亦私商學院
YEEHONG BUSINESS SCHOOL

Yeehong Business School and our Regulatory Science Programs

Peng (Penny) Han, Associate Professor
Deputy Dean & Director of Academic Affairs
Yeehong Business School of Shenyang Pharmaceutical University
September 17, 2016

Background

- Established in March, 2014.
- 成立于2014年9月
- The ninth secondary school of Shenyang Pharmaceutical University which was founded in 1931.
- 沈阳药科大学第九个二级学院
- The School implements a new management mechanism of Dean's prime responsibility under the leadership of the Council.
- 实行以理事会管理体制下院长负责制的新型学院管理机制

http://www.yeehongedu.cn

Where we are

http://www.yeehongedu.cn

- Take a course-oriented appointment for whole faculty;
- 实行以课程为导向的全员教师聘任制；
- To invite most influential scholars and experts from domestic and global to teach and research; To integrate the educational and researching resources and form a strong team of teaching and researching.
- 整合教育、研究资源，邀请国内外最具实力的一流学者、业内专家开展教学与研究，形成强大的师资教研队伍。

http://www.yeehongedu.cn

亦弘目标 OBJECTIVES

学院价值观VALUE

弘道亦弘人，兴道亦兴业。

To clear the objective law and educate people

To spread the knowledge and promote the development of industry and society

学院愿景 VISION

锻造医药发展最具影响力的商学院；铸就百战归来医药英才的新起点。

To forge a most influential business school in pharmaceutical development；To form a new starting point for experienced pharmaceutical talents.

学院使命 MISSION

培养根植中国、面向世界，兼具专业水准和系统思维，勇于担当的医药行业发展推动者。

To cultivate the promoters for pharmaceutical industry, rooted in China with international insights, with professional expertise & systematic ideas.

http://www.yeehongedu.cn

学院特色 FEATURES

以行业发展需求为导向

To take the needs of industry development as orientation.

以全球视野和国际水准为目标

To regard global insight and international level as target.

以适用型人才培养为重点

To take the cultivation of applicable talents as emphasis.

以课程精品化为基础

To make high-quality courses as basis.

以管理创新为保障

To use innovative management as guarantee.

http://www.yeehongedu.cn

亦弘课程 PROGRAMS

学位教育项目
Degree Education (on the job)

高层经理研修课程
Modular Executive Education

高层经理培训课程
Executive Education

定制教育项目
Customized Education

亦弘大课堂
Master Class

研发	R & D
临床	Clinical
注册	Application / Registration
生产	Manufacture
质量	Quality
管理	Management
投资	Investment
市场	Market

http://www.yeehongedu.cn

师资团队 FACULTY

超过75%
拥有海外工作经历
75% of overseas work experience

四分之一
具有国内外药品审评经验
25% of review experience with FDA or CFDA

百余位
高学历博士
More than 100 of PhDs

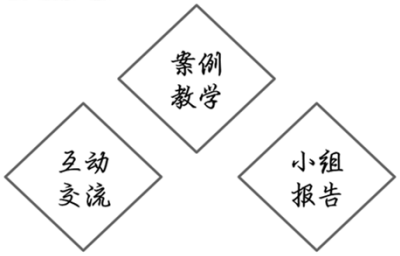
150余名
顶尖教师

半数以上
为医药百强高管
50% of senior executives of well-known companies

行业深耕十五年以上者
多达85%
85% of more than 15 years of Industry experience

http://www.

课 堂 CLASS



Interactive communication

Case teaching

Group discussion

http://www.yeehongedu.cn

部分学员单位 Student Employers

课题研究 RESEARCH

- Center for Research
- Center for Case Study (under construction)
- *The mutual support between teaching and researching*
- *Through reseaching to be involved in promoting the development of the industry and the regulation*
- *About 60 experts from regulatory agency, industry and institutions have been invited as Researchers of the School.*

