Research and Global Standard

Kiat Ruxrungtham

Professor of Medicine

Chula VRC (Vaccine Research Center),

Chulalongkorn University;

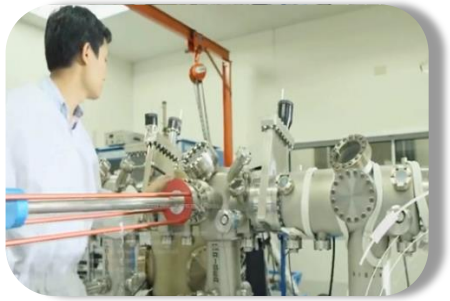
Types of Researches

Goals of Researches

Policy impact

Economic Impact

Social Impact



Industrial Impact

Health impact

Cultural Impact

Frontier - New Discovery

Research Management

Researchers,
Assistants

Meaningful,
Measurable
Goal

Integrity
Quality Standard
Management

Local & International
Universities and
Industries

Deliver real
impact output

What are the critical issues of research?

Ethic

Safety

Quality

Valid & Reproducible

Inter-country product registration: Standard Harmonization

Global and National Mechanisms to Ensure **Ethic, Integrity, Quality** of the Research

International, National

International, National

Ethic committee (EC)
FDA
Authorized parties
Institute/University
Authorized parties
Notified body

Ethic committee (EC)
FDA
Authorized parties
Notified body

Global Standard on Research

From Designing, Conducting, Reporting, Ethic *and* Complying to the Regulatory authorities

Integrity

“ **Doing the right thing** even when nobody is watching”

C.S. Lewis

ความมีศีลธรรมจรรยา ความซื่อสัตย์

Research Integrity

*Is critical for **all kinds of researches***

***Cardinal Sins* on Research Misconducts**

1. *Plagiarism* ลอกเขา
2. *Fabrication* ปั้นน้ำเป็นตัว
3. *Falsification* แอบแก้ให้ดูดี

Science

Woo Suk Hwang: Fabrication

황우석

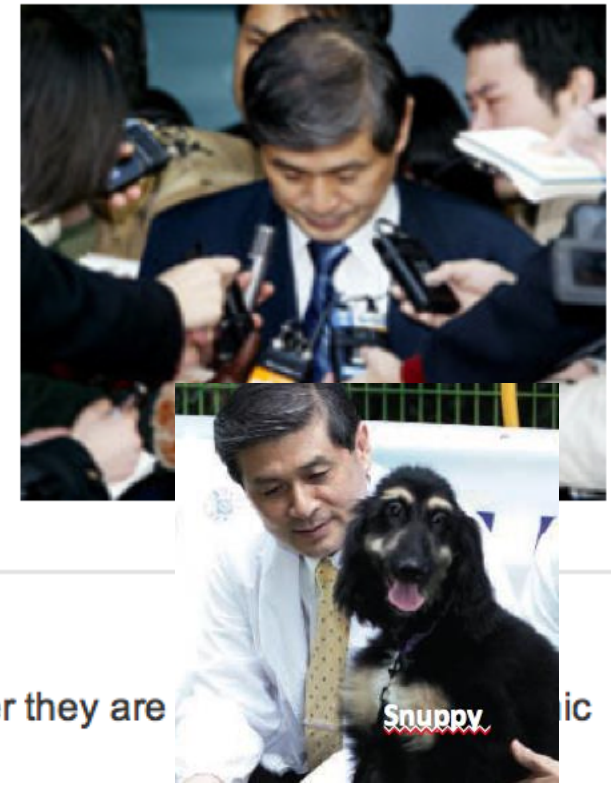
South Korean Cloning Researcher Resigns

by Sei Chong on 23 December 2005, 12:00 AM | Permanent Link | 0 Comments

Email Print | +1 0 More PREVIOUS ARTICLE NEX

SEOUL, SOUTH KOREA--Seoul National University (SNU) researcher Woo Suk Hwang submitted his resignation today after an internal inquiry by a university panel found that he deliberately fabricated much of the data in a groundbreaking stem cell paper published by *Science*.

ENLARGE IMAGE



Roe Jung Hye, dean of SNU's office of research affairs, issued the panel's preliminary report today, which said that out of the 11 stem cell lines Hwang claimed to have created in the paper, only two existed when the manuscript was submitted on 15 March. Four lines had died on 9 January because of contamination, three were observed only in the form of colonies, not stem cell lines, and no records exist for two lines. She said the university has requested DNA fingerprinting tests on the two existing stem cell lines to see whether they are ic clones.

