



## PhD program in Pharmaceutical Sciences

- *Advanced courses* -

*Faculdade de Farmácia  
Universidade de Coimbra*

### **Coordinator**

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FFUC/CQC

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### **ADVANCED COURSE**

#### ***“Regulatory Affairs & Patents”***

11-18 July, 2022

### **Objectives**

Regulatory Affairs & Patents Course aims at providing knowledge about regulatory science and medicine innovation, addressing the perspective of academy, pharmaceutical industry and regulatory authority.

The role of national and international regulatory agencies throughout the life cycle of medicines, encompassing the periods of pre-, marketing authorization application, and post-approval will be covered in a holistic perspective of the quality, safety and efficacy pillars. Also, the efforts and challenges faced by companies to integrate knowledge in the pharmaceutical development of new medicines will be emphasized through the implementation of Quality by design (QbD) principles, supported on computational frameworks for the establishment of factorial planning methodologies, process analytical technologies (PAT), and artificial intelligence (AI) tools.

The Course is divided into ten lectures covering different topics in the field, given by lecturers from the Faculties of Pharmacy of Coimbra, Porto and Lisbon, Companies and Regulatory Authority and concludes with a plenary lecture by Dr. Rui Ivo on "How regulatory science is Shaping Innovation Landscape".

### **PROGRAM**

#### **Monday, 11 July**

15h30- Introduction

*Carla Vitorino*

*Faculty of Pharmacy, University of Coimbra*

16h00- Medicine evaluation: the regulatory agency perspective

*Marta Marcelino*

*Direção de Avaliação de Medicamentos, Infarmed*



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17h00- Quality assessment: regulatory aspects  
*Domingos Ferreira*  
*Faculty of Pharmacy, University of Porto*

### **Tuesday, 12 July**

16h00- Process Analytical Technologies (PAT): a regulatory overview  
*João Lopes*  
*Faculty of Pharmacy, University of Lisbon*

17h00- Quality by design approach applied to pharmaceutical development: where are we?  
*Marta Simões / António Nunes*  
*Faculty of Pharmacy, University of Coimbra*  
*Bluepharma*

### **Wednesday, 13 July**

16h00 - Pharmacoeconomic assessment  
*Mariane Cossito*  
*Direção de Avaliação das Tecnologias de Saúde (DATS), Infarmed*

17h00 - Market access  
*Francisco Batel Marques*  
*Faculty of Pharmacy, University of Coimbra*

### **Thursday, 14 July**

16h00 - Market analysis: the regulatory agency approach  
*Ana Silva*  
*Direção de Informação e Planeamento Estratégico (DIPE), Infarmed*

17h00 - *Drug Discovery and AI*  
*Tânia Cova*  
*Department of Chemistry/Coimbra Chemistry Centre*

### **Friday, 15 July**

16h00 - Patents: legal basis  
*José Ricardo Aguilar*  
*Faculty of Pharmacy, University of Coimbra/Instituto Pedro Nunes*

17h00 - Patents, Innovation and Access to New Pharmaceuticals  
*António Donato*  
*Faculty of Pharmacy, University of Coimbra*  
*Tecnimed Group*



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**Monday, 18 July**

### 16h00- **Seminar: "How regulatory science is Shaping Innovation Landscape"**

*Rui Santos Ivo*

*President of Infarmed*

#### **Dr Rui Santos Ivo**

Dr Rui Santos Ivo has a degree in Pharmaceutical Sciences, University of Lisbon (1987). Specialist in Hospital Pharmacy, Ministry of Health (1992), Order of Pharmacists (2006) and Pharmaceutical Regulation, emeritus, Order of Pharmacists (1997). Postgraduate training in Health Law (Faculty of Law, University of Lisbon and National School of Public Health, 1997), Pharmaceutical Medicine (University of Basel, 1999), Regulation (London School of Economics and Political Science, 1999), Management of Health Units (Portuguese Catholic University, 2000), PADIS - Senior Management Program for Health Institutions (AESE Business School, Lisbon, 2015).

He began his professional career as a hospital pharmacist at Hospital de Egas Moniz, currently Centro Hospitalar de Lisboa Ocidental, in Lisbon. In 1993, he joined the Autoridade Nacional do Medicamento e Produtos de Saúde, I. P. (INFARMED, I. P.), where he held the positions of member/vice president (1994 -2000) and president (2002 -2005). Director of the European Medicines Agency (EMA) in London (2000 -2002). Member of the Board of Directors of EMA (2002 -2005). First chairman of the European Union Medicines Authorities Coordination Group (2004 -2005). Administrator at the Pharmaceutical Products Unit/Directorate-General for Business and Industry, European Commission (2006 -2008). Executive Director of the Portuguese Pharmaceutical Industry Association (APIFARMA), which represents the pharmaceutical industry operating in Portugal (2008 -2011). From November 2011 to September 2014, he held the position of vice-president of the board of directors of the Central Administration of the Health System, I. P., with the responsibility of managing human resources and health resources, including the coordination of the area of the Health Center Invoice Conference (CCF). Since September 11, 2014, he has held the position of president of the Central Administration of the Health System, I.P., the entity responsible for coordinating financial and human resources, management of benefits and organization of health resources. He is an invited assistant professor, member of the coordination committee of the Master's Degree in Regulation and Evaluation of Medicines and Health Products and responsible for the discipline of Medicines Regulation, Faculty of Pharmacy, University of Lisbon.

In April 2004, he was awarded the Almofariz Prize «Personality of the Year 2004» in the pharmaceutical sector. In 2014 he was appointed European Corresponding Member of the Académie de Pharmacie, France. In 2015 he received the Distinguished Service Medal-Grade Gold, by the Minister of Health. Currently, he is the president of INFARMED I.P..

17h30- Evaluation