Academic relationships that support pharmaceutical excellence: the role of Centers of Excellence

A presentation for NTU, September 2024

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Topics for Thought

The USC Academic Approach

What is a Regulatory Science Center of Excellence?

How Does Academia Support the CoE?

- Established in 1880
- One of the world's leading private research universities
- Consistently ranked among top 20 U.S. Universities
- Home to 48,000 students and more than 4,000 faculty members
- Top destination for international students
- 23 academic colleges
- Trojan family global network of alumni
- Global network of offices

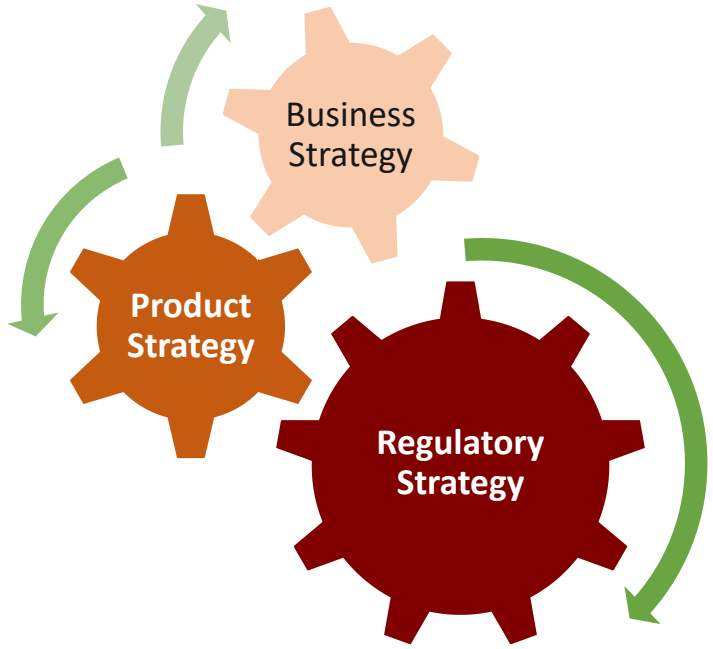
What is Regulatory Science and Why is it Our Focus?

It is the **scientific and technical work** conducted to ensure the safety, efficacy, and quality of medical products.

It involves **a set of disciplines and methods** that help regulatory agencies make informed decisions about the approval, monitoring, and regulation of their products.

The **science of developing and validating new standards and tools to**:

- Facilitate sound and transparent regulatory decision making
- Evaluate and assess [and communicate] the benefit/risk of medicinal products
- Through **analysis of regulatory frameworks**…advancing the knowledge of these systems



The D. K. Kim International Center for Regulatory Science

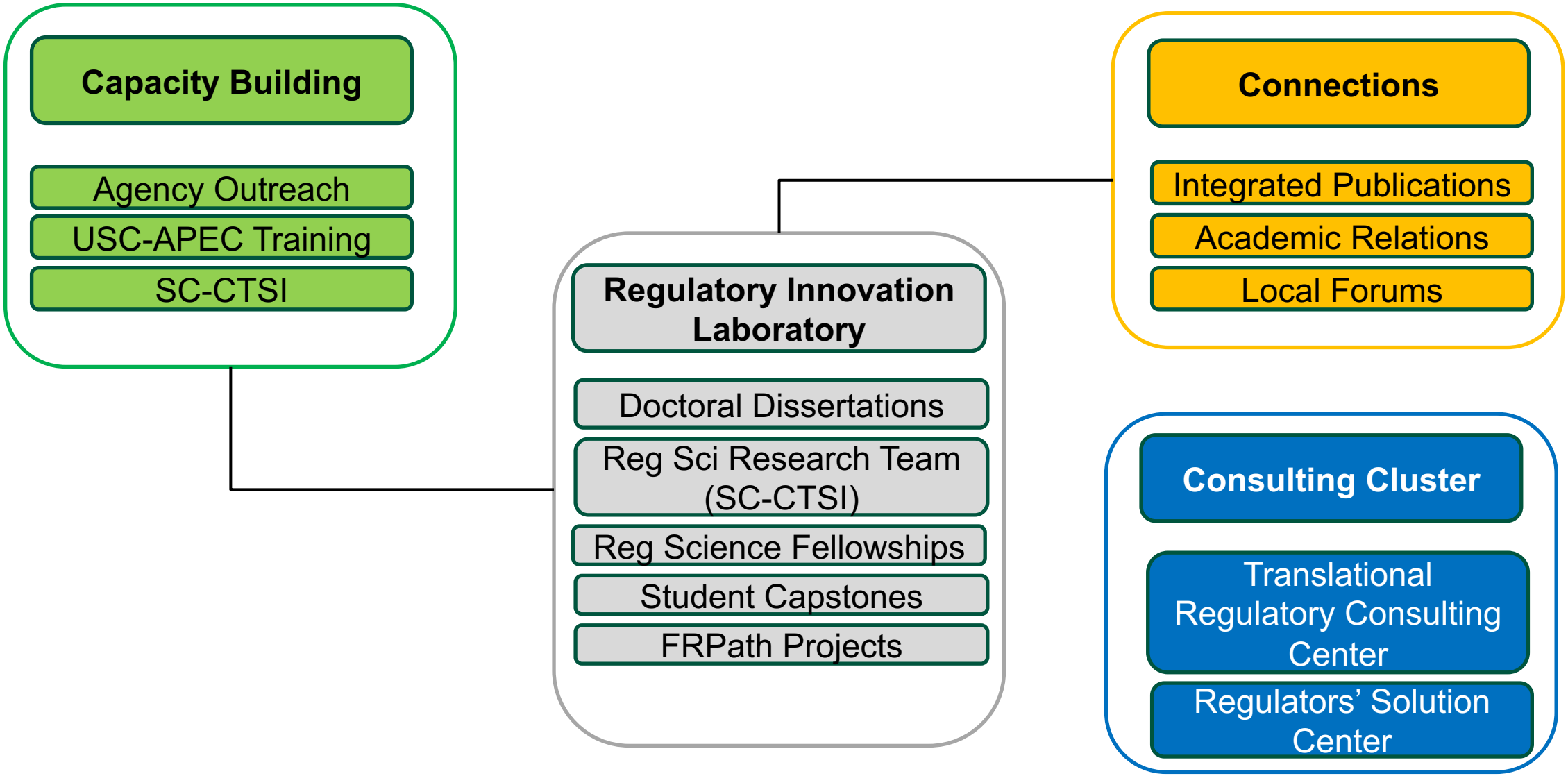
Mission: To apply regulatory science to regulatory and health solutions globally

