stockpile contracts.

04 **PAY FOR RESILIENCE**
Procurement preference or a transparent premium for quality, redundancy and domestic supply.

05 **WORKFORCE + CAPABILITY**
Apprenticeships, university partnerships and support for advanced operational skills.

06 **SHARED SCALE-UP PLATFORM**
Public-private test beds, modular capacity and shared infrastructure for smaller manufacturers.

THE SHARED OUTCOME

Enable manufacturers to finance, build and sustain competitive U.S. capacity
Faster approvals, qualified capacity, sustainable production, reliable supply.

Speed + Economics + Demand