

Advanced Pricing and Reimbursement Training Course

Professional Development Training Course Outline

Category	Biotechnology and Pharmaceutical Development	Duration	10 Days
Base Fee	\$4,000 USD	Delivery Mode	Online / On-site Hybrid

Course Introduction

The landscape of healthcare access is undergoing a profound transformation, moving rapidly from traditional cost-plus models to a system focused on Value-Based Healthcare and demonstrable Patient Outcomes. Securing Market Access and optimal Reimbursement for innovative therapies is no longer a downstream commercial task but a critical, cross-functional strategic imperative that must be embedded from early product development. Companies face intense pressure from global payers, Health Technology Assessment (HTA) bodies, and governments leveraging External Price Referencing (EPR) and complex Gross-to-Net (GTN) management to control spiraling costs.

Advanced Pricing and Reimbursement Training Course is specifically designed to equip senior professionals and future leaders with the strategic framework and technical mastery required to navigate these complexities. Participants will gain deep expertise in leveraging Real-World Evidence (RWE) and sophisticated Health Economics and Outcomes Research (HEOR) to construct an unassailable Value Proposition for Specialty Medicines and Advanced Therapy Medicinal Products (ATMPs). By mastering the art of Payer Negotiation and implementing cutting-edge Innovative Contracting models, graduates will be positioned to drive sustainable revenue growth and accelerate patient access in a highly scrutinized, global environment. The focus is on data-driven decision-making and risk-mitigation to ensure Launch Excellence and long-term Product Lifecycle Management.

Programme Curriculum

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Course Objectives

1. Master the integration of HEOR and RWE to establish a robust, evidence-based Value Story.
2. Develop multi-market Global Pricing Strategy frameworks that anticipate and mitigate the impact of External Price Referencing (EPR).
3. Navigate the complex requirements of Health Technology Assessment (HTA) agencies and optimize dossier submissions.
4. Design and implement innovative Value-Based Agreements (VBAs) and Outcomes-Based Contracts for high-cost therapies.
5. Forecast and manage the dynamics of Gross-to-Net (GTN) Revenue Management and its impact on profitability.
6. Formulate agile Market Access Strategies for Specialty Medicines and Orphan Drugs.
7. Evaluate the disruptive potential of Digital Health Technologies on pricing and reimbursement pathways.
8. Execute an effective Payer Negotiation strategy using advanced behavioral economics and objection-handling techniques.
9. Analyze the policy implications of the impending EU HTA Regulation and its impact on joint clinical assessment.
10. Build a best-in-class, cross-functional Launch Excellence plan for global product introduction.
11. Assess the financial and ethical trade-offs of Indication-Based Pricing and tiered pricing models.
12. Leverage Competitive Intelligence to pre-emptively counter competitor market access and pricing moves.
13. Structure a Patient Access Program (PAP) that aligns with reimbursement regulations and maximizes patient reach.

Target Audience

1. Global & Regional Pricing Directors/Managers
2. Market Access and Reimbursement Leaders

3. Health Economics and Outcomes Research (HEOR) Specialists
4. Commercial/Brand Directors
5. Senior Regulatory and Government Affairs Professionals
6. Business Development and Licensing Executives
7. Strategy Consultants
8. CEOs/SVPs of Emerging Biotech and MedTech Firms

Course Modules

1. Global Pricing Fundamentals in a Value-Based World

- Defining the core difference.
- The shift to Value-Based Pricing (VBP) and its global adoption drivers.
- Analyzing the interdependence of global prices via External Price Referencing baskets.
- Understanding the role of Transfer Pricing and its alignment with commercial strategy.
- The impact of biosimilar/generics on Lifecycle Pricing Management.
- Case Study: Analyzing a multi-country oncology drug launch delay to optimize its EPR starting price.

2. Advanced Health Economics and Outcomes Research (HEOR)

- Cost-Effectiveness (CEA) and Budget Impact Analysis (BIA).
- Critiquing and generating Quality-Adjusted Life Years and other outcome measures.
- Developing and stress-testing economic models for HTA submission.
- Integrating Patient-Reported Outcomes (PROs) into the economic value story.
- Understanding the payer's perspective on the Incremental Cost-Effectiveness Ratio threshold.
- Case Study: Challenging a negative NICE recommendation by re-modeling the ICER with a societal perspective.