Research and Ethic

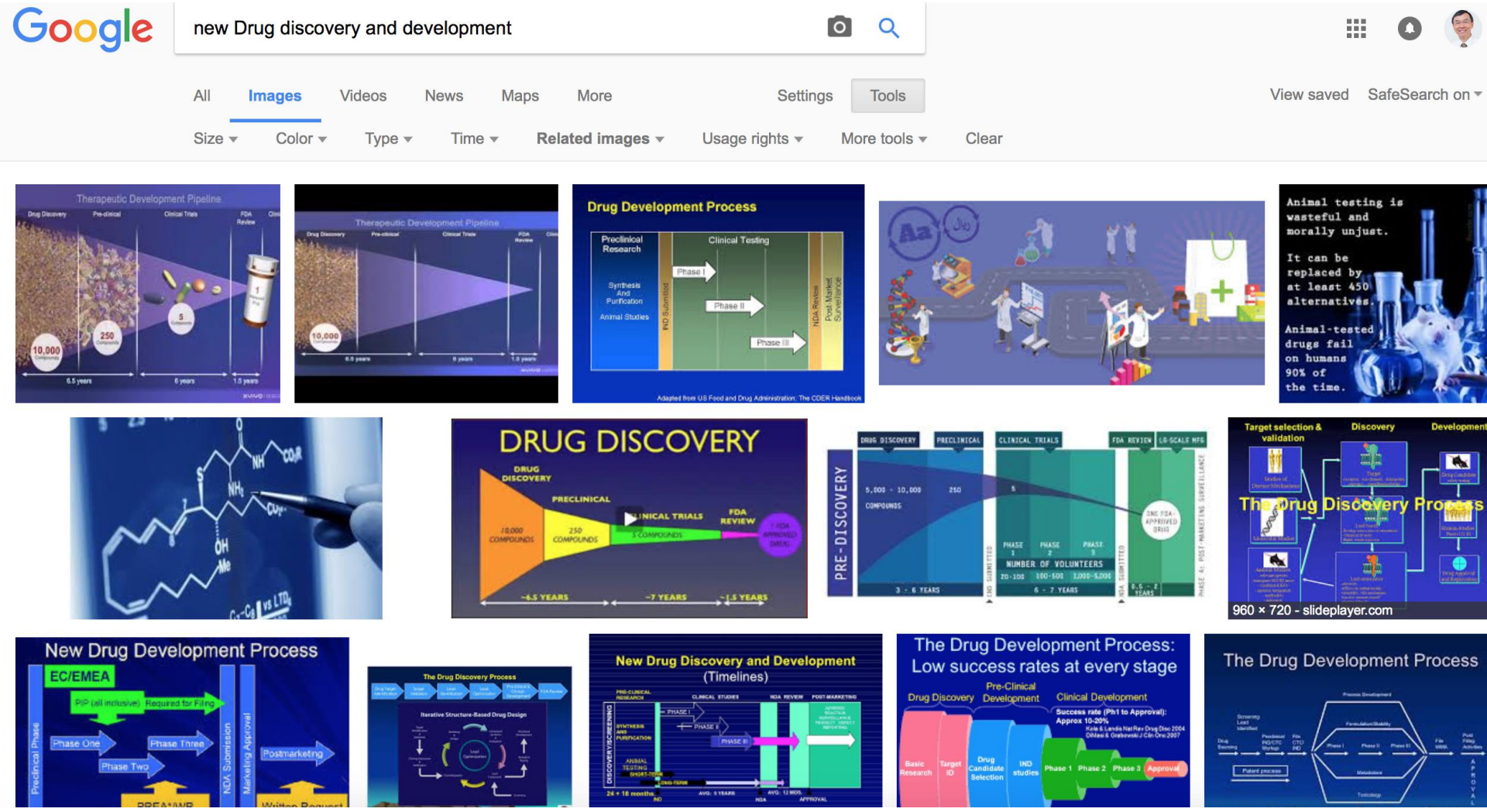
Conducting Research in **Human**

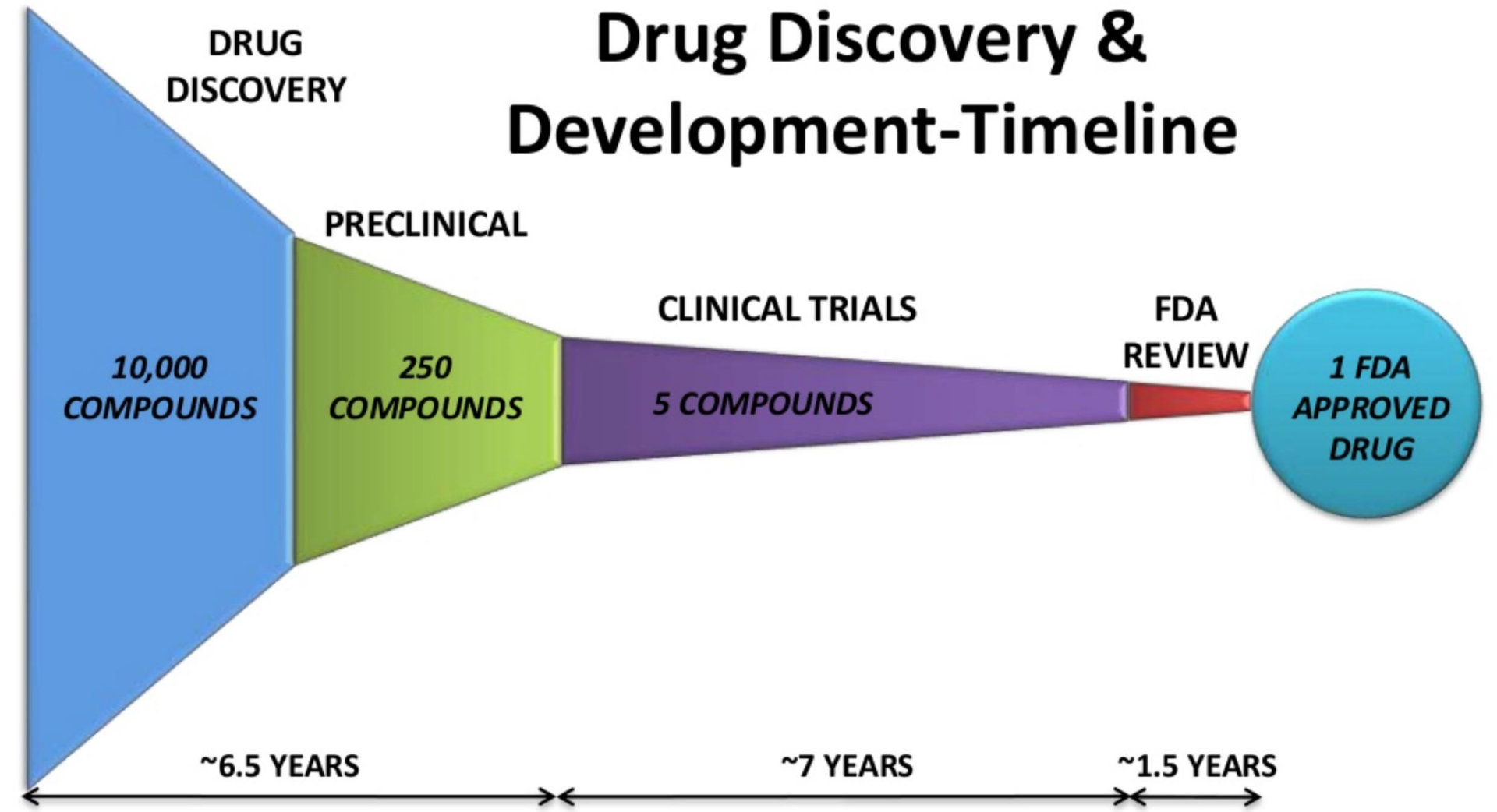
Both **scientific and social researches** that are involving human subjects , the researcher **must submit a proposal to** their institutional **ethic committee**

