Accelerating Combat Casualty Care

Regulatory Strategies for Additive Manufacturing and Digital Health Technologies in Military Medicine

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RESEARCH & DEVELOPMENT ®

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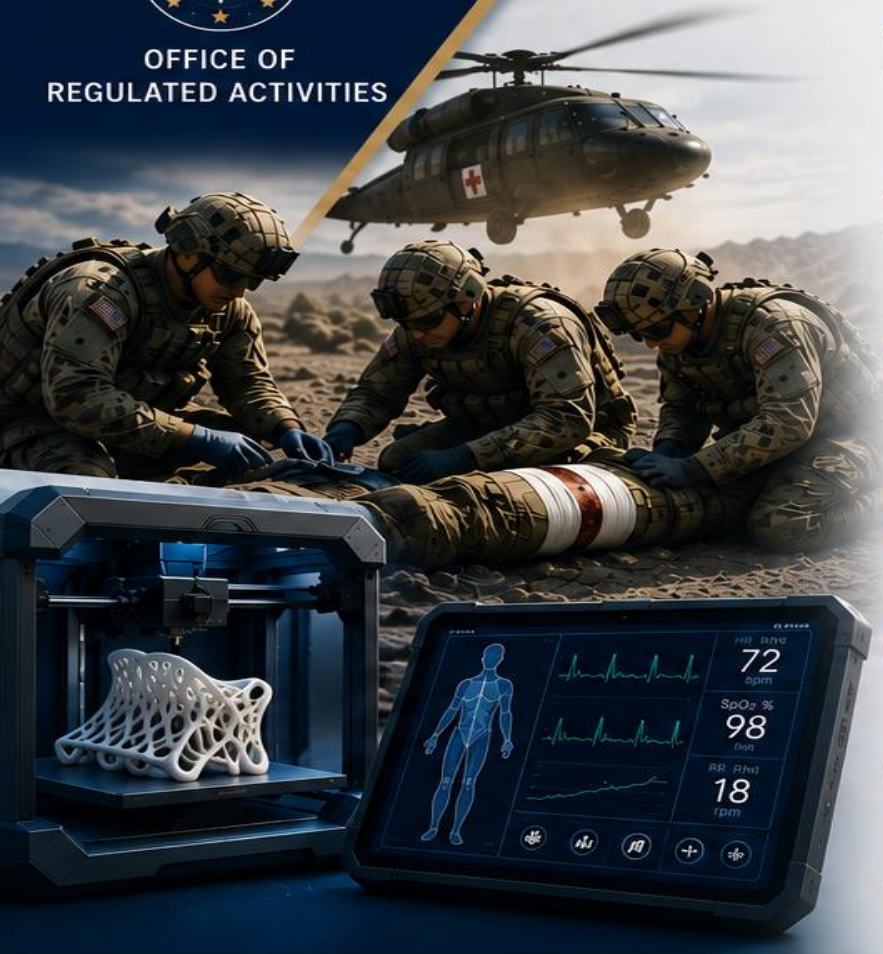