http://www.yeehongedu.cn

课题研究 RESEARCH

自主课题
Projects established on our own

- 药品注册相关专题研究课题
- Drug Registration related

承接课题
Projects entrusted

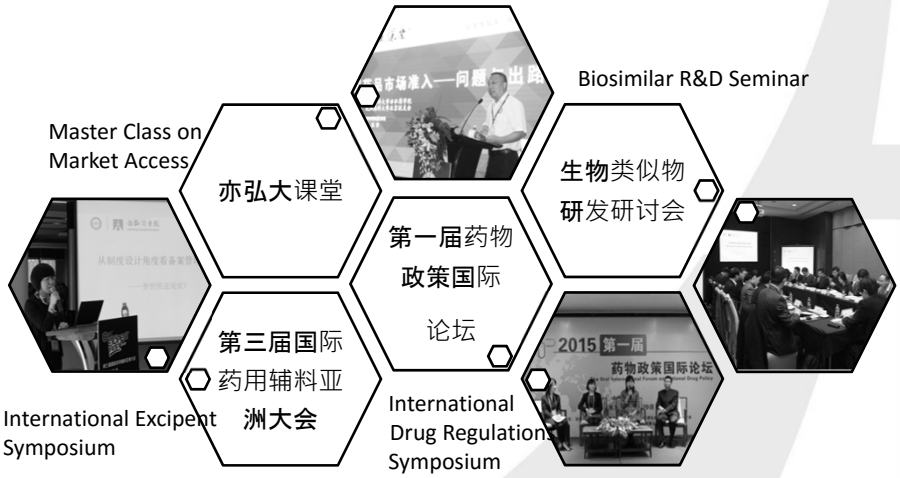
- 药用辅料备案管理制度研究课题
- 药包材备案管理研究课题
- DMF on Excepients and Containers
- 影响我国化学药品仿制药质量的因素分析项目
- influence factors on quality of Generic drugs

合作课题
Co-operative Projects

- 三生TCP中青年科研基金项目
- Sansheng TCP Youth Researcher Found
- 清华“药品法制研究课题”
- Tshinghua PhARM projects
- 生物类似物研发研讨课题
- Biosimilar Seminar