3. Harnessing Real-World Evidence (RWE)

- Defining appropriate sources and methodologies for RWE generation
- Strategic use of RWE to fill gaps in Phase III clinical trial data for HTA.
- Legal and ethical considerations in RWE collection and dissemination.
- Integrating AI and Machine Learning for rapid RWE pattern discovery.
- Building a prospective RWE generation plan to support post-launch price maintenance.
- Case Study: Using claims data RWE to prove a long-term compliance benefit not demonstrated in the original trial for a diabetes drug.

4. Health Technology Assessment (HTA) Mastery

- Deep-dive into the structure and critical differences between major HTA systems
- Strategic preparation for the EU HTA Regulation and Joint Clinical Assessment
- Developing a concise and persuasive Global Value Dossier
- Anticipating HTA critiques and preparing a robust defense strategy.
- Best practices for engaging and managing relationships with HTA experts and patient groups.
- Case Study: Simulating the preparation and defense of an HTA dossier for an ATMP facing high-cost and uncertainty challenges.

5. Innovative & Outcomes-Based Contracting

- Structuring complex Value-Based Agreements.
- Designing contracts that manage performance risk based on pre-defined Patient Outcomes.

- Operational challenges of tracking and measuring outcomes for contract compliance.
- Subscription/Capitation and Indication-Based Pricing.
- Legal, compliance, and anti-kickback considerations for contracting.
- Study: Drafting an outcomes-based contract for a gene therapy, linking payment milestones to 3-year durability data.

6. Gross-to-Net (GTN) Strategy and Management

- Detailed anatomy of the Gross-to-Net waterfall.
- Techniques for forecasting and mitigating GTN Leakage and volatility.
- The role of payer contracting and formulary placement in GTN dynamics.
- Financial reporting and the accounting implications of complex rebates.
- Using advanced analytics to optimize a channel strategy for net price realization.
- Case Study: Modeling the optimal rebate level to achieve preferred formulary status while preserving the minimum acceptable net price.

7. Strategic Launch Excellence

- Integrating Market Access strategy from Phase II into the Launch Roadmap.
- Defining the optimal Launch Sequence to protect global pricing.
- Pre-launch payer engagement and securing early access pathways.
- Developing a cohesive Value Story that speaks to clinical, economic, and humanistic benefits.
- Risk planning for unexpected HTA delays or negative decisions.
- Case Study: Developing a "Day-One-Access" strategy for an innovative medical device in a single-payer system.

8. Specialty Medicines and Orphan Drugs

- Understanding the unique HTA and payer psychology for Orphan Drugs.
- Navigating the Managed Entry Agreements (MEAs) often required for high-cost therapies.
- Developing value propositions based on unmet need and quality of life (QoL) improvements.
- The role of patient advocacy groups in securing and maintaining reimbursement.
- Exploring rare disease patient support and distribution models.
- Case Study: Benchmarking the pricing of two recently launched Cell and Gene Therapies (CGTs) and justifying a premium price.

9. Payer Negotiation and Communication

- Segmenting and profiling different Payer Archetypes
- Advanced techniques for framing the Value Proposition during negotiations.
- Mastering objection handling, especially concerning budget impact and uncertainty.
- Simulations in preparing a compelling Payer Value Deck.
- Building long-term, trust-based relationships with key payer decision-makers.
- Case Study: Role-playing a high-stakes negotiation with a major PBM over formulary placement.

10. Global vs. Local Market Access Execution

- Balancing global pricing consistency with local market access requirements.
- Adapting the Global Value Dossier (GVD) into locally relevant HTA submissions.
- Navigating decentralized market access systems
- Understanding the influence of health policy and political events on local pricing.

- Structuring the global and local market access teams for optimal synergy.
- Case Study: Modifying a European HTA submission for a US commercial payer audience, shifting from a cost-effectiveness to a budget-impact focus.