Built on a foundation of academic research-based activities that meet a diverse group of healthcare stakeholder interests

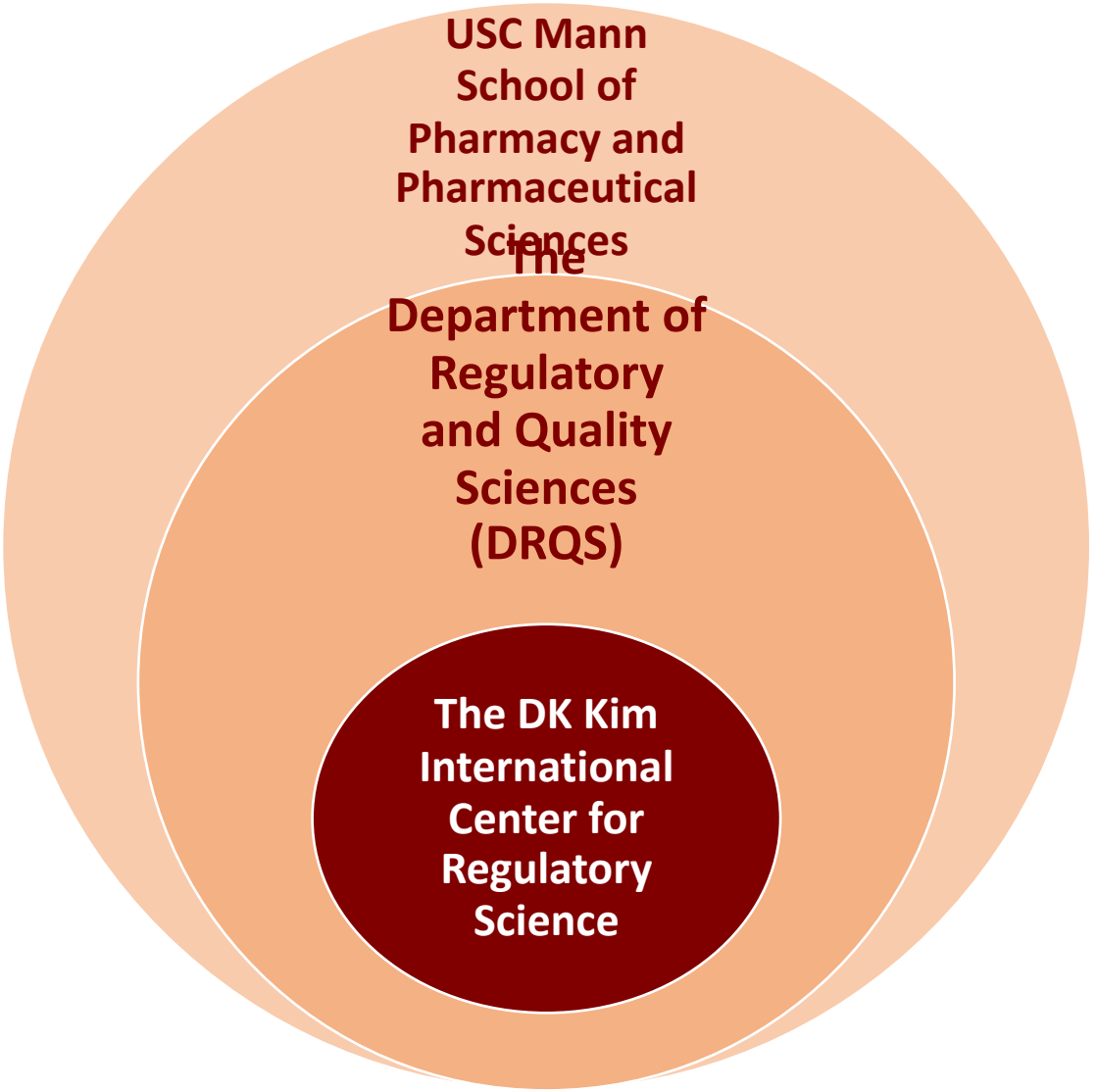
An educational and research institution

- Meets the growing need for professionals with the knowledge and expertise to navigate the complex international regulatory landscape both in industry and agencies
- Provides training in regulatory science to individuals with a scientific background
- Stimulates practical research that can be translated into real-world activities
- Offers collaborative research and experiential opportunities for academic partners and students at all levels