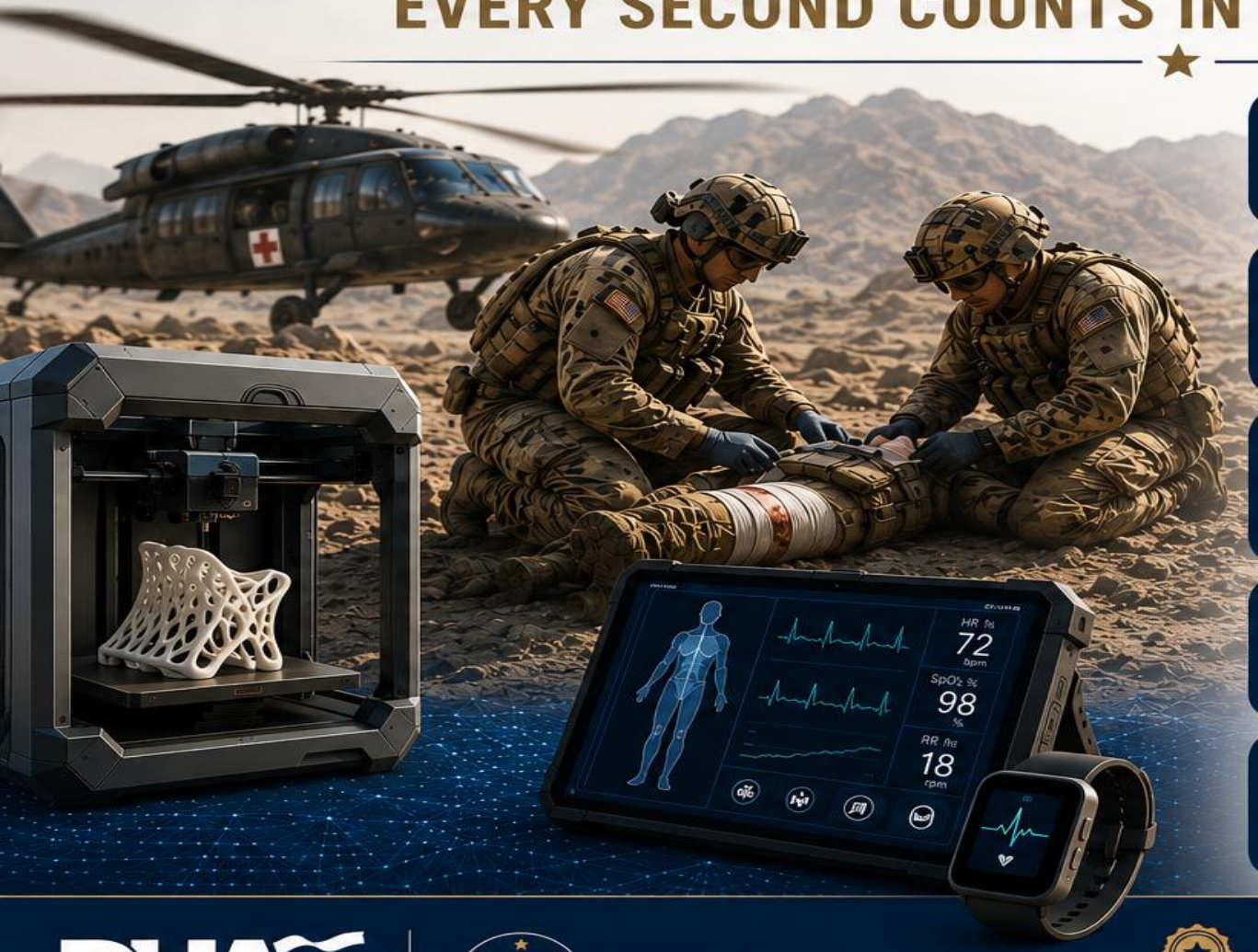
AGENDA

1. Introduction: The Imperative for Rapid MedTech Innovation in Combat Casualty Care
2. FDA Regulatory Pathways for AM and Digital Health Devices
3. Case Studies: Army-Sponsored FDA Submissions
4. DoW/FDA Collaboration and Innovation Frameworks
5. Challenges and Opportunities
6. Future Directions and Recommendations
7. Q&A

ENABLING TRUST. ENSURING READINESS.

INTRODUCTION: THE IMPERATIVE

EVERY SECOND COUNTS IN COMBAT CASUALTY CARE



- Battlefield injuries demand innovative, rapidly deployable medical solutions.
- Additive manufacturing and digital health are transforming combat casualty care.
- DHA and the Office of Regulated Activities are at the forefront of military med tech regulation.
- Regulatory science is the critical enabler, not a barrier.
- Practical lessons from real FDA submissions.

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QUALITY | ACCOUNTABILITY | COMMITMENT TO THE SERVICE MEMBER | INTEGRITY | RESPECT | COMMUNICATION

ENABLING TRUST. ENSURING READINESS.

