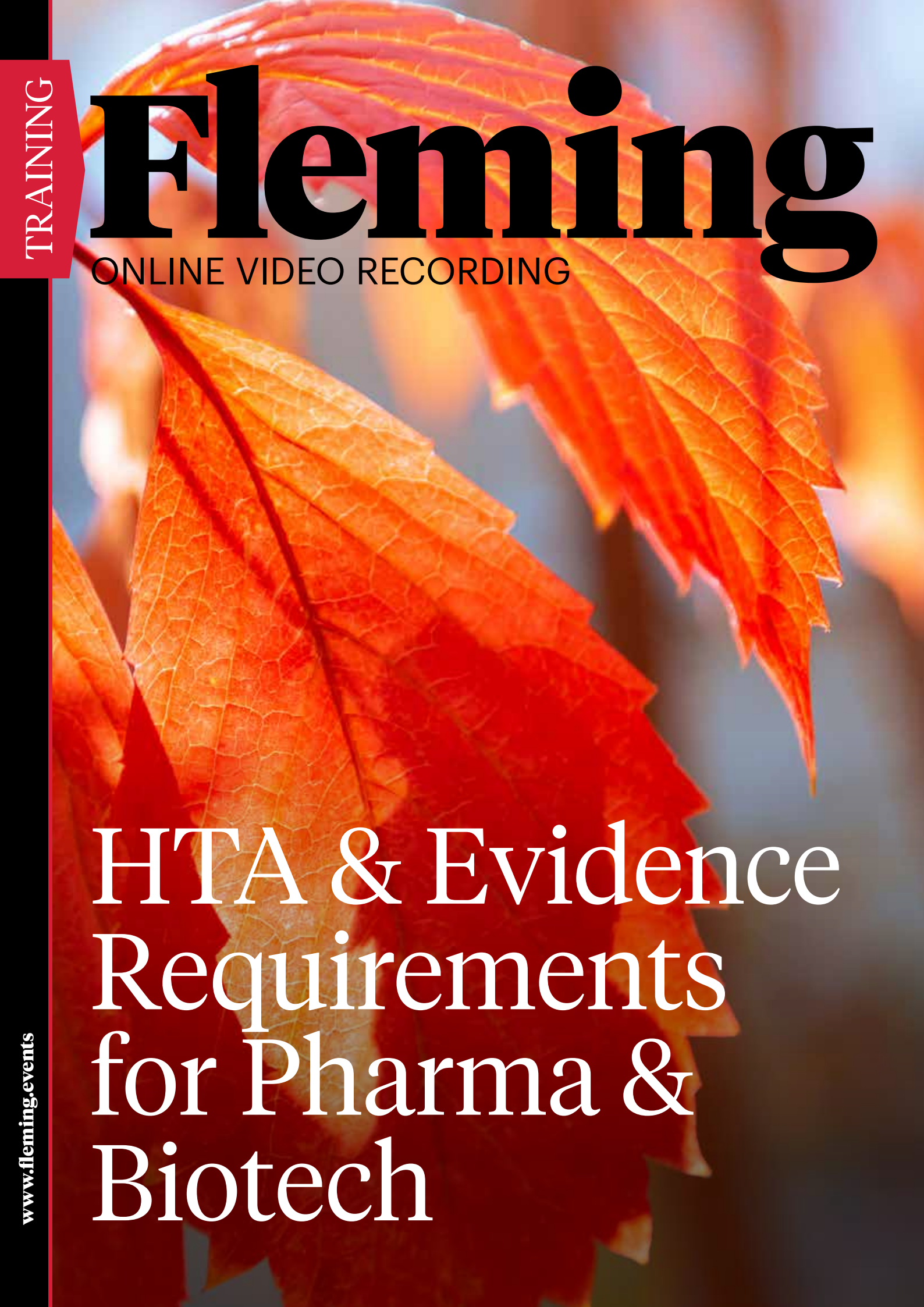
TRAINING

Fleming

ONLINE VIDEO RECORDING



HTA & Evidence Requirements for Pharma & Biotech

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Fully online

no need to travel, just sit back, relax and enjoy the learning experience

On any device

you can log in via mobile, tablet or laptop

Flexible Schedule

start when you want and follow the course at your own pace

Continuous access

you will continue to have access to the course for 3 months after completing your registration