Basic Ethical Principles

The Belmont Report 1979

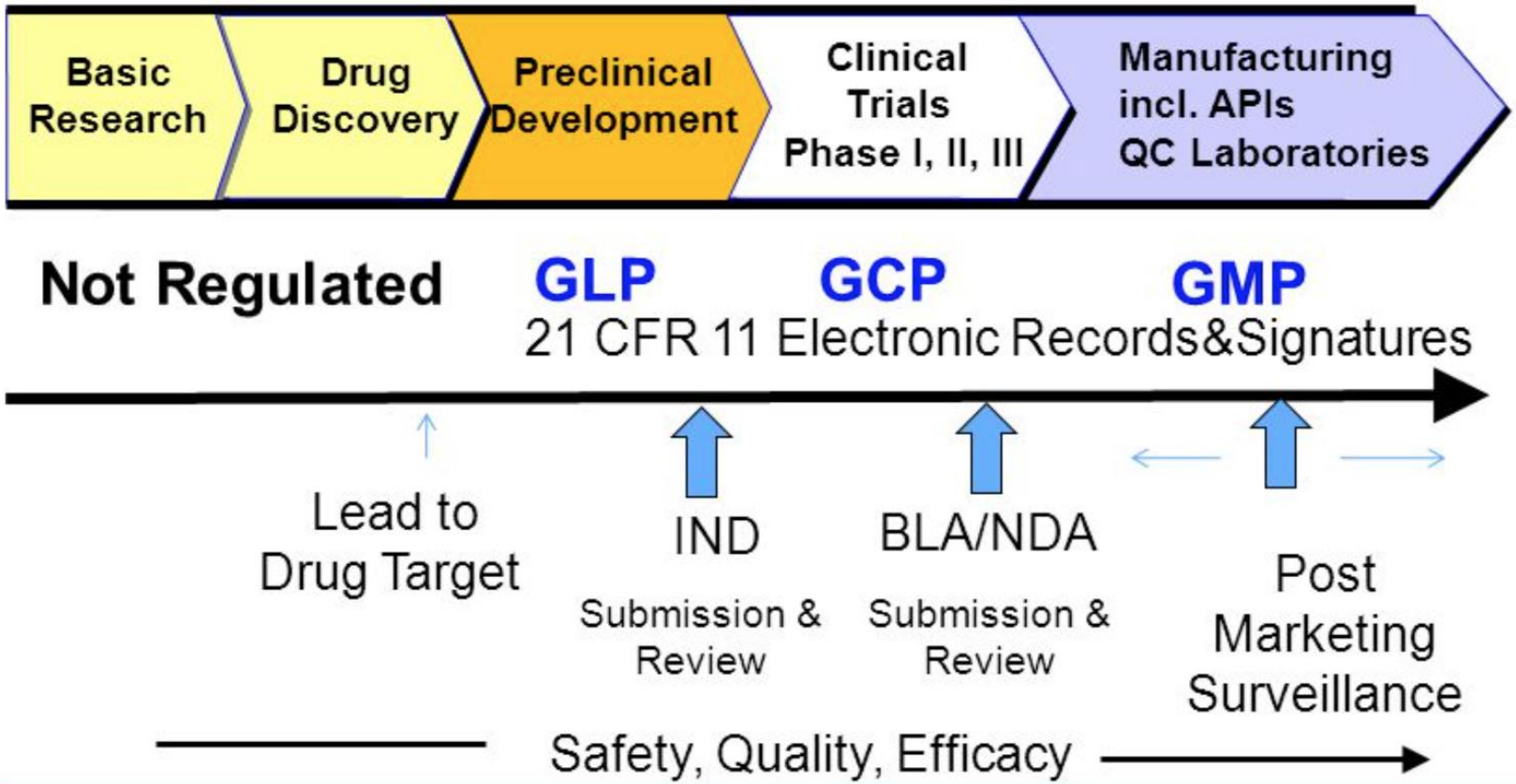
Drug Discovery & Development





rahul_pharma. Slideshare.net

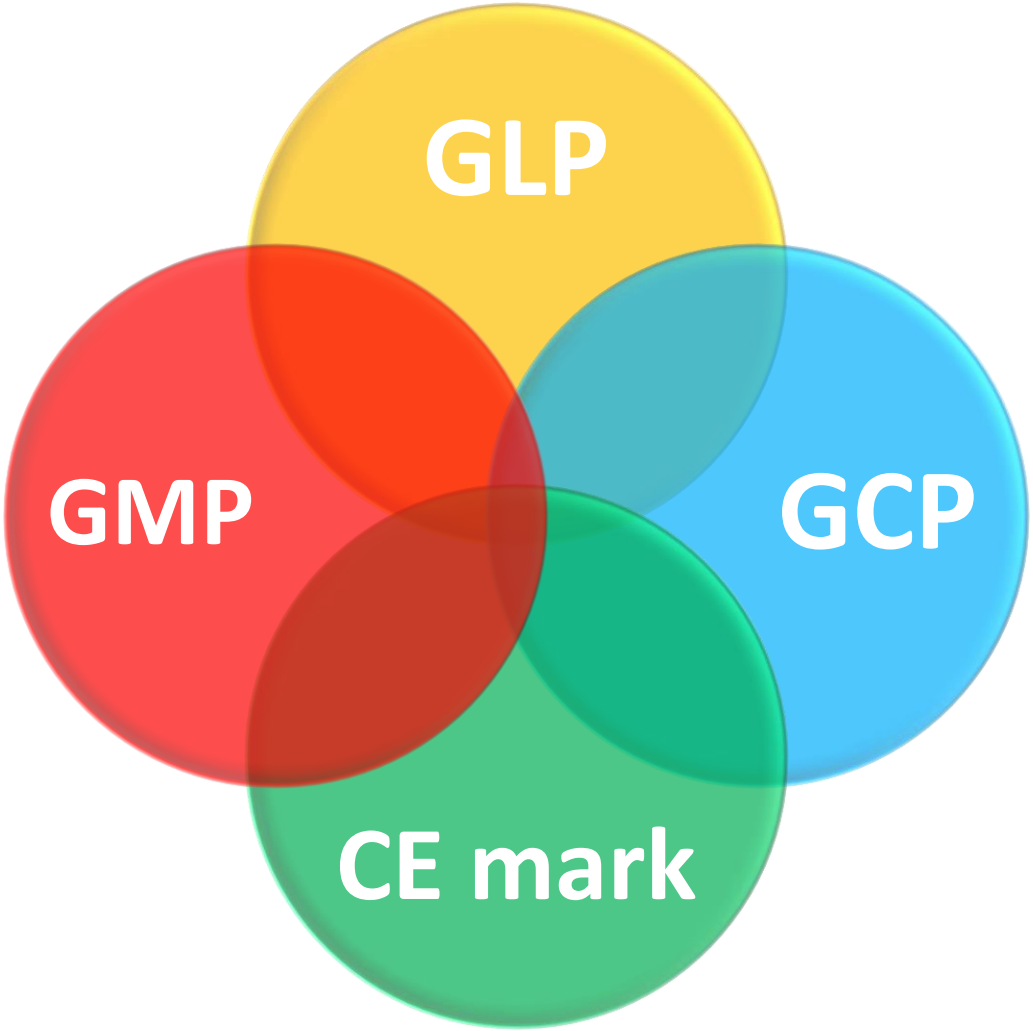
Regulations Along the Drug Life



GLP = Good Laboratory Practices
GMP = Good Manufacturing Practices
GCP = Good Clinical Practices

GxP = GLP+GCP+GMP = Predicate Rules
IND = Investigational New Drug Application
BLA = Biologic License Application
NDA = New Drug Application

Quality Systems for Medical Products Development



Google

GLP laboratory

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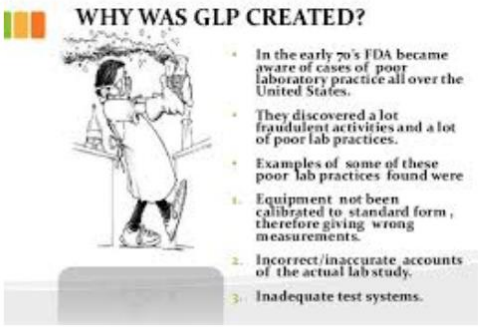

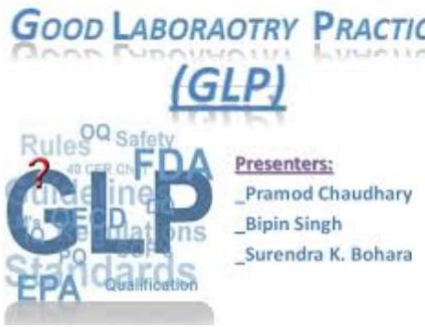

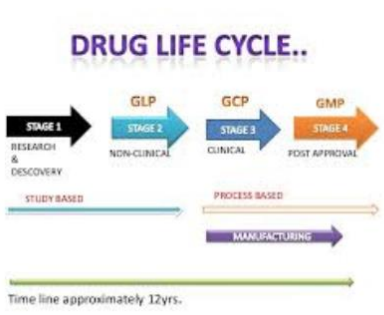

GLP : Good Laboratory Practice

- Is **a quality system** to ensure the tests are reliable and reproducible
- should be applied to the **non-clinical safety testing** of test items contained in
  - **Pharmaceutical products**
  - **Pesticide products**
  - **Cosmetic products,**
  - **Veterinary drugs**
  - **Food additives,**
  - **Feed additives**
  - **Industrial chemicals.**
- The test is to obtain data on **their properties and/or their safety** with respect to human health and/or the environment.

Good Laboratory Practice

- **a quality system**
  concerned with the organisational process and the conditions under which **non-clinical health** and **environmental safety studies** are
  - *planned,*
  - *performed,*
  - *monitored,*
  - *recorded,*
  - *archived and*
  - *reported*

GLP

quality reliability
consistency
reproducibility
integrity
uniformity

OECD EC FDA WHO


OECD.org
Data
Publications
More sites
News
Job vacancies
OECD
BETTER POLICIES FOR BETTER LIVES
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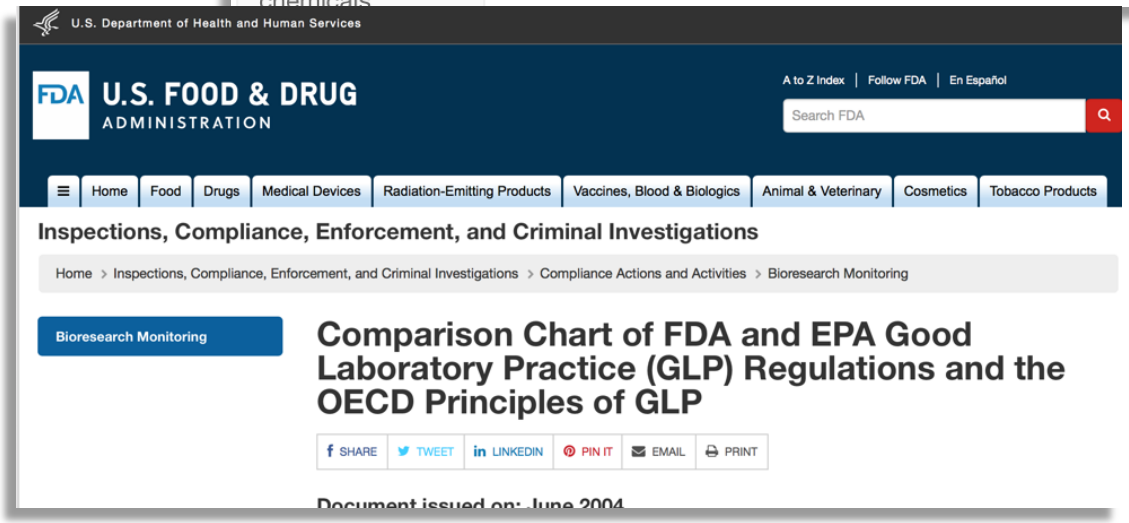
Français
OECD Home › Chemical safety and biosafety › Testing of chemicals › OECD Series on Principles of Good Laboratory Practice
Testing of chemicals
Assessment of chemicals
OECD Series on Principles of Good Laboratory Practice (GLP) and Compliance Monitoring


U.S. Department of Health and Human Services
FDA
U.S. FOOD & DRUG ADMINISTRATION
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Radiation-Emitting Products
Vaccines, Blood & Biologics
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Inspections, Compliance, Enforcement, and Criminal Investigations
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Bioresearch Monitoring
Comparison Chart of FDA and EPA Good Laboratory Practice (GLP) Regulations and the OECD Principles of GLP
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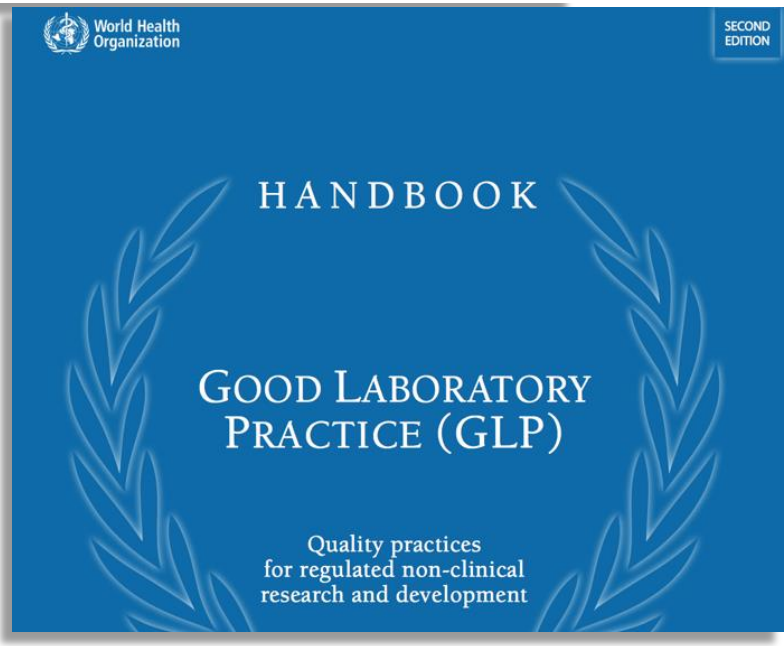
Document issued on: June 2004


World Health Organization
SECOND EDITION
HANDBOOK
GOOD LABORATORY PRACTICE (GLP)
Quality practices for regulated non-clinical research and development

LABORATORY ACCREDITATION PROGRAM

The College of American Pathologists (CAP's) Laboratory Accreditation Pro
laboratory test disciplines with the most scientifically rigorous customized ch

The CAP's peer-based inspector model provides a unique balance of regula
the most respected worldwide pathology organization.

