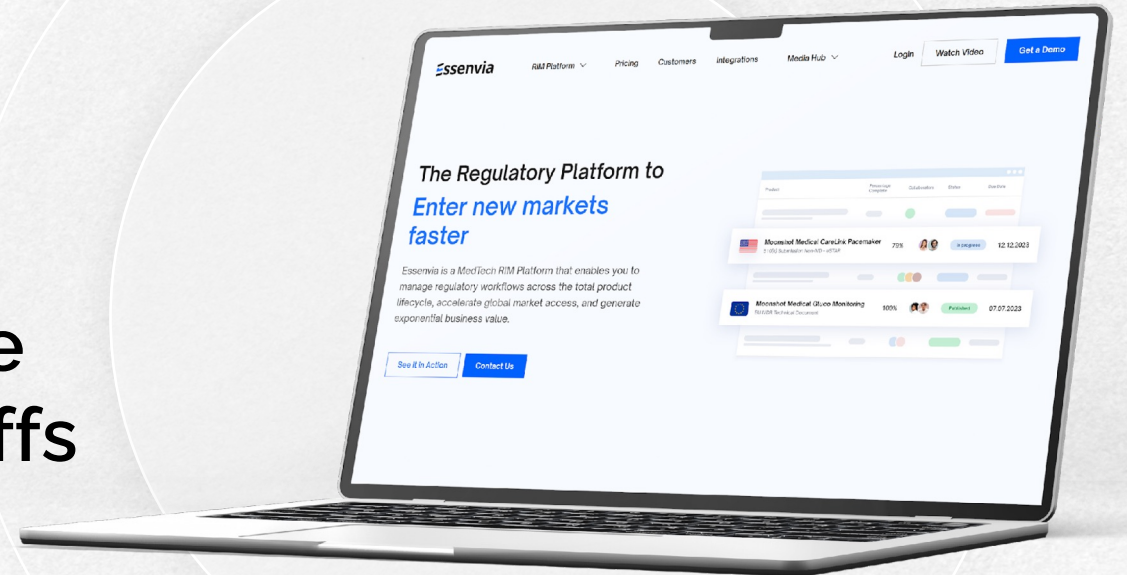




## Navigating the Perfect Storm:

# The New RA Playbook to Balance FDA Staff Reduction, AI, and Tariffs



# TODAY'S AGENDA

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1

Background & Context

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2

The Triple Threats for Medtech

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3

Global Supply-Chain Fallout

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4

Regulatory-Driven Strategy for Re-balancing Revenue

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## YOUR SPEAKERS

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**Soumya Mahapatra**

Founder & CEO

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21 years leading complex digital transformation. Specialized in implementation and adoption of AI-enabled automated Regulatory Technology Solutions at Top 10 Medtech.

**Essenvia**



**Ajit Sankar Mallik, MD PhD**

Strategy and Consulting – Medtech RA/QA

---

15 years in heading Regulatory & Clinical Strategy and Submissions for Class II and Class III medical devices in US, EU, MENA

**accenture**

**HAMILTON**  
**MEDICAL**

at**Heart**  
MEDICAL

# THE TRIPLE THREATS

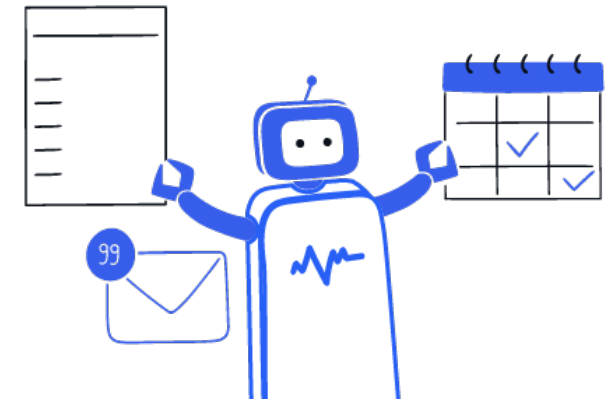
# FDA STAFF REDUCTION, AI & TARRIFF PRESSURES CONVERGE



3,500-person FDA layoff (-20 %, incl. ~200 CDRH reviewers).



