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ORIGINAL RESEARCH ARTICLE

Development of a Competency Framework for Medical Affairs Professionals in Australasia

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Abstract

Background and Objectives Medical Affairs (MA) plays a critical role in bridging the gap between research, clinical practice and business strategy. With the rapid growth in this field, it is essential to have a competency framework to support individuals' professional development. A well-defined competency framework will not only empower MA professionals to excel and develop in their roles but also contribute to better patient outcomes and improved stakeholder engagement. This paper discusses the development of a competency framework for Medical Affairs professionals in Australasia.

Methods The MA competency framework was developed using an iterative method by a team of MA professionals across Australia through a series of workshops and surveys over 2 years with the cooperation of the local MA community. The core development team debated and finessed the final framework over this time via meetings and discussions to arrive at the draft framework. This was pilot tested by a local pharmaceutical organisation and feedback informed some minor changes to the final framework. This was then endorsed by the Medical Affairs of Australasia (MAPA) Executive Committee.

Results The framework consists of six domains: Scientific/Technical Knowledge, Evidence Generation, Compliance, Governance and Ethics, Leadership/Professionalism, Communication and Collaboration and Business Acumen, each with specific competencies and across four clearly defined levels from novice to expert.

Conclusion This framework has been endorsed by the Medical Affairs Professionals of Australasia Executive Committee and provides a clear framework for the professional development of medical affairs professionals across our region. It is also applicable to MA professionals more broadly.

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Key Points

This paper details the development of a Medical Affairs (MA) competency framework in Australasia, created collaboratively through workshops, surveys and input from the local MA community over 2 years.

The resulting framework encompasses six core domains—including scientific knowledge, evidence generation, compliance, leadership, communication and business acumen—each with specific competencies and four defined proficiency levels (novice to expert).

Endorsed by the MAPA Executive Committee, the framework provides clear guidance for Medical Affairs professional development in Australasia and is broadly applicable to MA professionals in other settings.

1 Introduction

Medical Affairs (MA) is an established yet evolving profession situated within the pharmaceutical, biotechnology and medtech sector and supporting technology translation from research and development through to commercialisation [1–5]. Common accountabilities of MA professionals include the generation, evaluation and communication of evidence to support the quality use of medicines and devices. Effective delivery by the MA workforce is central to optimising value to healthcare professionals and patients, and to the industry's focus on trust [4, 6, 7]. MA teams work in close collaboration with many other professionals within the industry as part of the ecosystem bringing new therapeutic products to market to the benefit of patients.

The measurable characteristics required by an individual for effective performance in a given role or profession are referred to as 'competencies' [8]. A competency framework is therefore a framework listing the competencies required for effective job performance [9]. Such a framework generally comprises a set of core competencies, as well as the behaviour indicators and detailed definitions for each competency, along with performance levels at each stage of career development [10]. Such standardised, defined performance outcomes at various stages of professional development ensure that individuals can demonstrate increasing levels of competence as they progress in their career within a specific profession. Furthermore, competency frameworks provide a common language and clear criteria for self-assessment by individuals, as well as organisational assessment, thus providing a supportive structure for career advancement. In this case, they can be used by organisations to identify gaps in performance levels for individual competencies and enable structured training and development opportunities for employees to ensure they reach the competencies required for successful performance [11]. They can be used also by educational institutions and course providers to ensure they are providing adequate training for graduates to meet minimum competencies upon entering the workplace.

Individual companies may have their own processes and programmes to support assessment and development of their MA teams. There are also several training programmes available globally such as the highly respected model for Pharmaceutical Medicine Specialty Training through the UK Faculty of Pharmaceutical Medicine, the PharmaTrain programmes in Europe, South Africa and Japan and limited short certificate courses newly offered by MAPS, USA [12–15]. Diversity of educational and professional backgrounds in MA is a strength; however, it follows that capabilities and knowledge will vary within the group [2, 7, 13–15]. Members of Medical Affairs Professionals of Australasia (MAPA) identified a local need for readily accessible support for professional standards across the full range of roles within MA, independently of educational background. It was noted that some other professions in the therapeutic product development sector, such as regulatory affairs, clinical research, pharmacovigilance and health economics, have specific competency frameworks defining requirements by role [16–20].