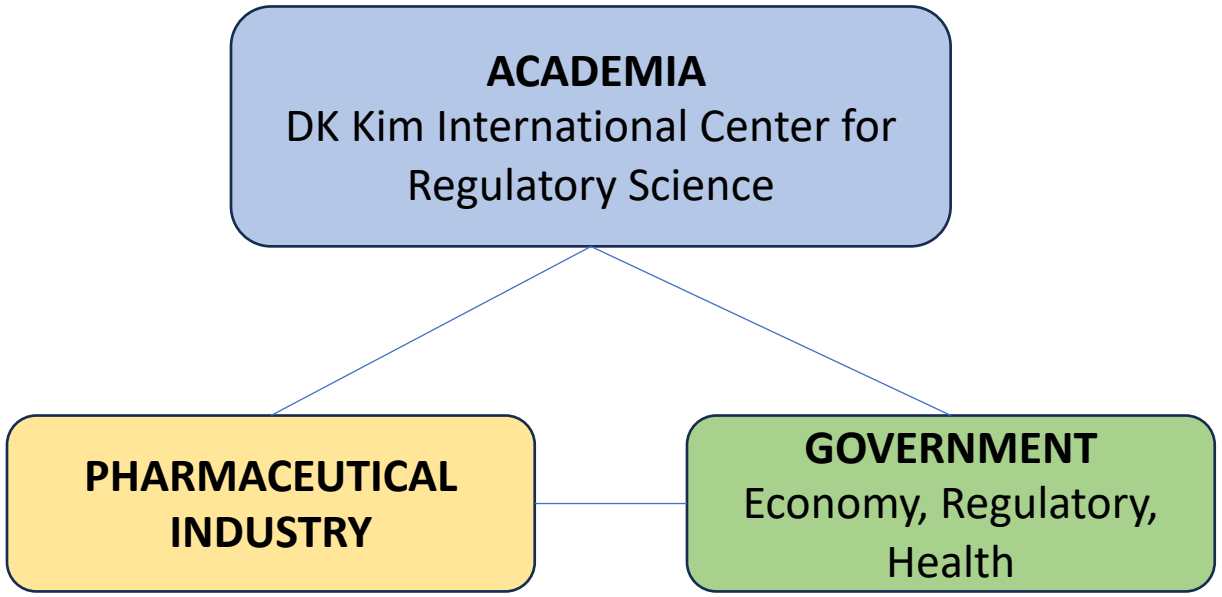
Kim Center Activities: The Cluster Approach



