

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

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# Disclaimer



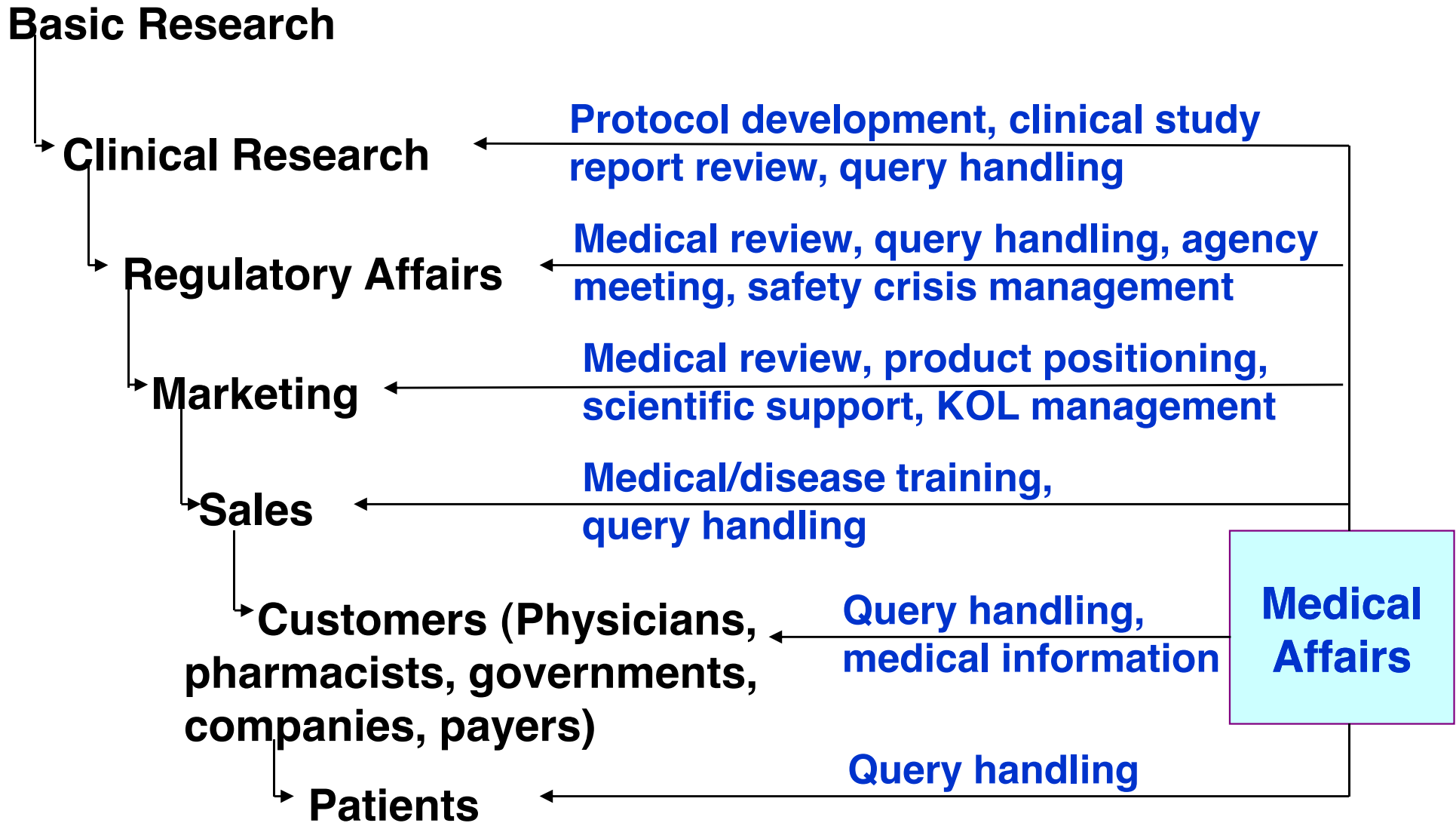
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# Perceived roles of the Medical Affairs Department



