



**ACADEMY**  
FOR PATIENT CENTRED  
EXCELLENCE AND INNOVATION  
IN REGULATORY SCIENCES



The Academy for Patient Centred Excellence and Innovation in Regulatory Sciences was launched under the auspices of the Malta Medicines Authority (MMA)



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## Introduction

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences was launched in 2019 under the auspices of the MMA which triggered the process for registration as a Further and Higher Education Institution. This focal milestone in the recognized track-record of the MMA serves to share the impetus, vision and commitment towards excellence in advanced sciences. Looking forward, the Academy shall design, develop and deliver programmes that meet stakeholder needs and expectations, encompassing the pertinent elements of innovation, optimization and accreditation.

## Mission statement

To advance and disseminate knowledge, innovation and skills development in the life-sciences sector, through collaborative reasoning and multidisciplinary educational initiatives that translate regulatory standards of good practice into day-to-day excellence.

## Rationale

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences was set up to serve as a key platform within the portfolio of the MMA, through which educational planning and academic development unfold, enabling the delivery of training that is tailored to the evolving needs of stakeholders. The established framework is intended to portend mutual benefits to regulators, policy makers, industry professionals and society at large.

## MAIN STAKEHOLDERS

- General public, students, patient groups and consumers
- Medical practitioners, dentists, pharmacists, pharmaceutical technologists and other healthcare professionals
- Marketing authorisation holders, manufacturers, importers, brokers, wholesale dealers, qualified persons, responsible persons, pharmacy owners and notified bodies
- Licensing Authority / Superintendence of Public Health
- Government and national institutions
- European institutions, including European Commission, European Parliament, Council of Europe, European Council, European Court of Justice, European Medicines Agency (EMA), Heads of Medicines Agency (HMA) and other National Competent Authorities within the EU network
- World Health Organisation and third-country National Competent Authorities
- Chambers, unions, associations, employees and suppliers
- Academia, media and others

## Aims & Objectives

To establish an ecosystem which merges research, education and best practices in science-based endeavours within a regulatory environment.

To offer a networking forum with a vision for excellence in science and technology.

To strengthen national and international collaboration in priority areas.

To design and organise training courses, embracing new trends and developments.

To provide for continuous education through interaction with experts in innovative spheres.

To sustain opportunities that facilitate the exchange of views, enhancing competence and overcoming emerging challenges through collaborative reasoning.

To disseminate scientific acumen and stimulate innovative research initiatives.

To support continuous quality improvement in processes and services, and spearhead community empowerment.

# 01

## Policy for Internal Quality Assurance (IQA)

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences supports a quality culture intended to encourage continuous improvement in the learning experience and corresponding outcomes. An ongoing cycle of reflective practices is fostered within the academic community, both internally and externally, as an integral component of a holistic, excellence-seeking approach. The Academy is backed by the robust, audited, Quality Management System (QMS) implemented within the MMA, which serves to ensure commitment towards consistently meeting established standards across guidance, policies and procedures, aligned with the organizational purpose and strategic direction.

### 1.1 The Quality Assurance System

- Underpins the responsibility that the Academy embraces for upholding continuous quality enhancement and accountability.
- Evolves on the basis of a quality cycle and is constantly reviewed to attest fitness for purpose.
- Considers the ethos of critical reflection, collegiality, and stakeholder engagement, as key drivers for the identification of opportunities for improvement.
- Ensures that the courses provided by the Academy are effectively devised, communicated and delivered, fulfilling the expectations of stakeholders.
- Reflects the National Quality Assurance Framework for Further and Higher Education (2015), the Standards and Guidelines for Quality Assurance in the European Higher Education Area (ESG, 2015), relevant Malta Further and Higher Education Authority (MFHEA) guidelines and applicable legislative provisions.

Quality policies and objectives are also based on ISO management principles – customer focus; leadership; engagement of people; process approach; improvement; evidence-based decision making; and relationship management. The current Medicines Authority Strategy to 2025 embraces research, technology, development and innovation among its key strategic goals, with feedback obtained from the corresponding public consultation highlighting relevant training needs identified by stakeholders. The five-year strategic planning cycle is supported by Key Tasks and Performance Targets (KTPTs), both qualitative and quantitative, which are developed on an annual basis, cascading on the operational plan, being communicated, monitored, reviewed and evaluated accordingly. Personnel may initiate the review/amendment/introduction of

processes through an established quality improvement procedure, which entails root cause analysis, action plan, implementation and appraisal. Processes and systems are subject to internal audit, through a risk-based plan. An overall risk register is in place, updated in line with input from management, staff, auditors, stakeholders, and public reports, among other routes. Ad-hoc audits may be performed and opportunities for quality improvement and corrective actions are identified as necessary. Management review oversees performance and measurable outcomes from each directorate, audit results, QMS processes including quality improvements and deviations, as well as customer feedback and complaints.

Quality assurance is effective across the organisational structure, adopting shared ownership and responsibility for efficient implementation of good governance and harmonisation of procedures. The MMA has an internal Audit Strategy Programme based on a 5-year cycle, in tandem to periodic assessments carried out by established institutions, reviewing efficiency and effectiveness, including the implementation and maintenance of the QMS. In 2013, the MMA was awarded the International Standard Organization (ISO) 9001:2008 certificate attesting its commitment towards meeting the needs and expectations of stakeholders and ensuring quality in its processes and output. The MMA was thereafter recertified in line with the new standard ISO9001:2015.

