

# BSCA Curriculum 2020

## Day One

7:00am to 8:00am

**Breakfast**

8:00am to 9:00am

**Introductions:**

Participants will briefly introduce themselves and what they hope to get from the Program

9:00am to 10:00am

**Session: Supply Chain Management of Biotech & Pharma**

**Presentation 1: “What’s unique about Supply Chain Management in Life Sciences?”**

- Does traditional SCM organizations/structure allow for success in Life Sciences?
- The Interdependent Stakeholders – Who are the partners, suppliers, and customers?
- Globalization where the World is Flat – Constraints facing modern Supply Chains
- Organizational Structure of SCM – Plan, Source, Make, Deliver and Return model
- Managing Demand Uncertainty, Product Quality, Patient Care & Risk
- Key Principles and Tools of Optimization of Cost, Quality and Service
- Best Practices of Supply Chain Leaders in Biotech & Pharmaceutical organizations (Gartner)
- Collaboration among internal and external supply chain partners for success

10:00am to 10:30am

**Coffee Break**

10:30am to 11:00am

**Session: Sales & Operations Planning**

**Presentation 2: “Proven Sales & Operations Planning – Systems, Organization Structures and Collaboration with 3rd Party Service providers for Clinical and Commercial Products”**

Sales and Operations Planning for Clinical and Commercial Operations drive the supply chain from end to end where the objectives of optimizing cost, lead time, quality and governmental compliance are pursued. The solutions require the systematic collaboration of the stakeholders from R&D scientists to functions with an enterprise and external ones providing services. Processes, Systems, Networks and Organizational Structures are the foundational components for driving the overall supply chain.

Stakeholders in the Enterprise and Supply Chain are often at odds with each other. The Sales organization wants to increase sales and make the customer happy while operations wants to optimize the running of equipment to reduce changeovers. An Effective Sales and Operations Planning delivers a

# BSCA Curriculum 2020

set of decision-making processes to balance demand and supply by integrating all levels and functions of the organization.

- This session will discuss how to effectively build an S&OP organization and processes. More importantly, we will discuss the various stages in the rollout to ensure a mature S&OP.
- How to prepare the organization for S&OP- The need for Change
- The maturity model of an effective Sales and Operations Planning process
- How to effectively rollout an S&OP Process
- A functional assessment of S&OP
- The future of S&OP in the Digital Supply Chain

**11:30am to 12:30pm**

## **Session: Inventory Management**

### **Presentation 3: “Dynamic Inventory Management in a Demand-driven Enterprise”**

Optimization of patient care with optimal inventories requires dynamic tools of demand sensing, prediction, simulation, rapid replenishment, AI, Machine Learning and utilization of Big Data.

**12:30pm to 1:30pm**

## **Luncheon Break**

**1:30pm to 3:30pm**

## **Session: Strategic Sourcing & Procurement**

### **Presentation 4: Procurement Vision, Strategy, Organizational Design, and Roles & Responsibilities**

What does Strategic Sourcing, Purchasing, and Supplier Relationship Management mean and what are the differences of each? Procurement’s place in the organization has been subject to significant critique and as a result, transformational change. Procurement Leadership, in defining Strategy and Vision, develops policy and governance, which has a wide impact to the business, for both direct and indirect spend operations and stakeholders. Benchmarking procurement processes and capabilities within Life Sciences and other, more mature industries (ie. Automotive, Commercial Packaged Goods, Aerospace) has become critical to developing optimized business processes and organizations. Besides goal-setting and key initiative development, the identification, recruiting, and development of critical staff has become imperative for success within Procurement organizations, as well. We’ll review and discuss what should be Procurement’s Top Priorities including (1) Gain greater control of business unit spend across all Categories and (2) Enhance supplier management capabilities through key initiatives such as the development of structured internal customer engagement processes and supplier performance and compliance management programs.

We’ll address the following:

- Procurement Vision and Strategy – How to Lead and Influence the Organization
- Internal Customers, Partnerships, and Stakeholder Development
- Organizational Design – Centralized, Center-Led, Decentralized

# BSCA Curriculum 2020

- Strategic Commodity / Category Management
- Supplier Relationship Management
- Risk, Quality, and Compliance
- Data Analytics & Master Data
- Procurement Career Path

## **Presentation 5: Procurement in Action**

Influencing the Organization by linking Supplier Risk to Business Impact. Now that we've established the Vision, Strategy, Organizational Design, and Roles & Responsibilities, we'll investigate and review the various Procurement operations. From establishing a Preferred Supplier/Vendor list and Supply Agreement/Contracts to ERP/MRP tactical operations focused on supply assurance and an uninterrupted flow of materials to Manufacturing Sites and Customers – The Strategic, Operational, and Tactical Procurement linkages will be subject to this second of two Strategic Sourcing/Procurement sessions. Foundations of Master Data, Analytics, and Visualization, as well as Supplier Quality and Compliance Campaigns (RoHS, REACH, Conflict Minerals, Corporate Social Responsibility, Supplier Diversity, Anti-Human Trafficking, Environment, Antitrust & Corruption, MDSAP/ISO 13485/cGMP) will be explored.