USC: Promoting Regulatory Science Throughout the Pharmacy Curriculum

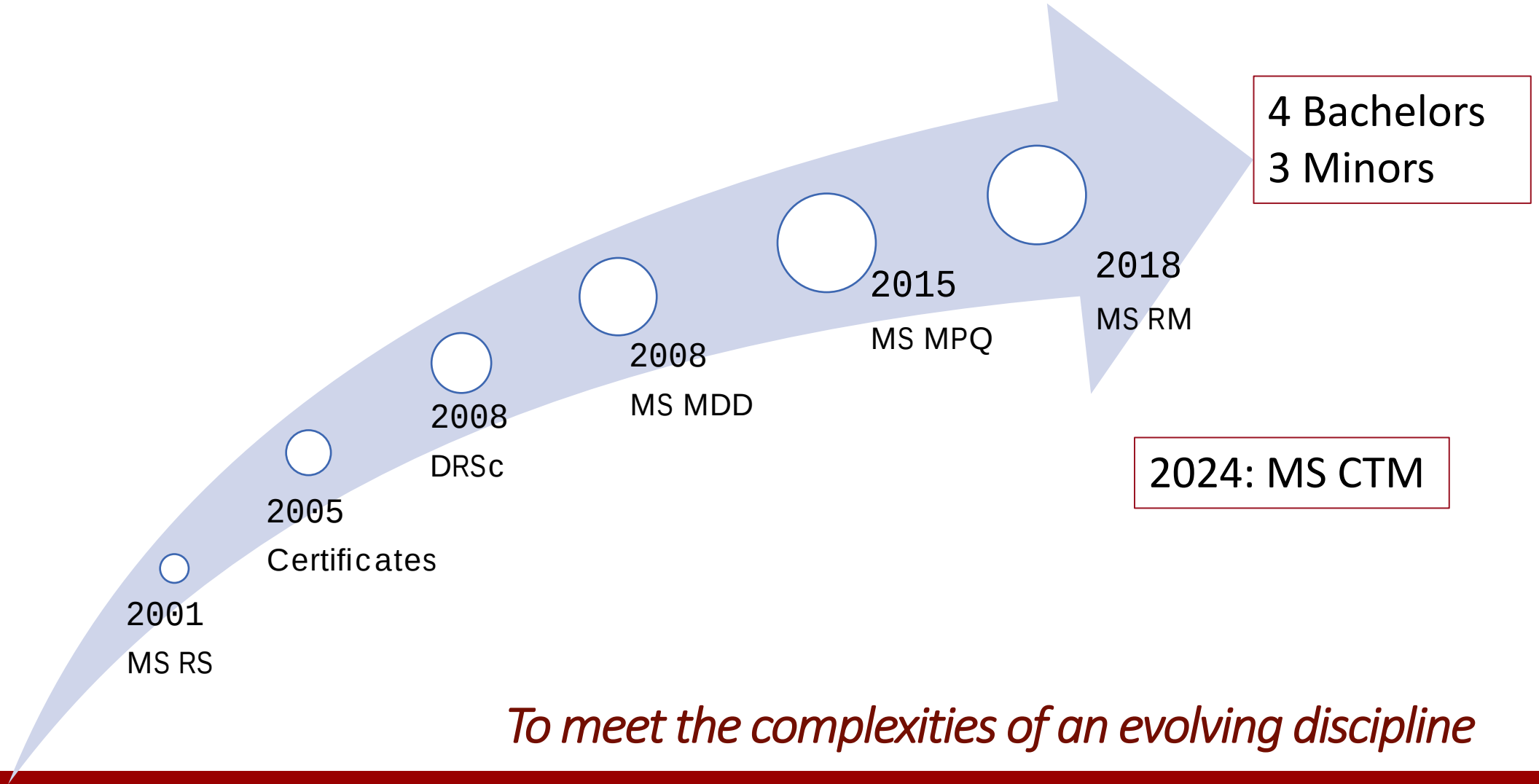


What Academia Brings to the Process



- Academic basis for educational outreach and research
- Open, accessible activities designed to encourage collaboration with faculty and students
- Financial stability through the D. K. Kim endowment
- US, EU and global connectivity
- Deep expertise in drugs and devices
- Expertise that can apply concepts of Regulatory Science to the real world

The USC Educational Program Evolution



To meet the complexities of an evolving discipline

MS Regulatory Science Curriculum

Medical Product Regulation

Drugs & Biologics

Devices

Foods

Medical Product Quality

Law

Clinical Trial Management

Regulatory Writing

- Global Regulations
- Risk Frameworks
- Seminar
- Clinical Trial Design
- Biomedical Business
- Food Science
- Chemistry, Manufacturing and Controls
- Ethics
- Medical Product Safety

Composed of core courses and electives

Doctoral Dissertations

To inform policy, assess implementation of new rules, and examine challenges and best practices

- US Regulatory Policy for **Human Factors Engineering in Medical Devices**: A Survey of Policy Impact on Current Practices
- **China's Role** in Global Drug Development
- Implementation of GVP IX for **Postmarketing Signal Management** in the Bio-Pharmaceutical Industry
- Exploring Critical Elements of First Time Approval: **Tool for Effective High-Quality Generic ANDA Submissions** (Challenges faced by generics industry to get first time approval and to avoid refusal to review)

Multinational Academic MOUs

China Pharmaceutical University	Nanjing	China
Tianjin Binhai FDA	Tianjin	China
Shengyang Pharmaceutical University	Shenyang	China
Universidad del Atlántico	Barranquilla	Colombia
University of Magdalena	Santa Marta	Colombia
University of Copenhagen	Copenhagen	Denmark
Hiroshima University	Higashihiroshima	Japan
Asia-Pacific Economic Cooperation (APEC) Life Sciences Innovation Forum	Singapore	Singapore
Sungkyunkwan University	Seoul,	South Korea
Yonsei University	Seoul	South Korea
Ewha Womans University	Seoul	South Korea
Taipei Medical University	Taipei	Taiwan
National Chung Kung University	Tainan	Taiwan
National Taiwan University	Taipei	Taiwan

Topics for Thought

The USC Academic Approach

What is a Regulatory Science Center of Excellence?

How Does Academia Support the CoE?

US FDA Centers of Excellence in Regulatory Science and Innovation (CERSIs)

Modernize development and ***evaluation*** of FDA-regulated products

Strengthen post-market surveillance and ***labeling*** of FDA-regulated products

Invigorate public health preparedness and ***response*** of FDA, Patients & Consumers

diálogo empresarial de las américas

Americas RISE for Health

Multistakeholder forum that harnesses the collective strengths of the **region's private sector and civil society** in **partnership with the region's governments** to build sustainable health economies and ecosystems.

- Trade and Investment: Capturing Health Investment and Manufacturing & Generating More Jobs in the Americas
- Regulatory Improvements: Good Regulatory Practices (GRPs) and Regulatory Convergence
- Sustainable Health Systems: Enabling Efficient, Effective, and Innovative Health Financing
- Ethics: The Foundation of Healthy Economies and Ecosystems
- Equity and Inclusivity: Creating Better Health for All Communities
- Digital Health: Making Healthcare More Accessible, Affordable, and Scalable