Values and ethics management covers all practices, translating into motivating working objectives for meeting deadlines and commitments, interdepartmental communication and coordination, adaptability, flexibility and mobility, corporate responsibility and integrity. Conflict of interest declarations are updated, at least annually, by all members of staff and external experts, with any applicable controls, such as defined measures/restrictions, being implemented accordingly. An internal newsletter is issued on a regular basis to keep staff members informed and engaged.

Academy staff spearhead the development of courses, entry regulations, methods of assessment, monitoring of participant progression and performance, and evaluation exercises. Speakers sustain quality enrichment in the training of participants, whilst encouraging adult learners to advance proactive responsibility for their own learning. Collation and analysis of contributions from stakeholders, with first-hand experience of the course itself, are considered crucial in maturing the Academy's IQA Policy. Regular appraisals of the implemented systems are essential in light of the rapidly evolving contexts. The Academy nurtures an extensive network of collaboration with recognized bodies and pertinent experts, portending significant potential for external peer reviews, to recognize areas for enhancement and exchange best practices. Public dissemination of the standards of quality assurance, described forthwith in this document, shall communicate the ongoing quality processes, portray the academic infrastructure and facilitate informed decisions by prospective course participants.

## 2.1 Leadership and management

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences, operates within a defined organizational structure (Figure 1). The Academy falls within the portfolio of the Advanced Scientific Initiatives Directorate, which is one of the directorates at the MMA. It is supported by central functions related to operations and human resources, quality, intelligence, information and communication technology, finance and corporate services.

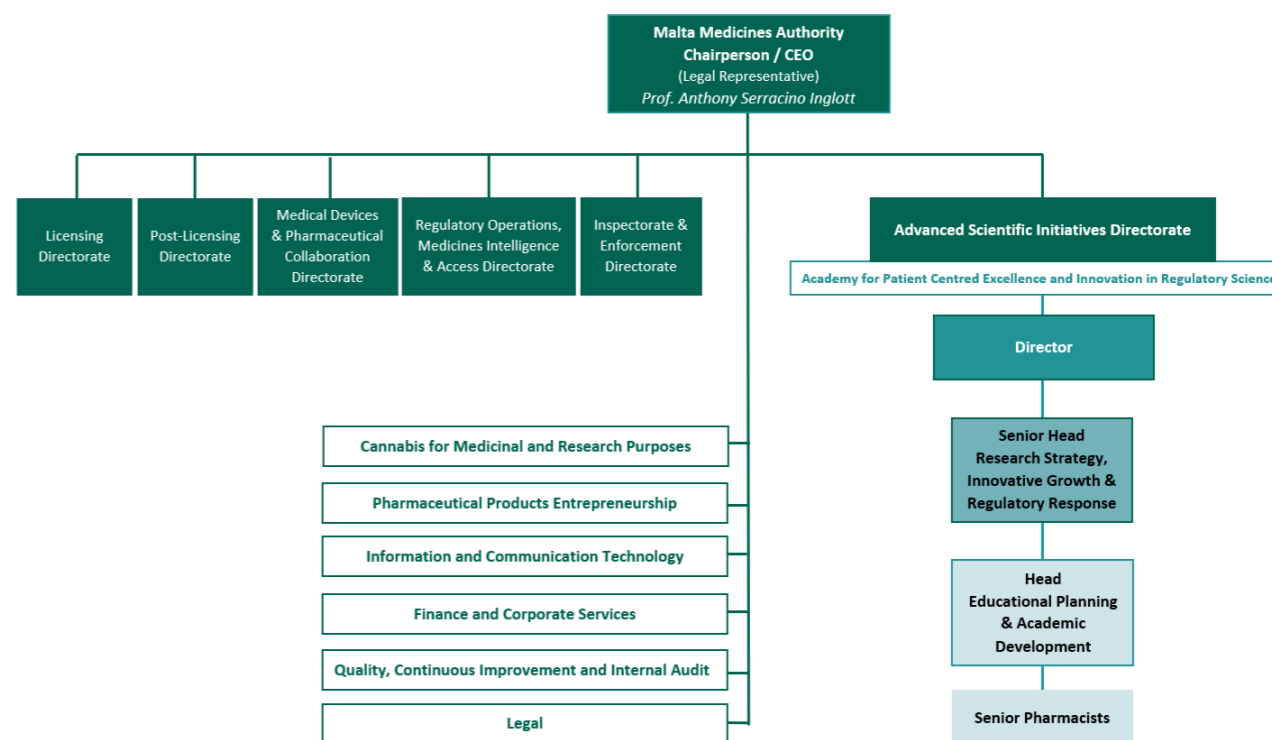


Figure 1: Organisational Structure

The MMA is established through the Medicines Act (Chapter 458 of the Laws of Malta). Appointments are based on the respective provisions and build upon the general guidelines on eligibility benchmarks defined in the Manual for Public Sector Entities: Delegation of Authority to effect Recruitment and Promotions. The respective calls for filling of vacant posts within the Academy include the overall purpose, engagement criteria and functions. The current minimum eligibility criteria for appointing a person in a managerial position are:

- (i) Proficiency in the Maltese and English languages;
- (ii) Proven commitment to learning and development;
- (iii) (a) A recognised Doctorate qualification at MQF Level 8 in Pharmacy, or a comparable professional qualification, plus two (2) years relevant work experience of which one (1) year must be in the area(s) identified for the post, e.g. management position, carrying out duties within an academic institution, scientific research dissemination, leading innovative projects; or
- (b) A recognised Master qualification at MQF Level 7 (subject to a minimum of 60 ECTS/ ECVET credits, or equivalent, with regard to programmes commencing as from October 2008) in Pharmacy, or a comparable professional qualification, plus three (3) years relevant work experience of which two (2) years must be in the identified area(s); or
- (c) A recognised Bachelor qualification at MQF Level 6 (subject to a minimum of 180 ECTS/ ECVET credits, or equivalent, with regard to programmes commencing as from October 2003) in Pharmacy, or a comparable professional qualification, plus five (5) years relevant work experience of which three (3) years must be in the identified area(s).

Applicants who do not hold a post-graduate qualification shall be required to register and attain a related post-graduate qualification within a stipulated timeframe.

Eligible candidates proceed through the selection process which involves a formal interview and grading against a marking scheme pre-established to determine fitness for the specific role. A one-year probational period applies and the process of performance appraisal monitors that the relevant goals are being achieved.

## 2.2 Finance

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences is supported by the central finance and corporate functions of the MMA. An annual rolling budget, covering at least three years, is prepared in line with the policies and initiatives to be implemented by the Academy. The financial planning process includes activity forecasts, revenue and expenditure estimates, taking into consideration the strategy and risks of the organisation. Resources requirements are identified in relation to key tasks and performance targets. The Academy analyses changes in requirements and financial trends, which are taken into consideration during budgeting and human resources plans, as applicable.

To ensure economic stability, the allocation of financial and human resources is based on set priorities, alongside fixed recurrent commitments, such as IT maintenance contracts and lease of property agreements. The draft budget is approved by the legal representative of the entity and communicated to the line Ministry. Forecasts may be revised along the year, in response to recognised variants, which inform the preparation of forthcoming budgets.

In line with Chapter 458 of the Laws of Malta, proper books of accounts are kept in such manner as the Minister of Finance may from time to time direct. Such accounts are audited by an auditor appointed for the purpose and are subject to audit by the Auditor General.

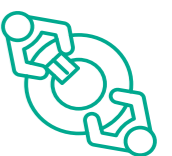
## 03

### Design and Approval of Programmes

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences nurtures a proactive approach in putting together a dynamic programme portfolio. A yearly plan is preliminary devised, supported by an ongoing evaluative review process which enables informed decisions on which courses shall be offered on a regular basis, which new areas need to be catered for, and also consideration of evolving contexts that may urge effectual development of tailor-made programmes.

#### Prospective programmes are identified through two main routes:

##### i. External feedback from stakeholders



The extensive dialogue of the MMA, and the Academy itself, with diverse stakeholders, allows the formulation of demand-led courses. Training-needs analysis is encouraged and discussed through regular stakeholder meetings and bilateral meetings with associations, industry representatives and individual operators. Proposals are also received through a stakeholder survey which is carried out on a periodic basis and through recurrent consultative exercises. External feedback on academic initiatives may be submitted any time through the online educational needs analysis form, while course feedback forms enable collation of comments on the specific initiative delivered, as well as future perspectives. Liaison with governmental entities responsible for education, health, consumers, business and industry growth, provides additional pointers.



## ii. Internal horizon scanning

Through active participation in important EU fora, including the Innovation Network (EU-IN) and the Network Training Centre (EU-NTC), apposite capacity for horizon scanning in relevant areas is developed. The Academy identifies thematics of particular importance, based on contextual developments, training availability through alternative sources, and relevance to stakeholders as prospective participants, whilst embracing European and national priorities.

### Programmes are drawn upon the general principles integrated within the processes for designing courses, which are intended to:

- Stimulate intellectual curiosity to novel heights
- Embolden advanced scientific research and innovation
- Foster the sharing of knowledge through critical thinking and networking
- Promote learning beyond boundaries for sustaining excellence in practice
- Inspire effective leadership and professional commitment
- Build on the potential of national, European and international stakeholders

### Steps involved in designing, developing, and approving a new course:

- (i) Identifying topic area and corresponding background research
- (ii) Formulating course title, target audience, aims & objectives and learning outcomes
- (iii) Determining duration, number of ECTS credits, type of course, MQF Level and eligibility criteria
- (iv) Drafting course content including primary subjects to be covered and corresponding resources
- (v) Establishing potential speakers, course dates and fees
- (vi) Confirming teaching methods, time to be allocated per subject, mode of delivery (face-to-face or online/blended learning) and methods of assessment
- (vii) Submitting application for 'Accreditation of Education Programmes within the Malta Qualifications Framework' to the MFHEA
- (viii) Upon approval, compiling and disseminating programme information leaflet, schedule and registration form

The **Director, Advanced Scientific Initiatives**, as Head of Institution (MMA Academy), has the overall responsibility to oversee and review the technical/scientific processes of course design, development and approval.