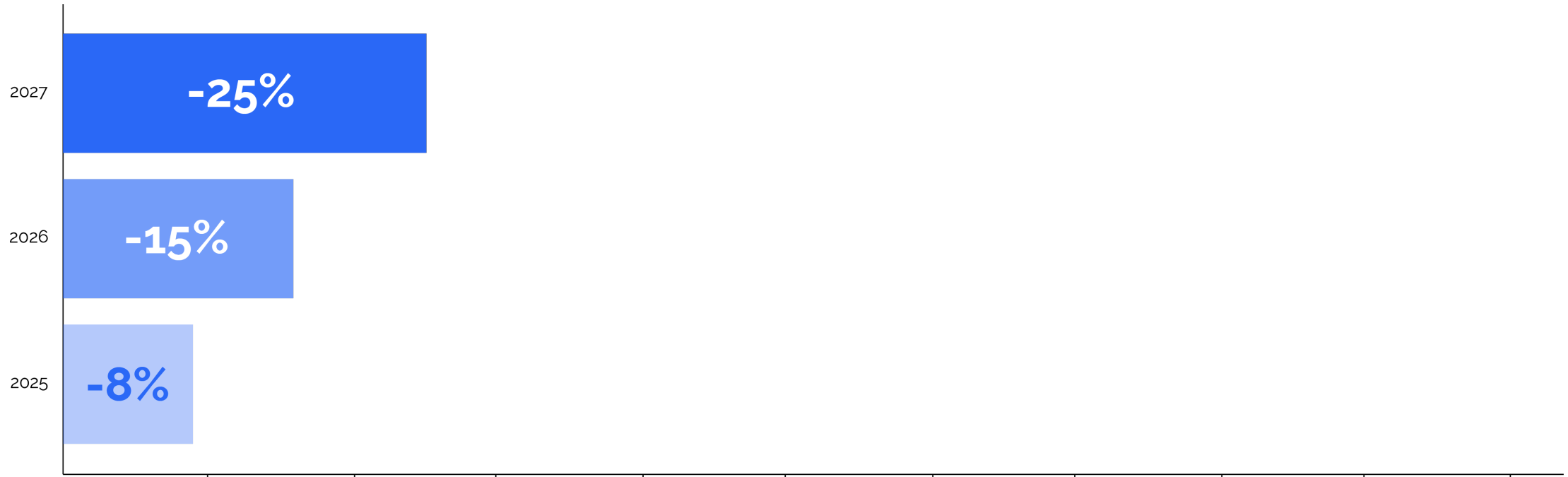
New U.S. tariffs adding 6-15 % to core device inputs.