- **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



# 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



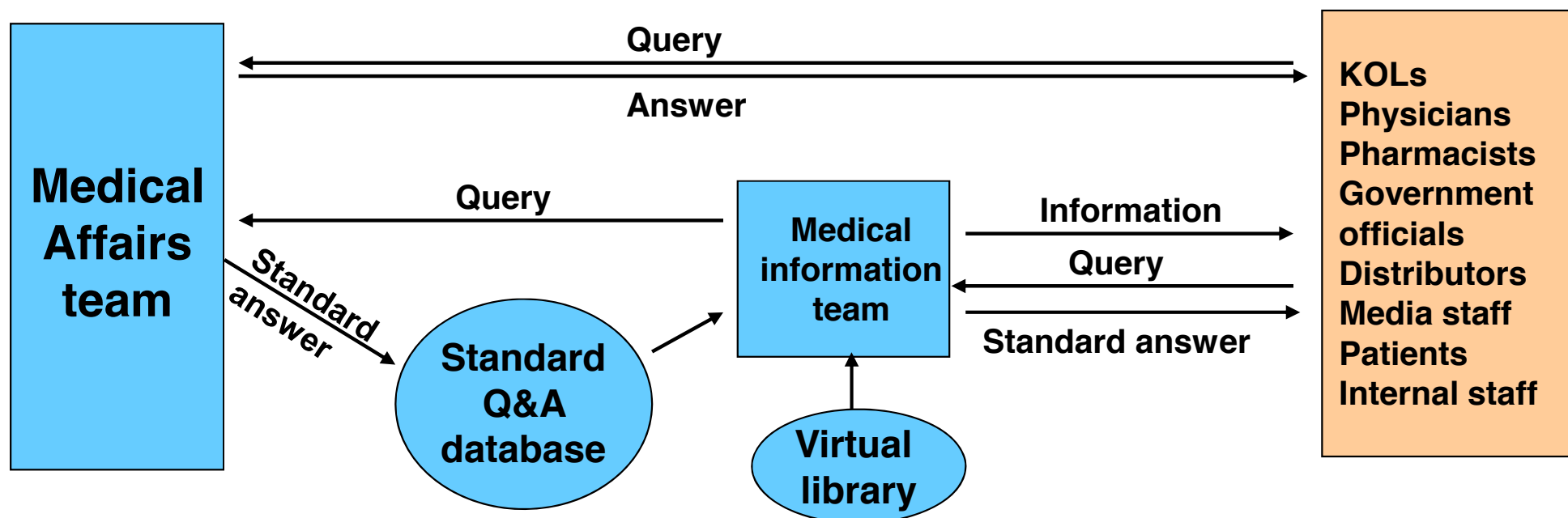
- **Rules to follow**
  - Company policy and review guidelines
  - Applicable China laws and regulations
  - Legal and regulatory regulations and requirements, particularly those specific to the pharmaceutical industry
  - Current medical and scientific knowledge
  - Product circular
- **Early involvement 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

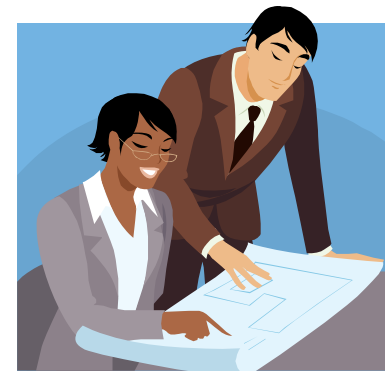




- **Basic training**
  - Self-learning manual
  - Training materials
  - Medical information searching
- **Advanced training**
  - Franchise-related scientific updates
  - Response to drug safety issues
  - Evidence-related medicine and literature evaluation