The **Head, Educational Planning & Academic Development**, has the responsibility to coordinate design, development and approval processes for scientific/technical courses; support designated employee(s); and ensure necessary approval(s) are in place.

## 04 Student-centred learning, teaching and assessment

The andragogical mindset of the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences aims to deliver an educational approach built around stakeholder needs, with an emphasis on the involvement and empowerment of participants. The focus of quality teaching and learning revolves around a process that advances individual aptitudes for continuous development, informed judgement and practical implementation of achieved competences.

### 4.1 Learning and teaching delivery, participant engagement and self-reflection

Participants are in the centre of all academic initiatives. Professionals within the Academy, by way of their learned experience, plan educational interventions which integrate knowledge dissemination and collaborative reasoning. Speakers are assigned training sessions in line with their relevant field of expertise which is leveraged in the delivery of interactive courses. Trainers and participants engage in discussions and debates, exchange ideas, and collectively analyze evolving scenarios and prospective outcomes. In tandem, participants are encouraged to work on independent critical thinking and become proactive leaders in their own learning process.

Course participants should spearhead personal growth and development through initiative, inquisitiveness, and informed choices. Programmes of the Academy stimulate individuals to challenge assertions, explore upshots and propose solutions, alongside effective communication practices which are key to a deep understanding. Participants shall recognize their own strengths while improving confidence to seek assistance through appropriate channels. A questioning approach is welcomed within the Academy, whereby trainers are reflective professionals themselves, creating an apposite backdrop for respectful interactions and quality feedback.

Through a dynamic educational approach, encompassing constructive communication and access to proficient peers, an amalgam of teaching methods is presented to enrich the academic experience. Speakers are encouraged to adopt techniques which involve participants, including learning that is case-based, problem-based, experience-based, and research-based. The face-to-face mode of delivery, in the form of classroom-based training, shall incorporate presentations and standard learning resources, alongside workshops, group tasks, interactive question and answer sessions, practical exercises and networking activities.

When deemed appropriate, in terms of course content and the anticipated learning outcomes, further flexibility may be offered to participants through the inclusion of an online learning component. Media platforms would accommodate online modules and recorded webinars, as well as live sessions that support full interaction, both verbal and written, among speakers and participants in the virtual classroom. Going forward, the provision of blended learning may be considered on a course-specific basis, subject to the relevant MFHEA review and approval processes. Irrespective of the learning environment or place of delivery, type, level or duration of the course, all sessions shall be prepared and delivered to the highest standards.

### Through the established systems, the Academy shall:

- Develop courses based on comprehensive integration of theoretical, regulatory and practical aspects, informed by current scholarly research and innovative developments;
- Impart distinguished standards of teaching, learning and assessment in liaison with thematic experts, to encourage the sharing and dissemination of best practices;
- Set and follow learning objectives, appropriate to the intended level, as established through MFHEA for accredited courses;
- Monitor and keep record of all work relevant to the delineated requirements and outcomes;
- Build on participants' prior knowledge while promoting independent learning where appropriate;
- Implement diverse study methodologies according to the aptitudes and expectations of the target audience;
- Provide complete schedules and individualized guidance, enabling participants to plan and progress within the respective programme;
- Measure improvements, through informal and formal assessments, as applicable;
- Recognize mistakes as an integral part of the learning curve, while acknowledging achievements and success;
- Evaluate feedback from all stakeholders to inform, inspire and ameliorate processes.



## 4.2 Assessment, evaluation and complaints

Assessment promotes involvement of participants through the understanding of their own learning strategies and progress. Participants may have different learning styles - activist, theorist, pragmatist and reflector. Programmes including assessments are designed to integrate multiple learning strategies to enable progress through the means by which the individual learns best. Formative feedback, particularly through timely verbal communication, is provided in response to effective questioning and engaging activities throughout the courses, emboldening dialogue and motivation, as well as knowledge recall, analytical thinking and evaluative skills. Interactive sessions are intended as an opportunity for course participants to assess scenarios, process information, spur reflections and consider potential areas for development. Learning resources, relevant to the respective courses, are made available to participants who may refer to the material covered for completing assessments. Participants shall actively contribute in the learning process and meet assessment requirements diligently, honestly, and punctually. Individuals are encouraged to discuss perceived difficulties and seek any clarifications on assessment procedures directly.

Academy staff, in liaison with expert speakers for the respective course, shall develop assessments, consistent with the learning objectives, providing good and equal opportunities for participants to succeed. Methods of assessment, involving formative and/or summative means, depend on the intended outcomes that participants are expected to achieve from a particular programme. Different assessment strategies and tasks include workshops, case-studies, multiple-choice questions, open-ended questions, practical exercises, situation analysis, oral communication through questions during classroom discussions or similar interactions such as quizzes, as well as reading, research, and relevant assignments. In general, all assessments are carried out in English and coursework is submitted in hard copy or electronic form, as specified for the individual course. To ensure assessment fairness and consistency, assessment is based on a pre-defined marking scheme, with clear alignment and uniformity across all assessors. When grading is entailed, the work is marked by a first assessor, followed by a second assessor's review and internal verification. The grading system is as follows: A+ (95%-100%); A (80%-94%); B+ (75%-79%); B (70%-74%); C+ (65%-69%); C(55%-64%); D+ (50%-54%); D (45%-49%); and <45% (F-Fail). The results are made available to participants in writing within around four weeks of completion. Suspected cases of potential academic dishonesty, misconduct or fraud, are referred to Academy management for consideration and investigation, such as screening through an established plagiarism detector. The respective participant would be informed of the outcomes and corresponding actions in writing.