http://www.yeehongedu.cn

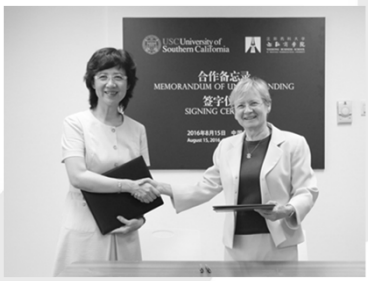
论坛 | 研讨会
Symposiums | Seminars



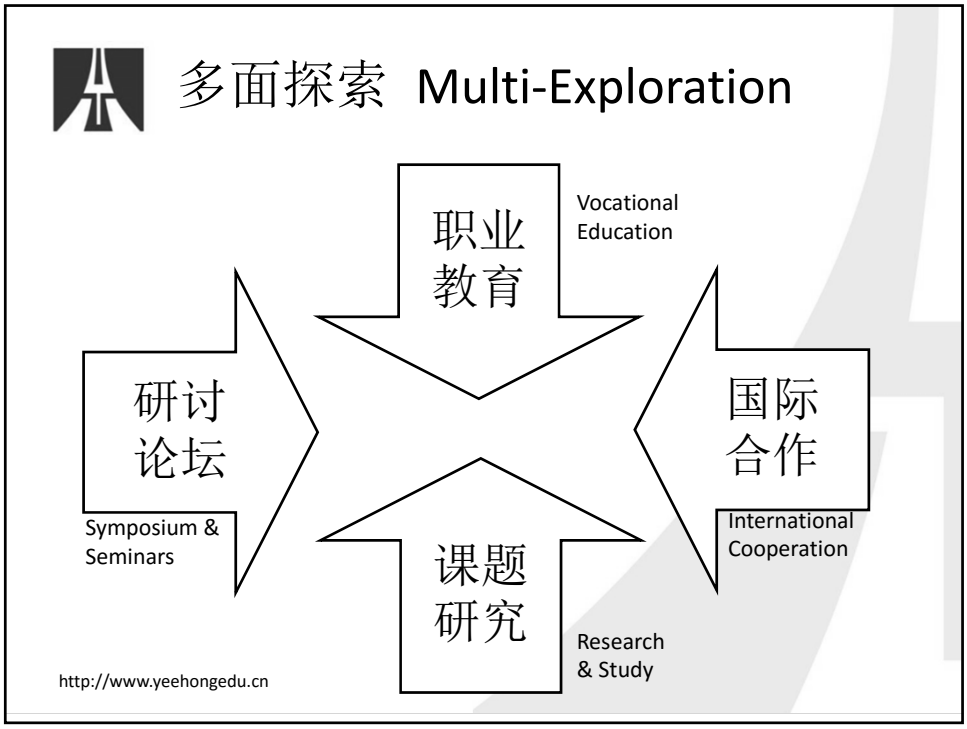
http://www.yeehongedu.cn

国际合作
International Collaboration

- **MOU with USC International Center for Regulatory Science**: August 15, 2016 in Beijing
- Curriculum/Programs
- Exchange Visit of Professors
- Research and Study
  - *Communication*
  - *Cooperation*
  - *Collaboration*
- ***To be a member of the Association of Graduate Regulatory Educators (AGRE)***



http://www.yeehongedu.cn


多面探索 Multi-Exploration
职业教育
Vocational Education
研讨论坛
Symposium & Seminars
国际合作
International Cooperation
课题研究
Research & Study
http://www.yeehongedu.cn

亦私商學院
YEEHONG BUSINESS SCHOOL
Education Programs

Current situations in China

- Pharmaceutical industry is fast developing and is expanding overseas.
- The regulations are reforming and the ICH technical guidelines and international standards have been more and more adopted.
- The quality of Generic drugs is a matter of great concern.
  - The Generic Drugs approved before 10/1/2007 should be re-reviewed for efficacy and quality before the end of 2018.
- The innovators are encouraged to meet the need of clinical needs.

http://www.yeehongedu.cn

Degree Courses

International Drug Registration Program	448 class hours
Drug R&D Management Program	416 class hours
Clinical Research Administration Program	being development
Market Access Program	being development

http://www.yeehongedu.cn

International Drug Registration Program

Master Degree Course

- The first on-the-job Master Degree Course:
  - *aims at launching products in foreign market, systematically teaches global regulatory science regarding drug R&D, manufacturing and management from drug registration perspective.*
  - *14 modules with 448 class hours, one module by one month*

http://www.yeehongedu.cn

International Drug Registration Program

Master Degree Course

- ***Objectives:***
- *To enables students to understand correctly regulations and guidelines of drug registration and*
- *To master necessary professional knowledge and expertise, and*
- *To foster strategic minds and abilities to handle international registration applications.*

http://www.yeehongedu.cn

PROGRAMS

Module	Core Course Name
Module 1	Global Macro-Drug Management
Module 2	DMF regulatory systems for APIs, excipients and packaging materials
Module 3	Generic drug registration (1): ANDA Regulations & Guidelines
Module 4	Generic drug registration (2): ANDA R&D and manufacturing
Module 5	Generic drug registration (3): writing and management of ANDA application dossier
Module 6	Innovative drug registration (1): IND &NDA Regulations & Guidelines

module	Core Course Name
Module 7	Innovative drug registration (1): IND &NDA international regulatory strategy for domestic innovative drugs
Module 8	International registration of biological drugs and biosimilars
Module 9	WHO drug procurement and pre-qualification
Module 10	Quality Management System of international registration
Module 11	Drugs Risk Management of post-market
	Practice Course

http://www.yeehongedu.cn

21

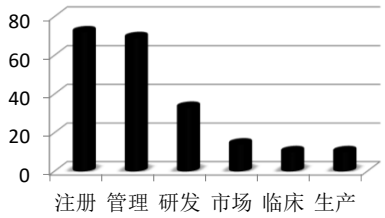
PROGRAMS

Module	Course Name	Course Contents
Module 12	Relevant professional courses (1)	Principles of Economics
		Fundamentals of Management Science
		Pharmacoeconomics
Module 13	Relevant professional courses (2)	Program management
		Intellectual property
		Cost-effective/Return on Investment Analysis
Module 14	Leadership course (3)	Informational intelligence
		Organizational Behavior and leadership
		Communication skills
		Cultural habits

http://www.yeehongedu.cn

首期班 The First Class

- 师：71位来自海内外的专家教授
- Faculty: Total 71 from local and abroad
- 生：15名个人学员+21位企业学员，208位
- Students: Total 208 attended the class



http://www.yeehongedu.cn

23

师资情况 Faculty

- Totally 74 of teachers from China, US, Canada, UK, New Zealand and UN and Taiwan； and 34 from abroad.

