The Role of University in Clinical Research Training

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An Old Paradigm

KNOWLEDGE

The only engagement of the University
How to achieve this goal?

TEACHING

and

RESEARCH
A New Paradigm

Emergence of

‘KNOWLEDGE BASED’

Society

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How to be competitive?

INNOVATION
New mission

KNOWLEDGE  →  INNOVATION

Entrepreneurial University
Technological routes

Basic Research

- T cell recognition
- Genetic polymorphisms
- Cytokine detection
- DNA sequencing
- Epidemiology

- Proteomics
- Antibody humanization
- Recombinant protein production
- cDNA array

- DNA vaccine
- Recombinant protein production
- Mass production
- Animal models

Cellular therapy

- DNA sequencing
- GMP, GLP, GCP

Therapeutic agents

Clinical trial

Patient Care
New Curriculum for Medical Education in Sao Paulo University (FMUSP)

1998

30%
Complementary Segment

70%
Nuclear Segment

Revista Brasileira de Cardiologia. 2000 ; 2( 2):70-77
**Scientific Initiation**

- More formation than information;
- research project development;
- rigorous observation and critical spirit.
Laboratories of Medical Investigation (LIM) Published Papers

Reference: LIMs Annual Reports

ISI: Institute for Scientific Information

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<th>Latin America (2)</th>
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ISI: Institute for Scientific Information

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Scientific Production and Patent

world participation (%)
Why Clinical Research at University?

- Improves Good Clinical Practices;
- Understands innovation in health;
- Fosters observation;
- Engages research and development;
- Provides science.
Clinical Research: A compromise with improvement

- Engagement of FMUSP in the clinical research setting
- Standardisation of all study-related procedures
- Launching of NAPesq (Support Center for Clinical Research)
Technological routes

Basic Research

- T cell recognition
- Genetic polymorphisms
- Epidemiology
- Cytokine detection
- DNA sequencing
- Proteomics
- Antibody humanization
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Cellular therapy

- Therapeutic agents
- Clinical trial
- GMP, GLP, GCP
- Mass production
- Animal models

Patient Care

- DNA vaccine
- GMP, GLP, GCP
- Antigenic properties
- Mass production
- Animal models
- Recombinant protein production
- cDNA array
- Antibody humanization
- Cellular therapy
- Therapeutic agents
- Clinical trial
- GMP, GLP, GCP
- Mass production
- Animal models

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What we can do?

- TECHNOLOGICAL POLE
  - Administration
  - Pre-clinic
  - GMP laboratory plant
  - Clinical Research

- REGULATORY QUESTIONS
  - Anvisa
  - Conep
  - INPI
  - Federal Legislation
Proposition

- Technological Pole at FMUSP

- Cooperation between: FMUSP, Pharmaceutic industry, São Paulo Government
  - Private administration,
  - Basic and Clinical Research in University,
  - Preclinic and GMP Laboratory Plant: Industry

- Regulatory questions:
  - Technological pole office and State Government.
Technical Cooperation for Scientific and Technological Development

- Science Technology and Development Government Department of São Paulo,
- FMUSP
- Brazilian Federation of Pharmaceutical Industries (FEBRAFARMA).
Related Interest: Government - University - Industry

- Innovation for development;
- Technological development changing scientific knowledge for society benefit;
- Economic and social improvement through scientific and technological development: knowledge-based society.
Thanks!!!

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