Mitigating circumstances are considered by Academy management on a case by case basis. Should a participant wish to contest exigent course-specific concerns related to performance, such as unsuccessful completion, the individual is to contact the Academy via email within one (1) week of becoming aware of the dissatisfying outcome.

The course participant shall be asked to provide the required details and will be entitled to an appointment with Academy management to discuss any questionable issues, as may be related to attendance and/or assessment, and thereafter, if still unresolved, may refer the matter, within one (1) week of the said appointment, to the Head of Institution for settlement. MFHEA shall act as guarantor of participant rights.

The Academy welcomes direct submission of comments, suggestions and other forms of constructive input via email ([academy.medicinesauthority@gov.mt](mailto:academy.medicinesauthority@gov.mt)) or alternative routes that may be deemed fit, after which the Academy shall revert back to the submitter. Complaints are also considered as source to identify opportunities for improvement. Procedures are in place to ensure that complaints are subject to a full and comprehensive investigation, receive a response and are examined for corrective and preventive actions. An online form is perpetually available for the lodging of complaints. Internal staff shall ensure that all complaints, irrespective of the inherent nature and submission route, whether orally stated or formally written, are dealt with fairly and promptly through the necessary measures, in line with the MMA communication, consultation and customer satisfaction policy that is effective across the organisation.

Upon course completion, evaluation forms are made available in an electronic format for real-time collation of feedback and subsequent analysis by Academy staff. Participants may provide feedback anonymously to ensure authentic and unfiltered responses. The evaluation of courses enables participants to comment, shape and improve courses through feedback on: teaching style and speaker characteristics; achievement of learning outcomes; course duration and difficulty; relevance to work or area of practice; points of interest and overall satisfaction. This provides a mechanism for Academy staff and speakers to reflect upon the effectiveness of course design, teaching, learning and assessment and to consider implementable changes for future courses. Enhancement prospects are followed up, with significant stakeholder involvement throughout the feedback cycle.



## 05 Student admission, progression, recognition and certification

Procedures covering the participant's educational cycle within the Academy shall be consistently applied through the phases of admission, progression, recognition and certification. Information on registration dates, mode of application and payment procedures for upcoming courses, shall be made available by the Academy via relevant media, together with course delivery dates and applicable terms and conditions. Applications shall be processed according to pre-defined criteria, established on principles of transparency and accountability. Participants must be registered and proof of payment made available before the first session of the course. Enrollment of a course participant may be invalidated, suspended or terminated if relevant requirements are not met.

### 5.1 Student admission

Individuals who wish to enrol for a course offered by the Academy shall submit an online registration form which includes the MMA Academy Student Agreement accessible through a link provided in the electronic information made available. In general, the following details are requested at registration stage: Title; Name; Surname; Identity Card/Passport Number; Nationality; Gender; Date of Birth; Age; Any type of impairment; Contact number; Email address; Office Address; Locality of Residence, Profession; Job title; Organisation name (if applicable); Upper Secondary Qualification; Country of obtainment of Upper Secondary Qualification; Highest Academic Level; Full title of Highest Academic Level Qualification(s); Country of obtainment of Highest Academic Level Qualification(s); Declaration; and Payment details. Prospective participants who are unable to compile the online form may contact the Academy for assistance in the registration process.



Upon receipt of application, the Academy validates all information provided, including evaluation of whether the prospective participant fits the course eligibility criteria and if any supporting documentation (e.g. certificates/CV/references), as may be relevant to the entry requirements, is deemed necessary. The Academy shall take into account prior educational experiences. In general, eligibility criteria and entry requirements relate to the academic qualification(s) relevant to the course being offered and the corresponding MQF level. The Academy management shall consider relevant work experience of mature individuals<sup>1</sup> as source of informal and/or non-formal learning to ascertain that their background is adequate to follow the selected course with benefit. Applicants are contacted via email to provide any missing information, or any additional documents required in completing the registration process. In cases of ineligibility, the Academy shall communicate with applicants and guide prospective participants in identifying apposite courses.

Once application processing is completed successfully, participant details are logged into an internal system for record and contact purposes. Within ten (10) working days, the Academy sends a confirmation email to the candidate who is informed about being accepted for the respective course. An induction package is prepared for registered participants, including background on the Academy, programme and speakers, any related upcoming courses, contact information, detailed course schedule, and any other relevant documentation.

<sup>1</sup>Individuals who have attained the age of 19 years, 21 years, or 23 years, for entry to programmes at MQF level 3, MQF level 4, or MQF level 5 (and higher) on the National Qualifications Framework respectively.

