## Coordenação do curso

Maria Beatriz da Silva Lima, PharmD, PhD

Beatriz Silva Lima is PharmD and PhD in Pharmacology and is full professor of Regulatory Science and Pharmacology, Head of Regulatory Science, researcher at Research Institute of Medidicne (iMED.UL) and Dean of Faculty of Pharmacy of the Universidade de Lisboa.

Beatriz served more than 20 years of experience as an expert in nonclinical and regulatory science at the medicines agency in Portugal, INFARMED, and at the EMA, UK. She has been up to July 2012 member of the Committee of Human Medicines (CHMP), Committee of Advanced Therapies (CAT) and Scientific Advice Working Party (SAWP). She has been Chair of the Safety Working Party (SWP) and has been involved as Co-Deputy in ICH discussions on multiple guidelines on behalf of the European Commission. Since January 2014, for four years (maximum allowed two mandates) she Chaired the Scientific Committee of the Innovative Medicines Initiative (IMI), a PublicPrivate Partnership between EFPIA and the EC which funded through >5 billion euros >160 research projects developed by consortia of Academia, Industries, Regulators, Patients, the main stakeholders in medicines research and development. between 2019 and 2022 she served as a member of the Emerging Issues Committee of the ILSI-HESI, USA.

Current areas of research: Regulatory Science, Nonclinical Safety, Oncology, Pharmacology of metabolic diseases;

Furthermore, Beatriz is highly involved in national and international education in the area of regulatory science. I) She Coordinates a second cycle Master Course on Regulatory Science in the Faculty of Pharmacy of the Universidade de Lisboa (RAMPS), ii) she contributes to the EUDIPHARM master course (University of Lyon), the MIND Course (University of Copenhagen), ATRIUM Regulatory Course (University of Copenhagen and Atrium, Denmark).

Beatriz is Editor in Chief of the Regulatory Science Section of the Journal Frontiers and she Co-coordinated with Prof Per Spindler (University of Copenhagen) and Dr Kirstin Meyer (Bayer Healthcare) a Nonclinical Module on Regulatory Guidelines of the European Master Course (IMI sponsored) SafeSciMet, iii) and of a similar master also IMI sponsored ECMDC, led by the Semelweiss University, Hungary, iv) she integrates the PharmaTrain Course EUDIPHARM lead by the University of Lyon, and she contributes as faculty to the Medicademy Regulatory course on Regulatory as well as to the MIND course (University of Copenhagen). Beatriz Silva Lima has been one of the founders of EUPATI-Portugal, (European Patient Academy, IMI-funded project) Portugal/National Platform, where she served as member of the Steering Committee of the European National Platform, Co-Chairing the Executive Committee.

**Helder Mota Filipe, PharmD PhD**

**Helder Mota Filipe** is PharmD and PhD in Pharmacology and is associate professor of Regulatory Science and Pharmacology at the University of Lisbon (Faculty of Pharmacy), honorary senior lecturer at the Centre Translational Medicine & Therapeutics, Queen Mary University of London and principal investigator at ISBE – Institute for Evidence Based Health. He is vice-president (past presidente) of AFPLP – The Portuguese-Speaking Countries Pharmacists Association, member of the National Council of Ethics for the Life Sciences and specialist in Regulatory Affairs (OF).
In February 2022 was elected President of Ordem dos Farmacêuticos - Portuguese Pharmaceutical Society, the regulatory body of the pharmaceutical profession.

Helder Mota Filipe is serving, since 1994, as an expert in nonclinical and regulatory science at INFARMED, the national competent authority Portugal, and at the European Medicines Agency (EMA). For a decade he was vice-president and president of INFARMED, and member of the management board of EMA. He is currently member of the Medicines Evaluation Committee (CAM) and former member of the HTA Committee (CATS) at INFARMED. He was member of the executive board at the Ethics Commission for the Clinical Research (CEIC). In addition to teaching and research at the Faculty of Pharmacy of the University of Lisbon, he frequently collaborates with other higher education institutions.
He has supervised 10 doctoral theses and more than two dozen master's theses in the areas of pharmacology, experimental medicine, regulatory science and medicines policy. He is the Author of more than 130 publications in international peer-reviewed scientific journals and more than 300 communications to scientific meetings in those scientific areas.

**Ana Filipa Alexandre**

**VP Pricing and Market Access EMEA at Santen**

Strategic and results oriented professional with over 12 years of experience in the field of HEOR/Market Access at Global, regional, and local level. PharmD from the Faculty of Pharmacy of the University of Lisbon, with a Master’s degree in Public Health (Health Economic Outcomes Research stream) from the

London School of Hygiene and Tropical Medicine. Hold a European Market Access University Diploma and recently obtained an INSEAD certificate in “Leadership Communication with Impact”.

