The Global Regulatory Environment and DoW's Ability to Create Room to Maneuver

LTC Andrea Mountney, Ph.D., PMP, RAC
Director, Office of Regulated Activities, DHA R&D

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RESEARCH & DEVELOPMENT ®

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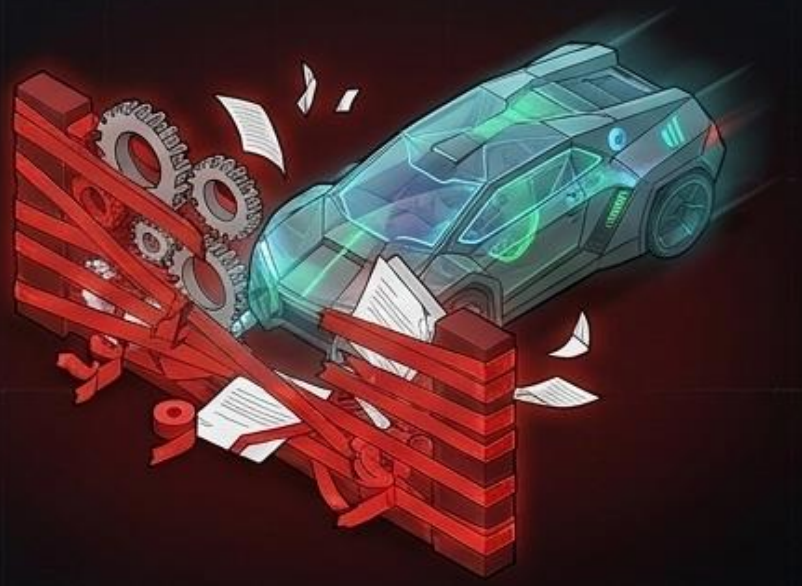
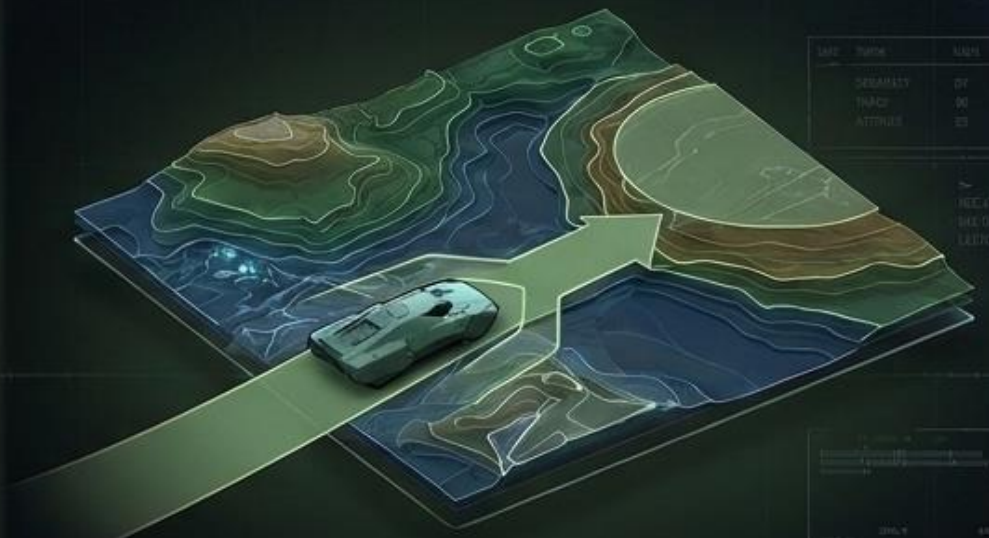
The Old Model: Obstacle



Treating regulation as a compliance wall at the end of a project produces delay, one-off waivers, and stranded capability.

The New Model: Terrain



Mapping the pathways early reveals where a product can and cannot move.

Core Doctrine: Alignment is maneuver space — not the price you pay for it.
A device built to a common regulatory grammar can move across theaters and allies.

Disciplined Initiative

Freedom to act on operational necessity.

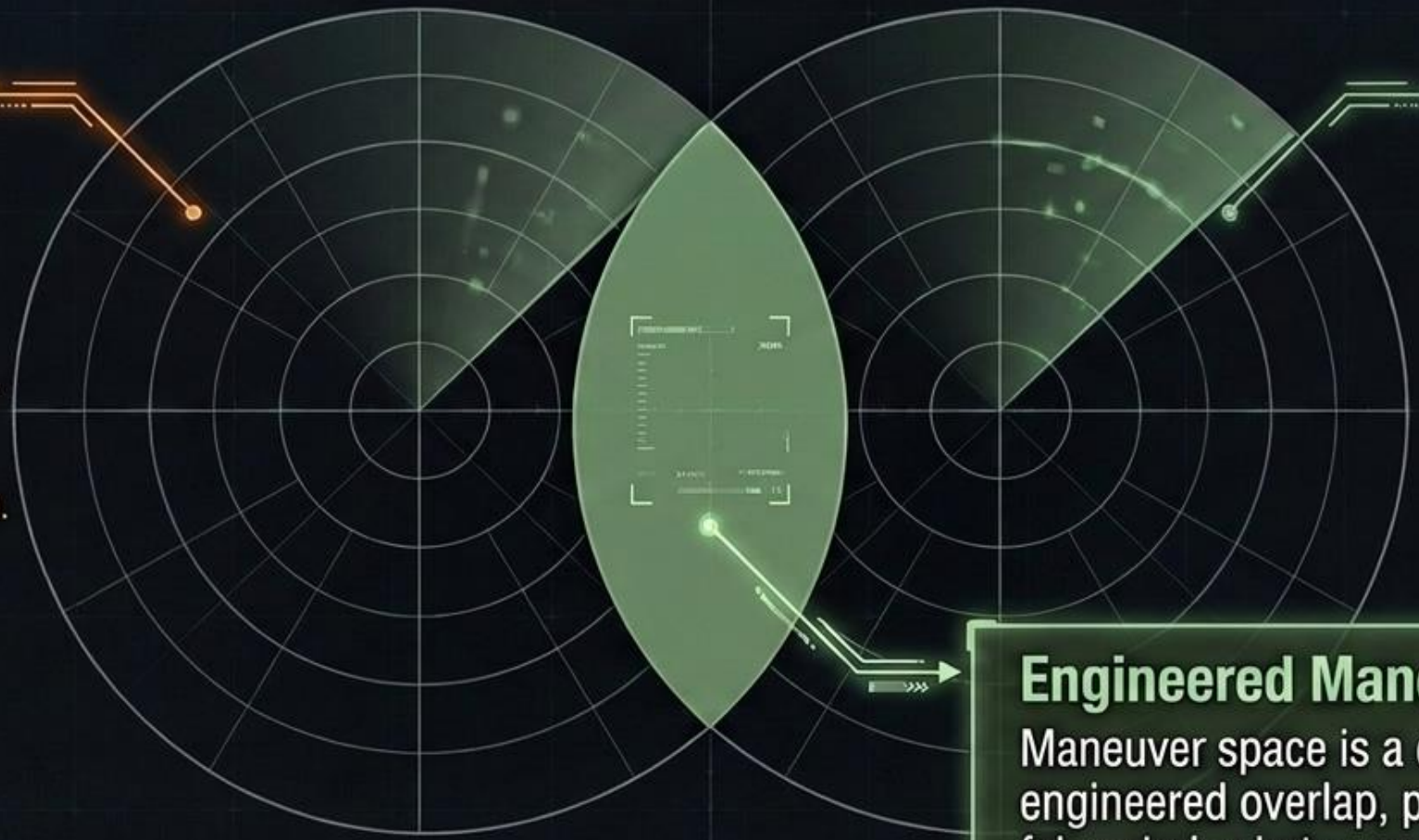
Fielding capability in contested/denied environments faster than commercial cycles.