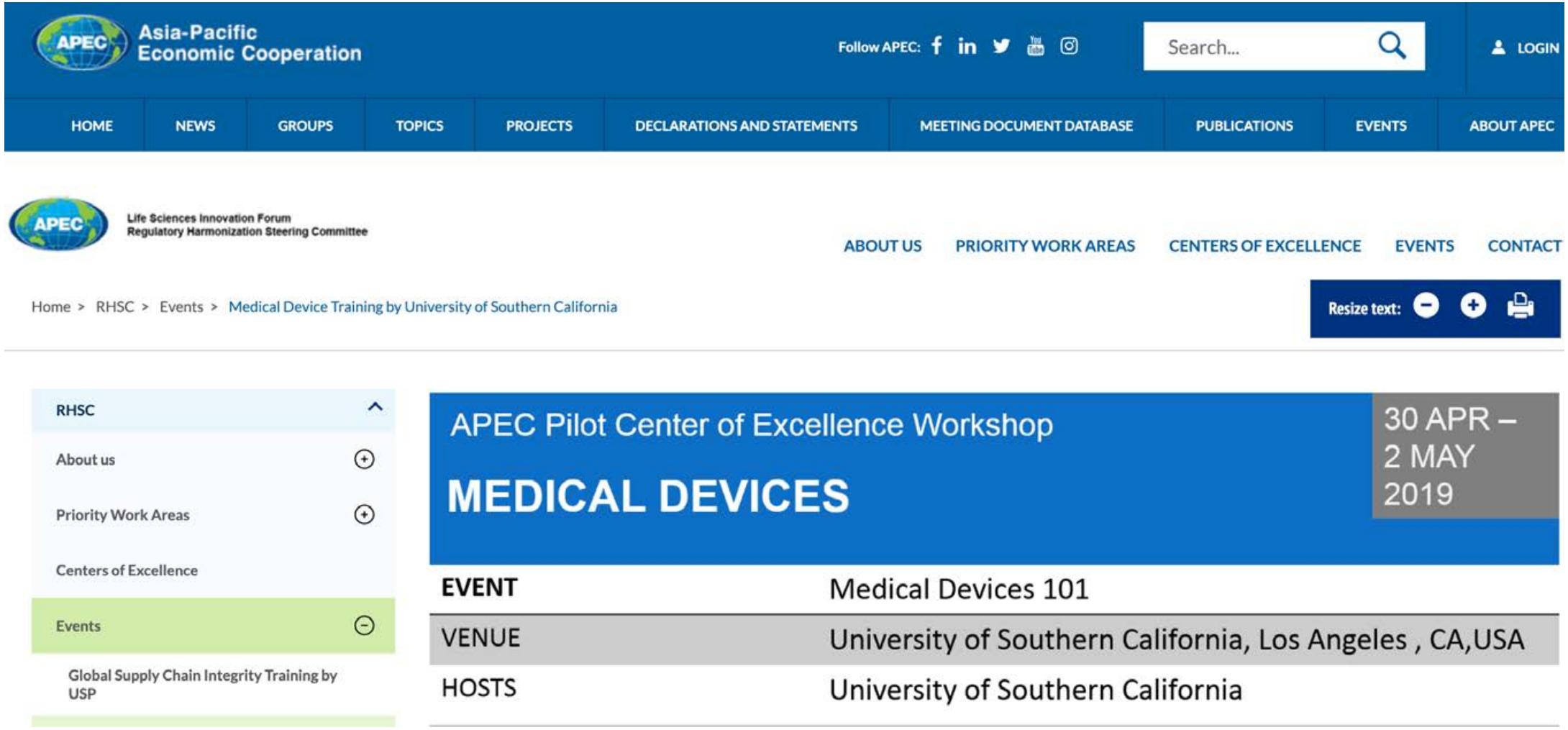
The APEC Centers of Excellence

- To **build human capacity** in regulatory sciences to bring safe, effective, and quality medical products to patients and people as quickly as possible;
- To **promote dialogue** with a view towards sharing understanding in science and best practices;
- To **avoid duplication of efforts** and leverage work that already exists and has a level of convergence
- To achieve a model of sustainable operation that includes periodic updates to maintain regulatory relevancy of materials and **ensures continued value to all participating entities**

APEC Centers of Excellence: Commitment and Criteria for Selection

- Trusted global educational/regulatory/science-setting organization and brand
- Ability to develop and deliver a training program with priorities set by the APEC RHSC
- Willingness to provide a full or part-time Director and appropriate staff to manage the CoE
- Ability & commitment to achieve objectives as agreed herein
- Ability to fund the administrative overhead over the life of the agreement (minimum 5 years)
- Demonstrated credibility in the topic area
- Location that provides, or the ability to travel to, a site easily accessed by participants
- Ability to provide qualified faculty; this could be visiting regulatory staff or other experts as required by the training program
- Ability to receive funding to support specific aspects of CoE training (e.g., to fund student/regulator travel)

The DK Kim Center is an APEC Center of Excellence for Training



USC Mann
DK Kim International Center for Regulatory Science

APEC
Asia-Pacific Economic Cooperation

Harmonizing Medical Device Regulation

October 12-13, 2023

Find recordings of the sessions, Speaker Profiles, the Agenda, and Core Curriculum and Slides at the links below

Recordings	Speaker Profiles	Agenda	Curriculum and Slides

https://sites.usc.edu/apec-training/events/harmonizing-medical-device-regulation/

Asia-Pacific
Economic Cooperation

- 1 Canada
- 6 Chile
- 1 Colombia
- 2 Indonesia
- 5 Malaysia
- 2 Papua New Guinea
- 1 Peru
- 2 Philippines
- 2 Poland
- 2 Slovenia
- 6 South Korea
- 4 Taiwan
- 13 United States

International Delegations Benefit from Onsite Training at the DK Kim Center

Aligning Medical Device Regulation to Optimize Risk Management
September 15-16, 2024