AI-assisted review at FDA and full-scale rollout starting Jun-2025

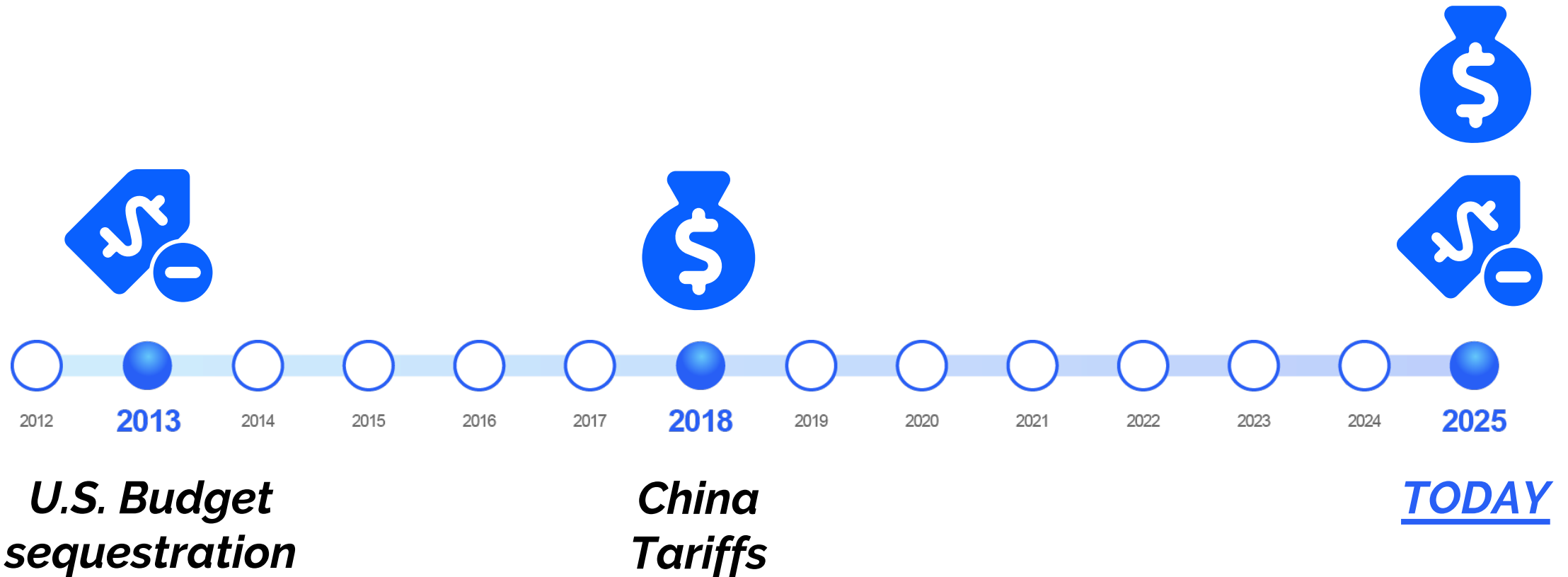
## IMPACT ON REVENUE AND OPERATING MARGINS

How are slower approvals + higher Cost Of Goods Sold compressing 2025–27 U.S. sales forecasts.



# WHY THIS IS UNPRECEDENTED ? —————

Parallel hits to regulatory velocity and cost structure have never coincided at this scale.



## DELAYS AND MARGIN DECLINE DEMAND A PIVOT FROM REG AFFAIRS / CXO

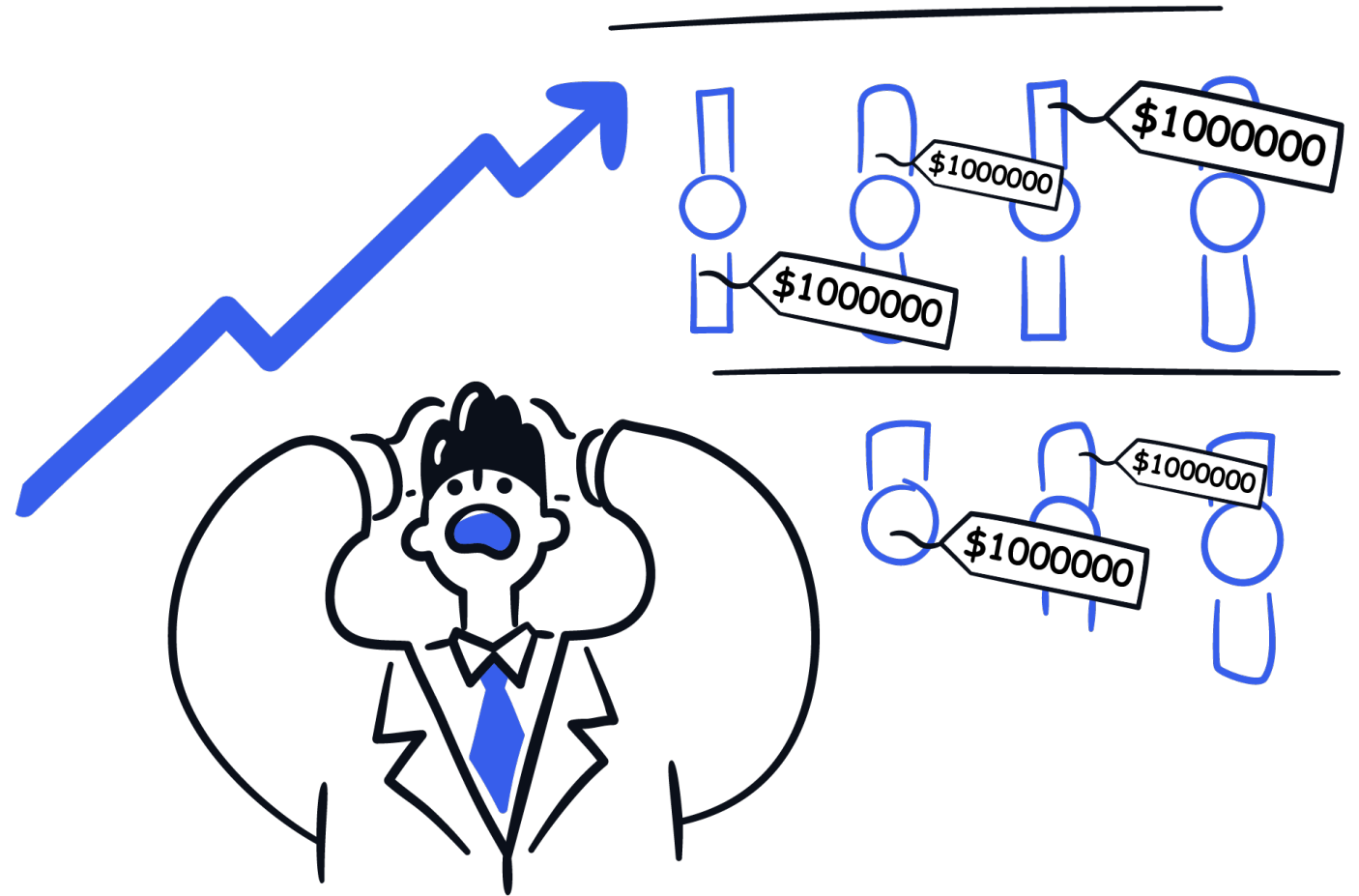
- Pipeline launch delays shift Enterprise Value
- Urgent board-level question: “Where do we replace U.S. growth?”



