



Chemon Inc Overview 2016

Chem  **n**
Nonclinical **CRO**

Overview

Company

Chemon Inc.



Establishment

2000. 1. 11.

C E O

Si-Whan Song, DVM, PhD.

Employee

Total 119 employee (109 researchers) by 2016

Business Area

Safety, Efficacy, PK, TK, ADME, Consulting, New Drug Development and etc.

Address

Yongin Facility (4,899m²) + **4,713m² under construction, by Apr 2017**
240 Nampyeong-ro, Yangji-Myeon, Cheoin-Gu, Yongin, Gyeonggi-Do, 17162, Korea

Suwon Facility (909.9m²)
10 & 15F, Gyeonggi Bio-Center, 147 Gwanggyo-ro Yeongtong-Gu, Suwon, Gyeonggi-Do, 16229, Korea

Partners

Seoul Samsung Hospital (Clinical study), Cerep (*in vitro* study), Korea Research Institute of Bioscience & Biotechnology (Monkey PK)

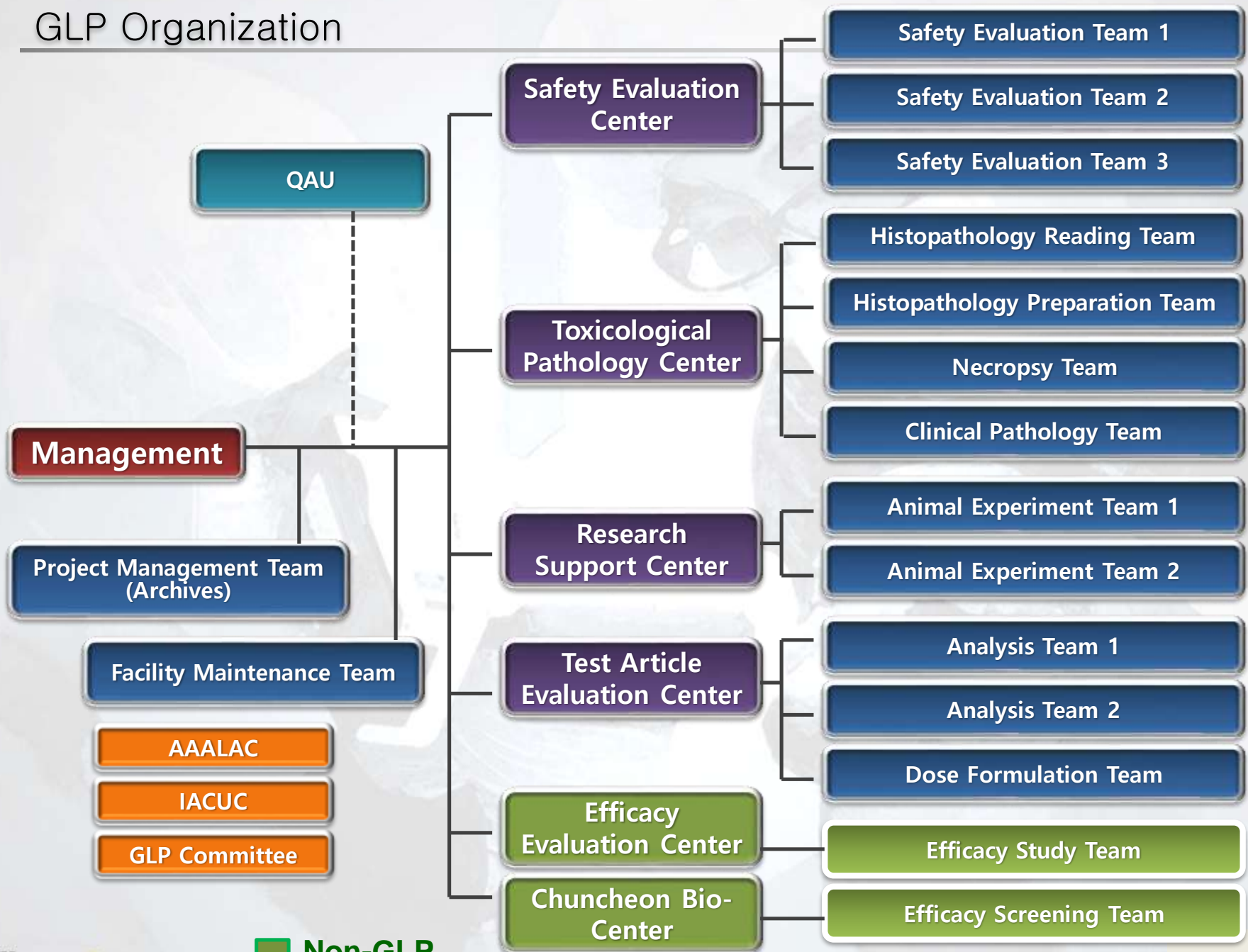
Homepage

www.chemon.co.kr

Brief History

Year	Achievements
2000	Establishment
2002	KGLP approval by KFDA (Acute and Genetic Toxicity)
2003	KGLP approval by KFDA (Repeated-dose, Reproductive, Immune and Local irritation test) •Designated as a Technical Innovation Company (by Inno-biz) •Designated as a High-Tech Company (by Korea Technology Credit Guarantee Fund)
2004	Completion of construction of Preclinical Research Center at Yangji and move to it (Approval by KFDA)
2005	•Accredited by RDA as an Agricultural Chemicals Test Organization •Gained "A" level from Inno-Biz
2006	KGLP approval by KFDA (Carcinogenicity Test)
2007	•KGLP approval by KFDA (Other toxicity tests) •Several units moved to Gyeonggi Bio-Center (Efficacy, Analysis and Genetic Toxicity) •Accredited by NIER (National institute of Environmental Research) as a Test Facility for Chemical Hazard Assessment etc.
2008	•Approval of the facility at Gyeonggi Bio Research Center as a GLP facility •Authorized by RDA as a Facility for Agricultural Chemical Safety Test •Selected by Gyeonggi-Do as a bright-prospect company
2010	•AAALAC full accreditation •Selected as a Gyeonggi-do promising small and medium business
2014	•Completion of #2 Bldg. •Launching Chuncheon Biocenter
2015	•Mock inspection By Quintiles for the submission to US FDA
2016	• Approved for hERG assay, Telemetry, Comet assay, MLA, Alternative test for phototoxicity (in vitro) •Start construction of a new building (# 3)