ADDITIVE MANUFACTURING

- Point-of-care production of surgical tools, implants, prosthetics
- Rapid prototyping for military-unique anatomical needs
- Forward-deployed manufacturing capabilities
- Reduced supply chain dependency

POINT-OF-CARE PRODUCTION

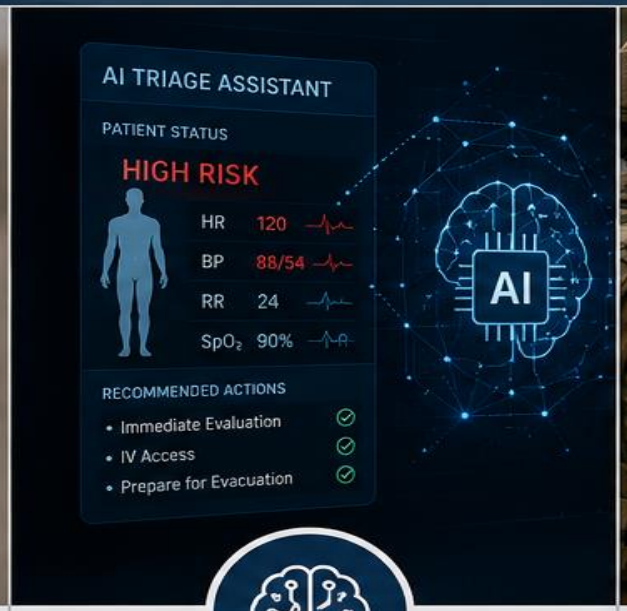
MILITARY-UNIQUE ANATOMICAL NEEDS

FORWARD-DEPLOYED CAPABILITIES

REDUCED SUPPLY CHAIN DEPENDENCY

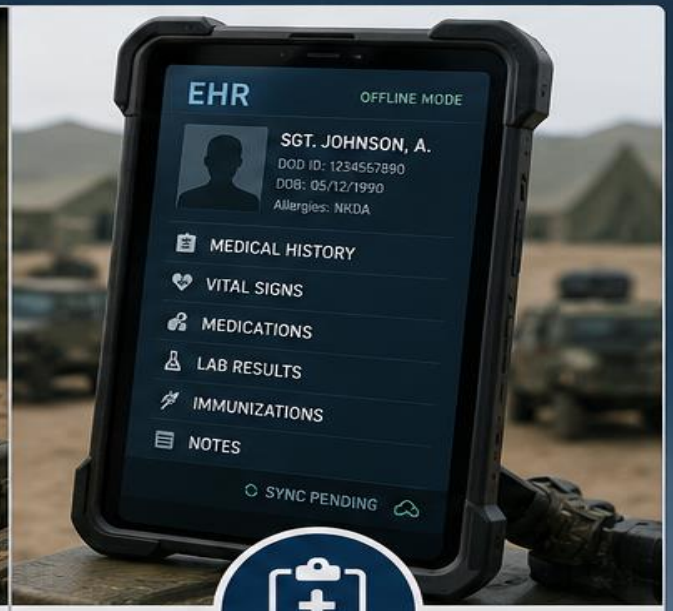
DIGITAL HEALTH

WEARABLE SENSORS
FOR REAL-TIME
PHYSIOLOGICAL MONITORING



AI-POWERED TRIAGE
AND CLINICAL
DECISION SUPPORT

TELEMEDICINE
FOR PROLONGED
FIELD CARE (PFC)



