

Regulatory Strategy Forum for Medical Devices

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RA as a Strategic Business Partner

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Overview

- Background – Business and Regulatory Environment
- RA as Strategic Partner – Management and Individual Level
- What do you need to know as a Strategic Partner
- How does RA interface with other business functions
- RA's Role in R&D projects
- RA's Role in Commercialization of products
- How should the RA Strategy support the Business strategy
- Communication Strategy
- Role of Regulatory in various business relationships

Business Environment

- Health care reform and the need to have more efficient and more productive product development
- More demanding regulatory requirements throughout the total product life cycle.
- Demand for more predictability and efficiency.
- Regulatory can play a key role in supporting these business goals.
- We must meet regulatory requirements but the ability to manage it in minimizing business risk to maximize business success is critical.
- Need to have strategy that:
 - Maximize patient benefit
 - Maximize financial return by minimizing business risk



Current U.S. Environment

CDRH Strategic Priorities:

- Strengthening the premarket review process – implementing recommended revisions to the 510(k) process
- Utilization of internal and external “Network of Experts” resources to adapt to evolving science and technology advances
- Expansion on the Innovation Initiative to reduce development and review time for innovative devices
- Continued emphasis on pre-approval inspection and enforcement of clinical and manufacturing
- Improved post-approval adverse event data collection and analysis through post-market clinical studies and reporting programs, e.g., MedSun/Sentinel



Current Concerns at FDA

- Continued Administration and Congress oversight and budget constraints
- Credibility with consumers regarding robustness of the review process and safety of approved/cleared devices
- Balancing the “safety first” mission interpretation against increased pressures to streamline the approval process.
- Increased transparency on decision-making



Key RA Functional Competencies

At any level, key regulatory competencies include:

- Global regulatory knowledge
- Global business acumen
- Effective communication and relationship building
- Strategic and critical thinking
- Planning and project management
- Providing valued results

Scope and depth expectations will vary depending on individual level.



Defy Stereotypical Role

Typical viewpoint regarding role of Regulatory and considerations for regulatory strategy development:

- Not concerned with P&L or revenue considerations.
- Does not take into account current business issues or challenges.
- Follow the historical formula - challenging the status quo engenders too much risk.
- Regulatory plan needs to focus what we can do and not taking risks to try something different
- Sole interpreter and decision-maker regarding the business risk tolerance from a compliance standpoint

Functional Expertise

Need to know:

- The regulations and the intent of the law
 - Congressional Intent
 - Food and Drug Law
 - Regulations
 - Guidances
 - Look for the FDA thought process in the published preamble content (responses to the public comments)
- Regulatory precedent
 - Other device or drug approaches, i.e., clinical study design/end points
 - Recent FDA approval or denial decisions
 - Advisory panel presentations and decisions
- Current regulatory environment hot spots
 - Recent FDA presentations to stakeholders
 - Public criticism

Know Your Stakeholders

Regulatory agency:

- Know the key regulatory review team members and management (previous interactions or use former FDA staff consultants):
 - Mindset on issues, limits and flexibilities, key motivators.

Project team functional peers

- Understand their role and deliverables, educate them on the criticality of their content in obtaining and maintaining approval

Business management

- Know the key business drivers for the project, positioning in the product portfolio, relative risk tolerance

Physician customers

- Understand the “real world” use, potential partners in negotiation with regulators and payors

Competitors

- Set a high bar for followers, key product differentiators

Regulatory Management Team Member

Integrate regulatory requirements into business strategy:

- Understand company mission, culture and strategic business priorities
- Understand the company's approach to risks (business, regulatory, compliance)
- Have the mindset that change is necessary and be adaptive

Pre-market:

- Enable business to gain/maintain competitive advantage
- Product positioning and portfolio management
- Regulatory approval linked to reimbursement considerations
- Labeling and claims development to support promotional messages
- Mergers/acquisition/business decision to attain growth target

Post Market

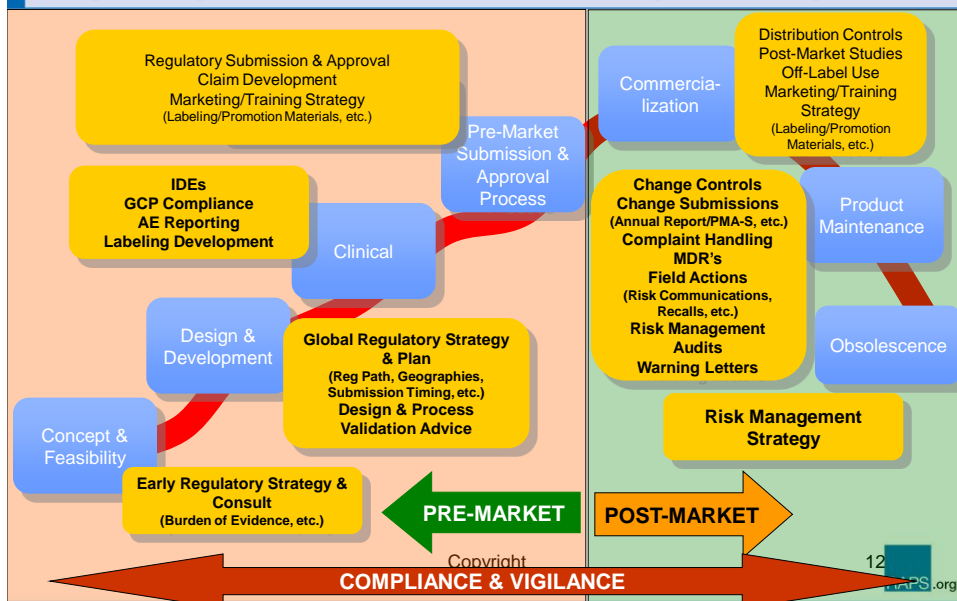
- Compliance strategy to maintain and improve company's reputation with all stakeholders (medical community; patients; payers; government) balanced with cost controls
- Set the “tone” of compliance and approach to risks
- Product Life Cycle Management