The Laboratory Accreditation Program inspects a variety of laboratory settings from complex university medical centers to physician office laboratories, and covers a complete array of disciplines and testing procedures.

GLP : setting up

Resources

Personnel and training
Facilities

Test characteristics

Test items
Test system

Rules of performing studies

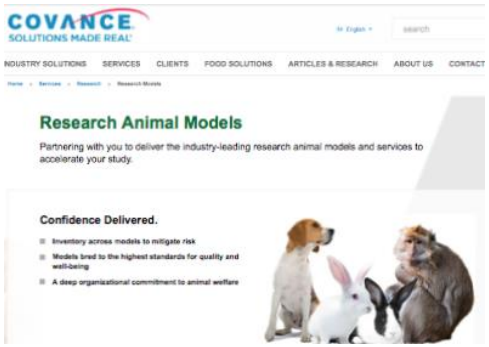
Study protocol, plan
SOPs

Results: Raw data, data collection

Records, recording
Reports, reports
Achieves, achieving
Tracking samples, specimens

Quality Assurance Unit

Review –protocol, SOPs
Audits, inspections
QA statements
QA files and reports



Ref: WHO GLP handbook 2001

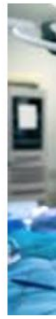
Medical Devices

Google | medical device

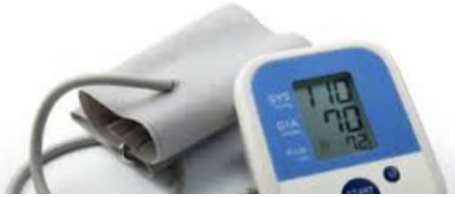
All | Images | Maps | News | Videos | More | Settings | Tools

healthcare | hospital | surgical | pharmaceutical | innovative | injection | simple | implantable | ivd | ultrasound | laser



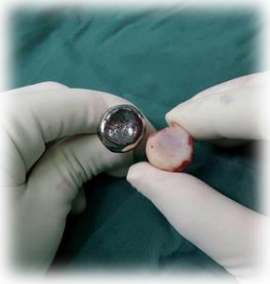


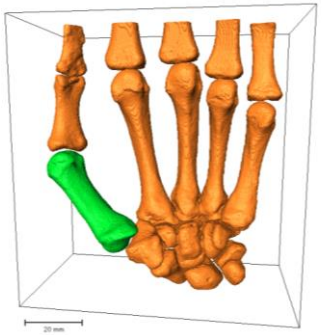


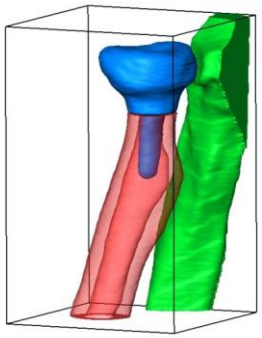



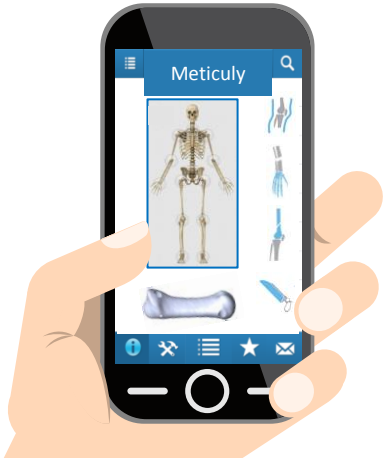
One Patient. One Implant. In One Day.

Each titanium implant is specifically designed based on the patient's CT scan to match precisely to the 3D model of the bone. Then the model is checked for biomechanics and finally the implant is created using 3D printing technology.





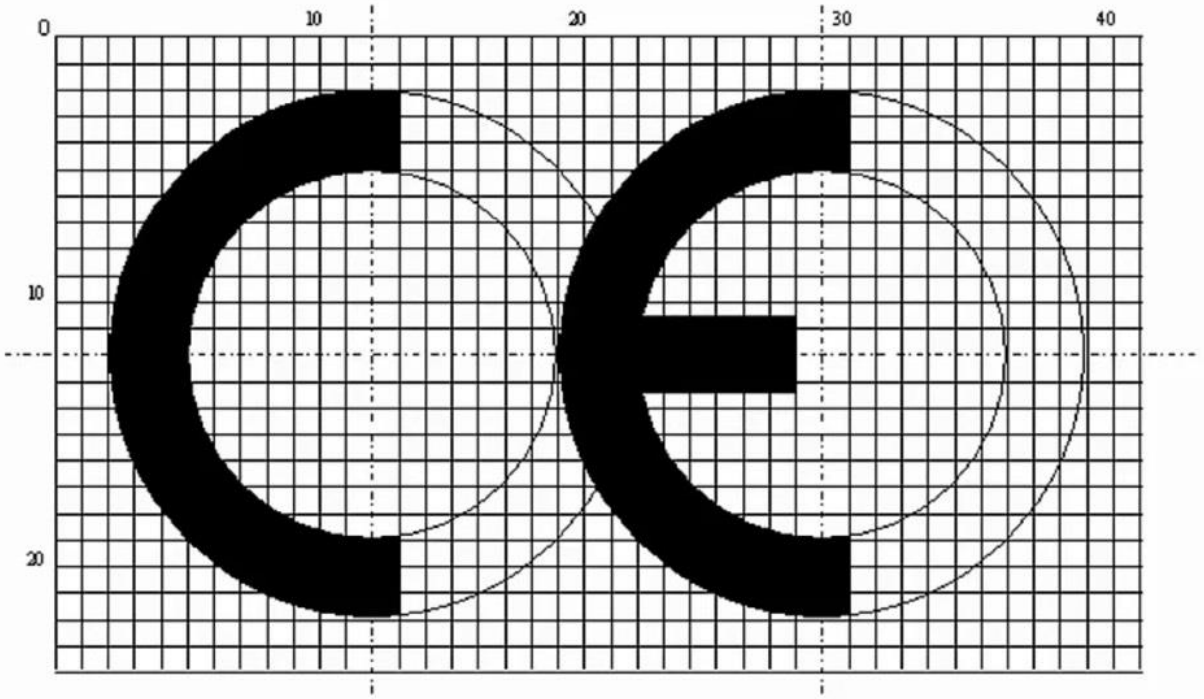




Inventor: Dr. Boonrat Lowongwat and his team

CE Marking

- Must be affixed and visible
- Applies to labeling
- Article 17 and Annex XII

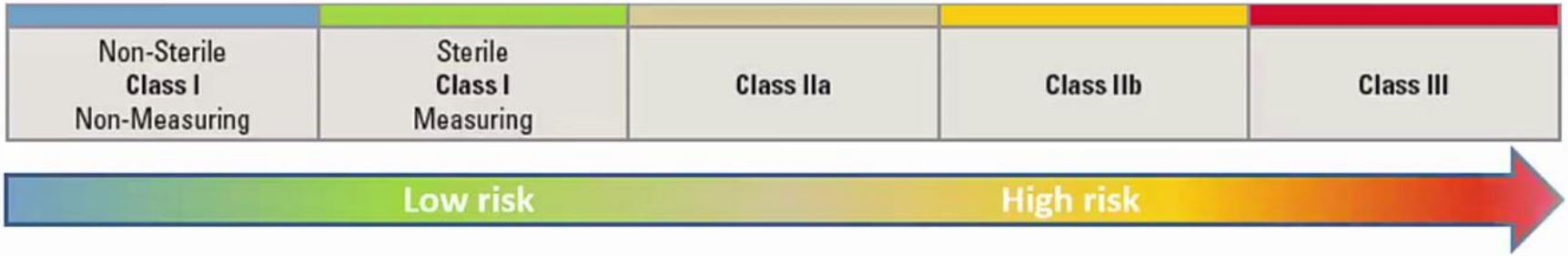


EUROPE

CE Marking gives you access to 32 countries in Europe

Medical Device Classification

- Four-tiered system (class I, class IIa, class IIb and class III)
  - Certification based on the risk to the human body
- Devices in higher risk classes are associated with more stringent regulatory requirements