The following topics will be part of the discussion:

- Supply Contracts: Strategic Vendors & Components – Make-to-Stock vs Make-to-Order
- Governance Forums – Business Reviews, Audits, Approved Vendor List, Quality
- Supplier Risk & Quality/Compliance Management
- Supplier Selection, Qualification, & Onboarding
- Spend Analysis: Process and Tools
- How to effectively do RFI, RFQ
- Make versus Buy Decisions
- New Product Introduction
- eProcurement

**3:30pm to 4:00pm**

**Coffee Break**

**4:00pm to 5:00pm**

**Team Assignments, Case Study and Homework Discussion Case Study**

**Case Study: “How do the Silos of Manufacturers, Distributors, Hospitals, Medical Service Providers and Insurance Companies Adversely Impact Patient care?”**

**5:30pm to 6:30pm**

**Reception**

# BSCA Curriculum 2020

6:30pm to 8:00pm

**Dinner with Guest Speaker**

“Drug Discovery, Clinical Trials and Commercialization”

8:00pm to 9:00pm

**Working Time for Teams**

## **Day Two – Delivery (Distribution)**

7:00am to 8:00am

**Breakfast**

8:00am to 10:00am

**Session: Distribution & Transportation**

**Presentation 6: Distribution & Transportation**

Presentation of the changing landscape of specialty drugs and insights and best practices for successful commercialization of specialty products. Learn more about the significant differences between traditional and specialty pharmaceutical supply chains, as well as dive into a pre-commercialization timeline to walk through key milestones as you move from clinical to commercial launch. Gain insights from experts on topics such as storage, shipping, packaging, and regulatory and compliance. Today's specialty drug pipeline is robust with many promising new treatments in the pipeline for a wide range of conditions – planning ahead for the successful commercialization of these products is critical.

The management of Global Logistics in Life Sciences is becoming increasingly more challenging. This is driven by the desire of regulators to demand continuous monitoring of all environmental conditions throughout storage and transportation. Notwithstanding this, the trend towards shipping Controlled Room Temperature (CRT), in addition to Cold Chain and Cryo Chain, is introducing a new dynamic to Global Logistics. The challenges of continuous monitoring is a growing concern for the industry.

This session will discuss how to effectively manage the various modes of transportation in the Global Logistics Network. We will discuss the growing trends to Global Logistics especially in regard to Vibration, Impact, CRT, Sustainability. The session will address a process on how to Qualify and Validate Transportation Lanes in the Global Logistics Network. Finally, we will discuss how to measure the effectiveness of the network in order to ensure optimal cost efficiency, effectiveness and timeliness to the customer.

“Temperature Management Trends and Solutions”

# BSCA Curriculum 2020

Moving temperature-sensitive products within the US and globally demands the custody of a capable and qualified process and established quality system to ensure compliance with temperature ranges often called “cold chain” and sensitive product needs. This has propelled the logistics into a regulated Temperature Management Supply Chain, resulting in higher costs for the manufacturers and distributors. Since there is currently no single standard, guidance, regulator, document or arbiter with the final say on a compliant cold chain for a given region, manufacturers oftentimes struggle to find a solution. This presentation will address the myriad issues manufacturers and distributors face and innovative ways solution.

**10:00am to 10:30am**

**Coffee Break**

**10:30am to 12:30pm**

**Presentation 8: Case Study Presentations and Debrief**

**12:30pm to 1:30pm**

**Luncheon Break**

**1:30pm to 2:30pm**

**Session: Meeting the Challenges of Global Logistics**

**Presentation 9: “People, Processes and Technology Trends in Transportation”**

- How to effective management modes
- Environmental controls during transportation
- Qualification and Validation of Global Logistics
- Applications of IoT, Blockchain, AI and machine learning

**2:30pm to 3:30pm**

**Presentation 10: Strategies for Life Sciences Supply Chain**

**Industry Guest Lecture: “Personalized Medicine Through Gene Immuno-Therapy”**

A transformation is underway in patient treatment where the science is moving away from a one-size-fits-all, trial-and-error approach toward a targeted approach that uses patients’ molecular information to inform health care decisions. Although many doctors still prescribe therapies based on population averages, it is clear that healthcare professionals are already seeing the potential for personalized medicine to have a measurable impact on their ability to deliver more effective treatment options. Next generation supply chain processes, technology and people/training are required to achieve the benefits from technological breakthroughs in the field of cell and gene therapy. These therapies have the potential to significantly improve the quality of life of millions of patients. Success depends on our ability to combine cutting-edge supply chain knowledge with innovations in manufacturing, clinical and regulatory – requiring multiple stakeholders in the eco-system to embrace significant change.

