

Guangshen Yu--Regulatory Affairs Associate for Drugs, Biologics, and Medical Devices

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Education Background

Northeastern University, Boston, MA

Sep. 2012-Mar. 2014

Master's Degree of Regulatory Affairs for Biologics, Drugs, and Medical Devices

Courses: Regulation Overview of Biologics, Drugs, and Medical Device, European Medical Device Regulation

Shandong Agriculture University, Taian, China

Sep. 2007-May. 2011

Bachelor's Degree of Biotechnology

Courses: Biochemistry, Organic and Inorganic Chemistry, Zoology, Botany, Microbiology, Genetic Engineering, Molecular Immunity and Molecular Biology, Biomedical Engineering

Research Experience

Shandong Agriculture University, Taian, China

- **Study about Breeding Wheat Cultivars With High Quality** **Sep. 2009-Sep. 2010**

Directed by Professor Li Sishen

- **Study about the Germplasm Resources of the Wheat** **Sep. 2009-Sep. 2010**

Directed by Professor Li Sishen

Qingdao Agriculture University & Ocean University of China, Qingdao, China

- **Study about Selecting Algae with High Rate of Producing Bio-oil** **Sep. 2010-Mar. 2011**

Directed by Professor Yi Yanjun

Leadership Experience

Shandong Agriculture University, Taian, China

Assistant of Commission for Discipline Inspection

Sep. 2007-May. 2008

Monitor of Class 3 of the Biotechnology in College of Life Science

Sep. 2007-May. 2009

Skills

Language: Fluent in Mandarin Chinese, Experience in English-Chinese Translation

Computer: Proficient in Microsoft Office Suite; Extensive Internet Research Skills

Biotechnology Professional: Familiar with the Experimental Apparatus; Fluent in Conducting the Scientific Experiments

Regulatory Affairs Professional: Familiar with the Approval Process of Biologics (BLA), Drugs (NDA), and Medical Devices (510K and PMA); Acquainted with eCTD format; Know well about the FDA's Food and Drug Law and Regulation, and ICH guidance.