Regulatory Sciences as applicable to Cannabis for Medicinal and Research Purposes

29-30 May, Malta Life Sciences Park, San Ġwann, MALTA

Addressed by:
Hon Dr Deo Debattista
Parliamentary Secretary for Consumer Rights, Public Cleansing & Support for the Capital City
Professor Anthony Serracino Inglott
Chairperson, Malta Medicines Authority

Speakers and contributors:
TOPRA trainer 1 (tbc)
TOPRA trainer 2 (tbc)
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Training outline

Practical overview on EU regulation of medicines and herbals, good practices, quality standards and guidance documents.

Target audience

Professionals with a patient-centered interest in cannabis for medicinal and research purposes, including representatives from industry, legal, recruitment and consultancy firms, project management, clinical and regulatory operations.

Provisional Programme	**29 May**
09:30	Introduction and welcome
10:00	Scope and objectives
10:15	The regulatory framework for medicines in the EU, including distinction between authorised medicinal products and other cannabis-based products
10:45	Medicinal product development process
11:30	Non-clinical development
12:15	The European clinical trials process
13:00	**Lunch**
14:00	EU Marketing Authorisation Application dossiers, including overview on well-established use
14:45	How medicinal products are registered and approval maintained – EU marketing application procedures (national, DCP, MRP, CP) – variations, extensions
15:30	Safety surveillance
16:00	**Coffee Break**
16:15	Lifecycle management
16:45	Regulatory strategy – generics, information protection, early access, trade names, scientific advice
17:30	Overview and interactive quiz
18:30	Transport from MLSP to social event
19:30	**Networking refreshments at The Sheer Bastion, Senglea**
22:30	Transport from social event to MLSP

	30 May
09:30	Cannabis for medicinal use – the local scenario
10:15	Quality and Pharmacopoeial standards
10:45	EMA guidance on herbals
11:15	GACP
11:45	GMP with focus on cannabis dosage forms such as dried flowers and oils
12:15	Panel discussion and Q&A
13:00	**Lunch**
14:00	Duties and responsibilities in manufacturing – QP, QA, QC
14:30	Workshops
16:00	**Coffee Break**
16:15	Consolidation, including common pit-falls in the field
17:00	Feedback and evaluation
17:30	**Close**