- **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**



- **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



- **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**



- **Academic meetings**
- **Industry meetings**
- **Publications**

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

**Educational requirements**

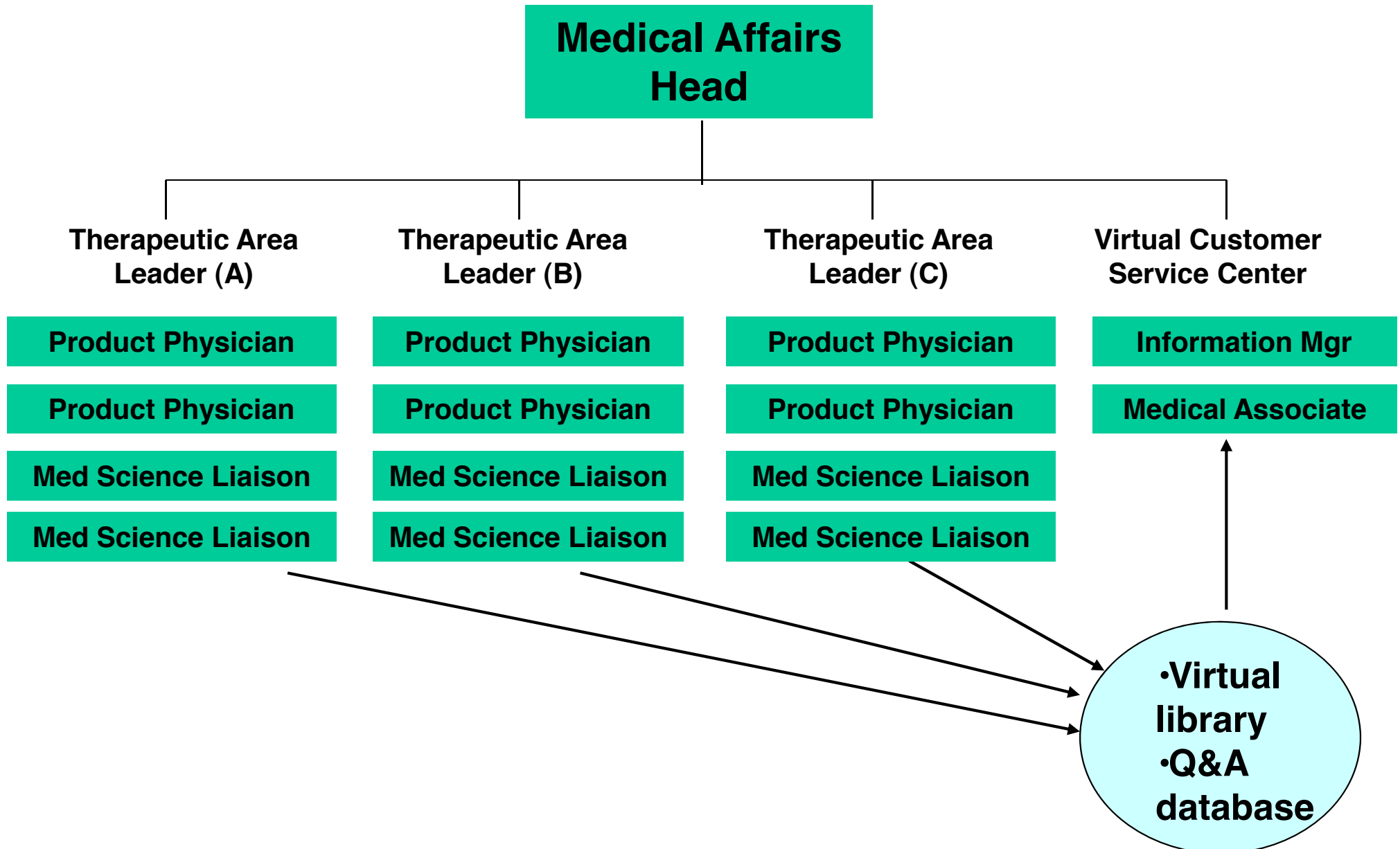
**Essential competencies**

# 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 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**