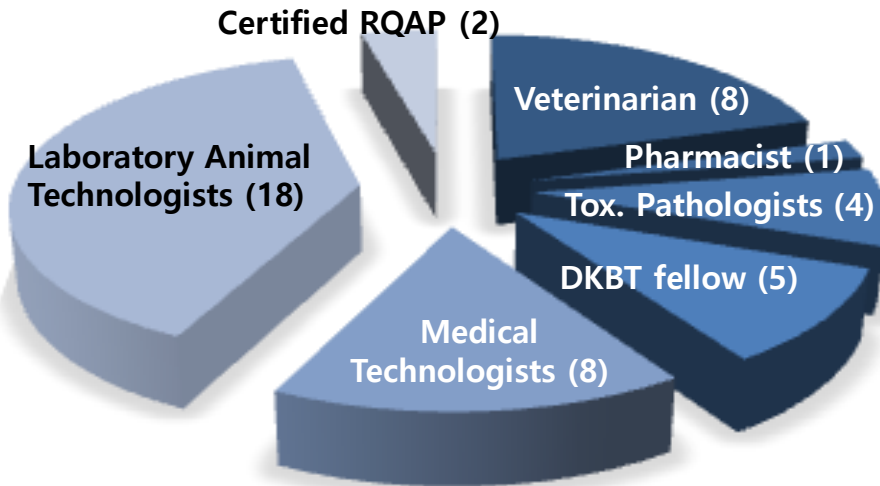
GLP Organization



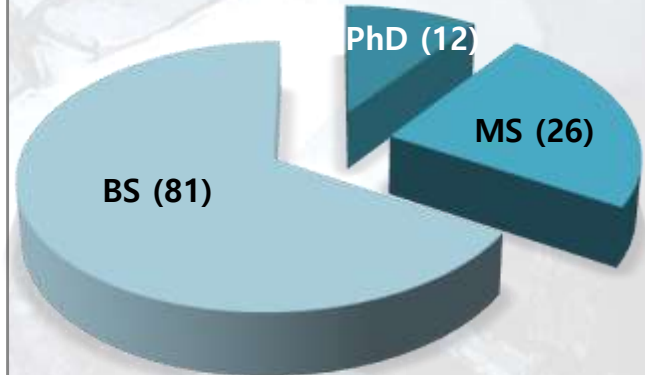
■ Non-GLP

Manpower

Qualification



Educational Background



Description	PhD	MS	BS	Total
Researcher	11	32	68	111
Business	-	4	1	5
Administration	-	-	7	7
Total	11	36	76	123

Manpower

Position	Name	Education	Career
CEO	Si-Whan Song, DVM, PhD.	Seoul Nat'l Univ.	Korea Institute of Toxicology
Management	Kap-Ho Kim, DVM, MS.	Chungbuk Nat'l Univ. Doctoral candidate	Korea Institute of Toxicology, Biotoxtech
Tox. Eval. Center	Hyun-Kul Lee, PhD.,	Chungnam Nat'l Univ.	Korea Institute of Toxicology
Tox. Eval. Center	Jongmin Kim, PhD., Pharmacist	Kyunghee Univ.	Chemon Inc.
Tox. Eval. Center (Safety Pharm.)	Sun-Don Kim, DVM, PhD.	Seoul Nat'l Univ.	Research Professor, Seoul Nat'l Univ.
Tox. Pathol. Center	Bu-Hyun Kang, DVM, PhD.	UC Davis, USA	Korea Institute of Toxicology
Tox. Pathol. Center	Ying-Hwa Lee, DVM, PhD.	Kyungbuk Nat'l Univ.	Korea Institute of Toxicology, Biotoxtech
Tox. Pathol. Center	Min-Soo Kang, DVM, PhD	Seoul Nat'l Univ.	Chemon Inc.
Analysis Center	Won Kim, PhD.	Konkuk Univ.	Yuhan Corp., Korea Institute of Toxicology
Efficacy Center	Chul-Gyu Lee, MS, Doctoral candidate	Sungkyunkwan Univ.	ShinPoong Pharm. Co.

Facilities (Yongin in 2017)

