Advanced Product Development & FDA Regulatory Considerations for Vendors

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Purpose

To enhance understanding of medical product Advanced Development (AD) and related Food and Drug Administration (FDA) Regulatory Affairs considerations

- AD Overview
- Planning for Product Transition
- AD Governing Processes
- Commercial Solutions
- How to Access and Work with AD
- FDA Regulatory Considerations
Panel Members

- Ms. Kathleen Berst - Deputy for Acquisition, US Army Medical Materiel Development Activity (USAMMDA), USAMRMC

- Dr. Tyler Bennett - Deputy for Acquisition, US Army Medical Materiel Agency, USAMRMC

- Dr. Carolyn Laurencot - Senior Regulatory Affairs Advisor & Acting Director Clinical Services Support Division, USAMMDA, USAMRMC

- CDR Joseph Cohn - Director, Advanced Development, Defense Health Agency Research, Development & Acquisition Directorate
From Science to AD

Requirements Pull

Office of Management and Budget Science & Technology Priorities

Defense Health Program Science & Technology Priorities

Army 2025 & Beyond

Capability Needs Assessment

Technology Push

Knowledge Product Recommendations

Near-term Emerging Technologies

Future Technology Revolutions

New Ideas from Labs
DoD’s Medical RDTE Enterprise

User Needs

Technology Opportunities & Resources

Research

Materiel Solution Analysis

Tech Maturation & Risk Reduction

Eng & Manufacturing Development

Production & Deployment

Operations & Support

Science and Technology Management

Managed by Services or DHA Joint Program Committees

- Focus is on best research aligned to military gaps
  - Intramural laboratories
  - Extramural partners – industry, academia, other Government Agencies

Advanced Development Management

Managed by Service Project Managers or DHA AD Program Manager

- Focus is on testing and manufacturing safe, effective, affordable, and sustainable solution to meet military requirement
  - Extramural partners – industry, academia, other Government Agencies
  - Intramural laboratories
Overview: The 5 “Ws”

Why?
To fill validated DoD gaps that provide solutions in saving Warfighter’s lives

What?
Partnerships w/ industry, academia, & other gov’t agencies to develop & deliver affordable, effective and timely solutions

When?
Early in the development process; after proof of concept studies, before & during preclinical and clinical trials

Who?
Certified Acquisition professionals w/ extensive project management & medical product development experience

Where?
Service specific Army AD is located at Fort Detrick, MD & partners with industry & clinical sites worldwide

AD Translates Research Into Products
Translating Research Into Fielded Products

**Core Competencies**
- AD and Regulatory

- Advanced Medical Product Development
- FDA Regulatory Management
- Clinical Development
- Force Health Protection

**Bridging the Valley of Death**

Regulatory considerations start while the product is still in the tech base, before it enters AD.

Fielded Products = Medically Ready Force
What constitutes a “fielded” product?

- Approved or cleared by the FDA for intended use
- Environmentally suited
- Acceptable to the user community
- Translatable into clinical practice
- Reimbursable
Integrated Product Teams

*IPTs are critical to AD success*
*Broad expertise is needed to develop and field products*

- Other Service Reps
- Regulatory
- Contracting
- Medical Advisor/SME
- Logistics
- ORTA
- Legal
- Clinical Operations
- Combat Developer/User
- Product Tech Operations
- Quality Mgmt

**AD Translates Research Into Products**
Planning Successful Transitions

- Begin with the end in mind
  - Know the requirement
  - “Good enough” now is better than perfect later
  - Avoid losing focus on what is really important
  - Keep focused → Avoid the allure of “bright, shiny objects”

- Integrate early → Many disciplines are on the critical path to product fielding
- Engage the FDA → Reviewers see more potential products in a month than most scientists do in a career
- Document transition agreements → ensures critical thinking & commitments when putting pen to paper

AD Translates Research Into Products
Product Development Issues

Is there a DoD need (aka requirement)?