# BSCA Curriculum 2020

3:00pm to 3:30pm

Coffee Break

3:30pm to 4:30pm

## **Presentation 11: “CAPA | Root Cause Analysis and Recall Management”**

The regulation and product quality standards in the Life Science Industry are becoming more difficult each year. The Integrated Supply Chain, historically, has lagged the business in Quality Systems. Typically, the supply chain has been reactive in compliance to standards and requirements. The increased regulatory requirements for more stringent controls throughout the chain of custody of products, requires the supply chain to become more diligent in ensuring complete compliance to all quality and regulatory standards.

This session will discuss the implementation of a Corrective and Preventative Action (CAPA) process throughout the integrated supply chain. We will discuss best practices in developing a supply chain CAPA program. We will also study Root Cause Analyses as part of the CAPA program. Finally, the session will discuss how to build an effective reverse logistics (returns) process to facilitate and Post-Market Actions.

- How to develop and implement an effective CAPA in the integrated Supply Chain
- Effective Root Cause analysis
- Managing Post-Market Actions and building a robust return process

4:30pm to 5:30pm

## **Team Assignments: Case Study and Homework Discussion**

**Case Study: “Developing and Implementing an Effective CAPA System in My Supply Chain”**

Teams will take what is learned and their own experience and detail a CAPA system complete with root cause analysis.

## **Day Three**

7:00am to 8:00am

Breakfast

8:00am to 9:00am

**Session: Optimization of the Supply Chain Network**

# BSCA Curriculum 2020

## **Presentation 12: “Optimization of SCM Network Tools and Caser Studies”**

Geographic footprint – Where should manufacturing exist around the globe?

- Contract Manufacturing Organization (CMOs) – Make vs. Buy
- Operations Standard Costing – Material, Labor, Overhead = Standard Cost
- Manufacturing Performance Metrics – Non-Standards reporting – Variances, E&O, Inventory, etc.
- Plant to Plant Quality – Internal Supplier Management
- Organizational/Network Redundancy

## **Session: QA & Risk Management**

### **Presentation 13: QA and Risk Management**

- History of Serialization Regulations: USA & Europe
- Track, Trace and Serialization: Regulatory and Business Imperative
- Drug Supply Chain Security Act (DSCSA)
- QA from Supply to Delivery of Patient Care
- Risk Management

**9:00am to 10:00am**

## **Session: Disruptive Technology**

### **Presentation 14: “Rewiring the Supply Chain with Disruptive Technologies – Case Studies”**

Today the supply chain has become demand-driven where the technologies of Internet, Digitalization, Mobility, IoT, Artificial Intelligence and Machine Learning and Blockchain are enabling unprecedented levels of efficiency, service, quality and governmental compliance.

**10:00am to 10:30am**

## **Coffee Break**

**10:30am to 12:30pm**

## **Session: Career & Talent Development**

All current surveys on supply chain talent indicate an increasing shortage in skilled supply chain talent. This is further complicated by a shortage in future supply chain leaders. Most recent surveys show that for every 6 open supply chain positions (non-warehouse labor), there is only 1 person to fill the position. This trend is alarming when you realize that most current supply chain executives are eligible for retirement now or within 5 years. When you couple this with the fact that the majority of company executives believe that there is a shortage of supply chain talent with the right combination of knowledge, skills, experience and behavioral maturity; future Supply Chain Leaders will need to understand their own skillset shortfall and develop the necessary skills to prepare for succession. This session will discuss the trends that are impacting the skill shortage. We will look at the skillsets necessary for the new Digital Supply Chain. The session will talk about the new technical and business skills along with the behavior/traits that are necessary to ensure Digital Dexterity. What are characteristics of the Supply Chain Leader of the future and how you can prepare yourself for a career

# BSCA Curriculum 2020

towards Executive Management? By analyzing one's personal strengths and weaknesses, each attendee will be able to capitalize on opportunities and divert threats through a robust career plan.

## **Presentation 15: "Skills and Career Development in Bio-pharma: The Supply Chain Management Path"**

- Trends driving the need for changing skillsets – technical, business and behavioral
- The leadership skills necessary to become a Talented Supply Chain Leader
- Understanding your Personal SWOTs necessary for a successful career
- Building your future Looking into the future – your career path in 2, 5, 10 years
- Guest Lecturer on soft skills needed for success

**12:30pm to 1:30pm**

**Luncheon Break**

**1:30pm to 3:00pm**

**Team Presentation on CAPA**

**3:00pm to 3:30pm**

**Coffee Break**

**3:30pm to 4:30pm**

**Session: Delivering to Customers in Markets**

**Presentation 16:** Keynote speaker to talk about the challenges of last mile delivery of vaccines and other new therapies in the most developing countries.

**4:30pm to 5:00pm**

**Debrief and Wrap Up**