Retaining control of design and supply chain.

Interoperability

The ability to field one qualified device across allied forces.

Shared logistics, data formats, and casualty handoffs across coalition roles of care.



Engineered Maneuver Space

Maneuver space is a deliberately engineered overlap, preventing the false choice between moving fast alone and moving slowly together.

FOUR PRESSURES FORCING OPERATIONAL ADAPTATION

Quadrant 1: Multi-Domain Coalition Ops

Medical interoperability with allies is no longer a luxury; it is a strict warfighting requirement.

Quadrant 2: Contested Logistics

Assuming long supply lines will fail upon contact forces production toward the point of need.

Quadrant 3: Edge Casualty Care

Prolonged field care with denied reachback requires pushing decision support and autonomy forward.

Quadrant 4: Globalizing Regulations

IMDRF and MDSAP are harmonizing rules globally, presenting an open window to shape them rather than inherit them.

THE REGULATORY BATTLESPACE

BLUF: A product designed to move freely across all areas possess maximum operational maneuver room

INTEROPERABILITY AS A FORCE MULTIPLIER

GEAR 1: STANDARDS

A common regulatory grammar unlocks mutual recognition.

GEAR 2: DATA

Device outputs must be vendor-agnostic and readable across allied clinical and command systems.

GEAR 3: DOCTRINE

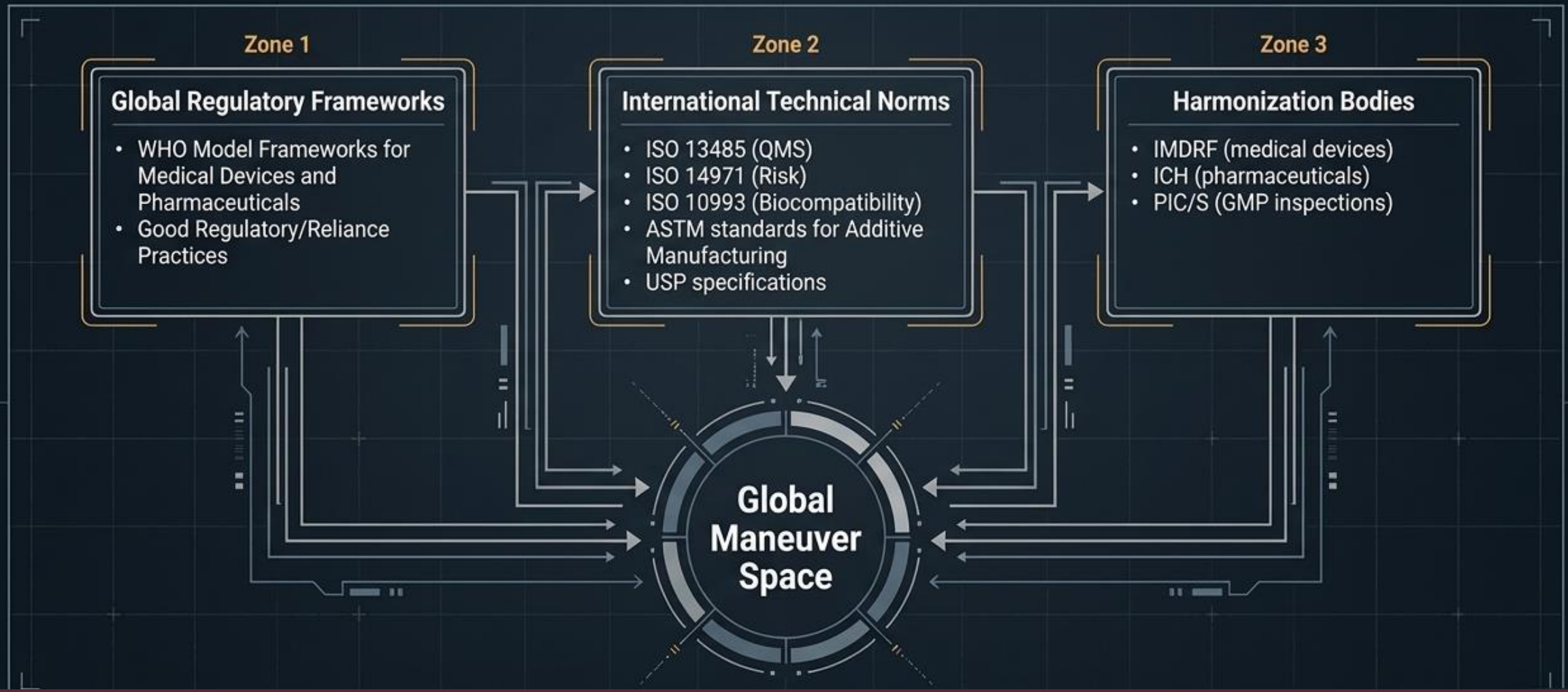
NATO AJP-4.10 and STANAGs allow casualties to move seamlessly across coalition

