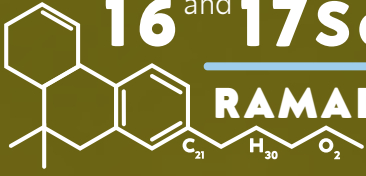


# PROGRAM

**16 and 17 September 2021**  
**RAMADA LISBON HOTEL**



## DAY 16

**PARTICIPANTS RECEPTION: 8H30 – 9H00**

**OPENING SESSION 1<sup>ST</sup> DAY: 9H00-9H30**

### Medicinal Cannabis Legislation Framework & Licensing and submission:

#### Pre licence to license

9h30-10h40

- > Portugal Overview
- > European Overview
- > Types of licenses
- > Applicable requisites
- > Main stages for acquiring a medicinal cannabis license

*Speakers: Eduardo Nogueira Pinto and Pedro Lomba, PLMJ*

**COFFEE BREAK: 10H40-11H10**

### Cannabis: A European market overview

11h10-12h05

- > Who are the licensed producers, the clients and the products?
- > Medicinal Cannabis and Hemp Differences and Similarities

*Speaker: Lukas Röth and Tobias Viegener, CSCLife*

### Route from GACP to GMP

12h05-13h00

- > Is there really a boundary?
- > Classification of medicinal cannabis operations - GMP or GACP

*Speakers: Nuno Santos, Stepwise Pharma & Engineering Miguel Fagundes, Botanical Holdings Plc.*

**LUNCH BREAK: 13H00-14H30**

### GDP for Medicinal Cannabis

14h30-15h15

- > Storage Conditions
- > Transport - Validation and Monitoring
- > Suppliers and Clients Qualification
- > Requesting an Import and Export permit

*Speaker: Hugo Barbosa, Rangel Pharma*

### Quality System for Medicinal Cannabis

15h15-16h00

- > General overview
- > Is there a difference between a GACP and GMP Quality System?

*Speaker: Fátima Godinho Carvalho, LEF*

**COFFEE BREAK: 16H00-16H30**

### Commissioning, Qualification & Validation

16h30-17h15

- > What is Commissioning, Qualification and Validation?
- > What are the requirements for GACP and GMP licensed facilities?
- > Best Commissioning, Qualification and Validation Strategies

*Speaker: Aldo Vidinha, Stepwise Pharma & Engineering*

### Traceability of Medical Cannabis Products

17h15-18h00

- > “Seed to sale” technologies
- > Traceability Systems and IT infrastructures required in a production and distribution facility

*Speaker: Rob Perry, GrowerIQ*

**WRAP-UP: 18H00-18H15**

### Wine & Cheese Moment

18h15-20h15

## DAY 17

**PARTICIPANTS RECEPTION: 8H45 – 9H00**

**OPENING SESSION 2<sup>ND</sup> DAY: 9H00-9H30**

### Quality Control for Medicinal Cannabis

9h30-10h15

- > Quality Control Challenges
- > Pharmacopeia monographs overview

*Speaker: Ana Brízio, LEF Sara Figueiredo, LEF*

### Medicinal Cannabis Security Measures - is there a standardization?

10h15-11h00

- > Understanding of the new requirements regarding Ordinance 83/2021
- > Security Requirements for cultivation, manufacturing and distribution facilities

*Speaker: Sérgio Bagulho, TAP | ANF*

**COFFEE BREAK: 11H00-11H30**

### Regulatory Requirements for Market Entry in Portugal

11h30-12h00

- > Requirements to obtain a market authorization in Portugal
- > Challenges
- > Practical aspects
- > Clinical indications

*Speaker: Cristina Toscano, LEF*

### Regulatory Requirements for Market Entry in Israel

12h00-12h30

*Speaker: Amit Edri, Portocanna*

### Regulatory Requirements for Market Entry in Uruguay

12h30-13h00

*Speaker: Carlos Lacava, FIP*

**LUNCH BREAK: 13H00-15H00**

### Audits and Inspections:

#### Sharing Experiences

15h00-17h00

- > Experience from the authorities
- > Experience from growers and manufacturers

*Moderator: Maria Jorge Costa, ANF*

*Speakers: Graça Flores, Clever Leaves Miguel Fagundes, Botanical Holdings Plc. Vera Broder, Mediane*

### Q&A Session

17h00-17h30

**CLOSING SESSION: 17H30-18H00**

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