This project arose out of another research project, on the impact of MA on the quality use of medicines, being undertaken by two authors (MB, OC; personal communication). By 2022, we and members of MAPA had aligned on the need for further support for professional standards in MA in Australasia, starting with development of common language around the competencies, skills and capabilities required. The MAPA Professional Standards Working Group was formed to lead this work, with the aim of this research being to develop a competency framework applicable to all MA professionals in Australasia, regardless of specific role, company size or structure, representing a first step in professionalising the MA role in industry in Australasia.

2 Methods

2.1 Study Design

This was a qualitative study focused on developing a competency framework for MA professionals in Australasia. Our study utilised a mixed-methods approach, combining surveys and workshops to gather data.

2.2 Data Collection

The study began with a survey conducted among members of the Medical Affairs Professionals of Australasia (MAPA) regarding professional standards in MA. The survey included questions about the perceived need for a competency framework, with 22 participants responding. The survey content was designed to gauge current perceptions and needs regarding MA competencies, and participants were informed that their responses would be used for research purposes, with consent obtained accordingly. Responses gathered from the survey included whether the medical affairs profession would benefit from a competency framework, what were the most important competencies and capabilities for medical affairs professionals, whether it would be useful for competency frameworks to be used to identify an individual's performance and whether further training and accreditation would be useful to the Australasian MA community.

Subsequent to the survey, members of the Working Group delivered two workshops at the MAPA-Medical Affairs Professionals Society (MAPS) summit in late 2022, with approximately 60 attendees at each workshop. During these workshops, survey results were presented and participants engaged in discussions about essential MA competencies. The workshops aimed to provide context through comparisons with existing competency frameworks, such as those from the Regulatory Affairs Professionals Society and the Association of Clinical Research Professionals (ACRP) [19, 20]. Specific questions debated in the workshops included "Would MA professionals in Australasia benefit from a competency framework?", "What competencies do we need?", "What skills and attributes are needed for MA?", "How relevant are other models to the Australasian context?" and "What should our next steps be?"

The initial input from these workshops formed the basis for the draft competency framework. Further volunteers joined the Working Group, which is composed of both experienced and aspiring MA professionals, as well as relevant academics (the authors of this paper).

2.3 Iterative Development and Refinement

After these initial workshops, the Working Group held routine teleconferences and worked on identifying the main domains and competencies required for each domain. The working group reviewed existing competency frameworks for other professions within the pharmaceutical industry such as the regulatory affairs competency framework developed by the Regulatory Affairs Professionals Society, the competency frameworks for clinical research professionals developed by the Association of Clinical Research Professionals (ACRP), the Clinical Research Associate competency framework developed for ARCS Australia and nascent frameworks under development by the Dutch Medical Affairs Association (NVFG) and the MAPS list of capabilities and competencies [15–21]. The training programme for the UK Faculty of Pharmaceutical Medicine was reviewed also to identify relevant competencies [22, 23].

The MA competencies identified were allocated to the main domains that had been developed in the workshops. They were then further categorised into four levels of experience: novice, intermediate, advanced and expert to allow for growth within the profession and to distinguish the requirements for different functions within MA. The decision to include four levels was based on our experience in developing other competency frameworks, reviewing the range of frameworks available for other pharmaceutical professionals, our individual experience as medical affairs professionals and knowledge of the different roles within MA in Australasia.

The draft framework was taken to the 2023 MAPA-MAPS summit, along with the survey results, and workshop participants debated and refined the wording. Our goal was to develop a framework that would be suitable for use across the MA function in Australasia regardless of company size, and adaptable to differing role definitions between organisations. The revised draft from the workshop was then further refined by the Working Group.

2.4 Pilot

In early 2024, the Working Group called for a volunteer pharmaceutical company to pilot test the framework. The pilot testing project is described in the companion publication. The framework and the results of the pilot were then presented to the MAPA-MAPS 2024 summit, feedback was incorporated, and the final draft submitted to the MAPA Executive Committee in March 2025 for their final review and endorsement.