Build Business Acumen at the Individual Contributor Level

- Be cognizant of business strategy and ensure regulatory strategy links to/supports the business plan
- Educate your project team members on the regulatory environment and requirements
 - Understand their role and deliverables
 - Communicate the overall message of the submission to ensure supportive content in documentation
- Understand and be able to leverage from development to support competitive claims and favorable reimbursement
 - Assess the return on investment of expanded bench, animal or clinical studies

Regulatory Affairs in Total Product Life Cycle

Regulatory Affairs - Total Product Life Cycle Management



Key Functional Collaborations

- Quality
 - Close collaboration in many areas – design review, pre and post approval inspections, response to inspectional observations, risk management, etc.
 - QS changes impacting product registrations
 - Choice of Notified Bodies or 3rd Party Reviewer
- Supply chain
 - Managing change control, knowing the requirements
 - Understand business metrics (e.g. cost reductions, supply issues) and integrate into regulatory submission strategy
 - Specific State distribution requirements and setting up controls – e.g. “Good Distributor Practice” type requirements

Key Functional Collaborations

- Finance
 - RA department costs, budget planning and compliance
- R&D
 - Standards, approval of test procedures, change control
 - RA management as part of design reviews per quality system
- Marketing and Sales
 - Understand competitive landscape
 - Provide best strategy for optimal outcome – be able to articulate your rationale and assumptions
- Financial Considerations
 - Priorities for business regarding projects and expenses
 - Submission costs, reimbursement

Regulatory Role in R&D Projects

Development team member mindset:

- Shared ownership for overall program
- Success is not limited to regulatory approval, but achieving key business goals pre and post-approval.
- Strategic input (not ownership) to other functional plans and deliverables.
- Project management of the submission(s) directly accountable successful completion of key regulatory milestones.

Responsibilities of Regulatory Team Member

Examples of Responsibilities:

- Monitor regulatory changes to formulate strategic and be adaptive.
- Formulate strategy integrating company approaches.
- Actively collaborate between team members – especially those related functions (clinical, quality, etc.).
- Proactively address potential cross-functional issues, especially if inter-dependencies are involved and issues cannot be resolved on an individual level.
- Keep team members, leader, and RA functional head/management team apprised of progress and issues related to project milestones.
- Seek input and advice from functional heads and experts (internal or external) to provide best regulatory advice to team.
- Active participation in team process and is prepared to contribute to discussions.

Business Considerations for Global Regulatory Plan

Business Plan/Strategy Outside U.S. – What country when?

- Company infrastructure (OUS offices, infrastructure, in-country care taker/agent?)
- Clinical data? (whether needed for regulatory requirements or not)
- Reimbursement landscape (in key markets)
- Pricing and reimbursement policies; parallel import

For small companies without local offices overseas:

- What country/region should approval be sought first to get fast revenue stream?
- What can be done in house and with partners/distributors?
- Considerations that may drive global regulatory plan:
 - Import/Export Rules – Foreign agents; qualified person, distributors, etc.
 - AE Reporting/Vigilance Requirements/Infrastructure (medical personnel, etc.)
 - License Renewal Requirements
 - Device Tracking? (e.g. China?)
 - Post Market Surveillance Requirements (e.g. Japan)
 - Vigilance Reporting Requirement?

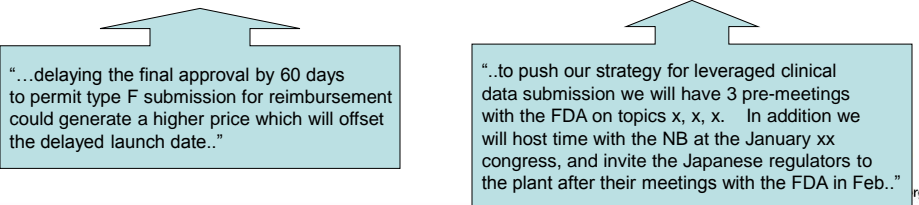
Regulatory Strategy Should Support Overall Business Strategy

- Regulatory strategy/plan should support business plan
- Regulatory Plan
 - Not just a submission and approval date
 - Not just a file/technical development Gantt chart
- Collaborate with other functions (marketing/reimbursement, etc) to identify desired claims and data requirements

Role of RA in Supporting Business Strategy

Commercialization Strategy:

- Time to market
- Fast follower?
- Make a big splash when launch
- Optimal reimbursement at commercialization
- Most claims/competitive claims
- Develop claims and data table prospectively – before key preclinical testing and clinical trials are designed.