Conveniently designed video content

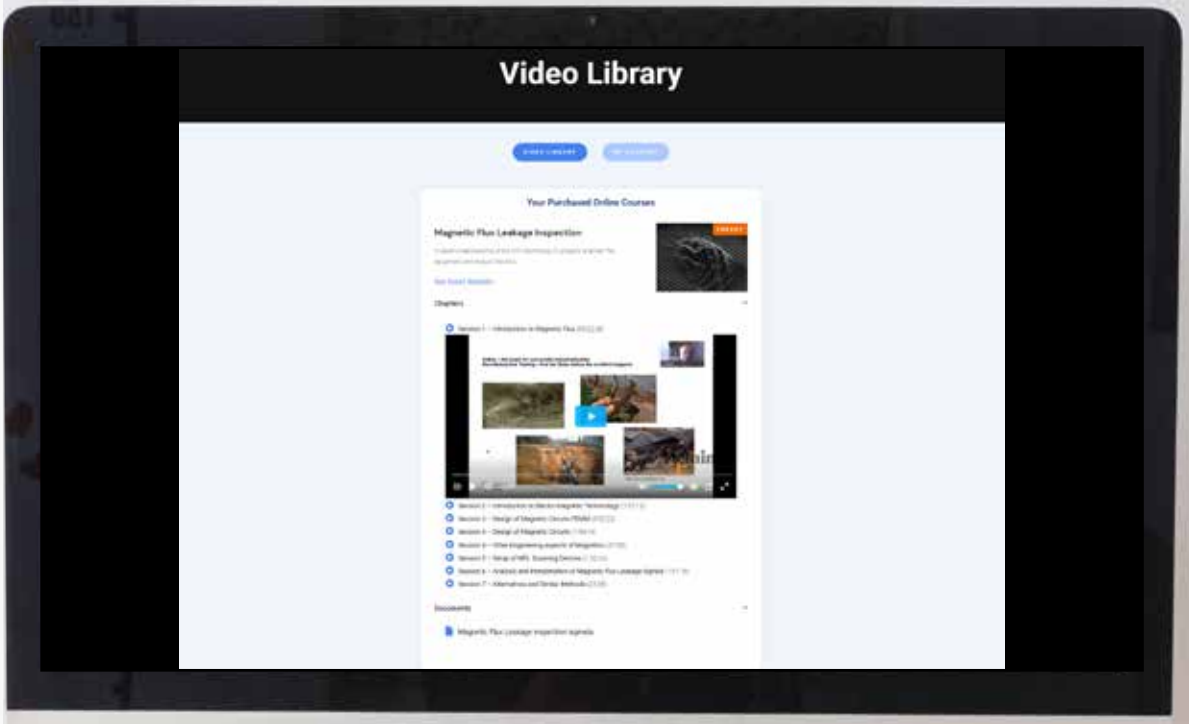
the course content is divided into shorter video lectures that will allow you to increase the attention span and improve the learning experience

Certificate of completion

upon the completion of the course you will receive the certificate of completion signed by the course leader

Full slide deck

you will be able to download the full slide deck to support your learning



Why Online Video Recording?

We all know that unpleasant feeling of conflicting schedules. You find an interesting training course that you really want to attend to help you gain new knowledge and improve your professional skills. However, when looking at a date you realize you already have another appointment scheduled exactly at the same time - and you will have to miss out on the opportunity. Well, now, you don't have to anymore! Fleming brings you the opportunity to follow a training course of your choice via the pre-recorded video lectures that are conveniently designed as individual sessions of the approximate duration of 60-90 minutes to help you boost the attention span. You can follow the training at your own pace, from the convenience of your home or office via any device - computer, laptop or mobile. You will also receive the full course slide deck to support your learning and upon completing the course you will receive the certificate of completion signed by the course leader. And the best thing of all? You will have access to this content for 3 full months after completing your registration. You won't have to rush and will be able to listen repeatedly to any of the lectures because we know that newly gained knowledge can be overwhelming and fade over short time unless the learned material is revisited. Take control of your learning now and sign up for one of our video recordings.

