BIOTECH PRIMER

COURSE SNAPSHOT

Business of Biotech

biotechPrimer
Life Science Training From Industry Experts

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ABOUT US

Biotech Primer Inc. develops and delivers training to help professionals understand the science, business, and regulatory processes essential to the biotechnology, pharmaceutical, molecular diagnostics and medical device industries. Our industry experts continuously create, update and deliver the most engaging instruction anywhere. We have the experience and expertise needed to prepare companies to make strategic business decisions, navigate important regulatory hurdles, and move healthcare products from the bench to the bedside. To accomplish these goals, we offer a diverse range of learning opportunities, ensuring participants retain and put into practice what they learn.

- Integrate your science and business operations
- Bring in-depth knowledge to your sales force
- Help your team converse more effectively with industry clients, colleagues, and scientists
- Enable your entire staff to recognize new opportunities

OUR SUBJECT EXPERTISE

- Biotechnology for Non-Scientists
- Drug Development
- Drug Manufacturing
- Business of Biotech
- Molecular Diagnostics
- Medical Devices

OUR DELIVERY PLATFORMS

Our training is offered using multiple platforms to better fit your learning preferences and scheduling constraints

- **Live Customized Courses** Tailored training delivered to organizations worldwide live online or live onsite. You can modify the master course agendas to meet your specific learning needs.
- **Live Master Courses** Prescheduled courses for individuals or schedule a master course for your organization.
- **Recorded Master Courses** Offers the same content, exercises and workbook as the live master course, with the ability to take the course on-demand, online when your schedule permits.

- **On-Demand, Short Classes** Short interactive classes for individuals or bulk purchased for organizations.
  - Class transcripts and subtitles available in 9 languages including English, Japanese, Chinese, Spanish, French, French Canadian, Hindi, Arabic, and Russian.
  - Certificate available upon successful class completion.
  - Ability to upload certificate to your LinkedIn education profile.
  - Two corporate account options available for on-demand, short classes
    - **Enterprise:** Manage your own company account with our Learning Management System (LMS). Assign classes and view individual's progress. Enterprise is intuitive and easy-to-manage. No extra cost.
    - **LTI Bridge:** Connect your organizations LMS to Biotech Primer's LMS. Participants log into their company's LMS and take our classes. Integration costs apply.

OUR PRICING

- **Live Customized Courses** The cost of tailored training depends on content, length of course, and number of participants. Discounts given to multiple classes purchased within one year.
- **Live Master Courses** Prescheduled two-day courses for individuals range from $1495-$1695 US.
- **Recorded Master Courses** These courses are 3-12 hours in length and cost $895 US. Participants are given three months to complete each course.
- **On-Demand, Short Classes** Each class is $150 US. BIO members receive special pricing of $120 US per class. Participants are given two weeks to complete the class.

Bulk discount pricing:

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

**For BIO member companies only*

OUR COURSE LEVELS

- **Level 1: Foundational** For non-scientists new to biopharma and for those who need a refresher on the fundamental science driving the healthcare 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.

OUR PUBLICATIONS

- **The Biotech Primer One: The Science Driving Biopharma Explained**
  Learn the basic science driving the biopharma industry in this fully illustrated 120-page book.
- **The Biotech Primer Two: Next Generation Therapies Explained**
  Learn how vaccines, therapeutic antibodies, cell therapy, gene therapy, and RNA therapeutics mitigate disease in this easy-to-read 170-page book. Books available for purchase on Amazon.
- **The WEEKLY**
  White papers that explain the science behind the headlines.

OUR INSTRUCTORS

Biotech Primer instructors offer extensive industry experience. By drawing on their various backgrounds, these seasoned professionals are well-informed on the real-world situations you face. They have developed drugs, diagnostics, and medical devices for companies ranging from multinational corporations to start-ups.

Biotech Primer courses are on point, thorough and taught by one dedicated industry educator, not a patchwork of invited academic lecturers.

You can expect:

- Limited class size so all your questions are answered
- Hands-on labs, thought-provoking case studies, and dynamic discussions so you practice what you learn
- Industry war stories to help you avoid lessons hard learned by others

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LIVE MASTER COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Understanding Commercialization Within Biopharma Course

OVERVIEW

Understanding Commercialization Within Biopharma is a two-day interactive course that uses real-world examples to explain the big picture of strategic commercialization and the tactics necessary for a successful pharmaceutical launch. Discussion points focus on creating the Therapeutic Target Profile (TPP), the power of market segmentation, crafting the value story, and building/sustaining competitive advantage. This course is for scientists and non-scientists who need to 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 20 minutes

Introduction to Commercialization
70 minutes
Strategic commercialization: What it is and isn't
Product life cycle phases: timing and activities
Decisions affecting commercial potential
Optimizing commercial value

Break 15 minutes

Early Planning 75 minutes
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 45 minutes

Pre-Launch Planning 90 minutes
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 15 minutes

Pre-Launch Planning *continued* 45 minutes
Case Study: Cialis vs Viagra
Business strategies: 5 key questions to ask
Creating a strategic brand plan
Activity: Uncovering the Strategic Plan

Wrap-Up 15 minutes

DAY TWO

Creating the Value Proposition 90 minutes
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 15 minutes

Launch Planning 45 minutes
Launch planning activities
Market access
Value-based payment models
Disease education, premarket development
Scientific pillars and key messages
FDA guidelines covering promotions and advertising

In-Line Planning 45 minutes
In-line planning activities
Key performance indicators (KPI)
Critical success factors
Post launch threats

Lunch 45 minutes

Building and Sustaining Competitive Advantage 60 minutes
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 15 minutes