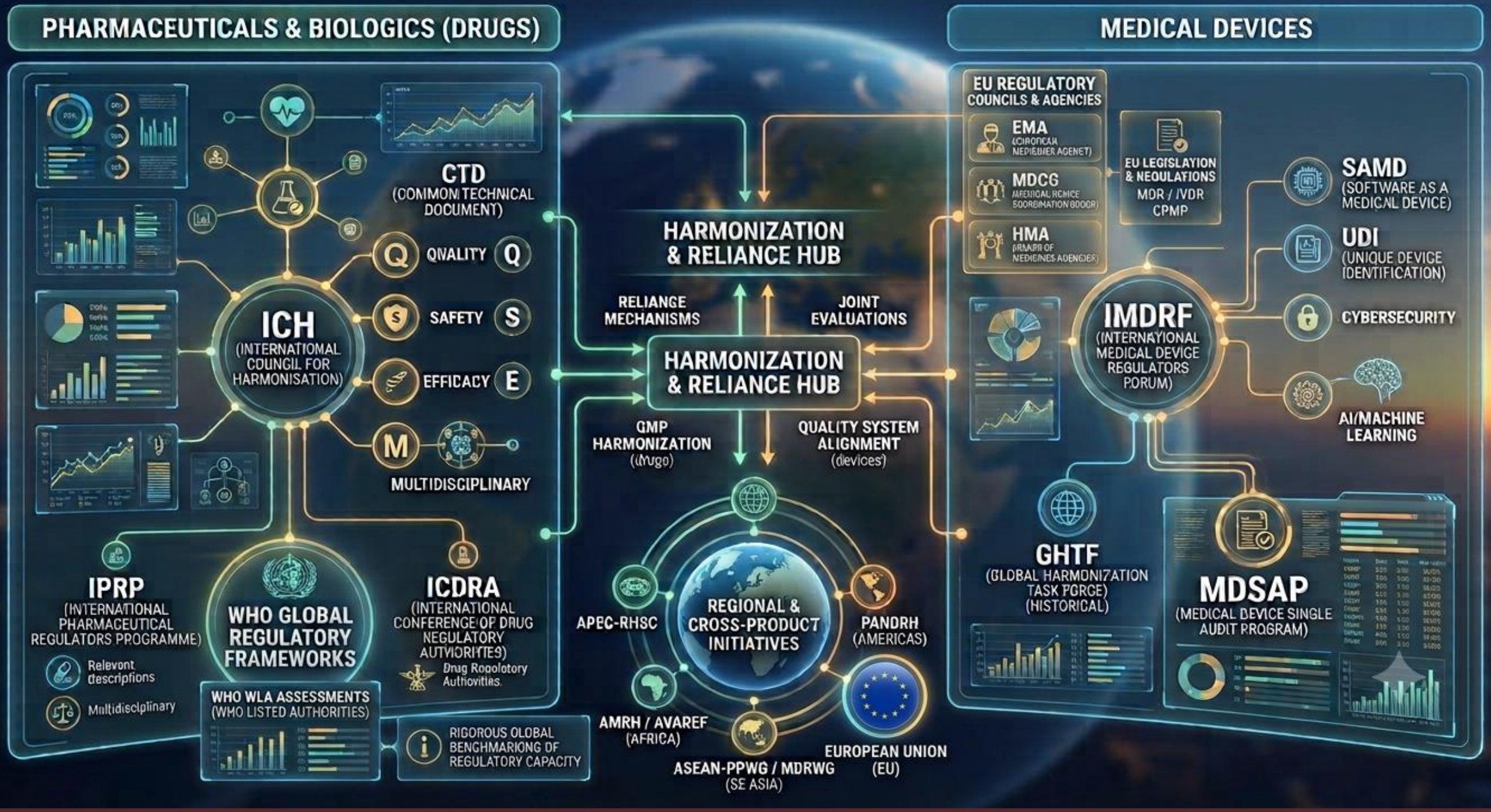
NATO Zero-Day Integration

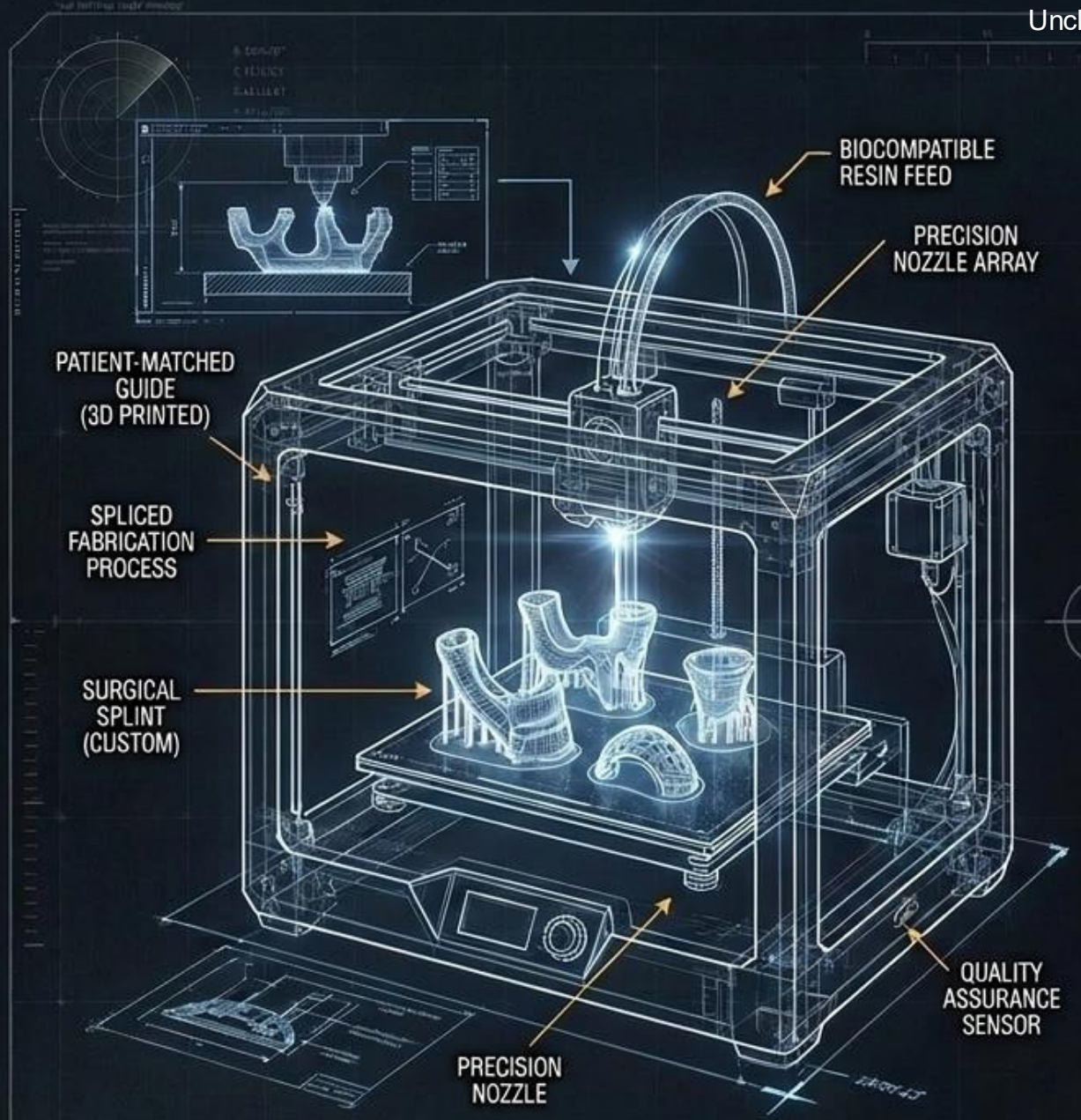
THE RESULT: ONE QUALIFIED DEVICE FIELDED ACROSS THE WHOLE COALITION, RATHER THAN *N*-BESPOKE, PER-NATION STOVEPIPES.

The Global Regulatory Grammar (Maneuver Corridors)

These standards are not restrictions; they are pre-cleared maneuver corridors that create freedom of action. Devices speaking this grammar deploy natively across borders.