### 5.2 Progression, recognition and certification

Participants are informed about progression requirements for course completion, including details on the time and effort involved, and effectively supported to pursue personal growth, development and progress. Programmes are supplemented with the necessary documentation including course and logistical material such as presentations and notes. At this stage, the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences is focusing on short courses, generally delivered over 25 hours, entailing limited analysis relevant to participant progression. Information, including attendance covering the respective schedules, assessment outcomes and evaluation records, pertaining to course participants is collected, monitored and retained for as long as necessary for the purposes for which it was processed (refer to section 8). Upon successful completion of a course ( $\geq 85\%$  attendance and  $\geq 45\%$  assessment), participants are granted a certificate with the the full name of the MMA Academy as approved by MFHEA, license number and category, name and surname of participant, title of the award/qualification as approved by MFHEA, the EQF/MQF level, the number of credits assigned, day/month/year when certificate is conferred, duration for the completion of the programme, the following statement as a clear indication that the programme has been accredited by MFHEA: "The Malta Further and Higher Education Authority (MFHEA) deems this certificate to be at level 'X' ('X' ECTS) of the Malta Qualifications Framework for Lifelong Learning.", logo of MMA Academy, logo of MFHEA, Head of Institution's signature along with respective full name and position within the MMA Academy, and unique identification number, ensuring transparency on the respective context, content and value.

The operational structure embraces ongoing discussions to provide a flexible and adequate engagement strategy for the required expertise. Multi-annual plans, covering human resources and capacity building, reflect the strategy, alongside potential market and contextual changes. Speakers in courses delivered by the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences are recognized professionals, appropriately qualified, with profound knowledge and practical experience in the relevant field. Expertise, coupled with applied understanding, enables enrichment of the teaching and learning experience within the programmes.

Tutors have qualification(s) of MQF levels higher than the courses delivered and additional requirements, such as thematic specialization which may be particular to specific programmes, as determined on a case-by-case basis. MQRIC recognition, prior teaching experience, communication skills, continuous professional development (CPD) and conduct are considered accordingly. Internal staff who contribute to the designed courses, hold pertinent academic degrees as well as a strong commitment towards educational initiatives and active participation in international fora. In ensuring the upkeep of competent human resources, additional training needs are discussed during management review, considering proactive feedback from annual one-to-one appraisals carried out by line management in their capacity as appraisers. Relevant appraisal records are kept in the employee's personal and training files. The ingrained principle of flexibility allows re-allocation of resources within or across departments, in line with determined priorities.

The open ongoing expression of interest provides a fair and transparent means to ascertain a continually updated database of external experts who may be engaged whenever additional resources are deemed necessary and to ensure that latest developments are integrated within Academy programmes forthwith. Systems are in place to facilitate outsourced expertise through contracts for service whereby specialized professionals are assigned defined workloads, or through agreements with recognized bodies that provide expert speakers in distinct technical areas. The respective processes are documented, approved, and evaluated in line with set practices. Additionally, Memoranda of Understanding (MoU) with other European counterparts are in effect, alongside strong collaboration within the European medicines regulatory network, to support the availability of external capacity if required.

The enabling framework in place portends the dissemination of up-to-date developments in the respective areas and promotes strengthening of the link between education, research and innovation. The latest teaching methodologies are explored and following review of respective personal files, including training records, during performance appraisals, the teaching staff is supported to upskill andragogical competences through CPD sessions and relevant exposures. Academy personnel review the material that speakers may wish to present in the respective courses, and follow the delivery of the programme itself, valuing the clarity of slides and theoretical explanations, communicative fluency, and response to queries. Any feedback relevant to the speakers, whether internal or provided by participants, is communicated by apposite means such as interface meetings and email correspondence, and opportunities for improvement discussed and documented.

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences is committed to provide an effective learning environment that facilitates access to coherent, high-quality resources. Support mechanisms shall accompany individuals from preliminary interest and enquiry, through application and registration, and all across the programmes.

### 7.1 Allocation of resources

Professional development and international exposures are a top priority within the MMA and as reflected in the budget, over 10% of the organisation's revenue is allocated to continuous staff training. The approach cascades to the Academy whereby systematic analysis of operational and training needs leads to a structured competence framework covering scientific and regulatory matters, leadership and soft skills. An established policy provides for the planning, implementation, monitoring, evaluation, certification and documentation of corporate training and development activities. Personnel participate in the EU Network Training Centre, both as trainees and trainers, as well as in targeted modules delivered by central government and other agencies on horizontal aspects including security, communication, IT, policy, personal development and management. Initiatives are extended to twinning projects and intensive programmes tailored to specific internal needs, such as train-the-trainer collaborations with The Organisation for Professionals in Regulatory Affairs (TOPRA). Performance appraisals and management review carried out on a yearly basis, internal and external satisfaction surveys carried out at appropriate intervals (example every three years), and feedback from

stakeholders, serve to identify areas requiring further allocation of resources. Results and outcomes are discussed by management and targets assigned accordingly.