• What are the product candidates/alternatives?
• What is the viability of the industry partner?
• What are the projected and sunk costs?
• What has been the product’s technical performance and schedule to date?
• What is the projected development schedule?
• Are there quality considerations?
• What is the sustainability of product in the marketplace?
• Is there an established manufacturing capability?
• What are the risks?
• What is the regulatory strategy for FDA regulated products?
Integration of DoD 5000 and FDA Regulation Process

DoD Acquisition

- Research
- Materiel Solution Analysis
- Tech Maturation & Risk Reduction
- Eng & Manufacturing Development
- Production & Deployment
- Operations & Support

FDA Regulated Development

- Discovery
- Preclinical Testing
- Proof of Concept Clinical
- Clinical Testing
- Marketing & Production
- Sustainment

Funding

- IND/IDE
- Marketing Application
- FDA Approval
- Procurement
- OMA

AD Translates Research Into Products
Why commercial solutions?
- Development complete, reducing cost to DoD
- Modifications (e.g. packaging, storage, etc) and operational testing (e.g., air worthiness) may be needed to employ for military use

Examples include:
- Vital Signs Monitors
- Tourniquets
- Oxygen Generators
- Computed Tomography Scanners
- Lab and X-Ray Equipment
- C-Arms

Issues
- User Acceptance and Air Worthiness Testing
- Information Technology - Authority to Operate and Risk Management Framework
Near-Term Products Needing Industry Support

➢ Products Under Development (3-5 years)
  • Post Traumatic Stress Disorder Treatment
  • Traumatic Brain Injury (TBI) Diagnostic
  • TBI Pharmaceutical Treatment
  • Soldier Readiness Monitoring: Non-invasive, near real-time physiological monitoring
    • Soldier worn and open architecture to improve actionable information
      – Currently based on the physiological strain index (heart rate based)
      – Additions to a comprehensive Soldier Readiness Score
        » Cognitive Load, Alertness/Fatigue, Musculoskeletal Load, Electrolytes, Metabolism, Chemical and Biological Exposure

➢ Fielded Products Requiring Modernization (3-5 years)
  • Deployable CT scanner
  • C-arm X-ray apparatus
  • Military oxygen generating system
  • Pneumatic tourniquet
How to Access and Work with AD

**Access**
- Sponsored Meetings (e.g., USAMRMC Vendor Day, MMPD, Military Health System Research Symposium)
- Response to Fed Biz Ops released requests

**Working with AD:**
- Cooperative Research & Development Agreements (CRADAs)
- Materiel Transfer Agreements
- Contracts - Full & Open Competition
  - Medical Product Research & Development: Indefinite Delivery, Indefinite Quantity
  - Small Business Innovative Research/Small Business Technology Transfer grants
FDA’s regulatory decisions are data driven & based on a benefit-risk assessment
• Unique for the disease, patient population, & agent(s) being evaluated
• Informed by science, medicine, policy, & judgment

FDA makes regulatory decisions are bounded by applicable law, regulations & policy (i.e., Food, Drug, and Cosmetic Act)

The goal is FDA licensure/clearance
• Understand information needed for package insert/product label prior to initiating clinical studies

Develop a regulatory strategy to mitigate risk & employ quality systems in all aspects of product development

Engage with the FDA early & often

Establish an experienced product development team & communicate with all members of the team regularly
The Scheme of Things

Good Manufacturing Practices (GMPs)
Regulations for manufacturers of Foods, Drugs, Cosmetics to assure the purity, quality and consistency of their product (Quality Systems for devices)

Good Laboratory Practices (GLPs)
Regulations to help assure the scientific quality and integrity of data from non-clinical (animal) laboratory studies

Good Clinical Practices (GCPs)
Regulations to help assure the scientific quality, integrity and ethics of clinical studies conducted on humans

From: Dr. Pilaro, CBER, FDA
Product development generates evidence to support product licensure and commercialization

Evidence generation should begin with the initial clinical trial
- Relative efficacy needs to be evaluated pre-market
- A ‘living’ process updated throughout the product lifecycle to reflect new internal data in addition to the latest external demands

Medical product manufacturers need to satisfy the sometimes divergent needs of both licensing authorities and payers

Time to market does not mean time to FDA licensing but time to reimbursement
Questions?

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Advanced Developers and Regulatory support teams deliver quality medical solutions to protect, treat, and sustain the health of Our Service Members.

For additional questions after the conclusion of the conference, send an email message to usarmy.detrick.medcom-usamrmc.mbx.mmpd@mail.mil