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Understanding Commercialization Within Biopharma two-day course.....3

Biopharma Revenue Forecasting two-day course.....6

Understanding Drug Pricing, Policy and Utilization one-day course 10

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Biopharma Revenue Forecasting That Drives Decision Making and Investments 7-hour course 12

Understanding Drug Pricing, Policy and Utilization 5-hour course 15

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Biopharma Business Acumen 45-minute online class 18

For more information contact

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Class registration @ BiotechPrimer.com

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Understanding Commercialization Within Biopharma Course

LIVE, ONLINE | LEVEL ONE

OVERVIEW

Understanding Commercialization Within Biopharma is a two-day interactive course that uses real world examples to explain both the big picture of strategic commercialization as well as the tactics necessary for a successful pharmaceutical launch. Discussion points focus on creation of the Therapeutic Target Profile (TPP), the power of market segmentation, crafting the value story, and building/sustaining competitive advantage. This course is for both scientists and non-scientists who need to better understand how therapeutics are successfully launched and commercialized.

Five Takeaways:

1. Identify key commercialization success factors and their value as a core, differentiating competency.
2. Gain access to a commercialization "toolbox" that can be immediately and practically applied.
3. Internalize a deep understanding of the product launch process.
4. Recognize key issues, opportunities, and challenges of effective commercialization strategy and tactics.
5. Discover tools needed to build compelling and effective value-demonstration stories that help optimize reimbursement and market access

AGENDA

DAY ONE

Introductions 9:00-9:20

Introduction to Commercialization 9:20-10:30
Strategic Commercialization: What It Is and Isn't
Product Lifecycle Phases: Timing and Activities
Decisions Affecting Commercial Potential
Optimizing Commercial Value

Break 10:30-10:45

Early Planning 10:45-12:00
Early Product Planning Activities
Evaluating an Opportunity
Developing a Target Product Profile (TPP)
Market Sizing: Assessing Commercial Potential
Activity: How the TPP informs the drug label which informs promotional claims

Lunch 12:00-12:45

Pre-Launch Planning 12:45-2:15
Pre-launch Activities
Creating the Brand SWOT
Insight-Driven Market Research
Leveraging Data to Inform Strategic Decisions
Mapping the Patient Journey
Differentiated Brand Positioning
Building a Value Proposition to Engage Customers

Break 2:15-2:30

Pre-Launch Planning *continued* 2:30-3:15
Case Study: Cialis vs Viagra
Business Strategies: 5 Key Questions to Ask
Creating a Strategic Brand Plan
Activity: Uncovering the Strategic Plan

Wrap-Up 3:15-3:30

DAY TWO

Creating the Value Proposition 9:00-10:30
Leveraging Health Economics to Create Value
Pay for Performance Models
Optimizing Value of HECON Assessment
Real World Initiatives
Pharmacoeconomics
Cost-Effectiveness Analysis
Health Technology Assessments
Ensuring Patients Have Access to Your Product

Break 10:30-10:45

Launch Planning 10:45-11:30
Launch Planning Activities
Market Access
Value-based Payment Models
Disease Education, Pre-Market Development
Scientific Pillars and Key Messages
FDA Guidelines Covering Promotions and Advertising

In-Line Planning 11:30-12:15
In-line Planning Activities
Key Performance Indicators (KPI)
Critical Success Factors
Post Launch Threats

Lunch 12:15-1:00

Building and Sustaining Competitive Advantage 1:00-2:00
Commercial Drivers, Levers, and Key Success Factors
Lifecycle Management Challenges
Risk Management Strategies
Multichannel Marketing
Key elements of Customer Engagement Model
Marketing Mix Resource Allocation
Developing Key Brand Performance Measures

Break 2:00-2:15

Loss of Exclusivity (LOE) Commercialization Planning 2:15-3:00
LOE Planning Activities
LOE Timing Considerations
Market Dynamics and Regulatory Challenges
LOE Strategies

Course Evaluation 3:00-3:15

Course Wrap-Up 3:15-3:30

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Life Science Training From Industry Experts

Biopharma Revenue Forecasting That Drives Decision Making and Investments

LIVE, ONLINE | LEVEL TWO

OVERVIEW

Biopharma Revenue Forecasting that Drives Decision Making and Investments is a two-day tactical course invaluable for organizations that work in both preclinical/early clinical development all the way to mature biopharma. Develop knowledge of the core elements of revenue forecasting including pricing, competitive assessments, and epidemiology. Understand how the geography of the US, EU, Japan, China and the rest of the world impacts revenue forecasting. Join our dynamic industry experts as they bring to life the 'logical process' of revenue forecasting using real-life case studies that participants work through together.