# SUPPLY-CHAIN FALLOUT

# TARIFF: SUPPLY-CHAIN FALLOUT

- Component classes hit (electronics, precision alloys, polymers).
- Weighted average BOM inflation: +9 % for a typical Class III system.



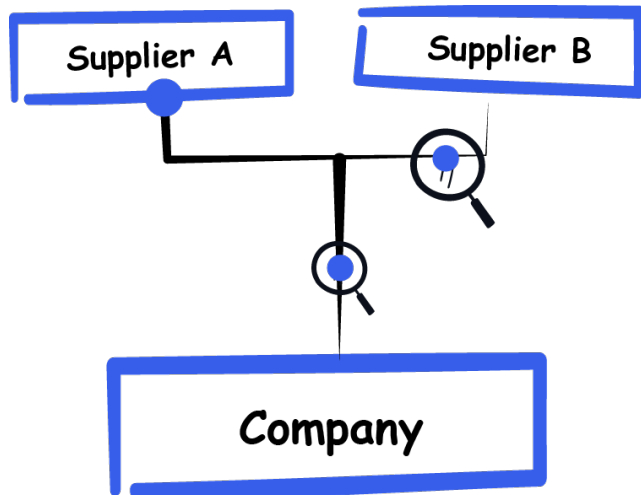
## NETWORK STRESS TEST

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- **Lead times +20–40 % for parts rerouted to Vietnam/ Mexico/Eastern EU.**
- **FDA site-change supplements add 3–6 months before production shift.**