PHARMACEUTICALS & BIOLOGICS (DRUGS)
MEDICAL DEVICES
CTD
(COMMON TECHNICAL DOCUMENT)
ICH
(INTERNATIONAL COUNCIL FOR HARMONISATION)
Q
QUALITY
S
SAFETY
E
EFFICACY
M
MULTIDISCIPLINARY
IPRP
(INTERNATIONAL PHARMACEUTICAL REGULATORS PROGRAMME)
Relevant descriptions
Multidisciplinary
WHO GLOBAL REGULATORY FRAMEWORKS
WHO WLA ASSESSMENTS
(WHO LISTED AUTHORITIES)
ICDRA
(INTERNATIONAL CONFERENCE OF DRUG REGULATORY AUTHORITIES)
Drug Regulatory Authorities
RIGOROUS GLOBAL BENCHMARKING OF REGULATORY CAPACITY
HARMONIZATION & RELIANCE HUB
RELIANCE MECHANISMS
JOINT EVALUATIONS
HARMONIZATION & RELIANCE HUB
GMP HARMONIZATION
(drugs)
QUALITY SYSTEM ALIGNMENT
(devices)
REGIONAL & CROSS-PRODUCT INITIATIVES
APEC-RHSC
PANDRH
(AMERICAS)
AMRH / AVAREF
(AFRICA)
ASEAN-PPWG / MDRWG
(SE ASIA)
EUROPEAN UNION
(EU)
EU REGULATORY COUNCILS & AGENCIES
EMA
MDCG
HMA
EU LEGISLATION & REGULATIONS
MDR / IVDR
CPMP
IMDRF
(INTERNATIONAL MEDICAL DEVICE REGULATORS FORUM)
SAMD
(SOFTWARE AS A MEDICAL DEVICE)
UDI
(UNIQUE DEVICE IDENTIFICATION)
CYBERSECURITY
AI/MACHINE LEARNING
GHTF
(GLOBAL HARMONIZATION TASK FORCE)
(HISTORICAL)
MDSAP
(MEDICAL DEVICE SINGLE AUDIT PROGRAM)



DOMAIN:
ADDITIVE MANUFACTURING (MEDTECH) AT THE POINT OF NEED

THE TERRAIN:

POINT-OF-CARE MANUFACTURING BLURS THE LINE BETWEEN MANUFACTURER AND USER. WHEN THE ROLE 2 OR 3 FIELD HOSPITAL IS THE FACTORY, THE QUESTION OF WHO HOLDS THE QUALITY SYSTEM CREATES REGULATORY FRICTION.

THE MANEUVER:

MAKE THE VALIDATED DESIGN FILE THE CONTROLLED ARTICLE. PRE-NEGOTIATE A POINT-OF-CARE QUALITY FRAMEWORK SO ANY QUALIFIED DOW NODE CAN PRINT TO SPEC, IN ANY THEATER.

ADDITIVE MANUFACTURING ACROSS THE DOW

ARMY

3rd Infantry Division soldiers test latest battlefield tech in Mojave Desert

By COREY DICKSTEIN
STARS AND STRIPES • June 25, 2026

Army Brings 3D Printing into Project Flytrap Exercise

5/18/2026
By Allyson Park

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U.S. Navy Flight-Tests 3D-Printed Composite Repairs for F/A-18 Super Hornets

July 7, 2026

Printing Light: Custom Radiation Detectors Through Additive Manufacturing

Published June 26, 2026
By Juan J. Manfredi Jr.
Air Force Institute of Technology

Asia Pacific

US Army tests fresh drones, 3D printers at 'Balikatan' drill in the Philippines

By Gordon Arthur
Friday, May 1, 2026

Navy, Marine Corps Experimenting With Large Scale Advanced Manufacturing Network During RIMPAC

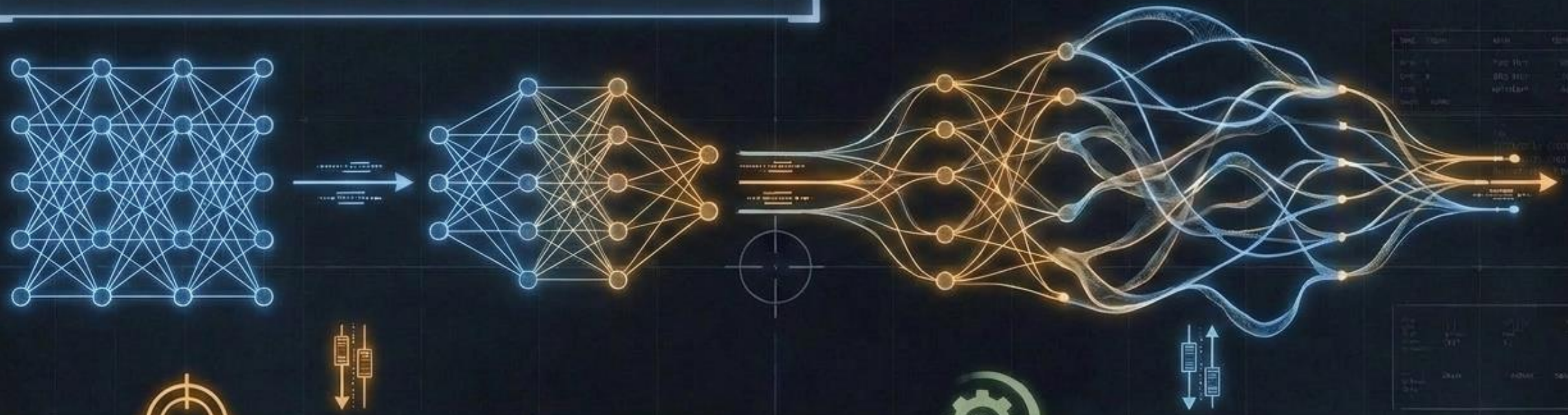
A U.S. soldier dons first-person view goggles before operating a drone during Project Flytrap at Pabradė Training Area, Lithuania.

DOMAIN: **ADVANCED MANUFACTURING & DISTRIBUTED SUPPLY CHAINS**

THE TERRAIN:
Resilience requires ensuring no single plant is a single point of failure. This shifts the regulatory challenge from qualifying a static product to qualifying a distributed process.

THE MANEUVER:
Design the process to MDSAP (Medical Device Single Audit Program) and utilize the FDA's Advanced Manufacturing Technologies Designation. Qualify once; produce across the coalition (U.S., Canada, Australia, Japan, Brazil).

DOMAIN: **AI/ML MEDICAL DEVICES** (TRIAGE, DIAGNOSTICS, AUTONOMY).