Meet the Training Leaders:

Susanne Michel MD, MSc
Ascenian Consulting, Germany
Co-founder

Susanne is a co-founder of Ascenian Consulting and responsible for Market Access and HTA. She has more than 11 years of experience of market access consulting and delivering measurable business results in new product development and repositioning products on the market. Typical projects include clinical trial assessment, payer positioning, value strategy, and pricing strategy. After working for the Ministry of Health in Berlin as senior adviser and followed by time at as a clinical trial assessor at IQWIG, Susanne joined the Department of Health in England where she was a strategy policy leader for six years when NICE was established and conducted clinical assessments at NICE. Susanne has worked for Pricewaterhouse Coopers in Luxembourg leading the Health Research Institute Europe and was responsible for the assessment of in licensing opportunities in cell and gene therapies. Susanne holds a medical degree and a Masters in Strategy from London School of Economics and Political Science. Susanne is located in Paris and Berlin.

Noemi Muszbek MSc
Visible Analytics, UK
Health Economics Director, Partner

Noemi is Director of Health Economics at Visible Analytics, based in Reading, UK. Previously, she was Senior Research Leader in the Modelling and Simulation group of Evidera for 13 years, and prior to that Health Economics Manager at Astra Zeneca for five years. Noemi has led multiple programs of work, that had various components including economic models, literature reviews, indirect comparisons, trial analyses, utility studies, retrospective database analyses, physician surveys, payer research and reimbursement submissions. She has worked on cost-effectiveness and budget impact models (cohort and patient level simulation models), for different purposes (reimbursement submissions, internal decision making, evidence generation planning, publications). She has prepared white papers in different policy issues and have taken part in guideline development for economic evaluation and for reimbursement process. Noemi has prepared and led submissions for multiple agencies, including the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC) in the UK, the Norwegian Medicines Agency (NoMA), the Pharmaceutical Benefits Advisory Committee (PBAC) in Australia, and the Canadian Agency for Drugs and Technologies in Health (CADTH). Noemi holds a Master's degree in Health Economics from the University of York, UK and one in Public Economics from the Corvinus University (then Budapest University of Economic Sciences, Hungary), and a Bachelor of Science degree in Economics. Noemi has presented studies at international clinical and health economic conferences and she has published numerous articles in journals such as Pharmacoeconomics, Clinical Therapeutics, Current Medical Research and Opinion, Blood Pressure and Health Policy.

Edit Remak MSc, PhD
Visible Analytics, Hungary
Health Economics Director, Partner

Edit has joined Visible Analytics as Director of Health Economics based in Budapest, Hungary. Previously she was a Senior Research Leader in the Modelling and Simulation group of Evidera for over 17 years. Edit 's main areas of interest are quantitative decision analysis and modeling. She has experience in developing different model types (cohort and patient level simulation models), serving different aims (cost-effectiveness models, budget impact models, pricing models), for different audiences (regulatory bodies, expert communities, internal decision makers). Edit has been involved in the preparation of a number of evidence submissions for the National Institute for Health and Care Excellence (NICE), the Scottish Medicines Consortium (SMC), the National Centre for Pharmacoeconomics (NCPE) in Ireland, the Tandvårds- och Läkenedelsförmånsverket (TLV) in Sweden and similar bodies in other countries. She has also coordinated multinational studies, prepared manuscripts, and training for pharmaceutical companies in the use and interpretation of models for cost effectiveness. Edit completed a PhD in Health Economics in 2015 at Brunel University and an MSc in Health Economics at the University of York. She was awarded Best New Investigator Podium Presentation by ISPOR in 2002. She has extensively published in journals such as the Journal of Clinical Oncology, European Journal of Health Economics, British Journal of Cancer, and Journal of Medical Economics.