Type	No	%
PhD	47	64%
Overseas Work	32	45%
Senior Executives	28	39 %
Review Experience	19	27%
Foreigners	32	46%

County/Region	No
China	39
USA	24
Canada	4
New Zealand	3
UK	2
China Taiwan	1
UN	1
Total	74

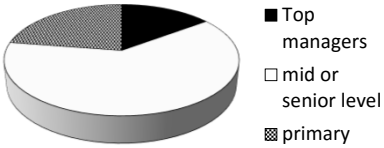
http://www.yeehongedu.cn

24

学员情况 Students

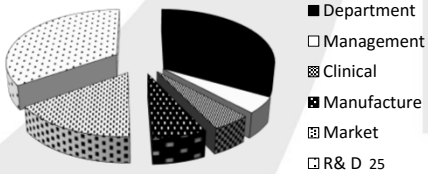
- Position levels

Titles	No
Top Managers	31
mid or senior level	130
primary	47
Total	208



- Departments

Department	No
Management	69
Clinical	10
Manufacture	10
Market	14
R& D	33
Registration	72
Total	208



http://www.yeehongedu.cn

25

共同营造“有质量的课堂”
A quality class experiences

系统完整
Systematic & comprehensive
引导授课
Enlightenment teaching
案例分析
Case study
实战分享
Practical experience
小组报告
Group report
互动参与
Interactive participation
头脑风暴
Brainstorming

http://www.yeehongedu.cn

26

Graduation Ceremony

- Exploration and Practice on the Road of Globalization Symposium & Graduation Ceremony
  - 2016/8/22, Beijing

http://www.yeehongedu.cn

药物研发的科学管理能力培养项目
（硕士研究生课程）
Drug R&D and Scientific management Program
Master Degree Course 2016/9-2017/11

药物研发与管理导论
General Introduction

仿制药研发的科学管理
Generics

新药物研发的转化科学和新技术平台
Translational Sciences

小分子化合物的新药研究与管理
Innovators-small molecule

后期临床研发的科学管理
Late Clinical

商务拓展和对外合作
Business Development

生物药的研发与管理
Biologics & Biosimilar

早期临床开发的科学管理
From IND to POC

课程内容 Course

培养研发决策能力
R&D decision making

增强组织实施能力
Organization & Implementation

提升实际操作能力
hands-on practice

课程目标 Objective

http://www.yeehongedu.cn

Executive Education

- *short term training within 3 to 4 days*
- *targeted for medium- and high-level managers to update and broaden knowledge and expertise*
- *Modular teaching and case studies*
  - To invite first-class experts worldwide to design, develop and teach
  - uses thematic methods and case studies, combine s theory and practices

http://www.yeehongedu.cn

Executive Programs

- *Post-market Study---Contents, Methodology and Application*
- *Excipient Regulations and Guidelines in the United States and Other Major Markets*
- *Key Problems analysis of CMC Study in Chemical Drug R&D*
- *Technology Transfer and Process Verification in Drug R&D and Manufacturing*
- *Drug Intellectual property rights and patent strategy*
- *Drug Market Access , etc.*

http://www.yeehongedu.cn

Customized Education

- *designed and developed for and targeted at certain demand requested by customer, industry, or for students in the school.*

Custom's Need Oriented	**Precise Course Design**
Coordinated Participation of Customers	**Vocational Education for Students**

Clinical Research Associate (CRA) Course
Regulatory Affairs (RA) Course

http://www.yeehongedu.cn

Teaching Quality— 4 Core Principles

- Steering Committee on Curriculum Development
- Professional Committee of Curriculum Development
- Program Director/Chairman

Experts and Professors as the core	Course Design on need
Curriculum Development with Efficient Work Flow	Continuous Evaluation, Revision & Improvement

http://www.yeehongedu.cn

32

Summary

- Globalization today involves everyone in an int ernational environment.
- We're facing the same challenges and opportunities in pharmaceutical industry and regulators.
- Talents demand is very large in this field.
- Continuing Education could do more and more for promoting the development of industry…

http://www.yeehongedu.cn

亦私商學院
YEEHONG BUSINESS SCHOOL

If you want to go fast, go alone.
If you want to go far, go together.

Thanks!

E-mail: hanpeng@yeehongedu.cn