Day 1: Sunday, September 15

8:30 AM PST	**Introductions and Orientation** Lawrence Liberti, PhD, BPharm, RAC Director, D.K. Kim International Center for Regulatory Science Susan Bain, DRSc Assistant Professor, Department of Regulatory and Quality Sciences
8:45 AM PST	**Risk Management: A Review of the Pre-Conference Instructional Material** Lawrence Liberti Susan Bain
9:15 AM PST	**IMDRF and GHTF: How do these Guidelines help us Address Risk?** Kim Trautman, MS International Medical Device Expert
10:00 AM PST	**Break**
10:15 AM PST	**Essential Principles of Medical Device Safety: Integrating Risk Analysis Methods with Design Controls** Gerald Loeb, MD Professor, Department of Biomedical Engineering and Neurology
11:30 AM PST	**Panel Discussion** **Moderator:** Susan Bain **Participants**: Speakers and Agency Representatives
12:00 PM PST	**Hosted Lunch**
1:00 PM PST	**How can Environmental and Human Factors Help to Limit Device Risk? Case Studies** Nozomi Yagi, MAS, RAC Senior Regulatory Affairs Manager, Infraredx a Nipro Company
1:45 PM PST	**Tools for Pre-market Risk Evaluation of Devices** Kim Trautman, MS
2:45 PM PST	**Break**
3:00 PM PST	**Analyzing Medical Device Adverse Events and Applying IMDRF Terms and Codes** Keith Morel, PhD VP Regulatory Compliance & Principal Consultant, Qserve
3:45 PM PST	**Group Activity (Aligning Pre- and Post-Marketing Risk Management)** **Session Lead:** Keith Morel, PhD
4:30 PM PST	**Day One Wrap-up**

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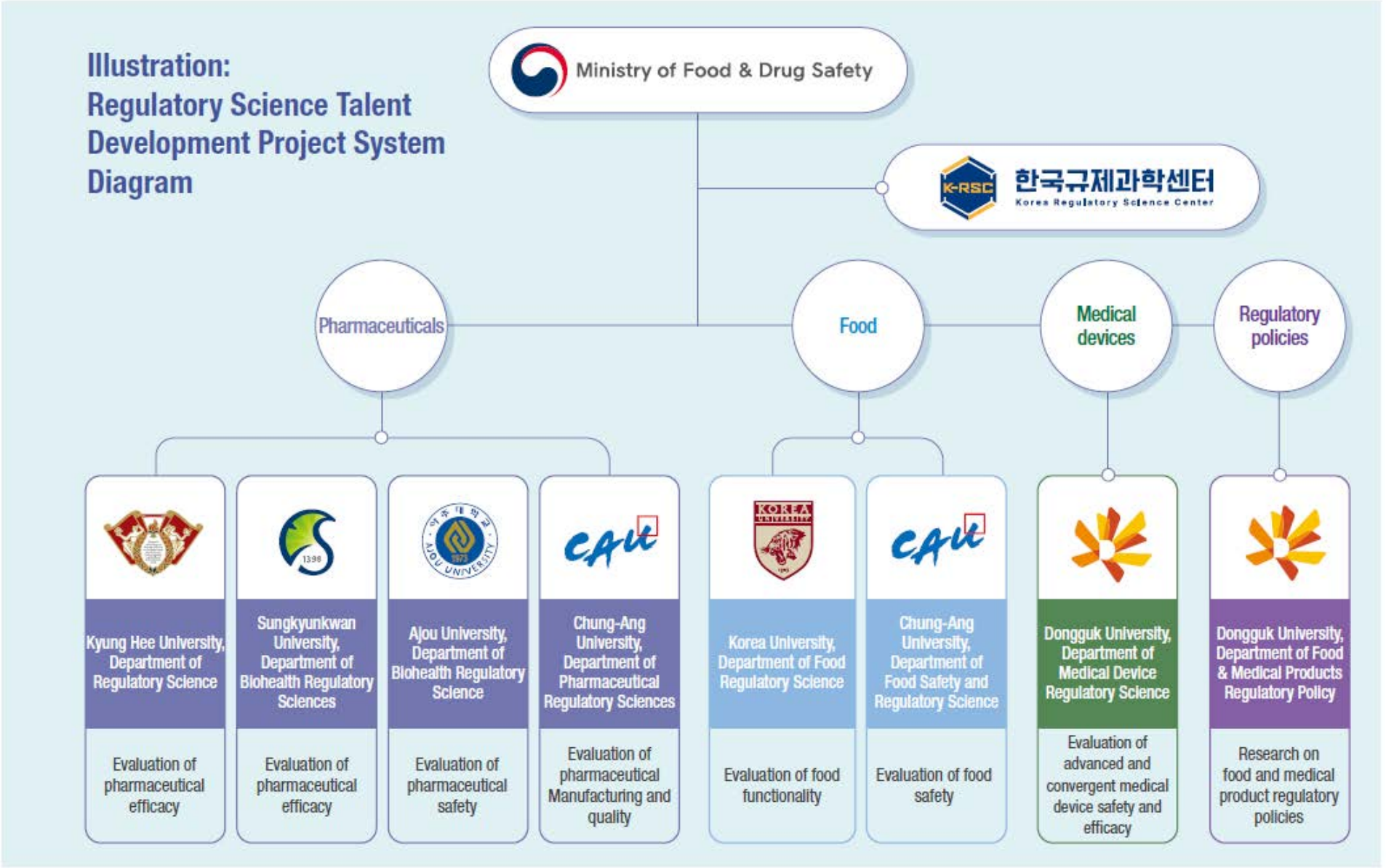
Day 2: Monday, September 16