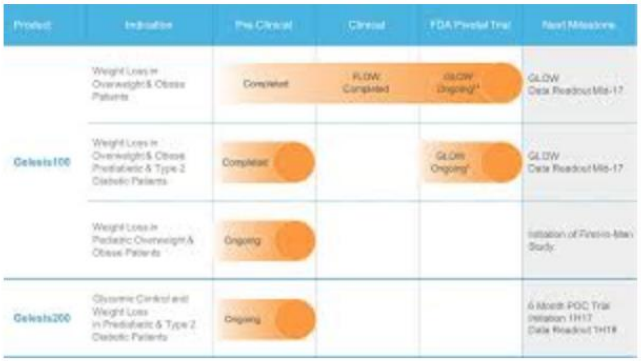
Quality Management System

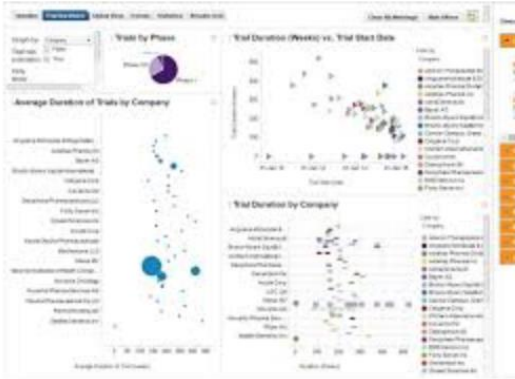
- Designed specifically for medical device companies
- Most commonly chosen way to comply in Europe

Google

Clinical Trials Innovation

ehavioral

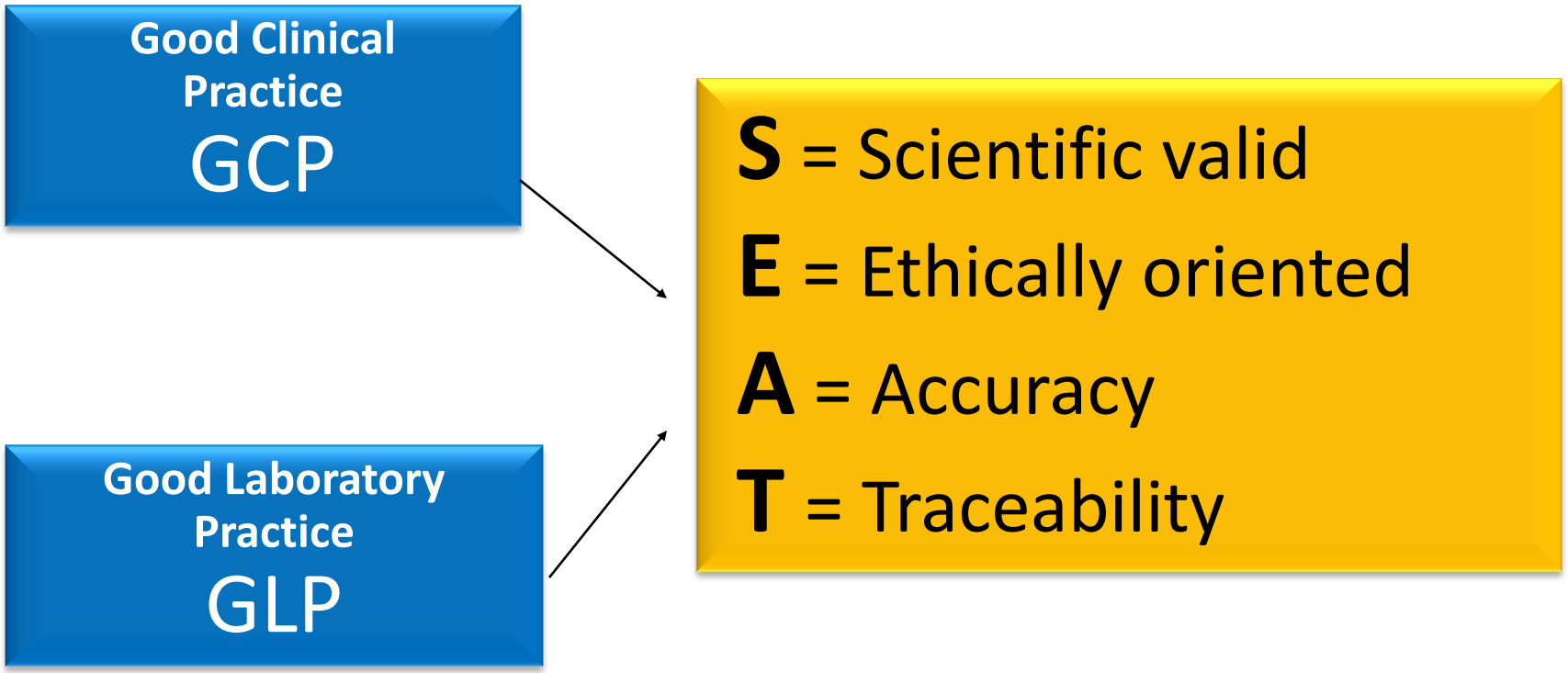




ICH GCP: USA, EU, Japan

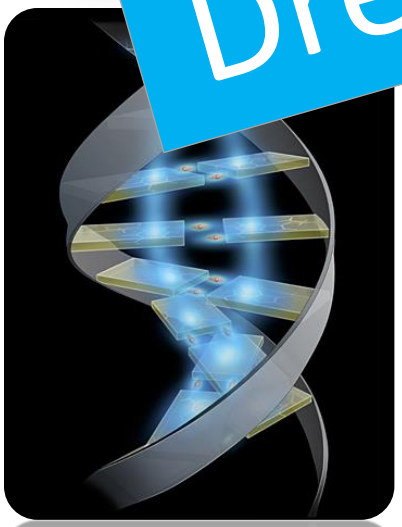
The ***International Conference on Harmonisation*** of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH)

Good Clinical Trial



To find a New drug or New Rx regimen or Strategy or Vaccine :
Better efficacy, less toxic, less expensive, better compliance, prevention of infection or cancer

Dream 1



Year 2030

Be able to develop ecosystem from R&D to global marketing of

- Vaccine
- Drugs
- Biomarkers
- Devices

Be able to get at least 0.1% of the global market share of **46.5 ล้าน ล้านบาท = “46,500 ล้านบาท “**