11. Digital Health & Diagnostics Reimbursement

- New challenges in pricing and obtaining reimbursement for Digital Therapeutics
- Pathways to securing unique billing codes and national tariffs for digital tools.
- Demonstrating the economic value of Diagnostics paired with new therapies (CDx).
- Integrating digital health data into the core value proposition and RWE strategy.
- Regulatory approval and Reimbursement for connected devices.
- Case Study: Mapping the reimbursement journey for a prescription-only digital therapeutic in Germany's DiGA framework.

12. Policy, Compliance, and Ethical Pricing

- Global anti-corruption and anti-bribery implications for patient programs.
- Addressing Pricing Transparency and media scrutiny.
- Understanding and ensuring compliance with local promotional and contracting regulations.
- Ethical frameworks for setting prices for life-saving medicines.
- Lobbying and shaping public policy to support patient access.
- Case Study: Responding to a public media backlash against the launch price of a new oncology breakthrough therapy.

13. Advanced Portfolio Pricing Strategy

- Developing a coherent pricing strategy across an entire product portfolio.
- Strategic pricing for line extensions, reformulations, and combination therapies.
- Using price differentiation to minimize cannibalization and maximize lifetime revenue.
- The impact of competitor launches and biosimilar erosion on portfolio maintenance.
- Designing a defensible "value ladder" across different indications.
- Case Study: Revising the pricing of an aging blockbuster in the face of two new competitive therapies and an upcoming biosimilar.

14. Financial Forecasting and Modelling

- Building advanced Price-Volume-Reimbursement (PVR) forecasting models.
- Sensitivity analysis and stress testing models for different payer scenarios.
- Integrating market access assumptions into financial projections.
- Forecasting the impact of a phased global launch on long-range financial plans.
- Quantifying the financial risk of specific HTA outcomes.
- Case Study: Creating a scenario analysis model for a drug where the HTA outcome could range from full reimbursement to restricted use.

15. Leadership in Market Access & P&R

- Building a high-impact, cross-functional Market Access team structure.
- Leading Organizational Change to embed the value mindset.
- Developing leadership skills for managing internal and external stakeholders.
- Coaching teams on advanced negotiation and communication strategies.
- Future trends and strategic planning

- Case Study: Developing a presentation to the Board of Directors justifying increased investment in RWE generation for a Phase III asset.

Training Methodology

This course employs a participatory and hands-on approach to ensure practical learning, including:

- Interactive lectures and presentations.
- Group discussions and brainstorming sessions.
- Hands-on exercises using real-world datasets.
- Role-playing and scenario-based simulations.
- Analysis of case studies to bridge theory and practice.
- Peer-to-peer learning and networking.
- Expert-led Q&A sessions.
- Continuous feedback and personalized guidance.

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Certification

Upon successful completion of this training, participants will be issued with a globally- recognized certificate.

Tailor-Made Course

We also offer tailor-made courses based on your needs.

Key Notes

- a. The participant must be conversant with English.
- b. Upon completion of training the participant will be issued with an Authorized Training Certificate
- c. Course duration is flexible and the contents can be modified to fit any number of days.
- d. The course fee includes facilitation training materials, 2 coffee breaks, buffet lunch and A Certificate upon successful completion of Training.
- e. One-year post-training support Consultation and Coaching provided after the course.
- f. Payment should be done at least a week before commence of the training, to FINESKILL TRAINING CENTER account, as indicated in the invoice so as to enable us prepare better for you.

Upcoming Scheduled Sessions

Start Date	End Date	Location	Price
07 Sep 2026	18 Sep 2026	Online	\$4,000

Start Date	End Date	Location	Price
14 Sep 2026	25 Sep 2026	Online	\$4,000
21 Sep 2026	02 Oct 2026	Online	\$4,000
28 Sep 2026	09 Oct 2026	Online	\$4,000
05 Oct 2026	16 Oct 2026	Online	\$4,000
12 Oct 2026	23 Oct 2026	Online	\$4,000
19 Oct 2026	30 Oct 2026	Online	\$4,000
26 Oct 2026	06 Nov 2026	Online	\$4,000

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