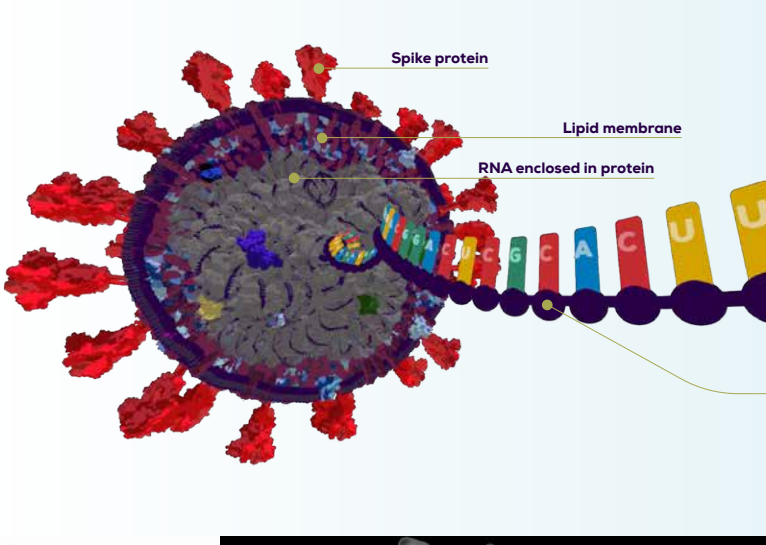
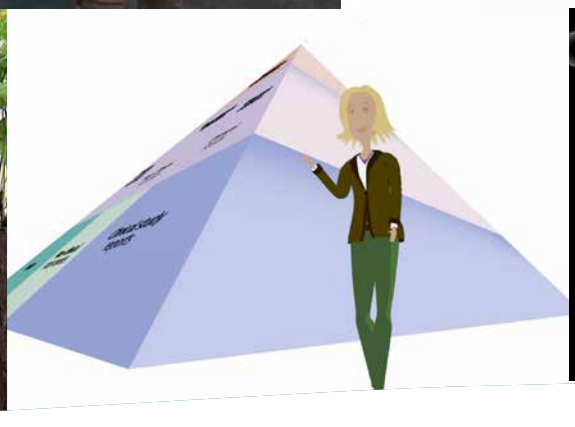




PAUL JANSSEN FUTURE LAB / LEIDEN

Boost your career

Creating future leaders in biomedical development

Paul Janssen Futurelab is an international learning initiative. Our online and on-campus course targets post-graduate entrepreneurial biomedical professionals with experience working in academia, start-ups, industry, and regulatory authorities.

www.pauljanssenfuturelab.eu

★★★★☆

Average rating of our courses

Market Approval

Five-week online course with online exam

Market approval is a crucial step in the development of a new biomedical product. In this learning-by-doing course, you will learn how to design a regulatory strategy to navigate the approval process. Real-world case studies, including the development of a gene therapy product and a fictitious mRNA vaccine, will be presented in order to familiarize yourself with regulatory strategic issues. Each week starts with an episode of our educational documentary entitled “The Rise, Fall and Return of Thalidomide”.

Next starting dates for this course
November 15th, 2021
March 7th, 2022

Five things you will take away from this course

1. Identify the essential characteristics (claims) of a product.
2. Translate these claims into a target product profile and design a market approval strategy.
3. Optimize the market approval strategy with information from authorities.
4. Initiate authority consultation meetings.
5. Use market approval strategies to increase product value.

With contributions from

Murray ‘Mac’ Lumpkin
Former director of the anti-infective drug division; deputy director, CDER; deputy commissioner, FDA

Onno van de Stolpe
CEO Galapagos

Spiros Vamvakas
Head of Scientific Advice
European Medicines Agency

And many more

Full program

Week 1 - Benefit / Risk ratio

A brief introduction to the history and current regulatory systems for receiving market approval of medicinal products, medical devices, and medical nutrition products. Futurelab talk by **Eline Bunnik** (Assistant Professor, Erasmus Medical Center) - "Ethics and autonomy in drug regulation".

Topics

- Clinical trials and informed consent
- Compassionate use and the "Right to Try"
- Benefit / Risk ratio
- Regulatory assessment criteria

Practical cases

- Melatonin, a medical product with many faces
- Bedaquiline for MDR tuberculosis, including the FDA advisory committee meeting

Introductory videocall

Week 2 - Stakeholders in market approval

Interview with **Julia Bernholtz** (COO, AM Pharma) - Target Product Profile. Futurelab talk by **Henk Schuring** (Chief Regulatory and Commercialization Officer, Prilenia) - "Developing medicinal products for orphan diseases".