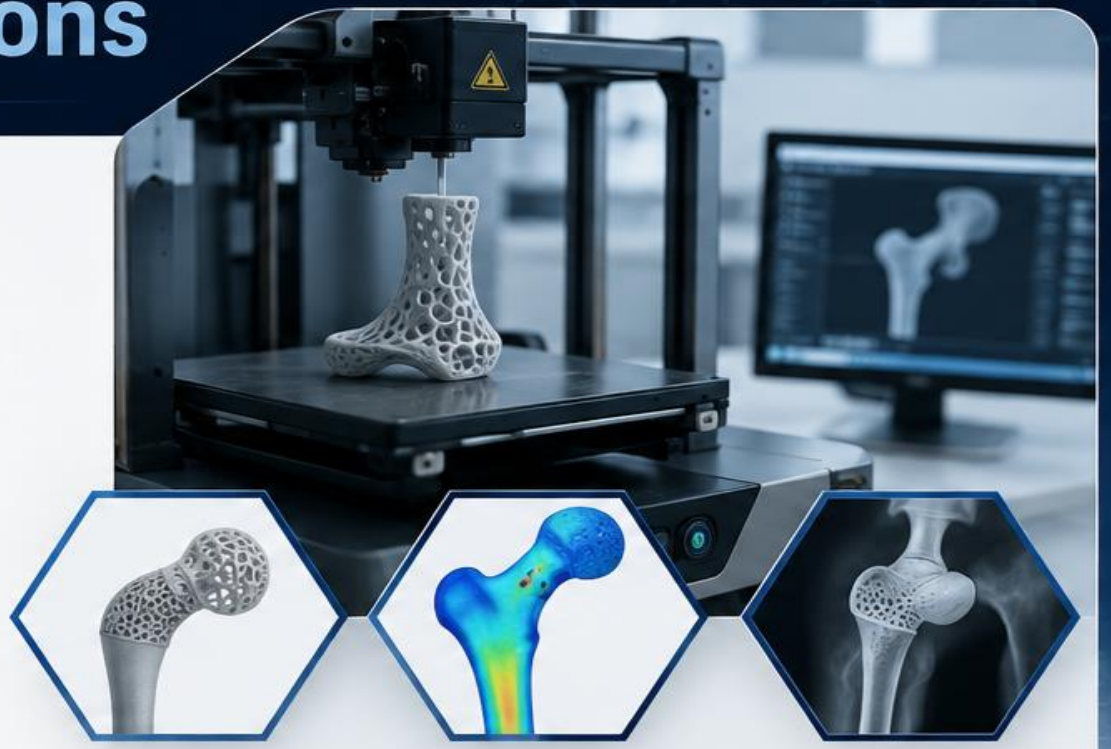
ELECTRONIC HEALTH RECORDS
IN AUSTERE ENVIRONMENTS

FDA REGULATORY PATHWAYS
FOR MILITARY MED TECH

PATHWAY	BEST FOR	TIMELINE	KEY REQUIREMENT
510(K) CLEARANCE	AM devices with predicate	3-6 months	Substantial equivalence
DE NOVO	Novel military-unique devices	9-12 months	Low-moderate risk, no predicate
PRE MARKET AUTHORIZATION (PMA)	High-risk AM implants	12-24+ months	Valid scientific evidence
SOFTWARE AS A MEDICAL DEVICE (SAMD)/ FDA'S DIGITAL HEALTH CENTER OF EXCELLENCE	Digital health, AI/ML tools	Varies	Software lifecycle, cybersecurity
EMERGENCY USE AUTHORIZATION (EUA)	Emergency/ crisis use	Days-weeks	Public health emergency declared
EXPANDED ACCESS / INVESTIGATIONAL DEVICE EXEMPTION (IDE)	Unmet need, no cleared device	Varies	Serious condition, no alternative

Additive Manufacturing Devices:
Key Regulatory Considerations

- FDA's Technical Considerations for AM Devices guidance (2017, updated 2024)
- Design and manufacturing process validation is critical – each build is a new manufacturing event
- Material characterization: mechanical properties, biocompatibility (ISO 10993)
- Post-processing validation: sterilization, surface finish, dimensional accuracy
- Point-of-care (POC) manufacturing adds complexity: who is the manufacturer?
- Software validation for CAD/design files used in AM production
- Quality Management System (QMS): 21 CFR Part 820 / ISO 13485 compliance
- Labeling requirements: must reflect AM origin and any patient-specific customization



AM DEVICES: UNIQUE REGULATORY CHALLENGES

- EACH BUILD IS UNIQUE
- PROCESS VALIDATION IS ESSENTIAL
- MANUFACTURER IDENTIFICATION (ESPECIALLY AT POC)
- SOFTWARE AND FILE CONTROL
- STRONG QMS AND TRACEABILITY REQUIRED