Key topics:

- HTA decision making across EU markets
- Requirements & evidence for HTA assessments
- A value proposition from an HTA perspective
- The role of patients in HTA decision-making
- Optimizing the generation and the use of evidence in HTA
- Cost-effectiveness model & budget impact
- Handling uncertainty, access schemes & contracting
- Scientific advice
- HTA for cell & gene therapies
- EU HTA pathway

Training audience:

The Training Course is of particular interest to Pharmaceutical & Biotech companies:

- HTA
- HEOR (Health Economics & Outcomes Research)
- Evidence & Value Strategy
- RWE
- Payer Value
- PRO/ePRO/PROMs
- Pricing & Reimbursement

Course Objective:

This unique course provides a practical & in-depth understanding of HTA decision making across EU markets and will focus on the evidence generation underpinning a convincing value proposition to different HTAs. It will provide the tools to understand and critically appraise the evidence and studies required for HTA submissions, and to be able to put together an evidence plan including the underpinning data requirements and understanding the role of patients, cost-effectiveness models, access schemes and scientific advice.

The training is structured in a way that participants can connect the strategic importance of process requirements to underlying methods and optimal evidence. The training offers practical insights of former payer decision makers, method specialists and direct experience from HTA dossier submission and defense in different HTA driven markets. While HTA methods and processes are likely to change in the 2020's significantly and rapidly, this course will allow understanding of current practices, learning about future plans, and discussing potential changes in both process and requirements.

By completing this course you will get familiar with the strategies for patient access in an evolving value-based and patient-centric healthcare.

Testimonial:

"A very comprehensive training with real world examples."

Maro Siakantaro, Payer Value Strategy Researcher, UCB Pharma, Finland

"Very detailed introduction in HTA processes in European countries. Thank you!"

Lidia Mukina, Senior Statistician HTA, MSD

"Interesting exchanges with trainers and other participants."

Jean Malacan, Global HEOR Sr Project Leader, Bayer

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Course program:

SESSION 1: HTA decision making

- Examples of topline HTA processes across England, France, Germany, Italy and Canada and highlight other markets
- Underpinning requirements and evidence for HTA assessments along therapeutics, diagnostics and preventative products

SESSION 2: A value proposition from an HTA perspective

- A good value proposition for HTAs is to meet requirements – so you better know them
- Differentiation across HTA perspectives
- The role of patients in HTA decision making
- Difference in value demonstration requirements for HTAs and pricing agencies

SESSION 3: Evidence generation underpinning a convincing value proposition to different HTAs

- Main differences in evidence requirements of key HTAs around the world with a focus on Europe
- Planning the clinical trials and real world evidence collection with HTA in mind
- Early modeling for identifying potential value messages and data gapsFrom efficacy in clinical trials to effectiveness for HTAs
- Extrapolating clinical trial data

SESSION 4: Evidence generation underpinning a convincing value proposition to different HTAs – Part 2

- Differences across markets on evidence expectations
- Cost-effectiveness and budget impact
  - Types of models
  - Conceptualization and assessing appropriateness

SESSION 5: Access schemes and contracting

- Types of access schemes – value versus commercial and taxonomy of access schemes
- Evidence considered for access schemes
- Trends

SESSION 6: Scientific advice

- Types of scientific advice
- Principles of scientific advice and how to decide for advice
- How to prepare
- How are following parameters relevant for scientific advice
- Patients' voice
- Orphan status
- QoL not picked up by utilities, innovation, end of life, process utility

SESSION 7: The HTA challenges for gene and cell therapies

- Level of uncertainty due to trial challenges
- How clinical uncertainty carries over to health economic uncertainty
- Payer approaches to deal with uncertainty

SESSION 8: Prepare for the EU HTA pathway

- Principles and implementation
- How to prepare

Create your own In-House Training

Are you looking for something more specific? Create your own In-House Training customized to the specific issues your company and your employees need to understand and resolve. Save time and cost while increasing implementation with an In-House Training held in the privacy of your company.

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Do you need a different topic, venue or date?

Create your own custom-made training.

In-House Training

- Specific industries face specific problems. They require niche information and solutions. **In-House Training** is precisely tailor-made to your needs.
- We find a trainer, draft topics, and then find the premises and dates which match your needs.
- Taking place in the privacy of your company, including real-life case studies and best practices, the course is led by an independent industry expert.
- Provide your employees a unique learning experience without having to leave the office.

"Knowledge is important, but implementation is crucial."