THE TERRAIN:

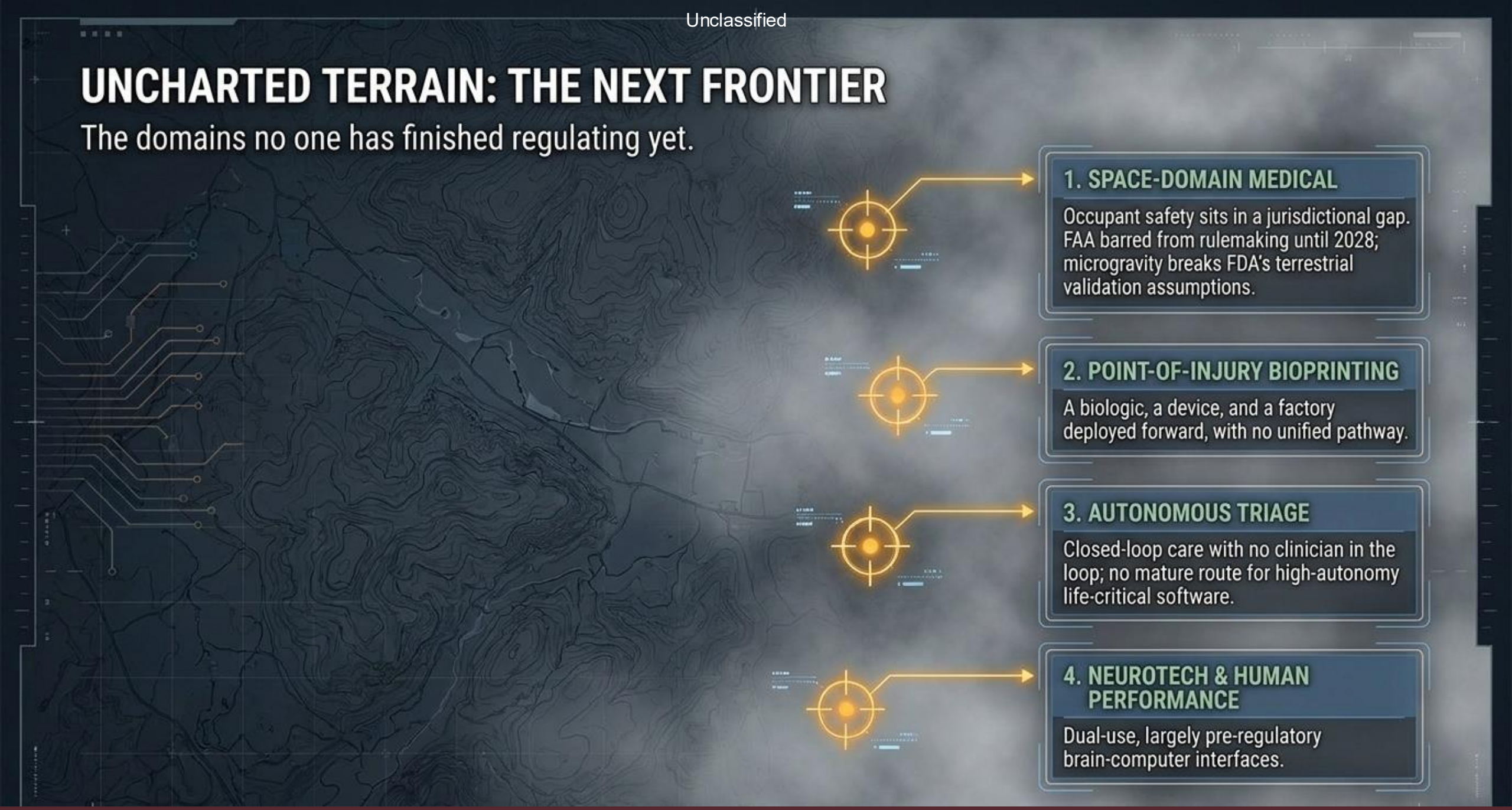
Locked models go stale, adaptive models drift. The battlefield introduces a severe distribution shift from original training data.

THE MANEUVER:

Utilize FDA Predetermined Change Control Plans (PCCP). Treat the PCCP as a pre-authorized adaptation envelope, allowing updates at operational speed within agreed bounds without re-clearing from zero.

UNCHARTED TERRAIN: THE NEXT FRONTIER

The domains no one has finished regulating yet.



1. SPACE-DOMAIN MEDICAL

Occupant safety sits in a jurisdictional gap. FAA barred from rulemaking until 2028; microgravity breaks FDA's terrestrial validation assumptions.

2. POINT-OF-INJURY BIOPRINTING

A biologic, a device, and a factory deployed forward, with no unified pathway.

3. AUTONOMOUS TRIAGE

Closed-loop care with no clinician in the loop; no mature route for high-autonomy life-critical software.

4. NEUROTECH & HUMAN PERFORMANCE

Dual-use, largely pre-regulatory brain-computer interfaces.

The UK MHRA pioneers guidance for orbitally-produced medicines

The 2026 Guidance

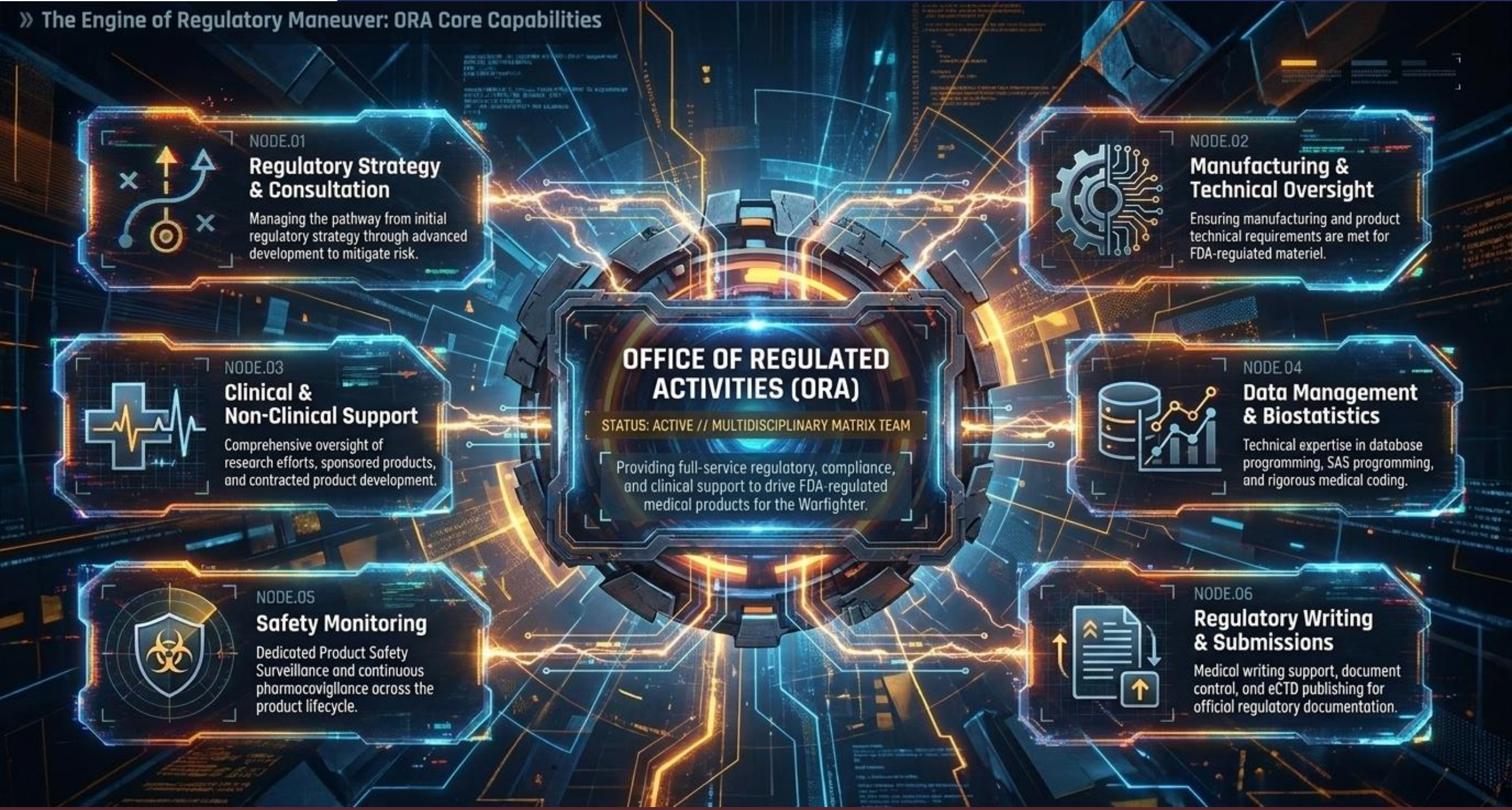
The Re-entry Regulatory Sandbox

Target Modalities

Regulatory burden shifts based on the product's origin and destination.