Digital Health: Key Regulatory Considerations

- **FDA Digital Health Center of Excellence (DHCoE):** primary point of engagement
- **Software as a Medical Device (SaMD):** IMDRF framework applies
- **AI/ML-based SaMD:** Predetermined Change Control Plan (PCCP) is essential
- **Cybersecurity:** FDA's 2023 cybersecurity guidance is mandatory for all connected devices
- **Clinical decision support (CDS):** does it meet the CDS exemption criteria?
- **Interoperability:** HL7 FHIR compliance increasingly expected
- **Real-World Performance Monitoring:** required post-market for AI/ML devices
- **2026 Update:** mandatory electronic submissions and enhanced data standardization

SAFETY & EFFECTIVENESS
Protect patients through reliable, secure systems

DATA QUALITY & INTEGRITY
Ensure accurate, complete, and standardized data

TRANSPARENCY & TRUST
Clear labeling, explainability, and user communication

CONTINUOUS MONITORING
Detect issues early and drive ongoing improvement

OUR GOAL: Safe, effective, secure, and trustworthy digital health technologies that improve outcomes for our warfighters and patients.

CASE STUDY 1: APPRAISE-HRI

AI-Enabled Software as a Medical Device for Assessing Hemorrhage Risk Index After Trauma

BHSAI
BIOTECHNOLOGY HIGH-PERFORMANCE COMPUTING SOFTWARE APPLICATIONS INSTITUTE

TATRC
U.S. ARMY TELEMEDICINE & ADVANCED TECHNOLOGY RESEARCH CENTER

WHAT IT IS

APPRAISE-HRI is an AI-enabled software as a medical device that analyzes routinely collected physiologic data within the first hours after trauma to generate a Hemorrhage Risk Index (HRI) to support early triage and clinical decision-making.

FDA CLEARANCE

- 510(k) Clearance (K233249)
- First FDA-authorized AI/ML–based SaMD for hemorrhage risk assessment after trauma

CLINICAL IMPACT

Provides rapid, objective risk stratification to identify patients at elevated risk of hemorrhage, enabling earlier intervention, improved prioritization of care, and better allocation of resources in deployed and austere environments.

RELEVANCE TO THE WARFIGHTER

Supports faster, data-driven decisions in the critical early window after injury—improving survivability and preserving fighting strength.

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Developed to meet an unmet operational need for forward-deployed care and to enhance combat casualty care (CCC).

KEY TAKEAWAY

APPRAISE-HRI represents a milestone in the use of AI and real-world data to deliver actionable clinical insight at the point of care—advancing the future of military trauma care.

510(k) Number: K233249 | **Classification:** Software as a Medical Device (SaMD)

CASE STUDY 2:
3-D MAC® TITANIUM CRANIAL PLATE (TCP) SYSTEM

FIRST FDA-CLEARED POINT-OF-CARE PATIENT-SPECIFIC IMPLANT SYSTEM

WHAT IT IS

- Patient-specific titanium cranial implant designed from CT imaging
- Manufactured using additive manufacturing (3D printing) within Walter Reed's 3-D Medical Applications Center
- Used to reconstruct complex cranial defects from trauma, cancer, or disease
- Incorporates pre-planned fixation features for improved surgical efficiency

FDA REGULATORY MILESTONE

- Traditional 510(k) Clearance (K253116)
- Applicant/Sponsor: The Surgeon General, Department of the Army
- Sponsored through the Defense Health Agency Office of Regulated Activities (ORA)
- First FDA-cleared point-of-care facility authorized to manufacture and distribute patient-specific cranial implants

CLINICAL IMPACT

- Personalized implant provides precise anatomical fit
- Shortens operative time through pre-planned implant fixation
- Improves cosmetic and functional outcomes
- Supports rapid reconstruction of traumatic cranial injuries

RELEVANCE TO THE WARFIGHTER

- Demonstrates FDA acceptance of hospital-based additive manufacturing
- Establishes a scalable regulatory framework for future point-of-care manufacturing across military treatment facilities
- Enables faster delivery of personalized implants for wounded Service Members while strengthening military medical readiness