Flexible, creative and results and solutions oriented, able to quickly familiarize with new projects and environments, Diplomatic person with the ability to deal with different cultural sensitivities, ways of working and teams. Skilled, committed, and passionate with a patient centric approach to daily work activities and excellent interpersonal skills. Possess a set of significant and well- rounded experience, including a deep understanding of launching products and life-cycle, of Health Technology Assessment, health and pricing systems at global, regional and local levels.

**Alexandre Baptista**

**Freelancer in the fields of HEOR, Market Access and Epidemiology/RWE**.

Has worked in the Data Generation team in Oncology and IBD for the European and Canada Regions at Takeda until January 2019. There, he had functions of Head of the Department and in the role of Manager.

Prior to joining Takeda has worked as a freelancer and external consultant in the fields of health economics, market access and epidemiology. Also, has worked as a Value Consultant in Adelphi Values where identified solutions and defined projects to inform the development of value propositions and communications to optimize pricing, reimbursement, and market access. Furthermore, worked as a global health economist, at the pharma headquarters of a top 20 company in Germany and Switzerland.

Scientific coordinator of training workshops in Health Economics and Market Access for the Portuguese Pharmacists Society. These workshops have the presence of international and national KOLs from Academia, Pharmaceutical companies, INFARMED, and from the National Association of Pharmacies. During the last 7 years more than 300 healthcare professionals received education in these workshops.

Completed the Foundation and Advanced Modelling courses from York University and holds a Degree in Pharmacy from the Faculty of Pharmacy of the University of Lisbon, a MSc in Epidemiology from the Faculty of Medicine of the University of Lisbon and a MSc in Health Economics from the University of York.

Recently has achieved an INSEAD certificate in the "Emerging Leaders in the Digital Age" course and a certificate at Oxford University in Health Economics Evidence in Clinical Trials.

# Programa Virtual de Acesso ao Mercado

# (1ª Edição)

## 1ª Semana – 4h (total: 4h) – 16 de Setembro

- Introdução ao curso e aos participantes **Ana Filipa Alexandre e Alexandre Baptista (1h)**
- Introdução ao acesso ao mercado **Prof. Beatriz Lima, Ana Filipa Alexandre e Alexandre Baptista (1h 15min)**
    - Importância do acesso ao mercado - história (30 min)
    - Conceitos e princípios básicos – (30 min)
    - Diferentes tipos de stakeholders e porque são tão importantes – (15 min)
- O papel do INFARMED e a sua importância na comparticipação de medicamentos – (1h) **TBC**
- Q&A (15min)

## 2ª Semana – 4h (total: 8h) – 23 de Setembro

- Acesso ao mercado e o que engloba **(30m) – João Pedro Henriques – Market Access Manager (Servier Portugal) / Global Pricing Manager Internal Medicine (secondment at Servier Global)**
- Sintese de Evidencia- **Osvaldo Santos (1h 30 min) - Coordenador do EnviHeB Lab, ISAMB; Professor Assistente da Faculdade de Medicina, Universidade de Lisboa, Portugal**
- Patient Reported Outcomes - **Zalmai Hakimi (1h 45min) - Director Health Economics Outcomes Research at Sobi, Swedish Orphan Biovitrum AB**
- Q&A (15 min

## 3ª Semana – 4h (total: 12h) – 30 de Setembro

- HEOR
    - Conceitos fundamentais, princípios e sua aplicabilidade - **Klara Dimitrovová (3h 30 min) - Consultora na MOAI Consulting**

- Q&A (15 min)

## 4ª Semana – 4h (total: 16h) – 7 de Outubro

- HEOR
    - Interpretação e análise de artigos - **Alexandre Baptista (1h45m)**
    - Modelos económicos e as suas diferenças – **Bruno Macedo (1h 45 min) Consultor em HTA**

## 5ª Semana – 3h30h (total: 20h) – 14 de Outubro

- Atividades chave de Acesso ao Mercado através do desenvolvimento de um produto até fase 3 - **Ana Palma (3h 30 min) - Senior Director Global Head of Market Access & Access Policy at Sobi - Swedish Orphan Biovitrum AB**
    - Epidemiologia da doença,

- Concorrentes
- Estratégia
- Planeamento, execução, e implementação de actividades (Early HTA advice, TPP, Dossiers de Valor, Modelos, etc)
- Cross functional activities - liaison com stakeholders internos (Desenvolvimento, Departamento Medico, Departamento Comercial, etc)
- Drivers e barreiras para o acesso

- Q&A (15min)