Earth-to-Orbit (COTS / Use in Space)	Orbit-to-Earth (Space Manufacturing)
Primary Law: Standard FDA/EMA/MHRA frameworks.	**Primary Law:** MHRA 2026 Space Manufacturing Guidance / Re-entry Sandbox.
Space Addition: Payload qualification, environmental tolerance (vibration/radiation).	**Space Addition:** Microgravity GMP, re-entry integrity, terrestrial handling upon landing.
Primary Risk: Human-system integration and payload safety.	**Primary Risk:** Post-re-entry product stability and biological efficacy.

» The Engine of Regulatory Maneuver: ORA Core Capabilities



STRATEGIC DIRECTIVES FOR ACQUISITION LEADERS

- ✓ Embed global regulatory strategy inside acquisition as a design input into first review after Material Development Decision (MDD).
- ✓ Write harmonization and interoperability into requirements documents alongside performance metrics.
- ✓ Enhanced partnerships within regulatory and standards bodies.
- ✓ Pre-negotiate edge and frontier frameworks before operational necessity hits, utilizing the standing FDA channel.

Maneuver space is designed in — not requested later.

You cannot waiver your way to freedom of action at the end of a program; you engineer it from the start. Read the terrain, design to the standard, and help shape the standard.

Backups for consideration…

The global regulatory supply chain balances precarious risks.

Compliance Risk

Compliance risk arises from the increasing burden of global regulations. Striving for compliance can inadvertently reduce product availability and manage supply chain behaviors.

Access Risk

Access risk concerns the ability of the supply chain to ensure actual product availability. Disruptions and regulatory hurdles can prevent essential medicines from reaching patients.

Stricter rules intended to improve quality—if not paired with regulatory cooperation and realistic transition pathways—paradoxically reduce product availability, especially for low-margin essential medicines.

THREE MANEUVER MOVES TO ENGINEER ADVANTAGE

HARMONIZE UPSTREAM

Design to IMDRF and MDSAP from day one. Achieve portability by construction, treating international standards as baseline design constraints.

STRATEGIC FREEDOM OF ACTION

SHAPE STANDARDS

Do not just consume rules; help write them. Maintain an active authoring presence in IMDRF and consensus standard bodies.

ENGINEER EDGE PATHWAYS

Pre-negotiate point-of-care frameworks and priority reviews through the FDA channel before operational necessity strikes.

ONE HORIZON FURTHER: THE UNREGULATED FRONTIER

SPACE-DOMAIN MEDICAL PRODUCTS

Jurisdictional gap. FAA is statutorily barred from occupant-safety rules until Jan 1, 2028. Microgravity/radiation break terrestrial FDA validation assumptions.

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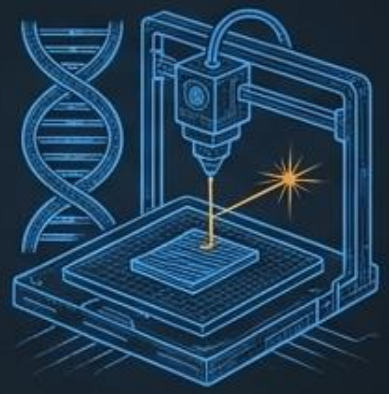


POINT-OF-INJURY BIOPRINTING

Printing skin/tissue at the casualty. It is a biologic, a combination product, AND point-of-care manufacturing simultaneously, with no unified regulatory pathway.

⚠ [STATUS: UNKNOWN]

AUTONOMOUS TRIAGE

Current pathways assume a clinician-in-the-loop. High-autonomy, closed-loop resuscitation life-critical software lacks a mature route.

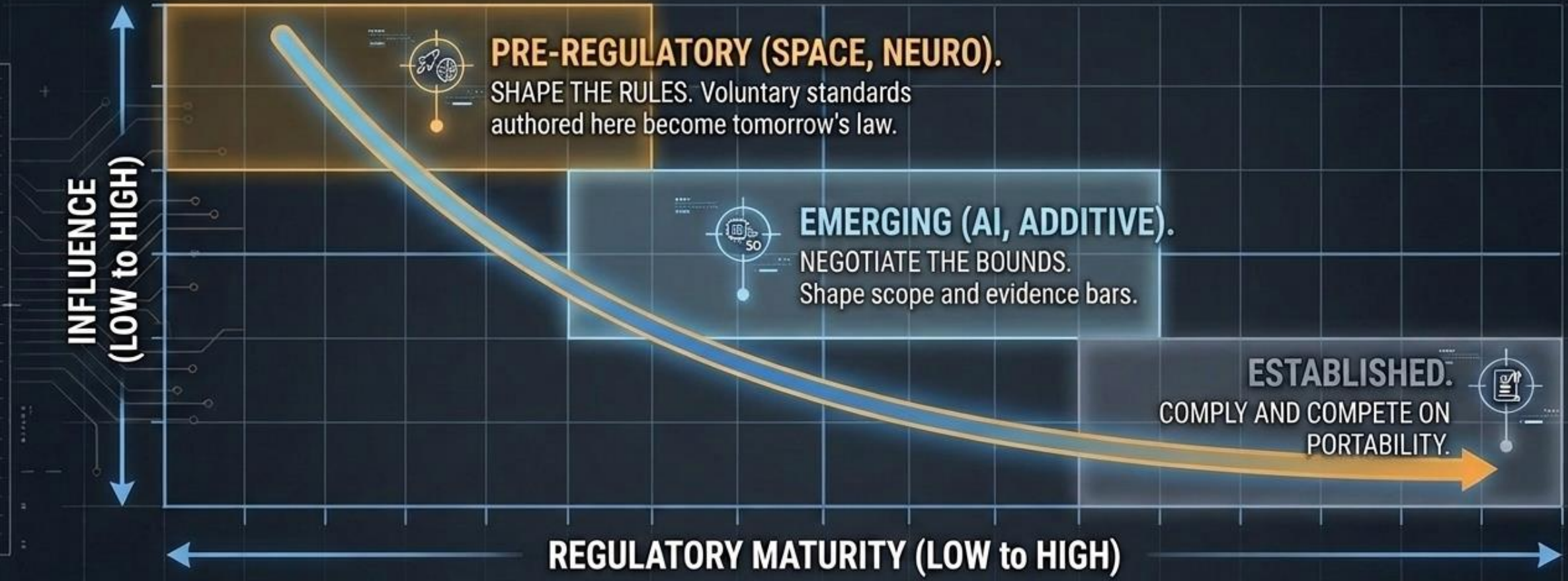
⚠ [STATUS: UNKNOWN]

HUMAN PERFORMANCE & NEUROTECH

Wearable neurostim and brain-computer interfaces are dual-use, largely pre-regulatory, and not definitively classified as medical devices.