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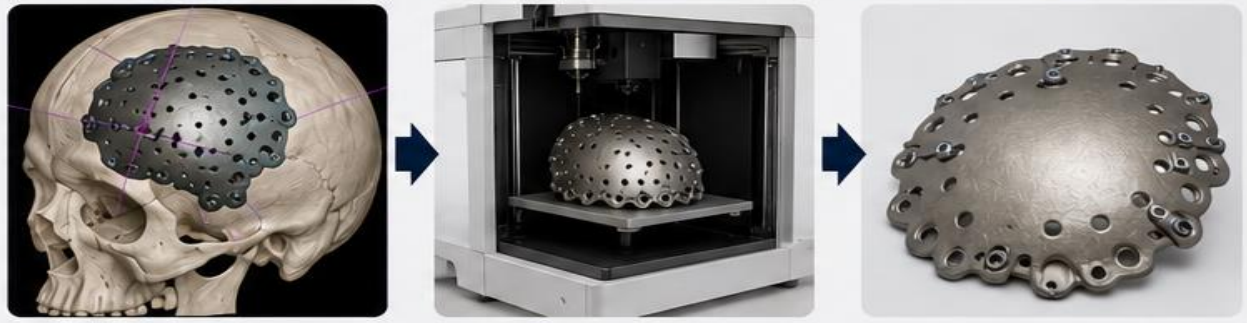
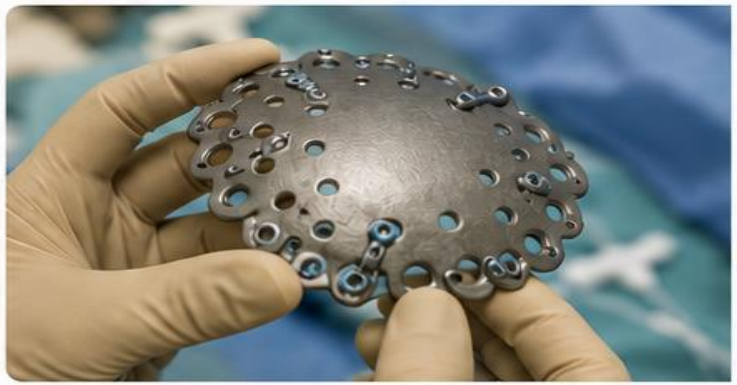
FDA Regulatory Sponsor: Defense Health Agency Office of Regulated Activities (ORA)

CT SCAN & DIGITAL PLANNING → **ADDITIVE MANUFACTURING** → **PATIENT-SPECIFIC IMPLANT**





KEY TAKEAWAY

The 3-D MAC® TCP System established the first FDA-cleared point-of-care additive manufacturing platform in the United States—creating a regulatory blueprint for future military medical manufacturing capabilities.

DoW/FDA COLLABORATION:
BUILDING THE BRIDGE

Formal MOU between DoW and FDA
establishes framework for collaboration on medical countermeasures and devices

Medical Device Development Tool (MDDT) Program:
Qualifies tools, methods, and endpoints for device evaluation

FDA's Digital Health Center of Excellence (DHCoE):
Direct engagement resource for military digital health programs

Real-World Evidence (RWE):
FDA increasingly accepts operational data from military training and deployments

Pre-Submission (Q-Sub) Meetings:
Formal mechanism to align with FDA before submission – leverage this tool

BARDA/DoW coordination:
Joint funding and regulatory strategy for dual-use medical countermeasures