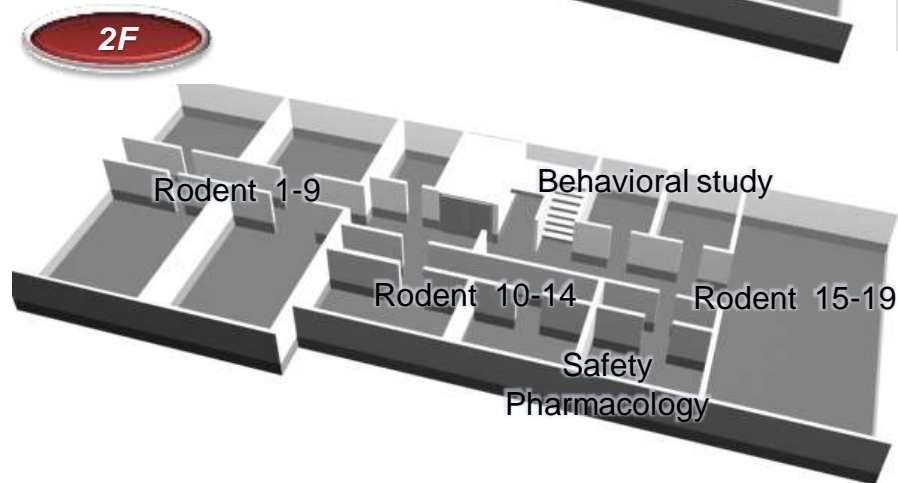
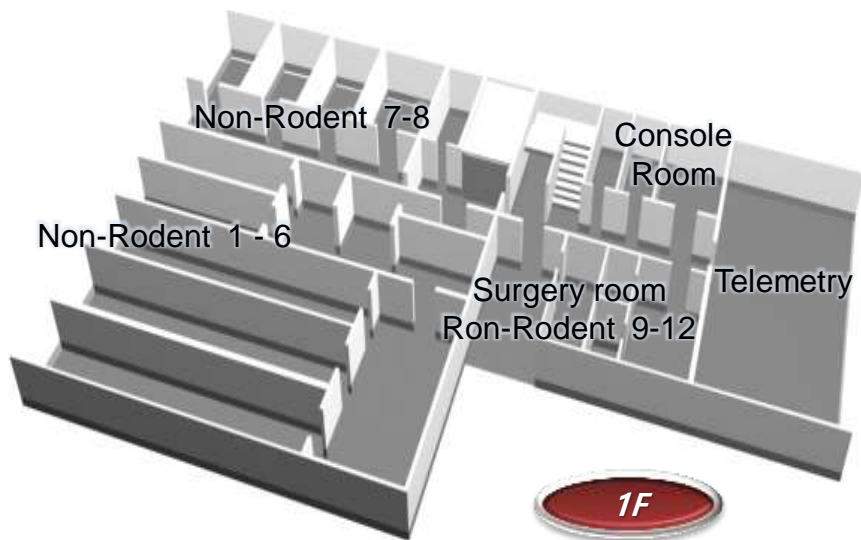
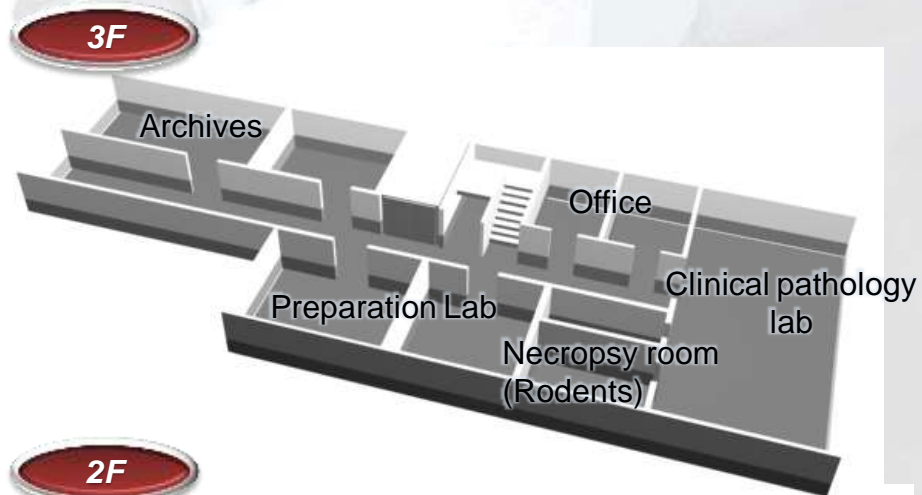


