COURSE DESCRIPTION

In today's competitive global pharmaceutical environment, more and more companies are faced with diminishing product pipelines and generic competition due to patent expiries. The traditional cash rich pharmaceutical companies are now faced with the challenge of tightly managing their operations and supply chains in an effort to reduce spend. At the same time, pharmaceutical companies are constantly faced with challenges of counterfeiting, global logistics and rising commodity prices. As a result of such changes to the pharmaceutical landscape, companies find themselves focusing on strategic supply chain, logistics and operations management area to effectively impact the bottom line.

The objective of this course offer students the knowledge of cost management, strategic sourcing, negotiation, procurement processes and supply management strategies for pharmaceutical companies.

The course is designed to give students the full perspective of the pharmaceutical and biotech lifecycle and the impact supply chain management activities have on the strategy and direction of the affiliated organizations.

PERFORMANCE ASSESSMENT

1. Class Participation – 30%

2. Case Study Assignment I – 35%

   HBR – Align Technology Inc.: Matching Manufacturing Capacity to Sales Demand

3. Case Study Assignment II – 35%

   Establishing a Perspective and Associated Value & Supply Chain for Modern Day Personalized Medicine – Cell & Gene Therapy Supply Chain Challenges and Design
Course Procedures:
1. Course lecture notes will be posted on canvas prior to each class. Students are expected to review the lecture notes prior to each class.
2. All assigned reading must be conducted prior to class.
3. Punctuality is important.
4. Respect for one another is mandatory during class discussion.
5. All cell phones must be silenced at the start of class to minimize disruptions. If you need to take a call, please exit the class room quietly so that the discussions are not disrupted.
6. If you will miss any class, make arrangements with the instructor for any material that may be missed. Missing more than one class will not be acceptable.
7. Participation is strongly encouraged and is a part of your grade. Everyone is expected to participate fully in class discussions.

ACADEMIC INTEGRITY

I do NOT tolerate cheating. Students are responsible for understanding the RU Academic Integrity Policy (http://academicintegrity.rutgers.edu/)

I will strongly enforce this Policy and pursue all violations. On all examinations and assignments, students must sign the RU Honor Pledge, which states, “On my honor, I have neither received nor given any unauthorized assistance on this examination or assignment.” I will screen all written assignments through SafeAssign or Turnitin, plagiarism detection services that compare the work against a large database of past work. Don’t let cheating destroy your hard-earned opportunity to learn. See business.rutgers.edu/ai for more details.

Any form of dishonesty will result in an “F” grade for the course. All of your written work must be your own. All references must be cited. Plagiarism will not be tolerated.

COURSE SCHEDULE

Semester Breakdown:

Week 1 – Pharmaceutical Operations Overview & Business Landscape
Resource:

- https://www.youtube.com/watch?v=c6iX-QnuMnQ
- https://www.youtube.com/watch?v=oQSGX93J50I

Case Reading:

- Rapid Change in the Life Sciences Supply Chain
- Health of the Healthcare Supply Chain
- Fast Forward – Future Proofing the Life Science Supply Chain
- HBR – Growth Strategies in the Pharmaceutical Industry

Topics:

1. Introduction to Pharmaceutical Purchasing and Supply Chain Management

2. Evolution of the supply chain operations departments within pharmaceutical operations
   a. Strategic sourcing
   b. Operations management
   c. Distribution/Logistics
   d. Technology

3. Driving a successful supply chain in the global pharmaceutical market

Week 2 – Drug Discovery Through Drug Product Commercialization and the Associated Supply Chain

Resource:

- https://www.youtube.com/watch?v=cFC1SO7yE3A

Case Reading:

- Drug Discovery and Development
Managing the Extended R&D Supply Chain

R&D Supply Chain

Topics:

1. Stages of pharmaceutical discovery
   a. The drug development process – Phase 0 through Phase IV
   b. Clinical, development and commercial operations interfaces with procurement and supply management

2. The impact of procurement and supply management on the bottom-line during the pharmaceutical chain lifecycle process
   a. Clinical operations supply chain networks
   b. Commercial operations supply chain networks

3. Revitalizing the pharmaceutical supply chain landscape

Week 3 – Pharmaceutical Distribution Network Systems

Resource:

- https://www.youtube.com/watch?v=KCN4hdxs8Kk
- https://www.youtube.com/watch?v=6Djftj0bwus

Case Reading:

- Implementing Pharmaceutical Serialization
- Key Logistics Trends in Life Sciences 2020+
- Securing the Global Pharmaceutical Supply Chain
- HBR – The Challenge of Curbing Counterfeit Prescription Drug Growth: The Perfect Storm
Topics:

1. The distribution networks
   a. Manufacturing  ➔  Warehousing  ➔  Wholesalers  ➔  Retailers

2. Wholesaler Value – Managing the end to end supply chain
   a. Wholesaler operations
   b. Relationship between manufacturers and wholesalers

3. Track and trace systems and impact of security networks

Week 4 – Pharmaceutical Sales & Operations Networks

Resource:

- https://www.youtube.com/watch?v=PdY_pfWpTzY
- https://www.youtube.com/watch?v=h9_I0IfAAI4

Case Reading:

- 21st Century Pharmaceutical S&OP
- Preparing the Supply Chain Pharma Needs
- HBR – The Game Plan for Aligning the Organization
- HBR – Metabical: Pricing, Packaging, and Demand Forecasting for a New Weight-Loss Drug

Topics:

1. Developing, implementing and managing the Sales & Operations Planning (S&OP) process

2. Optimizing inventory in the value chain

3. Supply chain operations interface with the organization

Week 5 – Pharmaceutical Operational Systems, Strategies & Trends
Resource:

- https://www.youtube.com/watch?v=m8mNBGEXCEQ
- https://www.youtube.com/watch?v=o1eGt8Gj8LI
- https://www.youtube.com/watch?v=zmGJMjl2esk

Case Reading:

- 2018 Life Science Trends
- The New Rx for Pharmaceutical Manufacturing
- Blurring the Lines – Preparing for Convergence
- Outlook on Pharmaceutical Operations
- New Frontiers of Growth
- The Impact of Cell and Gene Therapies on the Supply Chain

Topics:

1. Using ERP as a competitive procurement/supply chain tool

2. Future trends in pharmaceutical operations and their effect on procurement and supply management operations – Personalized medicine needs

3. The insourcing/outsourcing business models and its impact on the future pharmaceutical business model
   a. Understanding the Contract Research Organization (CRO), Contract Manufacturing Organization (CMO) and Contract Sales Organization (CSO) business model – advantages and disadvantages of outsourcing
   b. Regulatory impact of outsourcing
   c. Supplier management

SUPPORT SERVICES

If you need accommodation for a disability, obtain a Letter of Accommodation from the Office of Disability Services. The Office of Disability Services at Rutgers, The State University of New Jersey,

[Rutgers University-New Brunswick ODS phone (848)445-6800 or email dsoffice@echo.rutgers.edu]

[Rutgers University-Newark ODS phone (973)353-5375 or email ods@newark.rutgers.edu]

If you are pregnant, the Office of Title IX and ADA Compliance is available to assist with any concerns or potential accommodations related to pregnancy.

[Rutgers University-New Brunswick Title IX Coordinator phone (848)932-8200 or email jackie.moran@rutgers.edu]

[Rutgers University-Newark Office of Title IX and ADA Compliance phone (973)353-1906 or email TitleIX@newark.rutgers.edu]

If you seek religious accommodations, the Office of the Dean of Students is available to verify absences for religious observance, as needed.

[Rutgers University-New Brunswick Dean of Students phone (848)932-2300 or email deanofstudents@echo.rutgers.edu]

[Rutgers University-Newark Dean of Students phone (973)353-5063 or email DeanofStudents@newark.rutgers.edu]

If you have experienced any form of gender or sex-based discrimination or harassment, including sexual assault, sexual harassment, relationship violence, or stalking, the Office for Violence Prevention and Victim Assistance provides help and support. More information can be found at http://vpva.rutgers.edu/.

[Rutgers University-New Brunswick incident report link: http://studentconduct.rutgers.edu/concern/. You may contact the Office for Violence Prevention and Victim Assistance at (848)932-1181]

[Rutgers University-Newark incident report link: https://cm.maxient.com/reportingform.php?RutgersUniv&layout_id=7. You may also contact the Office of Title IX and ADA Compliance at (973)353-1906 or email TitleIX@newark.rutgers.edu. If you wish to speak with a staff member who is confidential and does not have a reporting responsibility, you may contact the Office for Violence Prevention and Victim Assistance at (973)353-1918 or email run.vpva@rutgers.edu]
If students who have experienced a temporary condition or injury that is adversely affecting their ability to fully participate, you should submit a request via https://temporaryconditions.rutgers.edu.

If you are a military veteran or are on active military duty, you can obtain support through the Office of Veteran and Military Programs and Services. http://veterans.rutgers.edu/

If you are in need of mental health services, please use our readily available services.
[Rutgers University-Newark Counseling Center: http://counseling.newark.rutgers.edu/]
[Rutgers Counseling and Psychological Services–New Brunswick: http://rhscaps.rutgers.edu/]

If you are in need of physical health services, please use our readily available services.
[Rutgers Health Services – Newark: http://health.newark.rutgers.edu/]
[Rutgers Health Services – New Brunswick: http://health.rutgers.edu/]

If you are in need of legal services, please use our readily available services: http://rusls.rutgers.edu/

Students experiencing difficulty in courses due to English as a second language (ESL) should contact the Program in American Language Studies for supports.
[Rutgers–Newark: PALS@newark.rutgers.edu]
[Rutgers–New Brunswick: eslpals@english.rutgers.edu]

If you are in need of additional academic assistance, please use our readily available services.
[Rutgers University-Newark Learning Center: http://www.ncas.rutgers.edu/rlc]
[Rutgers University-Newark Writing Center: http://www.ncas.rutgers.edu/writingcenter]
[Rutgers University-New Brunswick Learning Center: https://rlc.rutgers.edu/]

[Optional items that many faculty include:...]
- Students must sign, date, and return a statement declaring that they understand the RU Academic Integrity Policy.

- Students must sign, date, and return a statement declaring that they understand this syllabus.