The scope of this course includes:

- Geography: US, EU5, Japan, China, ROW
- Therapeutic area: oncology, specialty, rare diseases, gene therapy

Five Takeaways:

1. Develop a broad understanding of how and why revenue forecasts are developed to drive strategic decision making and investing in the biopharma industry.
2. Become fluent in the core elements of revenue forecasting including: epidemiology, competitive assessments, market share assignment, duration of therapy, pricing, gross-to-net margins, and annual price increases.

3. Understand how revenue forecasting varies across geographies and the considerations that need to be accounted.
4. Demonstrate the logical process (workstreams) that leads to effective, defensible revenue forecasting and the interpretation of its findings.
5. Generate insights and actionable decisions from the forecasting process.

AGENDA

DAY ONE

Revenue Forecasting Context 9:00-9:45
Forecasting's strategic and tactical roles
External and internal factors
Market perspectives: an art and science
Forecasting utilization in product life cycle
Forecasting approaches
Market assessment, product forecast, in-line product support

Competitive Assessments 9:45-10:45
Determining indication, geography, time frame, resources
Defining scope: Target Product Profile
Defining indication: Databases
How to mine data for in ClinicalTrials.gov
How to perform a technical review of data
How to determine if an agent is or is not a competitor
Netting out the competitive set
Competitive assessments with rare and genetic diseases
Adjusting risk when competitor is determined

Break 10:45-11:00

Market Share Assignment 11:00-12:00
Significance of market share
Measuring market share
Key factors: therapeutic value, number of competitors, launch speed
Market share models: advantages and disadvantages of each
McKinsey/MIT and Schulze/Rigel
McKinsey & Company/EvaluatePharma market share analysis

Lunch 12:00-12:45

Drug Pricing Today: What every biopharma executive should know 12:45-2:00
Today's drug pricing environment
US drug pricing legislation
Different proposals to modify drug pricing
Drug pricing definitions
US payers: Medicare, Medicaid, CMS, private
Role of the pharmacy benefit manager (PBM)
Elements of pricing: clinical value, HEOR, pharmacoeconomic models, MAPR, GTN, rare disease
Pricing outside the US
Pricing references and resources
Annual price increases
Generics
Additional forecasting assumptions: duration of therapy, compliance, gross-to-net discoun

Break 2:00-2:15

Revenue Forecasting Elements: Epidemiology 2:15-3:15
Basic epidemiology terminology
Prevalence as a rate
Types of prevalence measures
Incidence as a rate
Relationship between prevalence and incidence
Using survival data
Epidemiology study designs
Cross-sectional study design
Cohort study design
Case-control study design

Wrap-Up 3:15-3:30

DAY TWO

Epidemiology: Disease Rates 9:00-10:00

How and why disease rates are used
Types of disease rates
World standard rates, crude rates, age specific rates, age-adjusted rates
Case study: Japan vs Philippines renal cell carcinoma disease rates

Epidemiology: Role of Demographics in Epidemiological Projections 10:00-11:00

Data used in epidemiological projections
Prevalence and incidence: specific age and gender profiles
Example: cancer epidemiology profiles
Case Study: Japan vs Philippines: demographic changes influence future trends
How to use disease rates to project future patients

Break 11:00-11:15

Epidemiology: The Process of Determining Patient Populations 11:15-12:15

Quantitative epidemiology process overview
Defining the patient
Defining level of patient's epidemiology
How to build the patient tree
Literature acquisition and data sources
How to process, analyze and interpret data
How to create results: epidemiology calculations and meta-analysis