Loss of Exclusivity (LOE) Commercialization Planning 45 minutes
LOE planning activities
LOE timing considerations
Market dynamics and regulatory challenges
LOE strategies

Course Evaluation 15 minutes

Course Wrap-Up 15 minutes

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LIVE MASTER COURSE | LEVEL TWO
SUGGESTED PREREQUISITE: NONE

Biopharma Revenue Forecasting That Drives Decision Making and Investments

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

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

Break 15 minutes

Market Share Assignment 60 minutes
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 and Company/EvaluatePharma market share analysis

Lunch 45 minutes

Drug Pricing Today: What Every Biopharma Executive Should Know 75 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 discoun

Break 15 minutes

Revenue Forecasting Elements: Epidemiology 60 minutes
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 15 minutes

DAY TWO

Epidemiology: Disease Rates 60 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

Epidemiology: Role of Demographics in Epidemiological Projections 60 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

Break 15 minutes

Epidemiology: 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

Lunch 45 minutes

Epidemiology: Basic Sources of Epidemiological Data 45 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

Revenue Forecast Assumptions Summary 45 minutes
How to run a SEER query
Case Study: Epidemiology of AML

Case Study: Start Up CEO 45 minutes

Wrap-Up 15 minutes

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LIVE MASTER COURSE | LEVEL ONE
SUGGESTED PREREQUISITE: NONE

Understanding Drug Pricing, Policy, and Utilization

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 appreciate 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 lifecycle and supply chain issues in pricing, marketing, and reimbursement.
5. Understanding of the relationship between manufacturers, policymakers, pharmacies, and patients.

AGENDA

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

Drug Placement Into Formularies 30 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 role
Manufacturer rebates
Tiering systems, prior authorization, step therapy
Patient adherence considerations

Break 15 minutes

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

Lunch 45 minutes

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

Break 15 minutes

Drug Pricing and Marketing 60 minutes
Pricing strategies
Brand and generic/biosimilar drugs
Drug product lifecycle
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 30 minutes

Wrap-Up 15 minutes

Understanding Commercialization Within Biopharma

OVERVIEW

This is the recorded Understanding Commercialization Within Biopharma course with the same content, interactive exercises, and course materials that are given in the live version. You have 3 months to view this course.

Understanding Commercialization Within Biopharma is an eight-hour course that uses real-world examples to explain the big picture of strategic commercialization and the tactics necessary for a successful pharmaceutical launch. Discussion points focus on creating the Therapeutic Target Profile (TPP), the power of market segmentation, crafting the value story, and building/sustaining competitive advantage. This course is for scientists and non-scientists who need to 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

WEEK ONE

Introduction to Commercialization 67 minutes

Strategic commercialization: What it is and isn't
Product lifecycle phases: timing and activities
Decisions affecting commercial potential
Optimizing commercial value

WEEK TWO

Early Planning 72 minutes

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

WEEK THREE

Pre-Launch Planning 107 minutes

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
Case Study: Cialis vs Viagra
Business strategies: 5 key questions to ask
Creating a strategic brand plan
Activity: Uncovering the Strategic Plan

WEEK FOUR

Creating the Value Proposition 97 minutes

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

WEEK FIVE

Launch Planning 57 minutes

Launch planning activities
Market access
Value-based payment models
Disease education, premarket development
Scientific pillars and key messages
FDA guidelines covering promotions and advertising

WEEK SIX

In-Line Planning 83 minutes

Key performance indicators (KPI)
Post launch threats
Building and sustaining competitive advantage
Lifecycle management challenges
Risk management strategies
Multichannel marketing
Developing key brand performance measures
Lose of exclusivity (LOE) commercialization planning
LOE timing considerations
LOE strategies
Market dynamics
Regulatory challenges

Biopharma Revenue Forecasting That Drives Decision Making and Investments

OVERVIEW

This is the recorded Biopharma Revenue Forecasting course with the same content, interactive exercises, and course materials that are given in the live version. You have 3 months to view this course.

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 for.
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 lifecycle
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 20 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 and 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

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

WEEK SEVEN

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

WEEK EIGHT

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

WEEK NINE

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

WEEK TEN

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 ELEVEN

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

Course Evaluation 20 minutes

Understanding Drug Pricing, Policy, and Utilization

OVERVIEW

This is the recorded Understanding Drug Pricing, Policy, and Utilization course with the same content, interactive exercises, and course materials that are given in the live version. You have 3 months to view this course.

Understanding Drug Pricing, Policy, and Utilization is a 4.5-hour course that 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 lifecycle and supply chain issues in pricing, marketing, and reimbursement.
5. Understanding of the relationship between manufacturers, policymakers, pharmacies, and patients.

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 role
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 lifecycle
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

Biopharma Business Acumen

OVERVIEW

Biopharma Business Acumen was developed for those who need to 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, lifecycle management choices, and drug pricing challenges.

Five Takeaways:

1. List the basics financing vehicles used in the biopharma industry and state when to use them during the drug development process.
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 lifecycle.
5. Discuss ways to price a drug strategically.

AGENDA

Financing a Cure

- Basic financing vehicles
- Financing sources
- What investments are made when during the development process

IP Management of a Cure

- Key patent concepts
- Types of patents
- Exclusivity law in the US

Lifecycle Management of a Cure

- Lifecycle management defined
- FDA regulations regarding lifecycle management
- Drug revenue post launch
- Types of lifecycle management

Pricing a Cure

- US drug pricing explained
- US price influencers: insurance, PBMs, formularies
- Types of drug pricing
  - Value-Based Pricing
  - Strategic Pricing