2.5 Ethical Considerations

Participants involved in the surveys and workshops were made aware that their responses would contribute to research and informed consent was obtained.

3 Results

3.1 Stakeholder Engagement

The framework development process involved multiple rounds of stakeholder engagement. Results from the pre-workshop survey for the MAPA-MAPS summit workshop in 2022 indicated that 90% of respondents agreed that a competency framework would be beneficial to the Australasian

MA community. The survey also identified the major competencies required as communication skills, strategic skills, scientific knowledge and business acumen.

3.2 Identification of Domains and Competencies

The following six core competency domains relevant to MA professionals in Australasia were identified through these processes: Domain 1: specific scientific and technical knowledge; Domain 2: evidence generation; Domain 3: compliance, governance and ethics; Domain 4: leadership, strategic vision and professionalism; Domain 5: communication and collaboration; and Domain 6: business acumen. Domain 1 focuses on developing a deep understanding of the science underpinning therapeutic areas, products and the full product lifecycle; Domain 2 focuses on the individual's ability to design, interpret and communicate robust clinical and real-world evidence; Domain 3 covers patient safety, ethical standards and legal requirements which protect patients, maintain trust and ensures MA operates with integrity; Domain 4 emphasises that effective leadership combines strategic thinking, relationship building and a commitment to professionalism; Domain 5 supports the concept that clear, accurate and tailored communication—supported by strong collaboration—maximises impact and strengthens partnerships with internal and external stakeholders while Domain 6 ensures that MA professionals have an understanding of the business environment to ensure MA delivers value and supports organisational goals.

These main domains were further broken down into a total of 36 competencies with more nuanced definitions of each specific competency (Table 1).

3.3 Definition of Proficiency Levels

Four overarching proficiency levels were defined for the framework: Level 1—novice (foundational knowledge, requires supervision), Level 2—intermediate (independent execution of tasks, developing autonomy), Level 3—advanced (supervises, trains others and provides strategic input) and Level 4—expert (leads globally, provides high-level oversight and mentorship). These proficiency levels were described in more detail for each of the 36 competencies to aid in assessment. As an example, for Competency 3.2 Ensuring Patient Safety, the novice level states the person is "Aware of the principles of patient safety and pharmacovigilance. With coaching is able to apply principles in context and conduct routine tasks in this area. Able to contribute to internal safety discussions with supervision"; the intermediate level requirement states "Has a solid grasp on the principles of patient safety and pharmacovigilance obligations; and their application in practice. Able to apply these principles autonomously in routine situations"; the advanced level states "Recognised internally as a resource in teaching, coaching and supervising staff working in patient safety and ensuring company pharmacovigilance obligations are met. Serves as an escalation point for internal questions arising. Confident to take a leadership position in safety-related matters including audit and inspection readiness activities" whereas an expert level requires "Internal and external recognition as highly competent in teaching and applying relevant principles. Recognised in the global organisation as an expert in navigating complexities in this area including audit and inspection experience. Able to lead and inspire teams to support patient safety and meet or surpass all obligations through their activities. May be involved in external teaching on this topic". This example clearly shows the progression from novice to expert in the development of this particular competency.

The full framework is provided for all competencies in the electronic supplementary material (Supplementary Table 1).

Results of a pilot study conducted by Amgen are provided in the accompanying paper [24].

3.4 MAPA Endorsement

The draft framework and results of the pilot study were reviewed and endorsed by the MAPA Executive Committee in March 2025. Reflecting the need for the framework to meet the evolving needs of the profession, the endorsement is for the period 1 April 2025 to 31 March 2028.

4 Discussion

The MA competency framework is organised into six core domains: Scientific/Technical Knowledge, Evidence Generation, Compliance, Governance and Ethics, Leadership/Professionalism, Communication and Collaboration, and Business Acumen, which were developed iteratively through extensive consultation with the Australasian MA community and are designed to comprehensively cover the skills and knowledge required by MA professionals in the region. The framework is structured across four proficiency levels, from novice to expert, providing a clear pathway for skill progression within this profession.