Lunch 12:15-1:00

Epidemiology: Basic Sources of Epidemiological Data 1:00-1:45

Peer reviewed scientific/medical literature
PRISMA
Rare/orphan disease sources
Disease registries
Government health databases worldwide (US, Japan, Korea, China, Canada, EU, UK)
Case study: oncology data sources

Revenue Forecast Assumptions Summary 1:45-2:30

How to run a SEER query
Case study: epidemiology of AML

Case Study: Start Up CEO 2:30-3:15

How to run a SEER query

Wrap-Up 3:15-3:30

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Understanding Drug Pricing, Policy, and Utilization

LIVE, ONLINE | LEVEL ONE

OVERVIEW

Understanding Drug Pricing, Policy, and Utilization examines the complexities of the US healthcare market. Many believe patient access to medications and pricing are solely determined by the drug companies; however, this is far too simplistic. This course provides a comprehensive look at how competing forces including the federal government, the insurance industry, and healthcare providers influence formulary systems, which in turn determines how patients access, use, and pay for medications. Learn how commercial and government databases housing pharmacoepidemiology and pharmacoeconomic information also drive drug policy and pricing. Perform basic cost-effectiveness and quality of life calculations to help you gain an appreciation for the types of decisions faced by various persons on the drug development team. Created and taught by a healthcare economist and social scientist, this engaging course is a must for anyone new to healthcare policy and pricing.

Five Takeaways:

1. Familiarity with types of information used to inform drug policy.
2. Ability to apply different types of analysis to determine drug prices.
3. Rationale in drug placement on formularies, as well as their monitoring for continued safety and effect on patient outcomes.
4. Appreciation of the product life cycle and supply chain issues in pricing, marketing, and reimbursement.
5. Understanding of the relationship between manufacturers, policymakers, pharmacies, and patients.

AGENDA

Setting the Stage 9:00-9:30
Clinical development overview
FDA adverse events reporting system

Drug Placement Into Formularies 9:30-10:00
Types of formulary systems
Considerations and issues for placement
Value proposition and drug price
Medicare, Medicaid, private insurers
Single payer markets
Pharmacy benefits manager roll
Manufacturer rebates
Tiering systems, prior authorization, step therapy
Patient adherence considerations

Break 11:00-11:15

Pharmacoepidemiology and Drug Use Safety 11:15-12:15
Pharmacoepidemiology
Individual and population drug safety
Prospective drug utilization evaluation
Retrospective drug utilization review
Drug use research using commercial databases
Drug use research using federal databases
Evidence-based medicine
Development of drug use guidelines

Lunch 12:15-1:00

Pharmacoeconomics 1:00-2:00
Health economics
Cost-of-illness analysis
Cost-minimization analysis
Cost-benefit analysis
Cost-effectiveness analysis
Cost-utility analysis
Quality of life evaluation
Quality-adjusted life years

Break 2:00-2:15

Drug Pricing and Marketing 2:15-3:15
Pricing strategies
Brand and generic/biosimilar drugs
Drug product life cycle
Pricing surveys; pricing companies
Economic complements and substitutes
Specific buyers' contracts (VA, 340b program)
Price discrimination abilities
Marketing strategies
Patient assistance programs
Role of direct-to-consumer advertising

Activity: Start-Up CEO 3:15-3:45

Wrap-Up 3:45-4:00

Master Course Recording

Biopharma Revenue Forecasting That Drives Decision Making and Investments

LIVE, ONLINE | LEVEL TWO

OVERVIEW

Biopharma Revenue Forecasting that Drives Decision Making and Investments is a seven-hour tactical course invaluable for organizations that work in both preclinical/early clinical development all the way to mature biopharma. Develop knowledge of the core elements that influence revenue forecasting including pricing, competitive assessments, and epidemiology. Understand how the geography of the US, EU, Japan, China, and the rest of the world impacts revenue forecasting. Join our dynamic industry experts as they bring to life the 'logical process' of revenue forecasting using real-life case studies that participants work through together.

