Globalization and the international trade of drugs and medical products have progressed beyond any single regulatory authority’s ability to effectively ensure the quality, safety, and effectiveness of these products. In the U.S., the importation of foreign sourced products has increased tremendously, accounting for over 80% of the active pharmaceutical ingredients. However, varying drug regulations have resulted in gaps in oversight causing differing views on the acceptable level of risk in public health leading to drug quality related deaths and other serious harms. One clear reason for this compromised system is the differences in how these products are regulated from country to country. Nevertheless, the pharmaceutical and related industries are thriving in the global marketplace. This course is intended to be the first comparative survey into the regulatory frameworks of certain key countries, both developed and developing markets, along with international institutions, such as the World Health Organization, involved in promoting the access and development of safe, effective and quality medical products. This course will also identify the major international non-governmental stakeholders, and the multi-lateral schemes and treatises in which they operate that are intended to assist in the convergence of pharmaceutical laws and regulations.

Currently, there is no text or case book on this subject. The primary readings will be assigned by the professors.
<table>
<thead>
<tr>
<th>Class</th>
<th>September 02, 2016</th>
<th>Rik &amp; Mark</th>
<th><strong>Overview of Globalization and International Trade in Pharmaceuticals</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>September 09, 2016</td>
<td>Rik</td>
<td><strong>US FDA Overview: How Drugs get to the Market - The Gold Standard?</strong></td>
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<td>2</td>
<td>September 16, 2016</td>
<td>Mark</td>
<td><strong>CDSCO: India</strong></td>
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<td><strong>CFDA: China</strong></td>
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<td><strong>HSA: Singapore</strong></td>
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<td><strong>EU/EMA/EC</strong></td>
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**Assigned Reading**

1. Select definitions of drugs, and legal definitions of substandard/spurious/falsely-labeled/falsified/counterfeit (SSFFC) medical products from various State actors
2. Discussion on Global Supply Chains: (CPT Article on Track and Trace)
3. Certificates of Analysis
4. Regulations establishing “Quality” and what it means as a Proxy for Safety and Efficacy
5. Ng, Chapter 9, pp. 212-243 (familiarize; no need to commit to memory).

**International Drug Regulatory Systems (National Regulatory Authorities)**

1. Select Chapters in US Food and Drug Law
2. 21 CFR Part 314, Subparts B and C
3. 21 CFR Part 320
4. Ng, Chapter 8, pp. 176-192 (familiarize)

Selections of the Drugs and Cosmetics Act covering approval requirements and Imports/Exports

Selections of the Drug Administration Law covering approval requirements and Imports/Exports

2. Guidance on Medicinal Product Registration in Singapore, Chapters C and D
3. Ng, Chapter 8, pp. 193-207 (familiarize)
<table>
<thead>
<tr>
<th>Date</th>
<th>Speaker</th>
<th>Title</th>
<th>Terms of Reference</th>
</tr>
</thead>
</table>
| September 23, 2016 | Rik    | International Conference on Harmonization (ICH)                      | 1. Terms of Reference  
2. ICH  
M4 (Guideline on the Common Technical Document) |
| September 30, 2016 | Mark   | Pharmaceutical Inspection Convention and Scheme                      | 1. Terms of Reference: PIC/S  
2. Ng. Chapter 10 (familiarize) |
| October 07, 2016  | Rik    | The UN: Role of WHO, UNAIDS, etc.                                   | 1. WHA Terms of Reference  
2. Essential Medicines  
3. Prequalification Program |
| October 14, 2016   | Mark   | The World Medical Association                                       | 1. Declaration of Helsinki  
2. 21 CFR Part 50 |
| October 21, 2016   | Rik & Guest Lecture – USP Attorney | The US Pharmacopeia and the Pharmacopeia Discussion Group | 1. USP Articles of Incorporation (Defining its Purpose)  
2. Selections from the USP General Chapters and the Pharmacopeial Discussion Group  
3. Monographs from USP and the European Pharmacopeial (inherent characteristics) |

**Multilateral Treaties**

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<tr>
<th>Date</th>
<th>Speaker</th>
<th>Title</th>
<th>Terms of Reference</th>
</tr>
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<tbody>
<tr>
<td>Date</td>
<td>Lecturer</td>
<td>Topic</td>
<td>Notes</td>
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| October 28, 2016  | Mark & Guest Lecturer - FDA Attorney | Asia Pacific Economic Cooperation and the Regulatory Harmonization Steering Committee | 1. Select readings covering the history of APEC and creation of the Life Science Innovation Forum  
2. LSIF Strategic Plan |
| November 04, 2016 | Mark                             | Association of Southeast Asian Nations and the Pharmaceutical Product Working Group | History and goals of ASEAN and PPWG: Case Study: The ASEAN Common Technical Document and Stability |
| November 11, 2016 | Rik                              | The World Trade Organization                                          | 1. Understanding the WTO - Basics  
2. Article 39 of the Agreement on Trade Related Aspects of Intellectual Property Rights |
| November 18, 2016 | Mark                             | US Intellectual Property Enforcement Coordinator (IPEC) and INTERPOL  | Selections of the IPEC Joint Strategic Plan and findings from Operation Pangaea |
| December 02, 2016 | Rik & Mark Close Out              | Trade Associations: From PhRMA to GPhA  
Global Convergence or New World Order Class Discussion | 1. Introductions to global innovator and generic manufacturer trade associations  
2. Select Public Comments by trade associations |

Final Papers Due No Later than Dec 16th