Articulate Regulatory Risks and Mitigation Strategies In Plan

- Identify possible risks
- Rate probability (high, med., low, etc.)
- Technical Risks (e.g. supplier issues; out of spec. results in tests)
- Schedule Risk (e.g. competitor actions, FDA resources/priorities, pre-approval inspections, etc.)
- Compliance Risk (e.g. clinical trial conduct, GLP, etc.)
- Identify mitigation strategy
- Manage expectation/provide contingency plans/trade off options

Commercialization Achieving Competitive Advantage

- Understand your company's approach to risk regarding competitive activities
- Understand current regulatory environment and requirements, e.g. making comparative claims
- Treat your competitor as your competition
- Treat your regulator as your partner
- Support your claims with data

Communication Strategy

Know your key stakeholders and make decisions regarding:

- Who needs to know?
 - Functional head?
 - Senior management?
 - People who hold resources? e.g. Finance?
- When is a good time to communicate?
- What needs to be communicated?
 - Your key messages?
 - Level of details?
 - What do you need from them?
- What venue would be best?
 - One on one or group?
 - Face to face/teleconference/e-mail?
- Who needs to be with you when you communicate?
 - What is their role?
 - How do they help/not help?

Communicating Your Message

- Build credibility
 - Be knowledgeable (do your homework), and identify any knowledge gaps (and close them)
- Avoid “reg speak”
 - Tailor your message and language to the audience
- Educate your audience rather than yes/no
 - Explain regulatory basis for recommendation
 - Identify levels and likelihood of risks
 - Identify trade-offs (why options may not be desirable for other stakeholders)
 - Provide possible alternatives

Roles of Regulatory In Various Business Relationships

Role of Regulatory in Various Business Relationships

- Licensing
 - Regulatory Assessment
 - Right of Reference
 - Master Files
 - Protection of Confidential Information
- Joint Development
 - Joint Development Team
- Joint Venture
 - Joint “Steering Committee”
 - Joint Development Team
- Mergers and Acquisitions
 - Due Diligence
 - Integration Team
- Joint Marketing
 - Advertising and Promotional Materials Review
 - Adverse Event Reporting
 - Post Approval Studies
- Product Life Cycle Management (line extension)

Joint Development and Joint Ventures

- Provide input to business deals
- Know the terms of the agreement
- Protect confidential information (both ways)
- Understand the other company’s perspective and attempt to “speak” their language
- Understand your company’s policies and approach to regulatory agencies and business and compliance risks
- Build relationship with your counter-parts and related functions
- Educate and learn
- Serve as active problem solver
- Define clear roles and responsibilities between you and the other companies regulatory representatives
- Understand cultural differences (geography, company, agency) and be flexible
- Set process for communication with regulatory agencies
 - Key contacts
 - Meetings/telecom
 - Written
- Know when escalation is appropriate

In Licensing

Regulatory serves as part of in-license team:

- Regulatory Assessment of Technology
- Input into Licensing Agreement – e.g.
 - Provide regulatory intelligence to team
 - Assess Regulatory Assumptions
- Cognizant that different companies will have difference approaches to risks (e.g. approach to regulators and compliance)
- Need to agreement on team structure, governance, roles and responsibilities and conflict/issue resolution.
- Coordination/support of regulatory submissions
- Protection of Confidential Information
- Actions should link to Business Agreement
- Protect your company's interest

Joint Marketing and Product Life Cycle Management

Joint Marketing:

- Clarify roles and responsibilities
 - Promotional activities
 - Education activities
 - Adverse Event Reporting?
 - Distributorship?
 - Labeling/labeling issues?
 - State Licensing Requirements?
 - International (OUS) requirements?

Product Life Cycle Management:

- Exclusivity? Patent considerations
- Geographic expansion
- Post Approval Clinical Studies Issues

Mergers and Acquisitions

- Due diligence team:
 - Collaborate with other team members to define boundaries (e.g. quality, clinical, etc.)
 - Evaluate regulatory status of projects including supporting documentation maturity and gaps
 - Define process to transfer and advance projects
 - Develop timelines, scope of work and cost analysis for ongoing project support
- Acquisition integration team:
 - Post-acquisition reassessment of regulatory documentation and update risk mitigation and work plans accordingly.
 - Recommendation should include business considerations, especially involving compliance issues and human resource recommendations
 - Timely and proactive communication with regulators regarding compliance issues and resolution plans

Questions?

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