The scope of this course includes:

- **Geography:** US, EU5, Japan, China, ROW
- **Therapeutic area:** oncology, specialty, rare diseases, gene therapy

Five takeaways

1. Develop a broad understanding of how and why revenue forecasts are developed to drive strategic decision making and investing in the biopharma industry.
2. Become fluent in the core elements of revenue forecasting including: epidemiology, competitive assessments, market share assignment, duration of therapy, pricing, gross-to-net margins, and annual price increases.
3. Understand how revenue forecasting varies across geographies and the considerations that need to be accounted.
4. Demonstrate the logical process (workstreams) that leads to effective, defensible revenue forecasting and the interpretation of its findings.
5. Generate insights and actionable decisions from the forecasting process.

AGENDA

WEEK ONE

Revenue Forecasting Context 30 minutes

Forecasting's strategic and tactical roles
External and internal factors
Market perspectives: an art and science
Forecasting utilization in product life cycle
Forecasting approaches
Market assessment, product forecast, in-line product support

WEEK TWO

Competitive Assessments 60 minutes

Determining indication, geography, time frame, resources
Defining scope: Target Product Profile
Defining indication: Databases
How to mine data for in ClinicalTrials.gov
How to perform a technical review of data
How to determine if an agent is or is not a competitor
Netting out the competitive set
Competitive assessments with rare and genetic diseases
Adjusting risk when competitor is determined

WEEK THREE

Market Share Assignment 10 minutes

Significance of market share
Measuring market share
Key factors: therapeutic value, number of competitors, launch speed

WEEK FOUR

Market Share Models
40 minutes

Market share models: advantages and disadvantages of each
McKinsey/MIT and Schulze/Rigel
McKinsey & Company/EvaluatePharma market share analysis

WEEK FIVE

Drug Pricing Today 65 minutes

Today's drug pricing environment
US drug pricing legislation
Different proposals to modify drug pricing
Drug pricing definitions
US payers: Medicare, Medicaid, CMS, private
Role of the pharmacy benefit manager (PBM)
Elements of pricing: clinical value, HEOR, pharmacoeconomic models, MAPR, GTN, rare disease
Pricing outside the US
Pricing references and resources
Annual price increases
Generics
Additional forecasting assumptions: duration of therapy, compliance, gross-to-net discount

WEEK SIX

Revenue Forecasting Elements: Epidemiology 195 minutes

Basic epidemiology terminology
35 minutes

Prevalence as a rate
Types of prevalence measures
Incidence as a rate
Relationship between prevalence and incidence
Using survival data
Epidemiology study designs
Cross-sectional study design
Cohort study design
Case-control study design

Disease Rates 25 minutes
How and why disease rates are used
Types of disease rates
World standard rates, crude rates, age specific rates, age-adjusted rates
Case study: Japan vs Philippines renal cell carcinoma disease rates

Role of Demographics in Epidemiological Projections 15 minutes
Data used in epidemiological projections
Prevalence and incidence: specific age and gender profiles
Example: cancer epidemiology profiles
Case Study: Japan vs Philippines: demographic changes influence future trends
How to use disease rates to project future patients

The Process of Determining Patient Populations 60 minutes
Quantitative epidemiology process overview
Defining the patient
Defining level of patient's epidemiology
How to build the patient tree
Literature acquisition and data sources
How to process, analyze and interpret data
How to create results: epidemiology calculations and meta-analysis

Basic Sources of Epidemiological Data 60 minutes
Peer reviewed scientific/medical literature
PRISMA
Rare/orphan disease sources
Disease registries
Government health databases worldwide (US, Japan, Korea, China, Canada, EU, UK)
Case study: oncology data sources

WEEK SEVEN

Revenue Forecast Assumptions Summary 20 minutes
How to run a SEER query
Case study: epidemiology of AML

Course Evaluation 20 minutes

Master Course Recording

Understanding Drug Pricing, Policy, and Utilization

ON-DEMAND, ONLINE | LEVEL ONE

OVERVIEW

Understanding Drug Pricing, Policy, and Utilization examines the complexities of the US healthcare market. Many believe patient access to medications and pricing are solely determined by the drug companies; however, this is far too simplistic. This course provides a comprehensive look at how competing forces including the federal government, the insurance industry, and healthcare providers influence formulary systems, which in turn determines how patients access, use, and pay for medications. Learn how commercial and government databases housing pharmacoepidemiology and pharmacoeconomic information also drive drug policy and pricing. Perform basic cost-effectiveness and quality of life calculations to help you gain an appreciation for the types of decisions faced by various persons on the drug development team. Created and taught by a healthcare economist and social scientist, this engaging course is a must for anyone new to healthcare policy and pricing.