9:00 AM PST	**How do Quality Standards (ISO 14971:2019 and application of risk management) De-Risk Devices?** David Rutledge, PharmD, FCCP, FAHA President and CEO, Global Strategic Solutions
9:30 AM PST	**Group Activity**
10:30 AM PST	**Break**
10:45 AM PST	**Understanding the Tools for Post-approval Risk Management** Yu Zhao, MBA, MSc President, Bridging Consulting
11:15 AM PST	**How Audits and the MDSAP program support QMS** **Moderator:** Chiaoyun Kuo, PhD; Assistant Professor, Department of Regulatory and Quality Sciences **Participants:** Speakers and Agency Representatives
12:00 PM PST	**Hosted Lunch**
1:00 PM PST	**In vitro Diagnostic Devices: Special Risk Considerations** Christie Hughes, MPH, MLS (ASCP) Principal Consultant, Qserve
2:00 PM PST	**Break** *The following are USC original topics, not endorsed as APEC CoE topics*
2:15 PM PST	**Combination Drug-Device Products: Their Evaluation and Risk Assessment** James Wabby, MHMS Head, Global Regulatory Affairs Emerging Technologies, Combination Products, and Device, AbbVie Volwiler Senior Research Industry Fellow – Regulatory Science
3:00 PM PST	**AI and its use in Medical Devices: Mitigating Novel Risks** Yu Zhao, MBA, MSc
3:45 PM PST	**Closing Remarks**

The Korea Regulatory Science Center (K-RSC)

To contribute to the growth of the health industry and enhance public health.
By establishing a foundation for the biohealth industry and promoting research and development in regulatory science, the center aims to foster advancements in various sectors, such as food, pharmaceuticals, medical devices, and cosmetics.