## 6ª Semana – 4h (total: 24h) – 21 de Outubro

- Atividades de acesso ao mercado durante a fase 3 do desenvolvimento clínico e pré-lançamento - **João Carrasco - Director Global Market Access Lead Ophthalmology at Bayer & Ana Filipa Alexandre (3h 30 min)**
  - A matriz Global, Regional e Afiliada para um bem-sucedido plano de acesso ao mercado
  - Mensagens de Valor e Proposições de Valor
  - Gap analysis and prioritização
  - Atividades de Pricing (sequência de preço, referenciação externa de preço, payer research, estratégia de preço, ambiente de preços e comparticipações)
    - Exemplos práticos
- Q&A (15 min)

## 7ª Semana – 4h (total: 28h) – 28 de Outubro

- Atividades de acesso ao mercado durante lançamento e pós-lançamento (Life Cycle Management) em Portugal - **Bárbara Aranda da Silva (3h 30 min) - Head of Market Access Oncology at Novartis Portugal**

- Q&A (15 min)

## 8ª Semana – 4h (total: 32h) – 4 de Novembro

- Regulamento (EU) 2021/2283 em Avaliação de Tecnologias de Saúde (HTA) **Prof. Rui Ivo (1h 45 min) – Presidente do INFARMED** TBC
  - História – Inicio
  - Como a legislação contribuirá para a melhoria da disponibilidade de tecnologias inovadoras na área da saúde
  - Como esta nova framework se apresenta e quais as suas maiores vantagens

- Perspectiva do Payer – **Prof. Hélder Mota Filipe- (1h) – Prof. Associado na FFUL e Bastonário da Ordem dos Farmacêuticos.**

- Distribuição dos estudos de caso – **(1 h)**

## 9ª Semana – 4h (total: 36h) – 11 de Novembro

- Acesso ao Mercado em Portugal **Sergio Vilão (1h45m) - Managing Partner & Market Access Manager na Formifarma**
- Acesso ao Mercado nos UK - NICE e SMC **Rodrigo Almeida (1h45m) - EMEA Associated Director Health Economics Outcomes Research na Astellas no Reino Unido**
- Q&A (15min)

### 10ª Semana – 4h (total: 40h) – 18 de Novembro

- Acesso ao Mercado em França- **Marta Contente (1h 45 min) Senior Director Worldwide HEOR Cardiology, Immunology and Fibrosis at BMS**
- Acesso ao Mercado em Itália - **Paolo Di Rienzo (1h45 min) - Associate Director Health Economics Outcomes Research Astellas Italy**

### 11ª Semana – 4h (total: 44h) – 25 de Novembro

- Acesso ao Mercado em Espanha - **Patrícia Proença (1h45 min)- Global Head of Market Access at Pro.med.cs Praha a.s.**
- Acesso ao mercado na Alemanha - **Joern Hanusch (1h45 min) - Market Access & Health Economics Consultancy / Interim Management**
- Coaching of Case Studies - **(30min)** – grupos de 4 pessoas
- Q&A (15 min)

### 12ª Semana – 4h (total: 48h) – 2 de Dezembro

- Acesso ao Mercado nos Países Nórdicos **- Diogo Belbute (1h45m)- Senior Market Access Manager, Region North-West Europe at Novo Nordisk**
- Coaching no desenvolvimento dos Estudos de Caso (30 min per Case-Study)

### 13ª Semana – 4h (total: 52h) – 9 Dezembro

- Planeamento dos diferentes estudos que irão reforçar o valor do produto
    - RWD vs RWE
        - Diferentes tipos de estudo farmacoepidemiológico - **Prof. José Cabrita (1h 15 min) - Professor Catedrático Jubilado da FFUL de Farmacoepidemiologia**
        - Estratégia de execução - **Alexandre Baptista (1h 15 min)**
        - **Valor da Inovação /ISPOR Value Flower – Marta Contente (45 min)**
- Q&A (15 min)

### 14ª Semana – 4h (total: 56h) – 16 de Dezembro (manhâ)

- Acesso ao mercado e aprovação do medicamento pela EMA- **Peter Arlett (1h 45min) - Head of Data Analytics and Methods Task Force at EMA**
    - Diferenças e semelhanças
- RWD & RWE & PRO na parte de aprovação do medicamento pela EMA
    - Importância
    - Guidelines
- RWE e impacto na estratégia de acesso ao mercado – **Marta Contente (50 min**)
- Saúde Digital na Farmácia - **Ema Paulino (1h) - Presidente do Grupo ANF**

- Q&A (10min)

## 15ª Semana – Estudos de caso - 3h (total: 60h) – 16 de Dezembro (tarde)

- Apresentação dos estudos de caso – **Ana Filipa Alexandre, Alexandre Baptista e Ana Palma (2h 30 min)**
- Discussão geral sobre o curso, perguntas dos participantes - 20min
- Feedback - 10 min