The Australian National Medicines Policy aims to "achieve the world's best health, social and economic outcomes for all Australians, through a highly supportive Medicines Policy environment" [25]. The central pillars, principles and enablers of the policy align closely with the key domains of competence set out in the MAPA MA competency framework, highlighting its relevance to delivering on the National policy aspirations.

While this framework is not explicitly structured around categories such as 'core,' 'functional,' and 'meta'

Table 1 Domains and competencies of the MA competency framework

Domains	Competencies
1: Specific scientific and technical knowledge	1.1 Therapeutic area knowledge
	1.2 Product-specific scientific knowledge
	1.3 Therapeutic product development, supply and lifecycle knowledge
2: Evidence generation	2.1 Clinical trial design, conduct and analysis
	2.2 Real-world data, real-world evidence and evidence generation
	2.3 Scientific publication writing
	2.4 Using data-based decision making
	2.5 Critical evaluation of literature
3: Compliance, governance and ethics	3.1 Optimising Quality Use of Medicines (QUM)
	3.2 Ensuring patient safety
	3.3 Compliance with industry Code of Conduct/Practice
	3.4 Equity, diversity and inclusion (EDI)
	3.5 Leading ethical discussions and considerations
	3.6 Legal principles
4: Leadership, strategic vision and professionalism	4.1 Strategic insights and vision
	4.2 Professional integrity
	4.3 Leadership skills
	4.4 Influencing
	4.5 Relationship building
	4.6 Policy impacts
	4.7 Self-management and continuous learning mindset
	4.8 Maintaining understanding of the medical affairs profession and its evolution
5: Communication and collaboration	5.1 Omni-channel communications
	5.2 Communication and interpersonal skills
	5.3 Multidisciplinary and interprofessional teamwork skills
	5.4 Engagement with patient organisations
	5.5 Communication and engagement with external experts
6: Business acumen	6.1 Commercial knowledge
	6.2 Reputation of company/industry
	6.3 Finance and budgeting skills
	6.4 Data and digital technology integration into activities
	6.5 Role of therapeutics in improving health outcomes
	6.6 How to assess and present product value
	6.7 Knowledge and support of health economic submissions

competencies, it inherently incorporates meta-competencies—those higher-order capabilities that enable professionals to effectively acquire, adapt and integrate other competencies over time. Meta-competencies such as learning agility, critical thinking, ethical reasoning, strategic thinking, interpersonal adaptability and systems thinking are embedded across the domains (e.g., learning agility in scientific/technical and leadership domains; critical thinking in evidence generation; ethical reasoning in compliance; strategic thinking and self-awareness in leadership; interpersonal adaptability in communication; systems thinking in business acumen). Such integration aligns with established competency-based education approaches—for instance, IFAPP's model emphasises the progression of integrated abilities comprising knowledge, skills, values and attitudes adapted to evolving professional contexts [6, 26]. By embedding meta-competencies, the framework ensures MA professionals are equipped to navigate complex, dynamic environments and respond robustly to emerging scientific, healthcare and regulatory challenges.

The competency framework was developed in the context of the Australian MAPA member consultations and discussions, although many of the contributors have had international experience, and the Amgen experience has demonstrated the utility of this framework in the region (Australia, China and Japan; see the companion paper by [24] in this journal). This points to the possibility of our framework having broader applicability than just the

Australasian region and further testing by individuals and companies may solidify its broader applicability across MA professionals. This provides an opportunity to support and raise the standards of MA professionals across our region to support research, registration, funding and patient care more broadly. The different local environments may require differing levels of competence in different domains, but all remain relevant.

Other international jurisdictions have implemented higher medical training for medically qualified MA professionals, which incorporates the attainment of the Diploma of Pharmaceutical Medicine (or similar), and several years of workplace demonstration of competence under the guidance of a named higher training supervisor. This training has given employers and others confidence in the ability of individuals and companies when making decisions for where to place research or who ought to be hired for roles.