IMS Health Projection for 2020

www.imshealth.com

Thailand and Research
Quality Regulation Systems

EC/IRB √ GCP √ GMP √

GLP Lab √ Animal X

CE mark X
ISO 13485

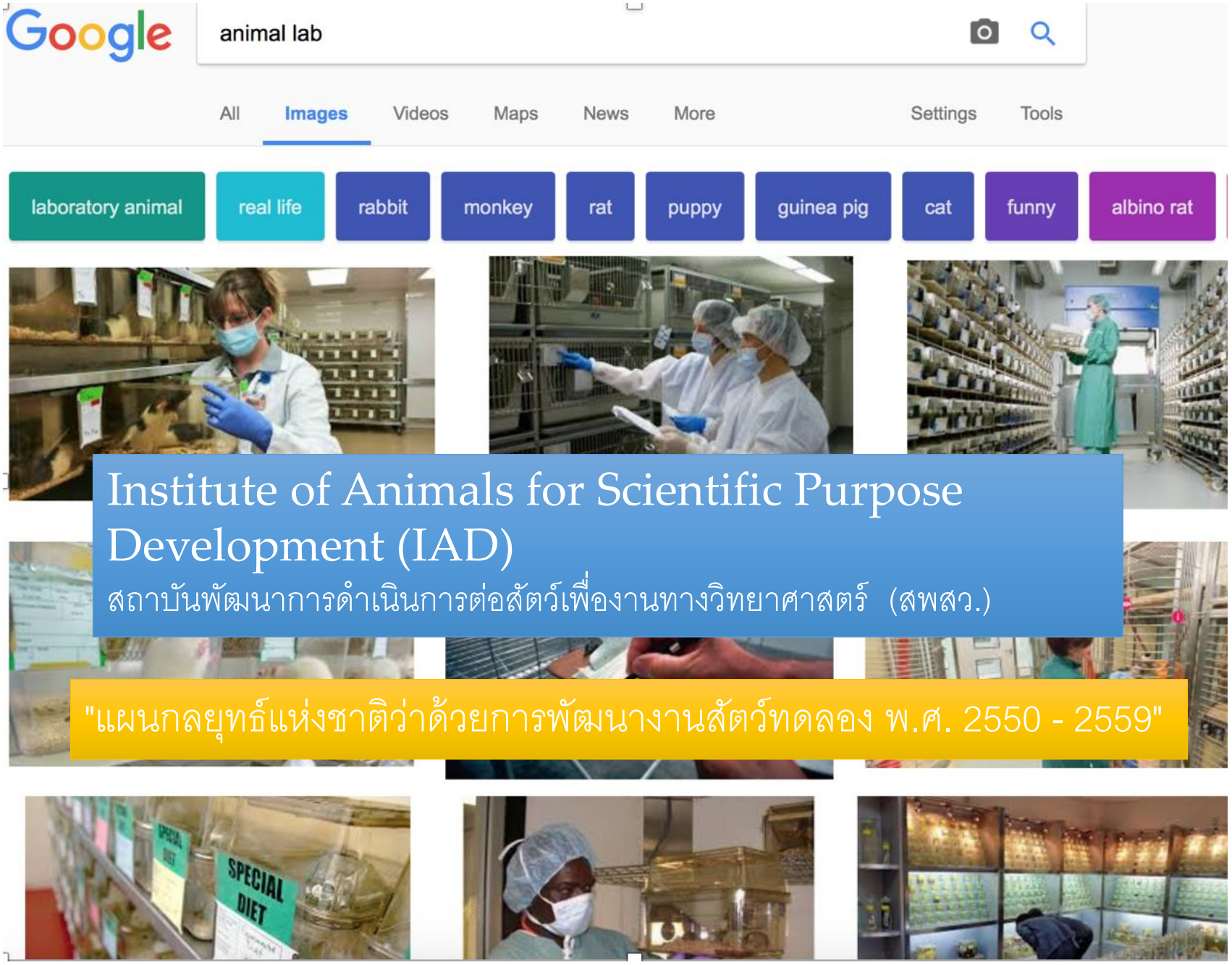
Law/ regulation

Thailand : Complying to International standard on safety and quality regulations –are under reforming to increase efficiency and speed

NRCT วช	Animal lab Human Research
DMSc กรมวิทยาศาสตร์การแพทย์	GLP
FDA อย.	IND, GCP

Transforming Challenges

1. New midnset
2. Under workforces
3. Efficient management system
4. Sufficient Budgeting



Institute of Animals for Scientific Purpose Development (IAD)

สถาบันพัฒนาการดำเนินการต่อสัตว์เพื่องานทางวิทยาศาสตร์ (สพสว.)

"แผนกลยุทธ์แห่งชาติว่าด้วยการพัฒนางานสัตว์ทดลอง พ.ศ. 2550 - 2559"

National Policy and Guidelines for Human Research 2015

มาตรฐาน
คณะกรรมการจริยธรรมการวิจัยในคน
(มคจค.)

อภินันทนาการจาก
สำนักงานคณะกรรมการวิจัยแห่งชาติ (วช.)

สำนักงานคณะกรรมการวิจัยแห่งชาติ (วช.)
พ.ศ. ๒๕๕๖

University and Global Standard

on Research And Innovation

Chula Research Strategy

Strategy

National Agenda

Research and innovation to strengthen country economy and sustainability

Regional and Global Agenda

Transforming the world with Research and Innovation

Cutting Edge

Frontier in science, health and social researches

Partnerships

Collaborating thru partnership with both domestic, international research institutes and private entities

Thailand National Strategy

Political, Economical

Stability

Prosperity

Sustain ability

National wealth
Community wealth

Inclusive Growth
Shared prosperity
Equity
Green growth

CU Innovation Ecosystem

Transforming how Thais live, learn & play

CU INNOVATION

Innovation Support | **Innovation Hub** | **Innovation District**

CU Innovation Support

- Human
- Funding
- Equipment
- Networks

Innovation Hub

- Innovator & Entrepreneur
- Commitment
- Acceleration & Valuation
- Practitioner
- Incubation
- Mindset, Process and Skill
- Academy

Business Startups
Licensing/ Social usage based on Chula Technology

Innovation Product, Process, Service
Innovation Champion
Innovation Culture

Graduates : Innovation Mindset
Interpersonal skill
Critical Thinking,

B) Startup

Health Aging and Biomed

Smart City Creative Economy

Robotic , Digital and Electronic Vehicle

Food / Energy / Water / Agriculture

Chula Innovation

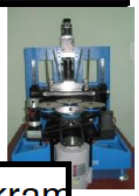
- Parkinson
- RichX
- M-Smart Brain
- Meticuly
- Superimposed
- Medical
- MRI Image
- DermaPromp

Superimposed Medical MRI Image

SMF

HelpMe!

เครื่องเจียรนัย

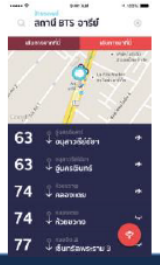


Tekram

AR

ShapeEd

Viabus



- Treasure
- Refun Bank
- Locall – Call Local
- Happy Worky
- Plan a Wed
- FlowFin
- SeeKute
- Design my trip
- EZ Learing
- My Gym You Play
- Alcohol breath tester