Topics

- Claims, evidence and reasoning
- Label claim: off-label use
- Target Product Profile (TPP)
- The project team

Practical cases

- TPP: a new indication for Sirturo® (bedaquiline)
- Genzyme's Cerdelga® (eliglustat)
- uniQure's Glybera® (alipogene tiparvovec)

Week 3 - Regulatory intelligence

Futurelab talk by **Bernd van der Meulen** (Professor of EU Food Law, University of Copenhagen) - "Phood: the interface between food and medicine".

Topics

- Product classification
- Regulatory guidelines
- The Market Approval Navigator tool
- Common Technical Document (CTD)
- Investigational Medicinal Product Dossier (IMPD)
- Regulatory dossier assessment

Practical cases

- Locate and read regulatory guidelines
- Use the Market Approval Navigator tool
- Gap analysis of a peptide product IMPD

Q&A videocall

Week 4 - Authority consultation

Interview with **Spiros Vamvakas** (Head of Scientific Advice, EMA) - “Best practices in authority consultation”. Interview with **Onno van de Stolpe** (CEO, Galapagos) - “Market approval of Jyseleca® (filgotinib)”.

Topics

- Preparation for authority consultation
- Pediatric development
- The briefing package
- Running a meeting with authorities
- Negotiation/communication with authorities

Practical cases

- Prepare authority consultation for a medicinal product with companion diagnostics in Alzheimer’s disease
- Exercise to run an authority meeting for a product used for pediatrics
- Genentech’s communication with the FDA in the process for market approval of Activase® (alteplase)

Week 5 - The product’s life-long positive Benefit / Risk ratio

Futurelab talk by **Sjaak Bot** (former head of Regulatory Affairs at Janssen) - “Regulatory life cycle management”.

Topics

- Product life cycle
- Pharmacovigilance and risk management
- Communicating the Benefit / Risk ratio to the general public
- Accelerating market approval
- Tolerability of risk
- Public assessment reports

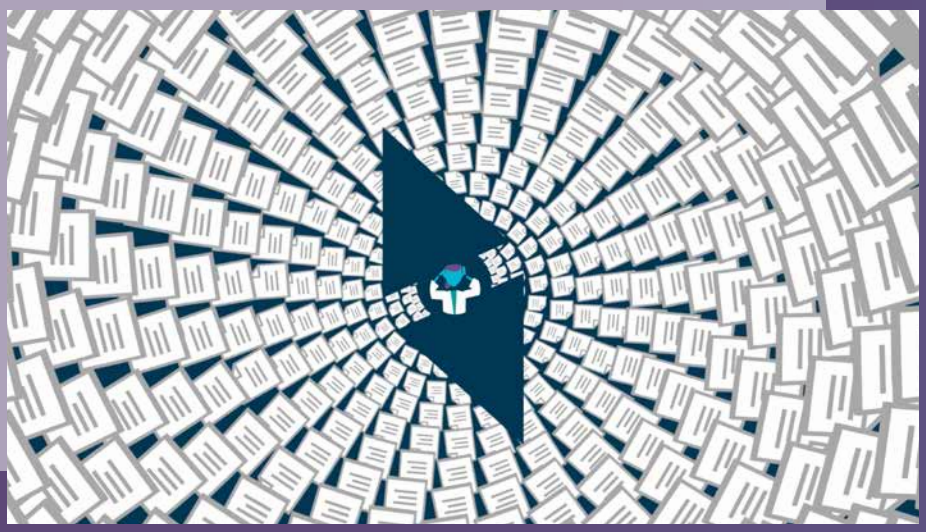
Practical cases

- Vioxx and killing a product’s development in time
- University of Oxford/AstraZeneca’s COVID-19 vaccine Vaxzevria® (ChAdOx1 nCoV-19)
- Biogen’s Alzheimer’s drug Aduhelm® (aducanumab)
- Development of a new mRNA-based vaccine

Final videocall

Final exam

You can schedule your online exam after completing week 5. Upon passing the exam, you will receive a certificate.



This all-new online course will start in fall 2021.
Space is limited, so be sure to sign-up on time.

