

The Key Ingredients for Medical Affairs Success

I am delighted to share some thoughts from Dr Sheuli Porkess, Director of Actaros Consulting, on the ingredients of a successful Medical Affairs Department.

Medical Affairs is an exciting speciality which has real potential to translate patient and clinical insights into meaningful developments in healthcare. Medical Affairs has grown and evolved significantly over the last years from being a few doctors reviewing materials to now including a diverse set of roles. However, despite the expansion of the function, Medical Affairs has struggled to define what it does and the value it brings to a pharmaceutical company. For example, it has been thought of as focussing only on compliance through to being mislabelled as a department of "super-reps". The result of this lack of clarity is that Medical Affairs leaders are continuously challenged to defend their budgets and headcount during the annual budget cycles.

The Medical Affairs department is the medical and scientific part of the organisation concerned with products, typically from phase 3 onwards. Specialists within Medical Affairs include:

- Medical Advisors who are typically doctors (physicians) in the UK
- Scientific Advisors who can be PhD or MSc scientists concerned with the scientific aspects
- Field-based medical roles such as Medical Scientific Liaisons who can be from medical, nursing, pharmacist or scientific backgrounds and are focussed on visiting clinicians.

The department may also include Medical Information roles which are often carried out by pharmacists, or scientists.

Changes in the Medical Affairs environment (such as changes in signatory requirements of the UK Code of Practice and development of the MSL function) have resulted in doctors, pharmacists and scientists in Medical Affairs being able to do different roles within the sector. Furthermore, different companies will use different terminology and definitions, which may reflect a company's approach to recruitment, the company's structure or also the skills of specific individuals in the company.

To have a successful Medical Affairs department, there are 4 essential ingredients:

- Product and therapy area knowledge
- People who can use their expertise effectively through learning, in a commercial environment
- People who can lead effectively
- Practical processes to make sure things get done in the right way.

Product and Therapy Area Knowledge

It is often necessary to hire an employee with specific expert knowledge, especially when a company is moving into a new therapy area of specific type of product. However, focussing only on the expert knowledge without paying due attention to how the team needs to work can result in that expertise not being utilised.

People who can use their expertise effectively through learning

A key to an effective Medical Affairs team is having an environment where the Medical Affairs team share their medical and scientific insights but can balance this with being able to learn from others in the extended medicomarketing team. There will be a requirement to learn many SOPs, Codes of Practice, clinical trial data as well as skills such as managing a medical affairs plan and understanding the brand planning process.

However, one of the biggest challenges for those clinical or academic experts who are new to medical affairs is to find themselves as a team member, rather than a team leader. This is especially challenging in a setting such as medicomarketing or company project teams where decisions may be made by someone with no clinical experience. This requires Medical Affairs specialists to be willing to learn how to work in a different team setting. This challenge combined with other challenges experienced during the transition into Medical Affairs requires support.

However, those who are eager to learn, rather than just willing to learn, will be much more successful in the long-run. New challenges emerge such as implementation of patient-centric ways of working, understanding digital healthcare, understanding the possibilities of big data, innovative clinical trial design, market access and the ever-present need to blend innovation and compliance within a regulated industry that require medical affairs specialists to keep learning.

People who can lead effectively

Medical Affairs needs to have strong leaders. As a speciality that it comprised of medical and scientific experts, it is not a given that someone who is successful in Medical Affairs will necessarily be an effective leader. Effective leadership is important for defining how the department works well within the company and for engagement of the members of the team. There are many specific areas of focus for Medical Affairs leaders. One area is support for new specialists making the significant transition into Medical Affairs as well as ongoing coaching of specialists.

Another area is for Medical Affairs leaders to define what does (and doesn't) need to be done in the department and the skills, expertise and processes needed to do this. Although often associated with bureaucracy and checklists, quality systems thinking is a good basis for this, whereby quality is delivering something to customers to their expectations every time.

Understanding what needs to be delivered and to whom, needs to be translated by the Medical Affairs leader into Medical Affairs team goals and targets. These goals and targets must be meaningful to those within the team and aligned to company goals.

Practical Processes

In addition to having the right product and therapy area expertise, and people who have the learning agility and interpersonal skills to flourish in the medicomarketing environment, a Medical Affairs leader needs to be able to accurately define how the team will work to get things done. Many Medical Affairs departments will be perceived to be governed by processes from global headquarters. However, unwritten “processes” are within the control of the team and can be more impactful in terms of Medical Affairs success. For example, it could be how the team approaches budget management, resolution of differences of opinion within the medicomarketing team, cross-cover for annual leave or how to manage medical review of urgent items. These approaches must be practical and must emphasise behaviours which help the team achieve its goals. Ignoring these aspects will be to the detriment of the team and the company.

In summary, there are 4 key ingredients which leaders in companies and medical affairs departments need to nature; understanding and addressing these will help companies ensure that the opportunity for patient benefit through effective Medical Affairs is realised.

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