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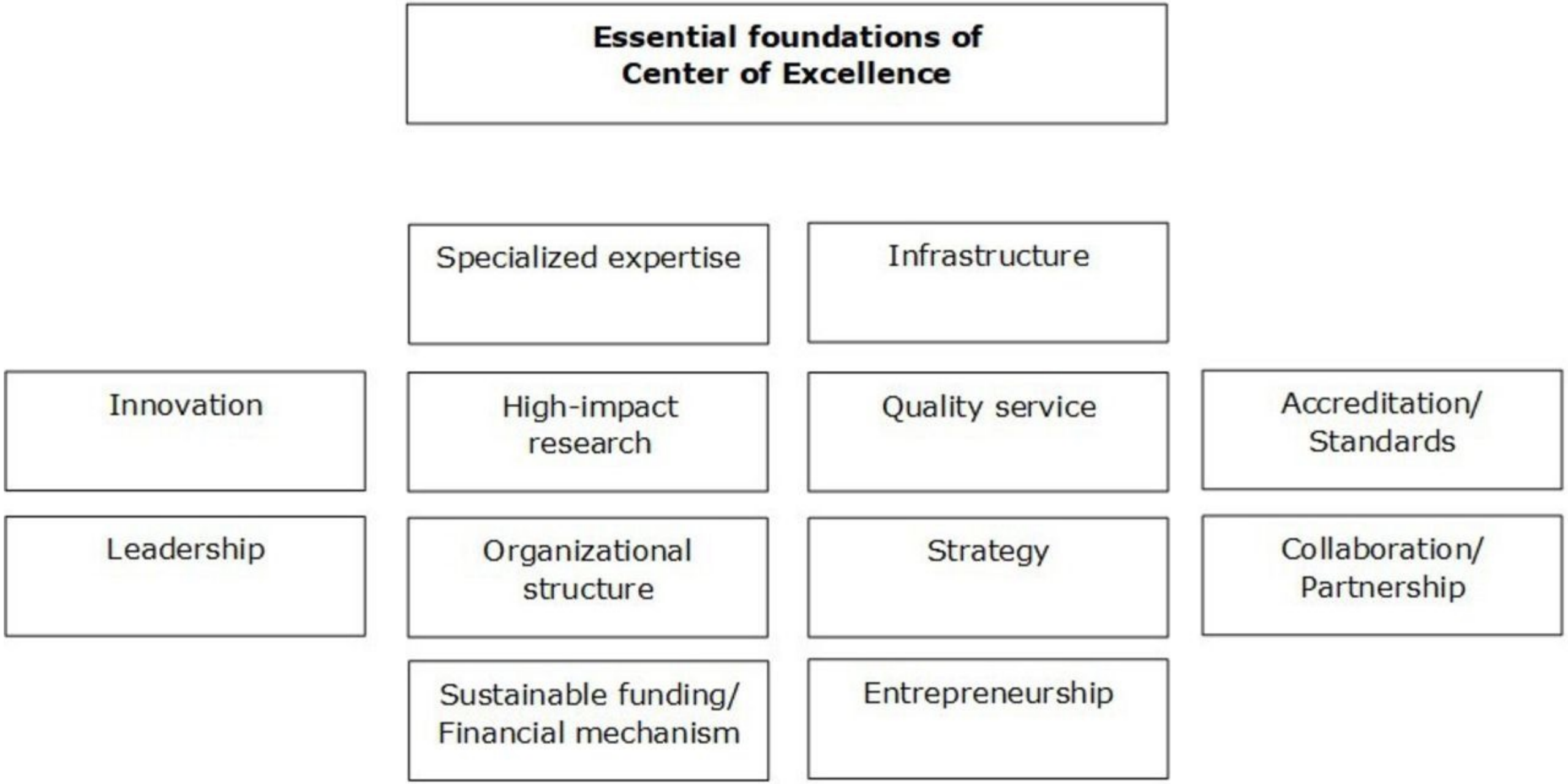
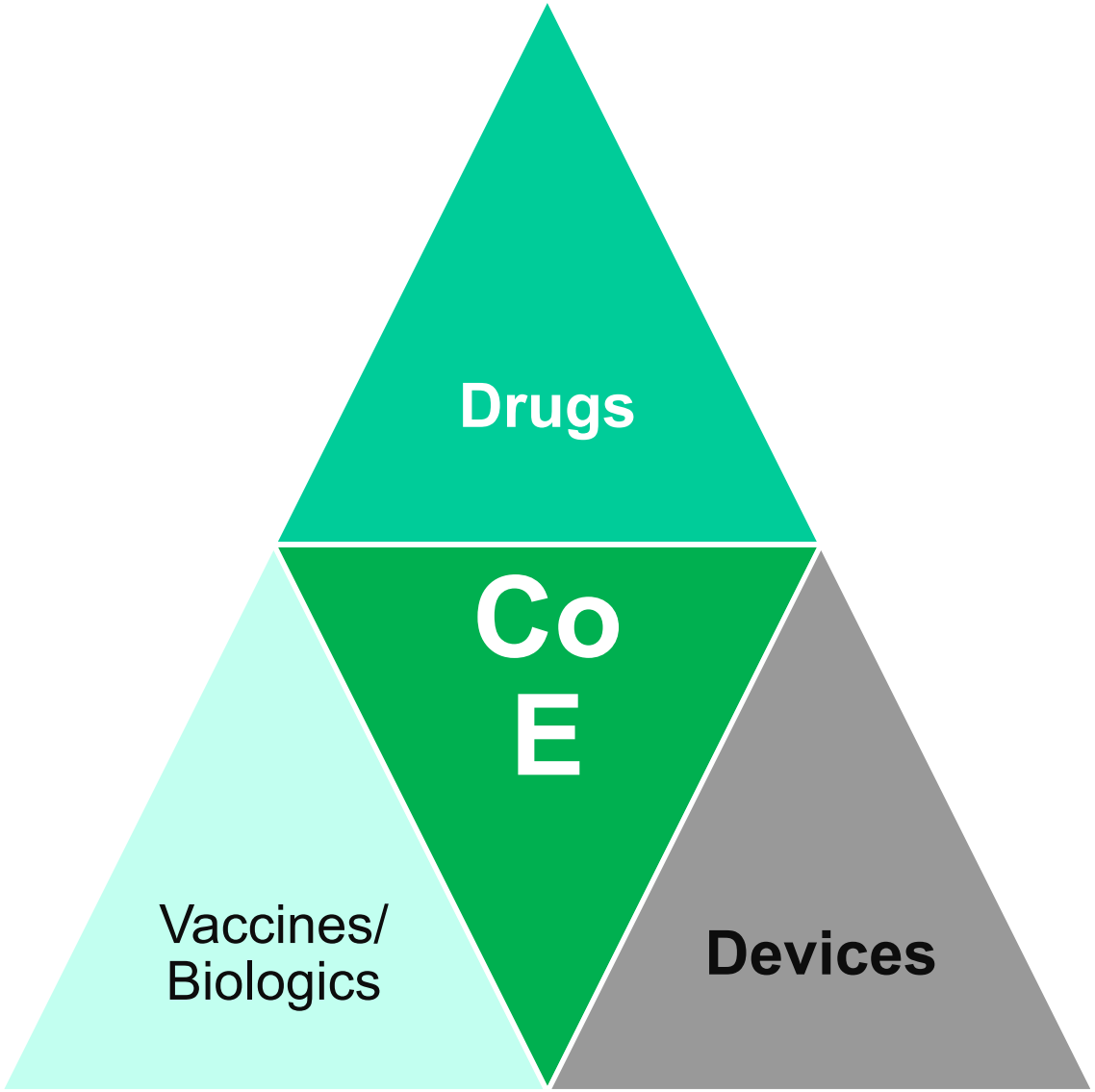

Essential foundations of
Center of Excellence
Specialized expertise
Infrastructure
Innovation
High-impact
research
Quality service
Accreditation/
Standards
Leadership
Organizational
structure
Strategy
Collaboration/
Partnership
Sustainable funding/
Financial mechanism
Entrepreneurship

What Areas of Need Should be the Focus of a CoE



USC Int'l Student Summer Program: Strengthening Partnerships

101 Participants, 24 Universities, 10 Countries

嘉南藥理大學
Chia Nan University
of Pharmacy & Science

國立陽明交通大學
NATIONAL YANG MING CHIAO TUNG UNIVERSITY

How a CoE Drives an Ideal Multistakeholder Innovation Model

ACADEMIA

- **Provides an environment that promotes innovative research**
- **Understands the value of stakeholder collaborations**

CENTRALIZED COORDINATION ORGANIZATION (CoE)

PHARMACEUTICAL INDUSTRY

- **Thinks about optimizing the value of their discoveries**
- **Seeks a collaborative environment**
- **Encourages involvement of new generation of thinkers**

GOVERNMENT

- **Values the role of the innovative industry to support public health**
- **Encourages multistakeholder collaborations**
- **Offer funding for important research**
- **Provides a supportive regulatory environment**

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