ALIGN EARLY | COMMUNICATE OPENLY | PLAN TOGETHER | EXECUTE EFFICIENTLY | DELIVER IMPACT

Challenges and Opportunities

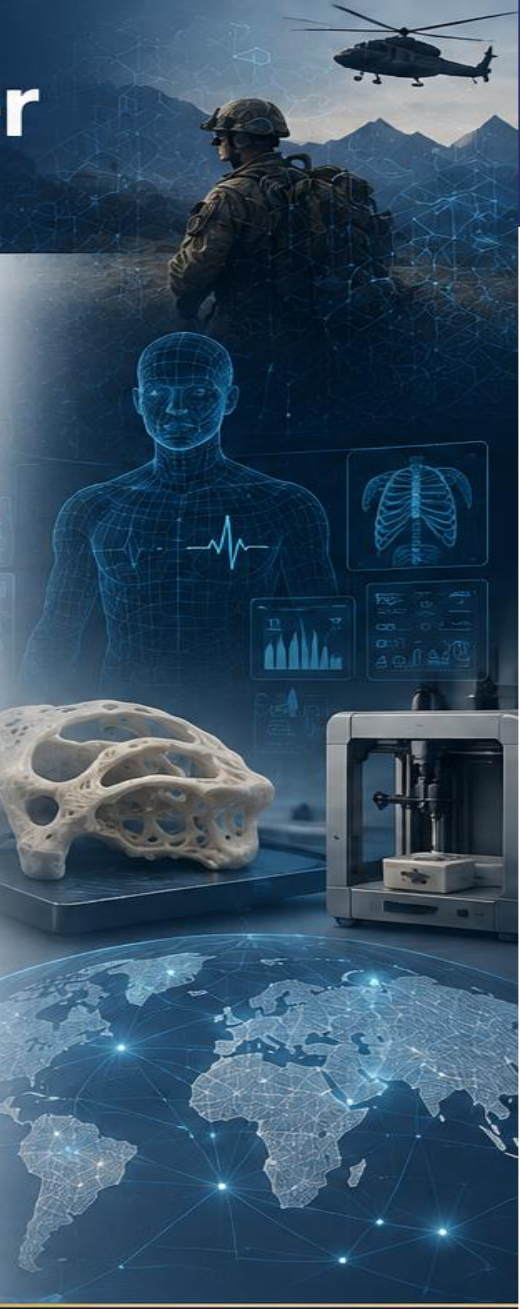
CHALLENGES

- No commercial predicates for military-unique devices
- Complex cybersecurity requirements for field-deployed systems
- QA/QC for AM in austere environments
- Data integrity across disconnected systems
- Speed of innovation vs. regulatory timelines

OPPORTUNITIES

- FDA's expanded openness to novel evidence frameworks
- Streamlined digital submissions (2026 updates)
- Expanded Access pathways for unmet military needs
- Growing acceptance of real-world operational data
- AI/ML PCCP enabling adaptive device approvals
- DoD investment in regulatory science infrastructure

Future Directions: The Next Frontier



AI-Enabled Triage Tools: Submissions incorporating adaptive algorithms for real-time battlefield triage are underway

Convergence of AI + AM + Digital Health: Next-generation CCC platforms will integrate all three modalities

Autonomous Medical Systems: FDA is developing frameworks for autonomous device decision-making - DoW must engage now

Forward-Deployed Digital Twins: Virtual patient models for surgical planning using AM and AI

Regulatory Science Investment: DHA is building internal regulatory science capability to accelerate submissions

International Regulatory Harmonization: Working with allied nations on mutual recognition for military medical devices

Continuous Learning Systems: Post-market surveillance frameworks for AI devices that learn from field data

Recommendations: A Call to Action

- **Start regulatory strategy on Day 1** of any MedTech development program - not as an afterthought
- **Engage FDA early and often** through Pre-Submission (Q-Sub) meetings - it is free and invaluable
- **Invest in Quality Management Systems** before the first prototype is built
- **Build cybersecurity** into device architecture from the ground up
- **Leverage real-world operational data** systematically for regulatory submissions
- **Grow regulatory science expertise** within DoW programs and acquisition offices
- **Engage with FDA advisory panels**, working groups, and public comment processes
- **Collaborate with BARDA, NIH, and industry partners** to share regulatory burden and lessons learned

Our Mission & Vision

Mission

Responsively and responsibly create, develop, acquire and deliver medical capabilities for the warfighter.

Vision

Lead the advancement of military medicine.

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