Delivery Robot

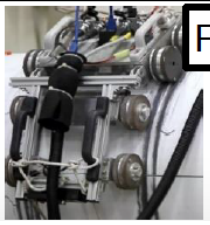
Powerbank Revo

Earphone Adapter
Get rid of sound

Intelligent 3D Printing

Social-Home-Healthcare Robots

Inspection-Monitor Robot

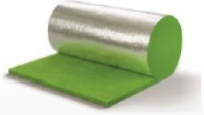


Rehabilitation Robots

Oasiz

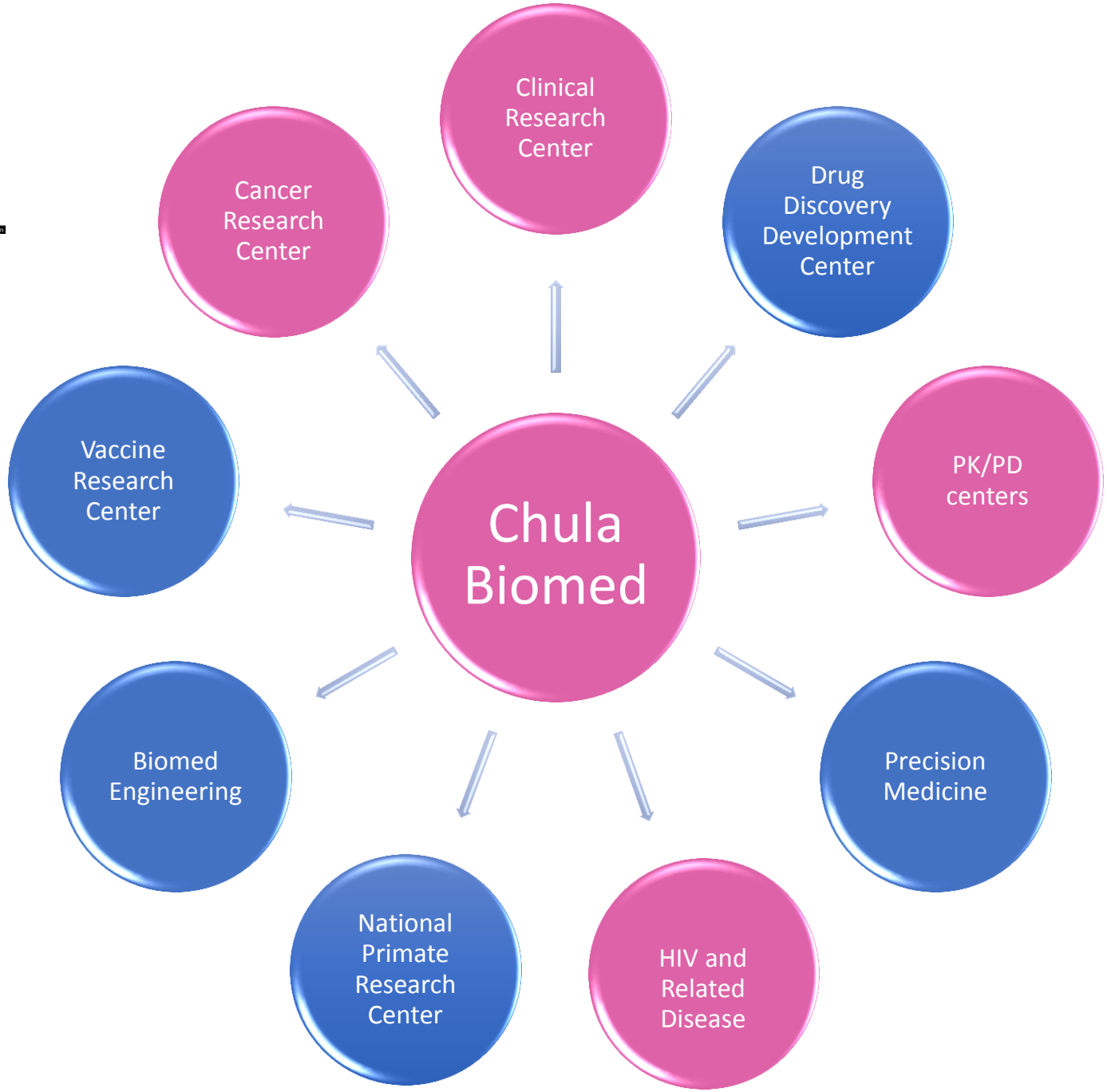
PlantD

Trumpdi



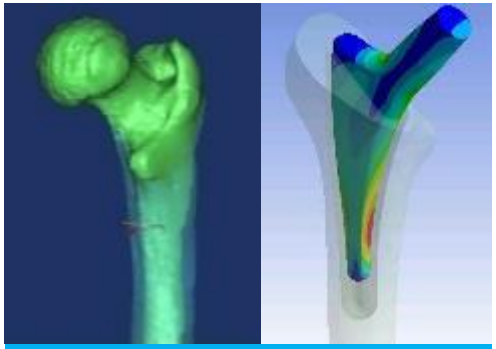
JuiceInno8

Ti2m
Siam Organic
Ingredient Box


Chula Biomed
Clinical Research Center
Drug Discovery Development Center
PK/PD centers
Precision Medicine
HIV and Related Disease
National Primate Research Center
Biomed Engineering
Vaccine Research Center
Cancer Research Center

Chula Medical Devices: Implants

Hip prosthesis

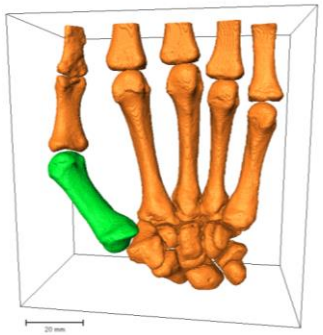


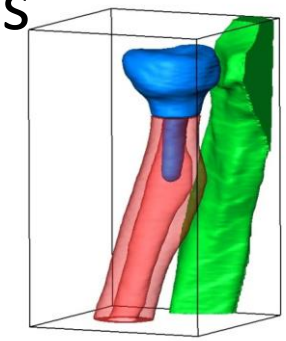
Thai Anatomy

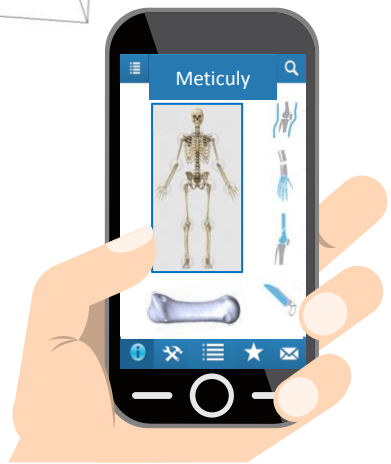
Hip Implant

Asst. Prof. Pairat Tangpornprasert

3-D Titanium bones

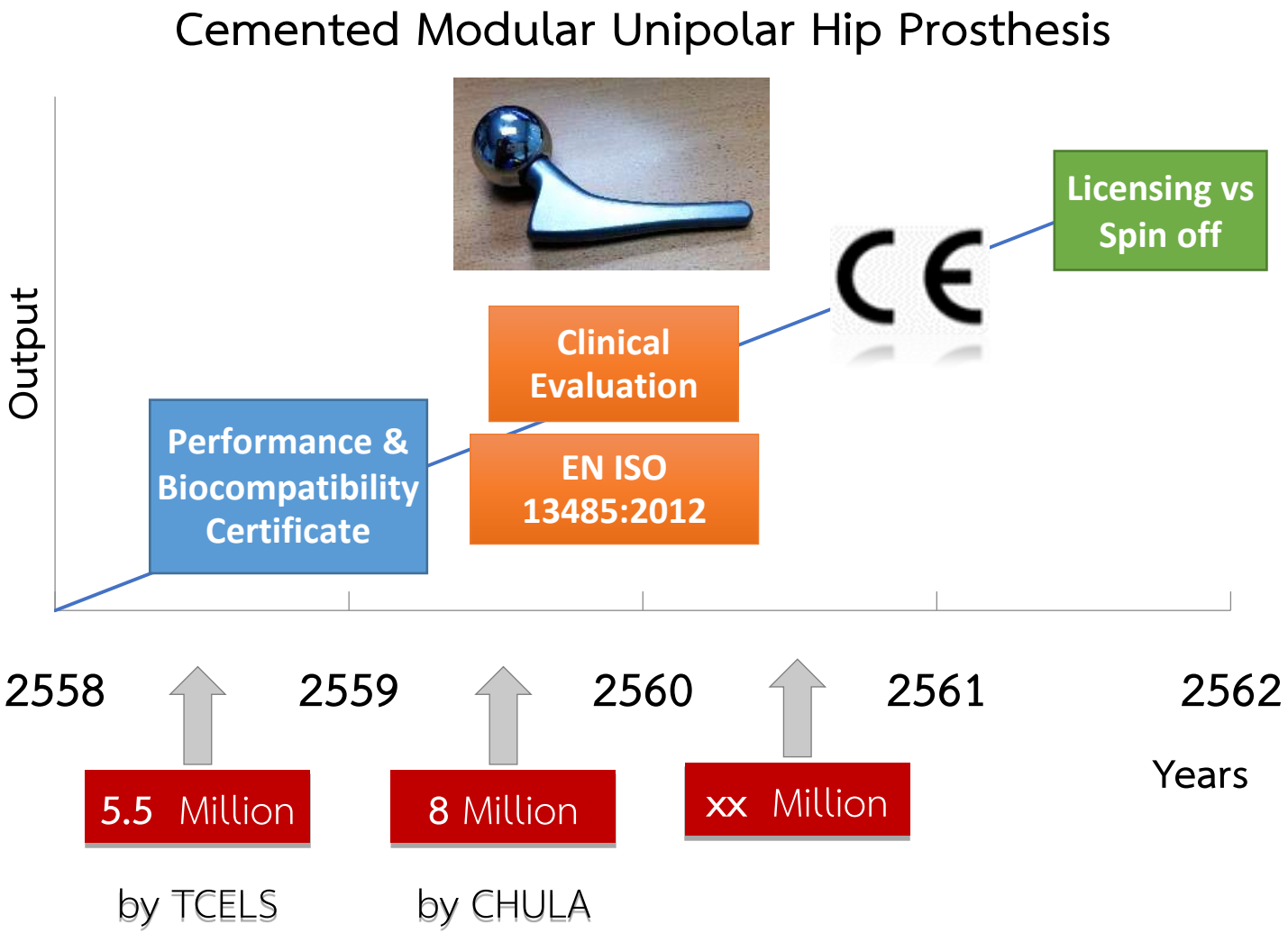






Dr. Boonrat Lowongwat

Development timelines and standard compliance of **Hip Prosthesis**



Cancer Immunotherapy Excellence Center

5 Research Groups

PI : Pokrath, Koramit, Supannikar

Cancer Cellular Immunotherapy

Therapeutic Antibody R&D

PI : Michael, Nattiya, Pornchai

PI : Trairak, Eakachai, Tanapat

Neoantigen and Cancer Vaccine

Cancer Biomarker

PI : Virote, Nipan

Tissue Bank, Genome & Omics Databases & Cancer Model

PI : Nattiya, Chanida

PI : Natawut, Duangdao

Chula VRC
Chula Vaccine Research Center
ศูนย์วิจัยวัคซีน จุฬาลงกรณ์มหาวิทยาลัย

Chula Vaccine Initiatives

ChulaVRC (Vaccine Research Center)