Diverse learning resources are available for academic staff through an established intranet which is regularly updated and includes legislation, guidelines, circulars, SOPs, policies, reports, training material, presentations and documentation from various fora. Affiliations and close cooperation are fostered with recognised institutions, including the University of Malta, through collaborative initiatives which support the sharing of expertise and information resources. Besides access to the wealth of knowledge hosted at the main national university, an in-house library is accessible to Academy staff, along with a number of scientific databases and active subscriptions in electronic form, including Up-To-Date (Wolters Kluwer), Pharmaceutical Press and Medicines Complete reference media. The virtual tools made available enable access to the latest resources for the preparation of course material which is provided to participants enrolling in Academy programmes. The ICT infrastructure, assisted by central back-up and technical support, offers a well-trying platform for the prospective delivery of online learning.

## 7.2 Support structure

The Academy shall guide and support all participants, understanding their learning and development aspirations, as well as work and personal commitments. The provision of a safe and inclusive environment, tantamount to the Academy's earnest value of equality, condemns all forms of discrimination related to age, gender, origin, religion, cultural beliefs, social status, disability, sexual orientation or any other grounds.

Information to participants on course specific resources will be included in the induction package. An open-door policy is implemented across the Academy which provides for various routes of communication, including one-to-one meetings in person, together with teleconferences and correspondence, both on academic and non-academic matters. A centralised email address ([academy.medicinesauthority@gov.mt](mailto:academy.medicinesauthority@gov.mt)) is made available on all means of communication, providing a route for seeking support at any stage, from pre-registration to post-completion. This generic mailbox is accessible to the Director, Head, and Senior Pharmacist who assess any requests received and identify the individual fit to address the matter. Queries related to enrolment, fees and logistics, as well as clarifications on course content, speakers, and certification are addressed by the Academy staff. Participants are encouraged to interact with speakers during the programme itself, albeit support measures such as ad-hoc meetings shall still be made available upon completion should the participants wish to connect on specific issues or to share further feedback. Evaluation forms made available upon course completion shall enable collation of feedback on academic support services.

Information gathered is managed in line with the EU General Data Protection Regulation (GDPR). An overview is available on the MMA website. A records management procedure is in place, highlighting where, and for how long, each category of document is maintained/retained/archived, as well as the responsible officer. The applicable media, file identification name, indexing method, retrieval, protection, retention period ( $\geq 40$  years), and disposal method are stipulated within the approved procedure. Information collected, analysed and monitored by Academy staff [Table 1] enables profiling of the participant population, course participation and assessment, retention and success rates and participant satisfaction. Relevant information is discussed with management in line with the corresponding exigencies and statistics are collated periodically for inclusion in the Annual Report.

Information security is part of the risk management process. The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences operates within the premises of the MMA, which are controlled with regulated access control, CCTV cameras and 24/7 security. The MMA has a fully-fledged ICT infrastructure, which is part of the quality management system. Procedures are in place to raise requests on newly identified needs. Information systems audits review appropriateness of data servers, back-ups and crisis management. The e-mail system can be accessed remotely over the Internet. A number of employees within each function, including the Academy, have access to the virtual private network, enabling continuity of work from outside the offices in case the premises are not available. Individual access profiles are assigned centrally through a change-management system on the basis of documented profiles, with different front ends being available depending on the level of access of the user. A paperless approach is implemented, albeit an electronic register is in place to track any incoming/outgoing paper documents.

i	Collected		Analysed		Monitored	
	When	How	When	How	When	How
<b>Participant details and admission records</b>	Upon application submission	Through Application Form and supporting documents; transcribed in records	At application validation stage	Review of completeness, correctness and relevance of submitted data	At registration stage	Participants are contacted in case of missing information, and when eligibility is confirmed
<b>Course participation and attendance</b>	At each session of the course	Through Attendance Sheets, compiled based on registered participants; transcribed in records	During, and at completion stage, of the respective programme	Review of attendance records and retention rate	Throughout programme	Participants who fail to attend are contacted, as deemed necessary
<b>Assessment</b>	During the course	Through formative/summative assessments; transcribed in records	Upon assessment submission	Reviewed, graded, and recorded, as applicable	Throughout programme	Constructive feedback is exchanged with participants
<b>Progress and achievement</b>	During, and at completion stage, of the respective programme	Through attendance and assessment records	At completion stage, of the respective programme	Review of records: registration, participation and assessment outcomes, leading to the granting of certificate(s), or otherwise	Retrospectively, including comparative analysis across programmes	Success rate evaluated
<b>Participant Satisfaction</b>	At the end of the programme	Through Course Evaluation Form	Upon evaluation form submission	Comprehensive assessment of responses	At completion stage of the respective programme and during periodic review meetings	Follow-up through course evaluation exercises

Table 1: Summary of data collection, analysis and monitoring

The communications policy effective within the MMA encompasses the functions of the MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences. The MMA website hosts information published by the Academy, including News & Events, and presents the possibility to subscribe for SMS and e-mail notifications. The subscription facility allows for the regular updating of an established stakeholder contact list. Dissemination through the active social media platforms - LinkedIn, Facebook and Twitter, supports stakeholder engagement and interaction. Regular evaluation exercises, for example through evaluation forms intended for course participants, and periodic surveys covering diverse areas, including needs and expectations, satisfaction levels, and suggestions for improvement, help in evaluating and ameliorating the effectiveness of public information and communication tools. Proactive measures to ensure transparency are implemented, with continual update of webpages and online reports. External representations, governed by the respective procedures, include presentations in international fora, participation in targeted media programmes, publication of information leaflets, as well as dissemination to generic electronic mail accounts.