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GET MORE INFORMATION

The team behind:

We are delighted to bring you the

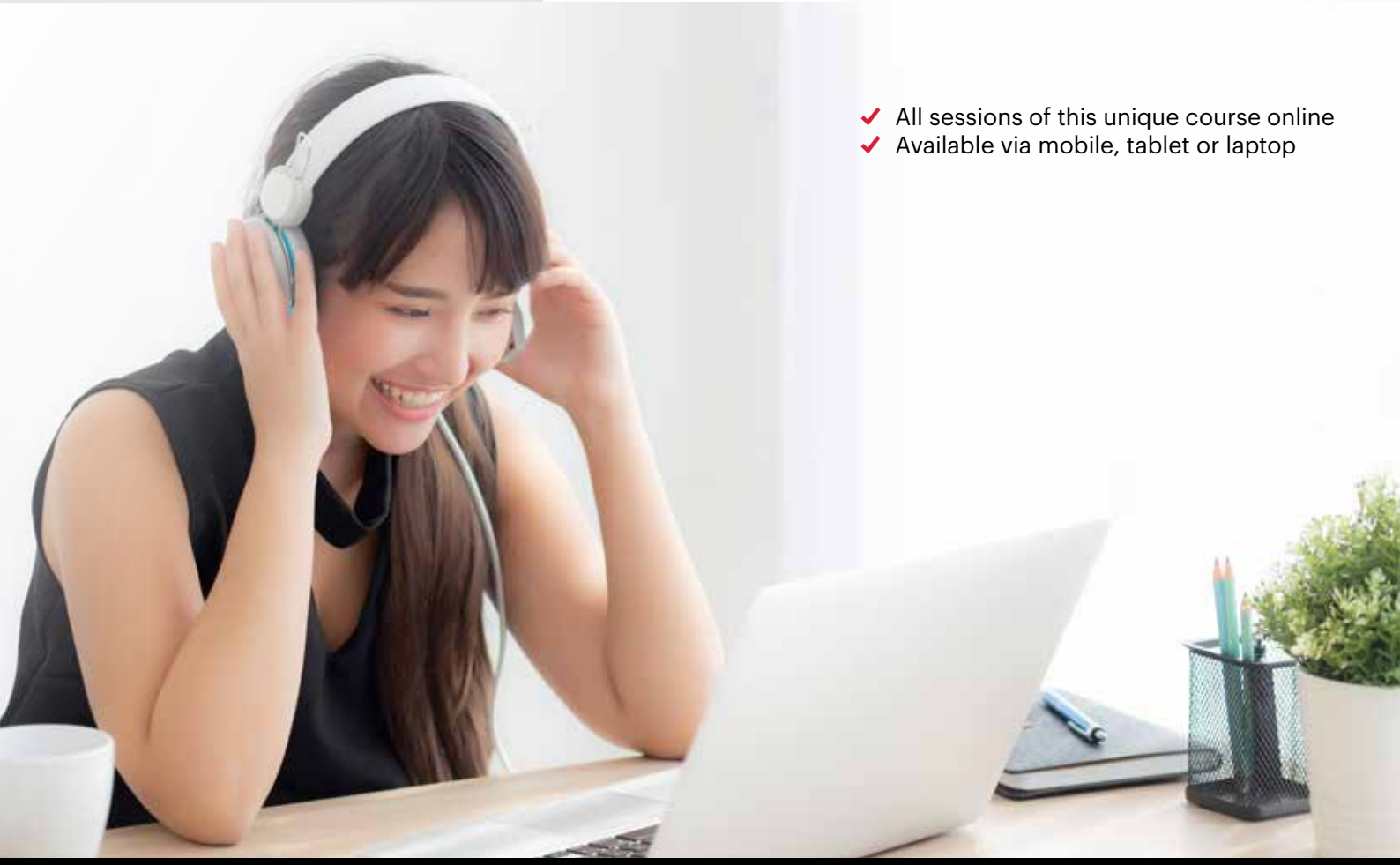
HTA & Evidence Requirements for Pharma & Biotech

Click on the ticket below to sign up

Or write to
event.inquiries@fleming.events
to get in touch with a member of our team

Dasa Janosikova
Production Manager - Life Sciences

Monica Jones
Marketing manager



- ✓ All sessions of this unique course online
- ✓ Available via mobile, tablet or laptop

REGISTRATION

Click Here & Register Online

You will be transferred to secure payment gateway

FROM

696 €

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