Faculty of Medicine, Chulalongkorn University

Thailand Dengue Vaccine Development

Projected Timelines

2016-17 **2017-18** **2018-19**

NHP study

GMP production

Phase I trial

Collaborator -KMUTT : Dr. Panit

House Mite Allergen Test and Vaccine Projects

Proposed Timelines

2016-17

Preclinical

Non-clinica

2018

GMP production

DNA vaccine

2018-19

Clinical Evaluation: Dx Test

Phase I trial: Vaccine

Assay evaluation

Phase I Vaccine trial

NATIONAL PRIMATE RESEARCH CENTER OF THAILAND

ศูนย์วิจัยไพรเมทแห่งชาติ

NATIONAL PRIMATE RESEARCH CENTER OF THAILAND
ศูนย์วิจัยไพรเมทแห่งชาติ

Chula National Primate Research Center

1.30 hours away from Bangkok

A = Administrative unit B = Breeding unit R = Research unit

Location: Chula Innovation and Pilot Plants Campus, Saraburi, Thailand

NATIONAL PRIMATE RESEARCH CENTER OF THAILAND
ศูนย์วิจัยไพรเมทแห่งชาติ

Chula National Primate Research Center

1.30 hours away from Bangkok

University : Transforming toward global standard on research and innovation

Established system

- **Research integrity regulation**: guidelines, training, screening on plagiarism
- IP office and Tech licensing office
- **Ethic committees** : GCP, มาตรฐาน EC
- **GCP** complied clinical research center (ChulaCRC): ICH GCP
- **GLP** complied clinical lab: College American Pathologists (CAP)
- **Animal use and animal research ethic committee** : พระราชบัญญัติสัตว์เพื่องานทางวิทยาศาสตร์

On going process

- **GLP, AAALAC Animal lab facilities**: 1. Small animal 2. Non-human primate
- **GMP pilot plants** : 2 pilot plants for implant hip prosthetic and 3-D bone : working on GMP approval and CE marking

Thailand Needs Further Strengthening

Thailand: Capacity Strengthening needed

I. Key stakeholders

- FDA: high priority
- All relevant research centers and researchers
- Domestic industries

II. How to

- Set up a clear roadmap with milestones-timelines and proper funding
- **FDA**:
  - Quickly increase their quality workforce
  - Recruit full-time experienced experts, consultants, authorized parties,
  - Training: workshop, on the job training
- **Universities**
  - Training, workshop, on the job training; outsourcing
  - Joint program with global university or industry
- **Domestic industries**
  - **SMEs**: Outsourcing, consultants (SMEs): Government –should provide services
  - **Big corporates**: Recruit experienced staffs,
  - **Training**

Regulatory Authority with **Useful Website** is Essential

Investigational New Drug (IND) Application

Emergency Investigational New Drug (EIND) Applications for Antiviral Products

IND Forms and Instructions

Investigator-Initiated Investigational New Drug (IND) Applications

Pre-IND Consultation Program

Regulatory Information for INDs

Investigational New Drug (IND) Application

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Spotlight

- Investigator-Initiated IND Applications
- Final Rule: IND Safety Reporting Requirements for Human Drug and Biological Products and Safety Reporting Requirements for Bioavailability and Bioequivalence Studies in Humans

Overview
Research and development
Marketing authorisation
Post-authorisation
Herbal products

Home › Human regulatory

Human medicines: regulatory information

This section of the website provides information on the regulation of medicines for human use in the European Union (EU). It particularly concerns the centralised procedure, where the European Medicines Agency (EMA) plays a key role.

For further information on EU legislation and procedures for the regulation of human medicines, see volumes 1-4 and 9-10 of the rules governing medicinal products in the EU.

- Overview
- Research and development
- Marketing authorisation
- Post-authorisation
- Herbal products

CFDA China Food and Drug Administration

Chinese(GB)

Contact CFDA

HOME | ABOUT CFDA | WHAT'S NEW | LAWS & REGULATIONS | REGULATORY GUIDE | DATA SEARCH | SITE MA

Search Go

What's New

(2017-07-21)

- 2017 BRICs cooperation meeting on drug supervision was held in Zhengzhou (2017-07-21)
- 2017 Annual's Ministerial Seminar on Drug Quality Management in Developing Countries

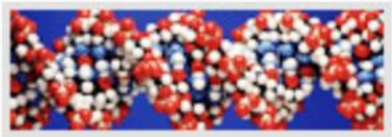
ABOUT CFDA

- Main Responsibilities
- Internal Structure
- Organizational Chart

REGULATORY GUIDE

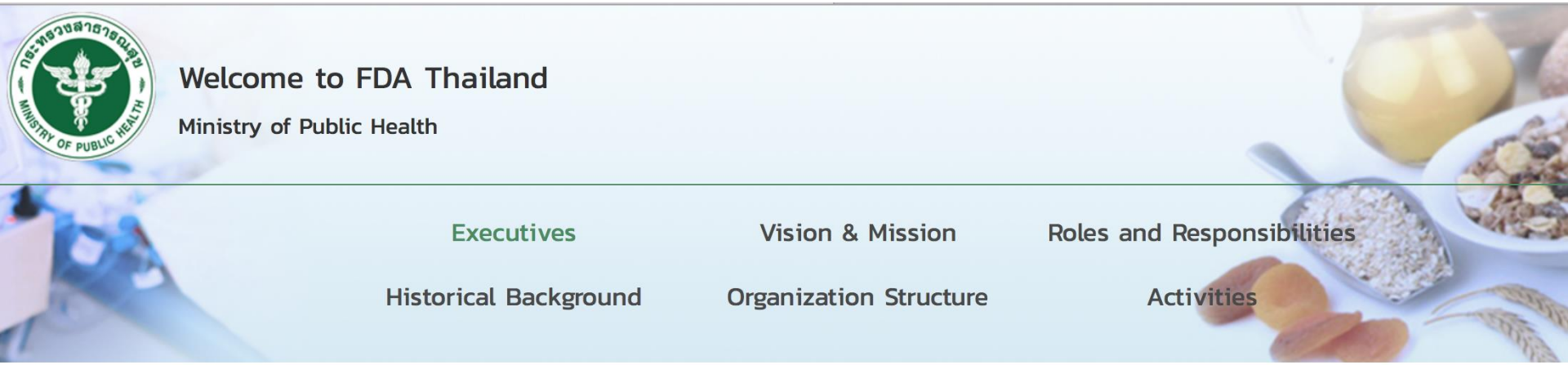
- Drugs
- Medical Devices
- Health Food
- Cosmetics

LAWS & REGULATIONS



- Drug Administration Law of the People's Republic of China
- Regulations for Implementation of th Drug Administration Law of the People's Republic of China

Thai FDA



The Roles and Responsibilities of Thai FDA

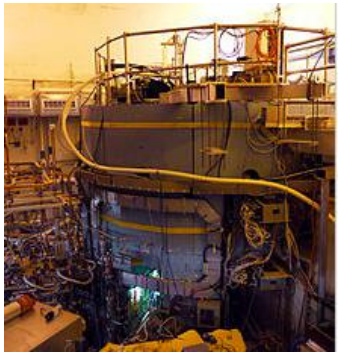
The main role of Thai FDA is to protect consumers' health thru ensuring safety, quality and efficacy of consumable products within its remit. These include: foods, drugs, psychotropic substances, narcotics, medical devices, volatile substances, cosmetics and hazardous substances available in the country. This has to be implemented in accordance with the national legislation and international agreements as follows:

1. Drug Act, B.E. 2510 (1967) and Amendment No. 2 (1975), No. 3 (1979), No. 4 (1985) and No. 5 (1987),
2. Psychotropic Substance Act B.E. 2518 (1975) and Amendment No. 2 (1985), No. 3 (1992) and No. 4 (2000)
3. Food Act, B.E. 2522 (1979)
4. Narcotic Act, B.E. 2522 (1979) and Amendment No. 2 (1985), No. 3 (1987) and No. 4 (2000)
5. The Emergency Decree on Prevention of Abuse of Volatile Substances, B.E. 2533 (1990) and Amendment No. 2 (2000)
6. Hazardous Substance Act, B.E. 2535 (1992)
7. Medical Device Act, B.E. 2551 (2008)
8. Cosmetic Act, B.E. 2558 (2015)
9. The Single Convention on Narcotic Drugs 1961, commentary on the protocol amended in Geneva on March 25, 1972
10. The International Convention on Psychotropic Substances, 1971

Thailand: Can we seriously reform ?

Investment on Human Capital !!

Human Development
A priority > not yet building



Professional

Full- time
Researchers
Career path

Ecosystem for high quality Research

Some of these photos are from websites for education use only

CHINESE ACADEMY OF SCIENCES

China policy is committed on **Infrastructure and Capacity Development**

104 Research Institutes

5 Universities

12 management organization

22 holding companies

There are 124 Institutions directly under the CAS by the end of 2012, with 104 research institutes, five universities & supporting organizations, 12 management organizations that consist of the headquarters and branches, and three other units. Moreover, there are 25 legal entities affiliated and 22 CAS invested holding enterprises.

We definitely can achieve these goals in the next decade !!, if we do have

- **a new mindset**
- **a real commitment, and**
- **a new way of efficient management system**
- **a reliably way of auditing on accountability**
- **a performance-based and block grant funding mechanism**

Value-based economy
with **strong quality and safety regulation systems**