As noted by Stonier and Jones (2025) and Silva et al (2025), the shift from informal on-the-job learning to structured, nationally accredited programmes have created clear expectations for scientific, regulatory and leadership competencies [12, 27]. These models—such as those promoted by the PharmaTrain syllabus—offer useful precedents for MA, particularly given the discipline's expanding remit and its interdisciplinary positioning at the intersection of science, policy and strategy.

Within the Australian context and to support international investment, the development of independent assessment of competence would provide similar reassurance that the personnel trained here are competent and able to take on board the development, registration and reimbursement of medicines. Additionally, local companies and recruitment agencies, when adopting the framework, would be able to articulate in a more consistent manner the competencies required for a role. The University of Sydney has already begun to create a suite of independent courses to support and certify attainment of competency across all domains and levels. Other private providers are likely to also develop similar programmes, and these will complement internal training opportunities that companies already provide. Companies committing to support their employees to progress their competencies through the framework will be at a competitive advantage for recruitment and retention of staff. In addition, where there is currently no alignment between organisations for the competencies required for a role which may have the same job title, a framework to standardise what would be expected or could be learned in a role provides greater clarity for job description composition, applications and salary benchmarking.

This structured competency framework provides a foundation for career development and professional standardisation in MA. As the field continues to evolve, this framework ensures that professionals remain aligned with industry best practices while enhancing their impact on patient outcomes/Quality Use of Medicine and healthcare decision making. Furthermore, by integrating competency assessments with training initiatives, the framework supports lifelong learning and continuous improvement in MA functions [26].

It is intended that this framework provide a basis for individualised assessment and tailoring of training and development plans for individuals in the medical affairs profession [21–23]. It aligns with MAPA's commitment to high standards for the MA profession and to further building recognition and trust (Fig. 1). Development of a recognised competency framework, assessment of an individual's performance against that framework and alignment of development programmes with the framework may lead to formal accreditation, professional registration, recognition and enhanced trust in a profession as it develops and matures, as depicted in Fig. 1.

It is acknowledged that the Medical Affairs environment will continue to evolve with political, budgetary, technological and other factors driving change. Thus, we propose the framework undergoes a 3-year review cycle, updating as necessary. The process for this will follow the original development process to continue to obtain feedback across the MAPA membership, representing medicines, devices and other research organisations to cover the breadth of experience and emerging influences. Future studies will assess long-term adoption, competency progression and its influence on career advancement within the MA ecosystem.

4.1 Limitations

We acknowledge the dynamic environment in which MA is evolving and that the framework is a 'living document' that will change as the MA profession matures. As such, the framework was developed and endorsed for a 3-year period and future reviews will incorporate ongoing feedback from the MAPA membership and broader stakeholders across the therapeutic development ecosystem in Australasia. Future research will evaluate long-term adoption of the framework, its impact on career advancement and its support for further professionalising the sector through formal education, training and accreditation. We expect that further testing across multiple geographies will help validate the framework's general applicability.

5 Conclusion

This framework bridges the gap between scientific expertise and practical application in a real-world setting, promoting excellence and consistency in Medical Affairs practices across Australasia. By clearly defining