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AGENDA

WEEK ONE

Setting the Stage 30 minutes
Clinical development overview
FDA adverse events reporting system

WEEK TWO

Drug Placement Into Formularies 60 minutes
Types of formulary systems
Considerations and issues for placement
Value proposition and drug price
Medicare, Medicaid, private insurers
Single payer markets
Pharmacy benefits manager roll
Manufacturer rebates
Tiering systems, prior authorization, step therapy
Patient adherence considerations

WEEK THREE

Pharmacoepidemiology and Drug Use Safety 60 minutes
Pharmacoepidemiology
Individual and population drug safety
Prospective drug utilization evaluation
Retrospective drug utilization review
Drug use research using commercial databases
Drug use research using federal databases
Evidence-based medicine
Development of drug use guidelines

WEEK FOUR

Pharmacoeconomics 60 minutes
Health economics
Cost-of-illness analysis
Cost-minimization analysis
Cost-benefit analysis
Cost-effectiveness analysis
Cost-utility analysis
Quality of life evaluation
Quality-adjusted life years

WEEK FIVE

Drug Pricing and Marketing 60 minutes
Pricing strategies
Brand and generic/biosimilar drugs
Drug product life cycle
Pricing surveys; pricing companies
Economic complements and substitutes
Specific buyers' contracts (VA, 340b program)
Price discrimination abilities
Marketing strategies
Patient assistance programs
Role of direct-to-consumer advertising

On-Demand, Online Classes

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LEVELS

Each on-demand, online class is given a level to help individuals choose the appropriate class based on their background and needs. For all level 2 and 3 classes a suggested prerequisite will be given but is not mandatory to take.

Level 1: Foundational For non-scientists new to biopharma and for those who need a refresher on the fundamental science driving the health care industry

Level 2: General For individuals who possess a general understanding of science basics

Level 3: Advanced For individuals who have a good grasp of the science and biopharma industry

PRICING

Each individual online course: **$150** BIO member price: **$120**

Bulk discount pricing:

Number of total courses	Discount per course	Price per course
10-20*	25%	$112
21–100	30%	$105
101–250	40%	$90
251–500	50%	$75
500 and up	70%	$45

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Biopharma Business Acumen

45-MINUTE ONLINE CL ASS | LEVEL 1

OVERVIEW

Biopharma Business Acumen was developed for those who need to better understand the unique considerations encountered by industry executives. The Oxford English Dictionary defines acumen as "the ability to make good judgments and quick decisions" and this course explores four areas in which good judgement and quick decisions can only be managed if one understands the basics of financing vehicles, intellectual property law, life cycle management choices, and drug pricing challenges.

Five Takeaways:

1. List the three basic financing vehicles used in the biopharma industry and when in the drug development process each financing vehicle is utilized.
2. Explain key patent concepts to determine if a claim is worthy.
3. Compare and contrast a supplemental new drug application and an abbreviated new drug application
4. List and explain the various strategies used by biopharma to extend a drug's life cycle.
5. Discuss ways to strategically price a drug.

AGENDA

- **Basic Financing Vehicles** lists the basic financing vehicles used in the biopharma industry, describes when in the drug development process each of the vehicles may be utilized, and describes what investors and companies give and receive in each financing scenario.
- **IP Management of a Cure** explains patents and exclusivity law, lists the criteria used by the USPTO to determine if a claim is worthy of a patent, and discusses key patent concepts.
- **Life Cycle Management of a Cure** discusses the parts of a biopharma drug's life cycle revenue curve from approval to off patent /exclusivity and lists and explains the various strategies used by biopharma to extend a drug's life cycle.
- **Pricing a Cure** reviews the factors involved in US drug pricing, lists drug price influencers, and describes ways to strategically price a drug product.