Building a competent Medical Affairs team to support business needs: A personal perspective

Jane Lin
WuXi AppTec

May 17, 2011 | Beijing
The views expressed in this presentation are those of the speaker and are not necessarily those of any company or its management.
Perceived roles of the Medical Affairs Department

- Medical authority, communicator, business partner, gatekeeper, police
- Trained to understand and communicate highly technical medical information
- Acts as central source of information on company products
- Discusses the science behind the products
- Conduct peer-to-peer interactions with health care professionals
Roles and responsibilities may vary in interactions with different functions

- **Basic Research**
  - Clinical Research
    - Protocol development, clinical study report review, query handling
    - Regulatory Affairs
      - Medical review, query handling, agency meeting, safety crisis management
  - Marketing
    - Medical review, product positioning, scientific support, KOL management
  - Sales
    - Medical/disease training, query handling
  - Customers (Physicians, pharmacists, governments, companies, payers)
    - Query handling, medical information
  - Patients
    - Query handling

- **Medical Affairs**
What can a competent Medical Affairs team do?

- Review promotional materials
- Provide medical/disease training to internal staff
- Establish professional relationship with key opinion leaders
- Provide medical information to, and handle inquiries from, internal and external customers
- Develop protocols and review report for local studies
- Provide academic support to internal staff (e.g., Marketing, Regulatory Affairs)
• Promotional materials
  – Are an important part of the company’s communications to customers
  – Enhance company image, impact prescribing, and create trust in products
  – Prevent company embarrassment and liability from inappropriate promotional claims

• Objectives
  – Be useful, accurate, and balanced
  – Support statements with scientific evidence
  – Present honestly, fairly, and in good taste
• Rules to follow
  – Company policy and review guidelines
  – Applicable China laws and regulations
  – Legal and regulatory regulations and requirements, particularly those specific to the pharmaceutical industry
  – Current medical and scientific knowledge
  – Product circular

• Early involvement in the creation of promotional materials is critical to ensuring their high quality
Medical information and customer-oriented service

- Handle medical inquiries from external and internal customers
  - External – Patients, physicians, others (agencies, distributors)
  - Internal – Marketing, Sales, Government Affairs
- Provide medical information to external customers (e.g., KOLs)
- Provide medical evaluation on potential litigation and written claims
Medical/disease training

- Basic training
  - Self-learning manual
  - Training materials
  - Medical information searching

- Advanced training
  - Franchise-related scientific updates
  - Response to drug safety issues
  - Evidence-related medicine and literature evaluation
Scientific support

- Provide medical advice/input on product positioning and strategy across product life cycle management
- Manage KOLs
  - Build professional relationships
  - Provide regular updated medical information
  - Facilitate investigator initiated studies (IIS)
- Support scientific seminars/workshops
- Counter competitor activity
- Manage product safety crises
Clinical trial support

- Local registration trials and post-marketing studies
  - Planning
  - Protocol development
  - Implementation
  - CSR review and publication

- Multinational trials
  - Local medical input
  - Feasibility evaluation
  - Local report review
Evolving role of Medical Affairs

- **Increased responsibilities and accountability**
  - Continuing medical education (CME), publications, and grants
  - Involvement in launch activities no later than Phase 3

- **Elevated position in the organization**
  - From supporting role to an equal partner
  - Reporting to a VP-level executive

- **More frequent communication with internal customers**
  - From monthly product planning and update meetings to informal daily contacts

- **Roles of Medical Science Liaisons**
  - Scientific exchange activities, KOL interaction, Phase 4 planning, product launch support, sales training, and medical information preparation
Building the competencies to fulfill the role

• Candidates with advanced degrees:
  – M.D.
  – Pharm. D./M. Pharm.
  – M.S.
• Capability in spoken and written English communication

• Self learning
• Training
• Workshops/seminars
• Information sharing
• Case studies
• Team building

• Understanding of rules and regulations
• Advanced medical knowledge
• Understanding of products/markets
• Strong communication skills
• Customer-oriented mindset

Educational requirements
Essential competencies
Building internal mechanism to streamline roles in Medical Affairs

• Clearly define the responsibility of each position
• Tailor training schedules to meet career development needs
• Create and establish SOPs to ensure quality standards and development timelines
• Provide competitive salary and bonus packages to attract and retain talent
Model of a franchise-based Medical Affairs organization

- Medical Affairs Head
  - Therapeutic Area Leader (A)
    - Product Physician
    - Med Science Liaison
  - Therapeutic Area Leader (B)
    - Product Physician
    - Med Science Liaison
  - Therapeutic Area Leader (C)
    - Product Physician
    - Med Science Liaison
  - Virtual Customer Service Center
    - Information Mgr
      - Medical Associate
      • Virtual library
      • Q&A database
Summary

• Medical Affairs plays an increasingly important role in the biopharmaceutical industry.

• It is a function with broad coverage.

• Its roles and responsibility may vary in its interactions with various functions.

• An internal mechanism is needed to ensure that Medical Affairs is given sufficient authority.

• A competent Medical Affairs team needs an environment of continuous learning.
Thank you