Market Approval Online - November, 2021

Course length	**5 weeks**	Videocall 1	**Nov. 18, 2021** **16:30 to 17:30 (CET)**
Study load	**5-7 hours a week**		
		Videocall 2	**Dec. 02, 2021** **16:30 to 17:30 (CET)**
Online course starts	**Nov. 15, 2021**		
Online exam period	**Jan. 17-23, 2022**	Videocall 3	**Jan. 13, 2022** **16:30 to 17:30 (CET)**

Market Approval Online - March, 2022

Course length	**5 weeks**	Videocall 1	**Mar. 10, 2022** **16:30 to 17:30 (CET)**
Study load	**5-7 hours a week**		
		Videocall 2	**Mar. 31, 2022** **16:30 to 17:30 (CET)**
Online course starts	**Mar. 07, 2022**		
Online exam period	**Apr. 18 - May 01, 2022**	Videocall 3	**Apr. 14, 2022** **16:30 to 17:30 (CET)**

Free
Demo

Scholarships available

Visit our website for a free online demo
ma.pauljanssenfuturelab.eu

film Paul Janssen Futurelab's documentary on the story of thalidomide.

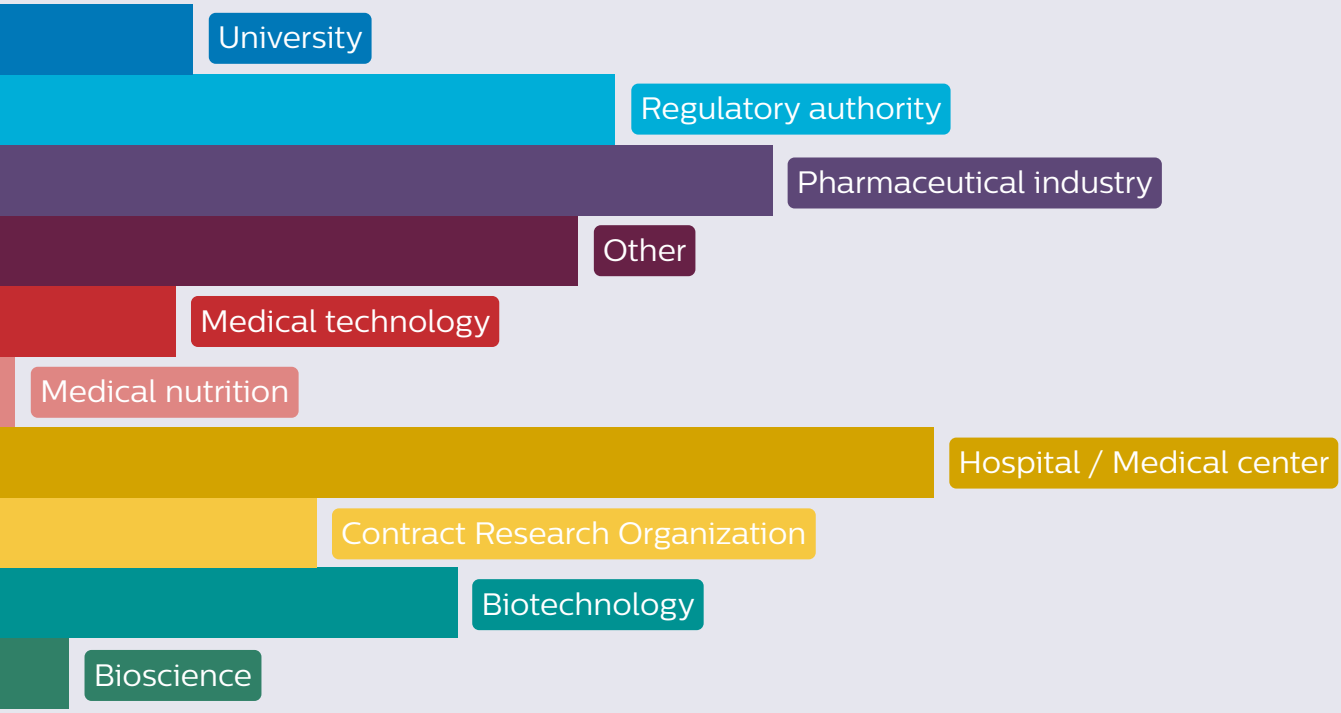
cases Real-life cases, involving AstraZeneca's Vaxzevria®, Janssen Therapeutic's Sirturo®, Genzyme's Cerdelga®, uniQure's Glybera®, Genetech's Activase®, Biogen's Alduhelm®, and fictitious cases with exercise and assignments.

tool Our Market Approval Navigator can help you locate relevant guidelines from the EMA, FDA, and ICH.

class Follow the course with a group. Meet fellow participants via chat boxes and videocalls, discuss assignments, and exchange insights regarding the topics of this course.

NVZA The Market Approval course is accredited (38 hours) by the Dutch Association of Hospital Pharmacists (NVZA).

Our participants come from all over the world and represent various disciplines, bringing their unique expertise, learning goals, and perspectives.



www.pauljanssenfuturelab.eu