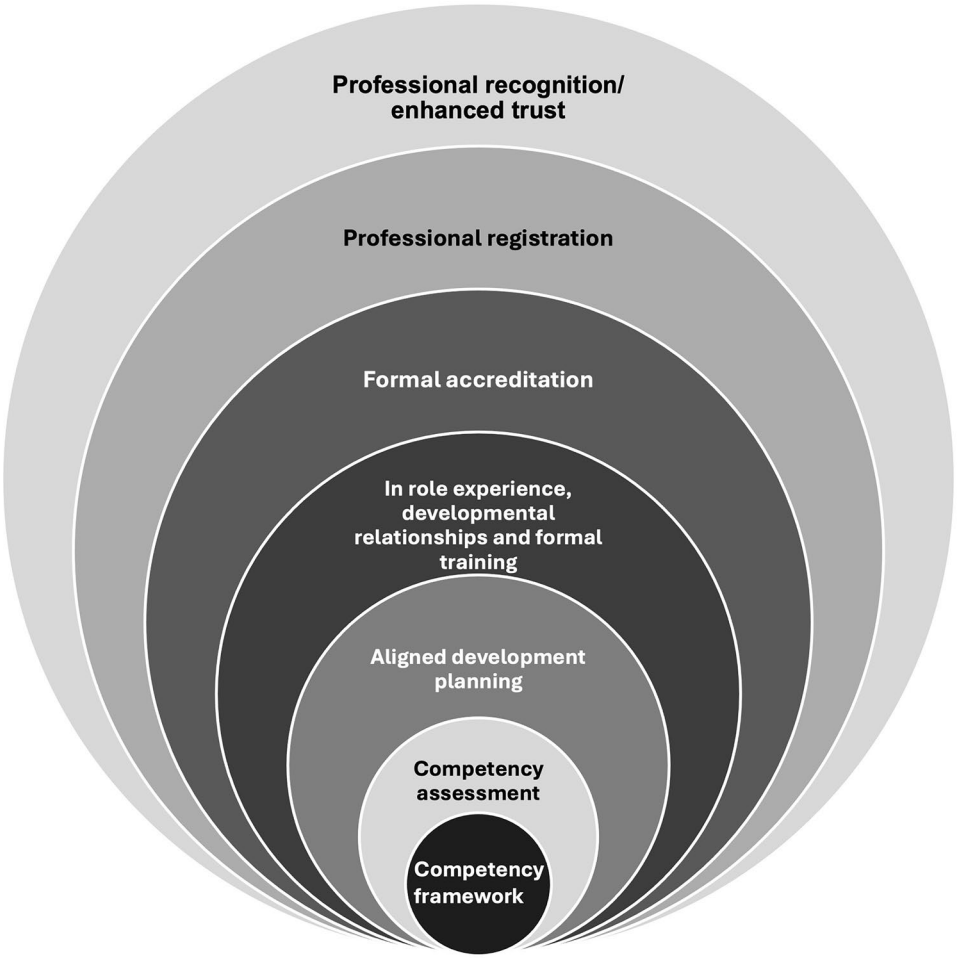

Fig. 1 Competency frameworks as a step toward professional recognition and trust. Assessments against an aligned set of competencies can support effective individualised development planning, including formal training tailored to identified opportunities. Over time it is envisaged that formal accreditation could recognise attainment and contribute to obtention and/or maintenance of professional registration. Ultimately formal processes of this nature are envisioned as supporting trust for the profession and the industry

six core competency domains and proficiency levels, the framework provides a structured pathway for career growth, role development and professional standardisation. The MAPA Competency Framework addresses the need for consistency, excellence and alignment in MA practices, benefiting professionals and aligning with quality use of medicines. It offers a practical tool for individuals, organisations and educational providers to guide training, performance assessment and workforce planning and provides a structured path for career growth and role development to help Medical Affairs professionals reach their full career potential.

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Declarations

Conflicts of Interest OC is an employee of the University of Sydney and was previously an employee of UNSW and has an adjunct appointment at UNSW; MB is a higher degree research student at UNSW and Medical Director at Medwise Consulting. CS is a current employee of AbbVie. AW is a freelance consultant, Non-executive Director of Faciobiotherapies and was previously an employee of Servier, Abbott, AbbVie, GSK, Gilead Sciences and Bayer. SM is the Medical Director of Amicus Therapeutics Pty Ltd. NA is an employee of Amgen. DT is an employee of the University of Sydney and a director of Axis Health Co Pty Ltd. He was previously Head of APAC information and Technology at Roche. VE is an affiliate of the University of Sydney and Chief Medical Officer at Qbiotics. She was previously an employee at Amgen. Views of all authors are their own and do not necessarily reflect those of their organisations.

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Ethics Approval Not a clinical trial.

Consent to Participate Not a clinical trial.

Consent for Publication Not a clinical trial.

Code Availability Not applicable.

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