⚠ [STATUS: UNKNOWN]

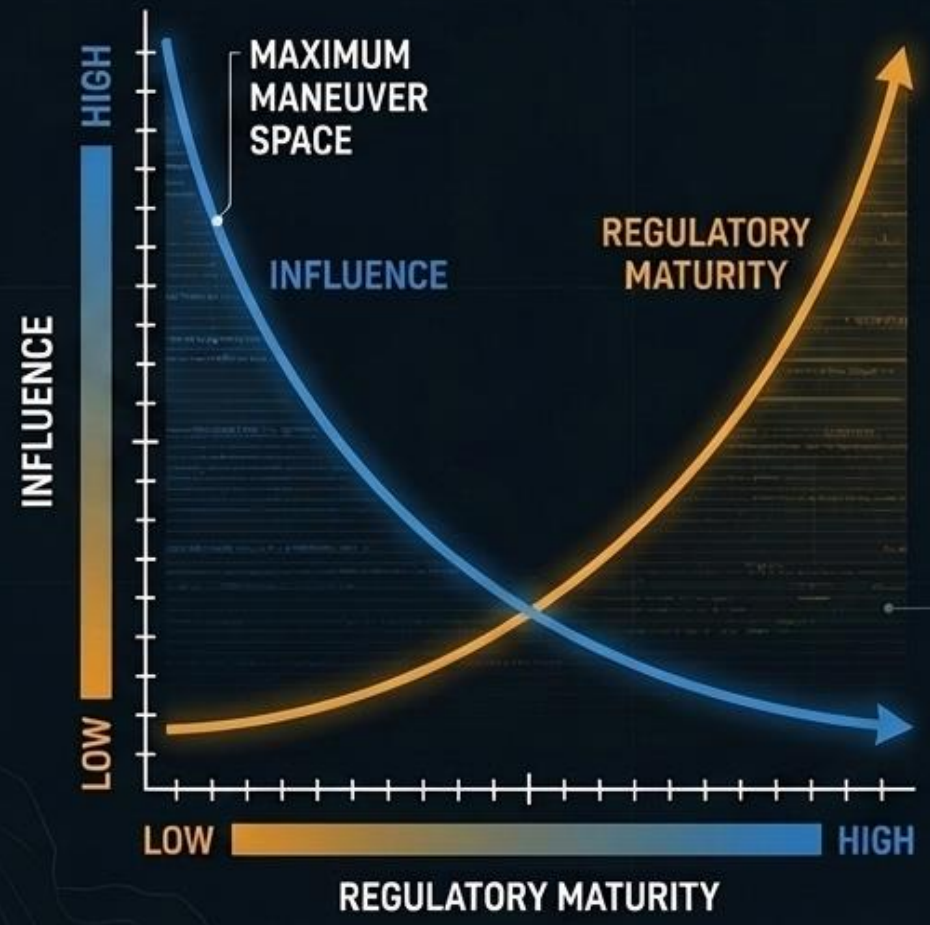
REGULATORY MATURITY & DoW INFLUENCE MATRIX



STRATEGIC THESIS: THE MANEUVER-SPACE THESIS IS STRONGEST WHERE THE MAP IS BLANK. MOVE FIRST, DO NOT WAIT.

THE STRATEGIC CALCULUS: INFLUENCE IS INVERSE TO MATURITY

KEY INSIGHT: The highest strategic value—the maximum maneuver space—lies in shaping the domains where frameworks do not yet exist.



DOMAIN TIER	MATURITY	INFLUENCE	STRATEGIC ACTION
Pre-Regulatory (Space, Neurotech)	⚠ LOW	HIGH	Shape and Author Voluntary Standards
Emerging (AI/ML, Point-of-Care)	MODERATE	MODERATE	Define scope, extend PCCP, build autonomy tiers
Established (Conventional Devices)	HIGH	⚠ LOW	Comply and compete on portability

THE CENTRAL TENSION REQUIRES ENGINEERED ALIGNMENT

SOVEREIGNTY

Freedom to act on operational necessity.

Fielding capability in contested/denied environments.

Retaining control of design, data, and supply chain.

INTEROPERABILITY

Fielding one qualified device across allied forces.

Shared logistics and data.

Seamless casualty handoffs across coalition roles of care.

MANEUVER SPACE

The strategic overlap. Alignment to global standards is not a tax on operational freedom; it is the mechanism that creates it.

REGULATORY MANEUVER SUMMARY: DOMAIN-SPECIFIC ACTIONS

DOMAIN	CORE CHALLENGE	REGULATORY LEVER	MANEUVER MOVE
Additive	Point-of-care quality	Design file control	Pre-negotiate node qualification.
Advanced	Distributed resilience	FDA Advanced Tech/ / MDSAP	Qualify the process, produce anywhere.
AI/ML	Model drift in the field	FDA PCCP	Pre-authorize the adaptation envelope.
Frontier	Jurisdictional gaps	IMDRF / Standards Bodies	Author the global grammar early.