Information on Academy accredited programmes, which may be accessed in electronic form by prospective participants through the MMA website, email dissemination and online media platforms, includes: course title, accreditation category, name of accreditation body, description, EQF/MQF level, number of ECTS, mode of attendance, duration, hours of total learning, dates, venue, learning objectives and outcomes, target audience, teaching and assessment methodologies, entry requirements including link to Identity Malta's VISA requirement for third country nationals, mode of delivery including language of instruction, time schedules, fees, link for registration purposes, contact details, and the award/certification conferred.

All material is compiled by Academy staff and is reviewed and approved by the Head of Institution prior to publication. Thereafter, it is followed up for ongoing relevance and user-friendliness of up-to-date information. Public relations and communications are coordinated centrally, in collaboration with governmental and non-governmental bodies as may be required.

## 10 Ongoing monitoring and periodic review of programmes

The quality culture fostered within the Academy entails commitment for continuous development and enrichment. A variety of methodologies are integrated for strategic and operational planning, including SWOT and PESTLE analysis, considering internal factors such as motivation, systems and infrastructure, and external factors such as stakeholder demands and contextual developments. Key performance targets are determined, and resources allocated, followed by a systematic approach including holistic evaluation of operations, for continuous quality improvement along a PDCA cycle.

Established internal processes facilitate training needs analysis and planning of course content, learning material and assessments, mapped to pre-established aims and objectives of the programmes offered. Developments in relevant ecosystems are studied through ongoing advanced research, high-level networking and horizon scanning. In developing the MMA Strategy, encompassing Academy initiatives, a series of consultation sessions with external stakeholders, including employers, are carried out to gather knowledge and understand their needs. This is considered essential to maintaining healthy industrial relations based upon mutual respect, which in turn is key to meet the respective expectations.

Longitudinal analysis involves evaluation of input from all stakeholders, including changes in training needs, as collated through consultation exercises, interface and bilateral meetings, satisfaction surveys and course feedback submissions. Liaison with MMA external experts, internal professionals who are actively involved in the delivery of high-level courses as lecturers within established universities, alongside ministries, organisations, and representatives from varied spheres, including health, consumer protection, business and industry, helps to identify areas of continuous importance that are being satisfactorily addressed and how Academy programmes may further assist to address current challenges and evolving contexts.

Planning is followed by actions to manage relevant changes, which may involve, for instance, the re-evaluation of course content and delivery, inclusion of new material within a course in the light of amendments related to legislation, guidelines or standards, prioritization of emerging topics in consideration of evolving trends, and triggering processes for the development and approval of novel programmes.



Implementation engages teaching staff, administration, and Academy personnel at different levels, depending on the inherent nature of the change itself. Effective information management and communication schemes enable course participants to also play a central role in the implementation process and at evaluation stage. The latter entails assessment of whether performance and outputs of the identified interventions, meet the anticipated targets in terms of execution, effectiveness and impact. Internal and external feedback, auditing and review, strengthen the evaluative component of the cycle through constructive proposals for improvement.

Besides ongoing monitoring, Academy programmes are reviewed bi-annually to ensure that the aims and objectives of each course are achieved, the content delivered is relevant and reflects the dynamic targeted needs, and that implementation is in line with the Internal Quality Assurance policy. All feedback collated from stakeholders including course participants is considered in these review processes. Whilst it is anticipated that a successful accreditation process for Academy programmes shall reflect the expected standard, internal review is also committed to assess performance. Progress is discussed at management level, through presentation of Academy reports, at mid- and end of year, as well as during ad-hoc minuted meetings. An overall summary is published in the annual report while outcomes which may be relevant at individual level are communicated directly. Going forward, outcomes of ongoing monitoring and periodic review inform the Academy in its quest to adapt, advance, and plan further.

The organization is subject to strategic reviews, internal and external audits. A team of professionally trained independent auditors from different directorates within the MMA, implement a five-year audit strategy through an internal audit programme based on ISO standards. Audits are prioritized based on criticality of the process, risk assessment, results of previous audits and timespan elapsed. Improvement is embedded in the systematic approach adopted, which takes into consideration benchmarking indicators and the needs and expectations of stakeholders. In parallel, there is oversight of performance by the line Ministry, as well as external audits by competent government bodies, including the Standards and Metrology Institute (SMI) and the National Audit Office (NAO). Through internal and external expertise, constant evaluation is underway for all activities, as may be related to scientific/technical functions, business processes, projects, finance, information systems, people management and the local/international profile.

The MMA Academy for Patient Centred Excellence and Innovation in Regulatory Sciences is committed towards the effective execution, endorsement and enhancement of the quality culture, and shall be subject to an autonomous QA audit by the MFHEA every 5 years. This shall serve to ensure regulation, monitoring and support of the Internal Quality Assurance policy, for compliance with relevant obligations while catalyzing improvement perspectives through external reflection and advice. The Academy shall work in tandem with MFHEA to ensure that recommendations are implemented responsibly in a timely manner, upholding accountability, credibility, and good practice in fulfilling the strategic educational mission embarked upon.



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