# STRATEGY FOR SUPPLY CHAIN RESILIENCE



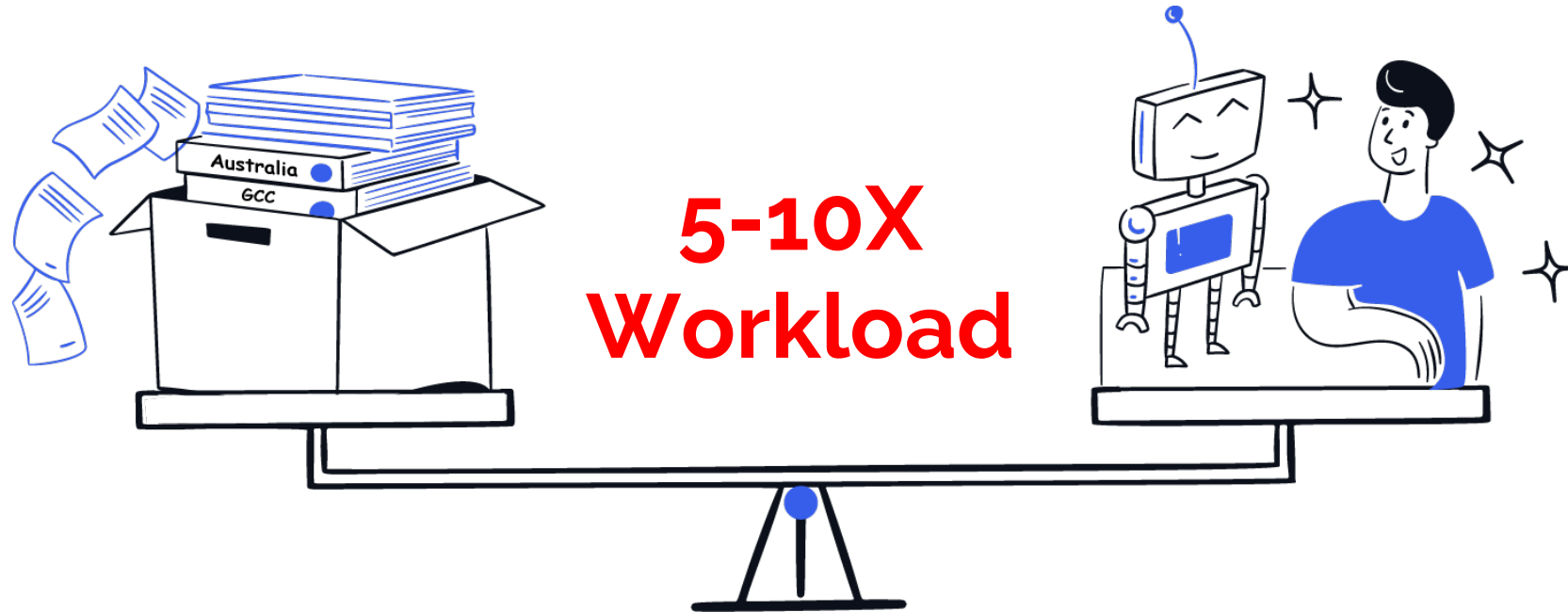
- **Dual-sourcing, regionalized final assembly, digital traceability (“digital thread”).**



- **Cost/benefit snapshot of three relocation archetypes.**

# **REGULATORY-DRIVEN REVENUE RE-BALANCING**

# RA MUST DELIVER TO DRIVE RESILIENCE VIA MARKET DIVERSIFICATION



- **Commercial Resilience:** Offset U.S. shortfall by accelerating products in more jurisdictions (TGA, ANVISA, PMDA, GCC, ASEAN).
- **Operational Resilience:** Adapt and support shifts like dual-sourcing, regionalized final assembly

# THE NEW HIGH-PERFORMANCE RA PLAYBOOK

From Submission Repository



Submissions Acceleration

From Regulatory Monitoring



“Just-in-time” Actionable Regulatory Insights

From Reactive Change Mgt



Proactive Real-time Change Impact

From Disjointed Orgs



Strategic Role-Based Collaboration

From “Add-on” Paper  
and Electronic



“AI-Native” Regulatory Systems



## GETTING STARTED ?

# RAPS Euro Convergence

— 13-16 MAY 2025 • BRUSSELS, BELGIUM —

### Session

Essenvia RIM Platform: Navigating the Perfect Storm:  
FDA Capacity Cuts, AI, Tariffs & the New RA Playbook

### Time

15:45 - 16:10 CEST

### Location

Exhibit Hall - 1. Spark!

### Speaker

Soumya Mahapatra



# Visit Booth #24



# THANK YOU

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**Anthony Drew**

Director, Regulatory AI Solutions  
Essenvia

[anthony@essenvia.com](mailto:anthony@essenvia.com)