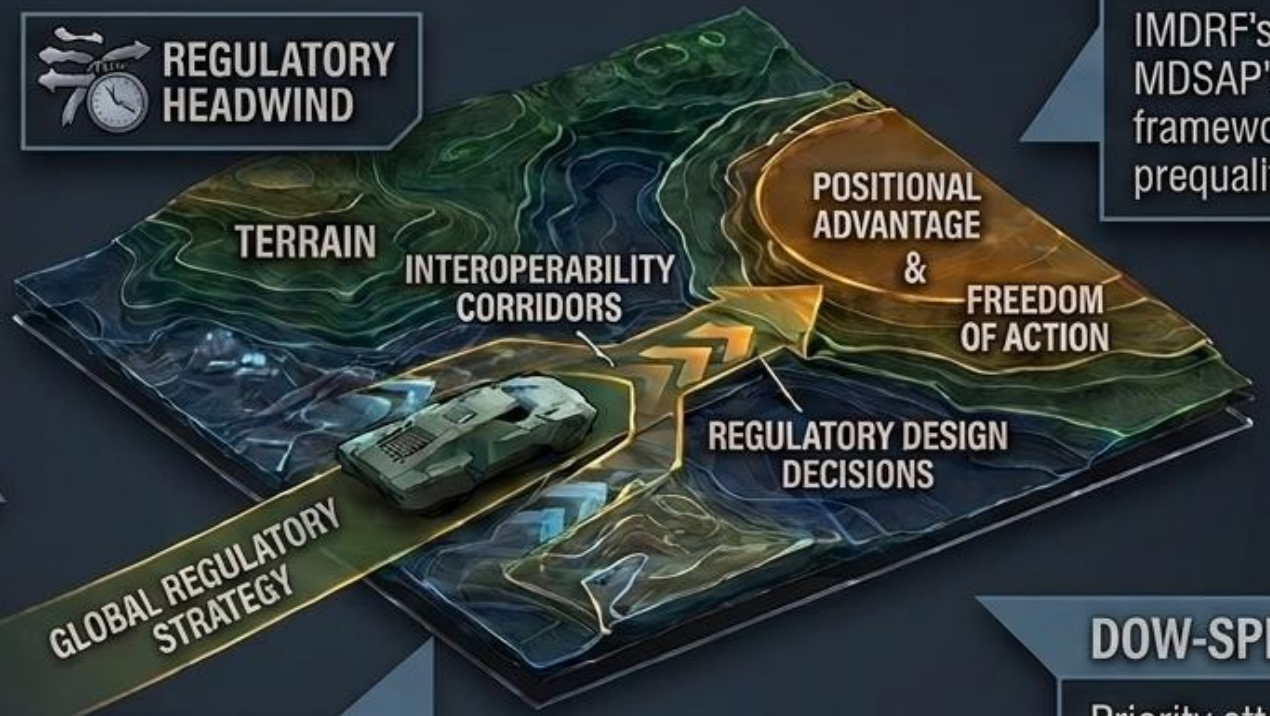
THE REGULATORY BATTLESPACE MAP

U.S. PATHWAYS

DEVICES: 510(k), De Novo, PMA, HDE, Breakthrough.

DRUGS/BIOLOGICS: IND, NDA, ANDA, BLA, Biosimilars, Expedited Programs.

EMERGENCY: EUA, Operational Necessity Authorities.



REGULATORY MANEUVER MAP

GLOBAL HARMONIZATION

IMDRF's common grammar, MDSAP's one-audit-five-markets framework, EU MDR, WHO prequalification.

DOW-SPECIFIC LEVERS

Priority attention pathways and interagency MOUs.

BLUF: A product designed to move freely across all three columns possesses maximum operational maneuver room.

AI/ML DEVICES: SUSTAINING CAPABILITY THROUGH CONTINUOUS CHANGE

CONTEXT

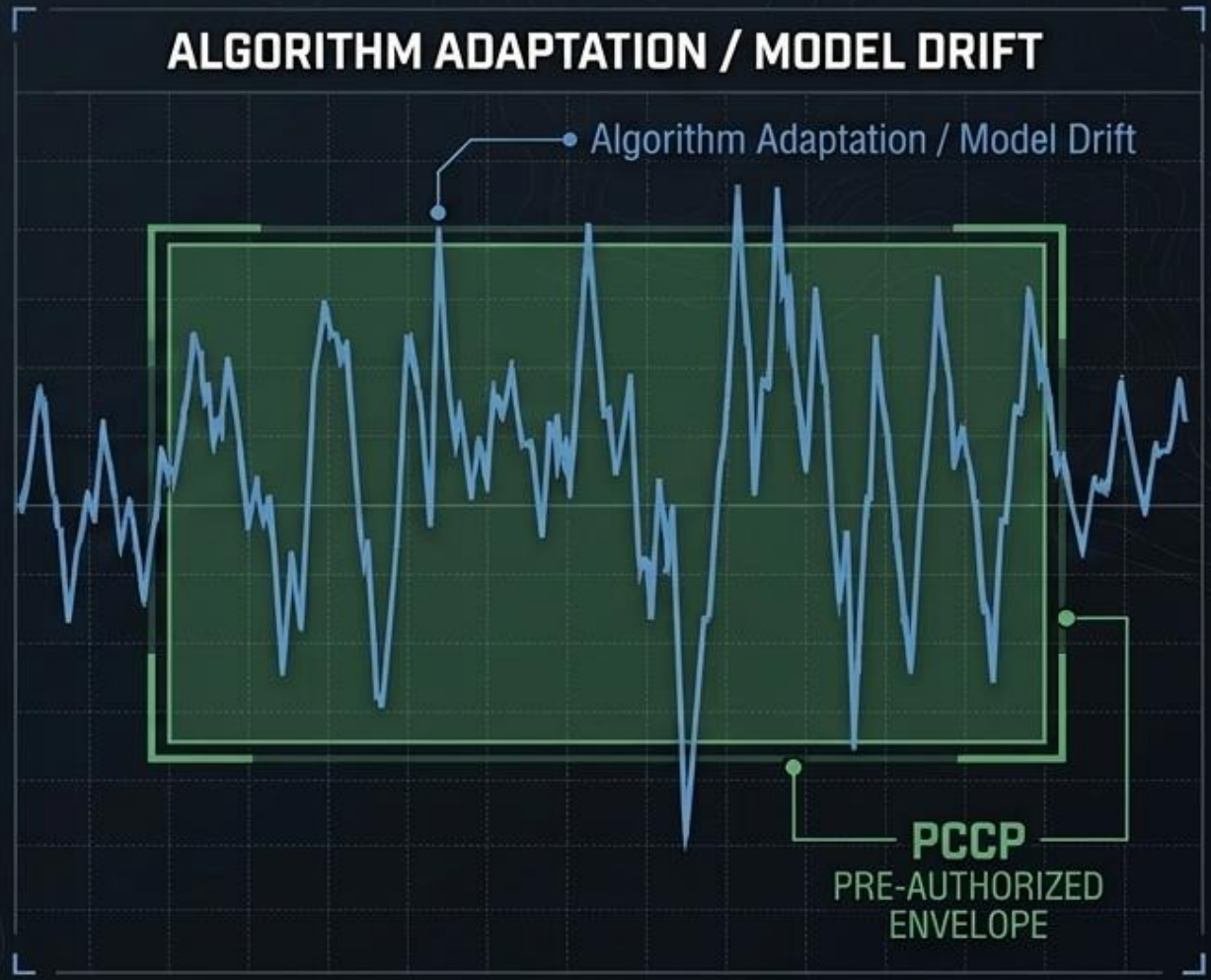
Locked models go stale. Adaptive models drift. The battlefield represents a massive distribution shift from training data. Prolonged field care with denied reachback requires continuous edge autonomy.

THE ENABLER

FDA's Predetermined Change Control Plan (PCCP) paired with Good Machine Learning Practice.

THE MANEUVER MOVE

Treat the PCCP as a pre-authorized adaptation envelope. Specify upfront how a model may change, then update within those agreed bounds at operational speed—without re-clearing from zero.



OPERATIONALIZING STRATEGIC RESILIENCE

	CONTESTED LOGISTICS 40%	THE MANEUVER ENABLER 40%
SOURCING STRATEGY	Concentrated API nodes & single points of failure.	Diversified nodes & parallel redundant supply.
REGULATORY POSTURE	Fragmented national dossiers & duplicative inspections.	Regulatory convergence & reliance arrangements.
TRACEABILITY	Siloed data & physical paper trails.	End-to-end digital serialization (DSCSA alignment).
QUALITY ENGINE	Reactive, localized compliance.	Embedded WHO Model Frameworks, ISO 13485 (QMS), and ICH/PIC/S guidelines.

Resilient global supply is no longer an administrative checklist—it is the prerequisite for operational maneuverability.