Facilities (Yongin) Research building #1

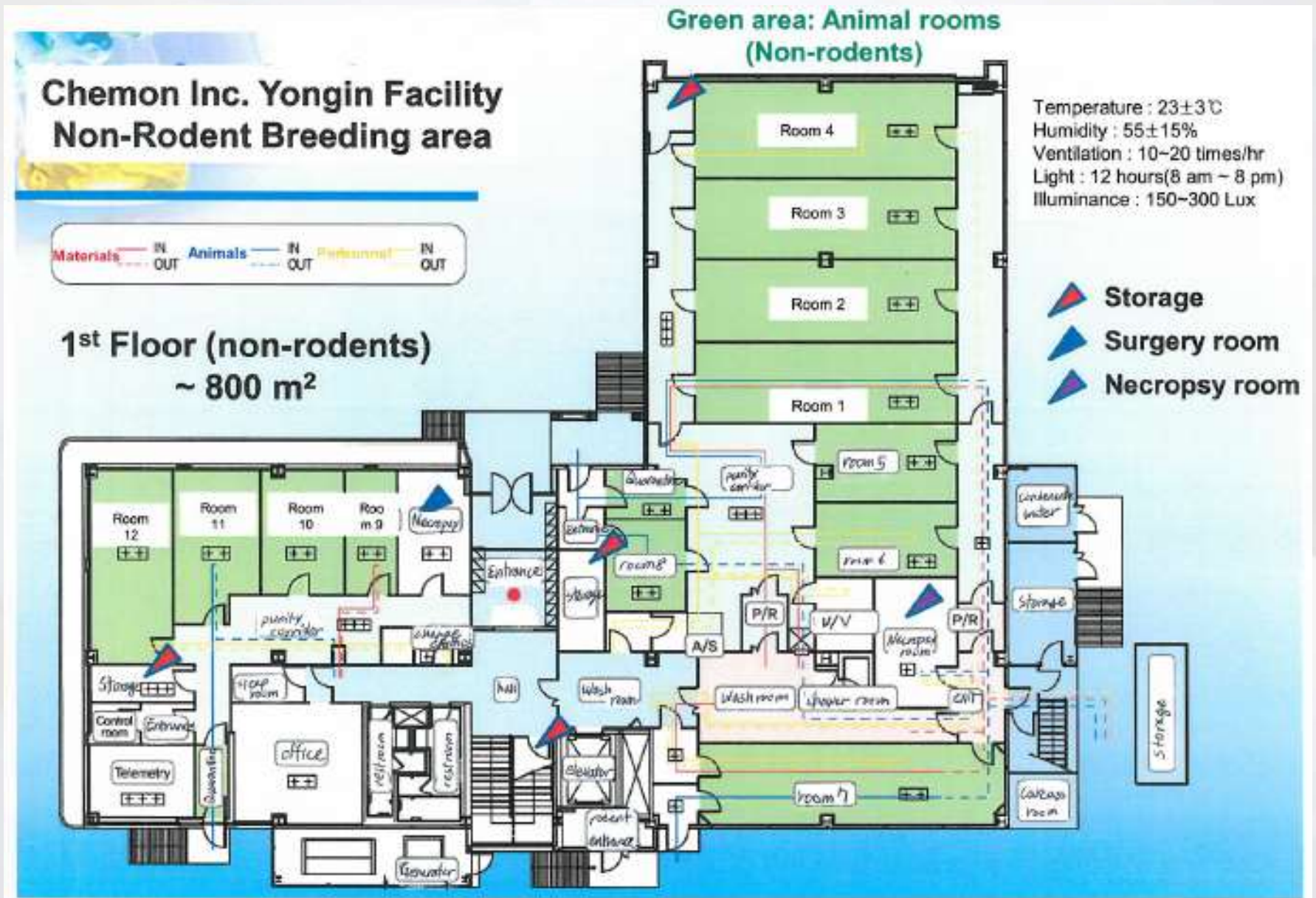


Yongin Facility

240 Nampyeong-ro, Yangji-Myeon, Cheoin-Gu, Yongin, Gyeonggi-Do, 17162, Korea



Facilities (Yongin) Research building #1



Facilities (Yongin) Research building #1

Chemon Inc. Yongin Facility Rodent Breeding area



2nd Floor (rodents)
~ 800 m²

Green area: Animal rooms
(Rodents)

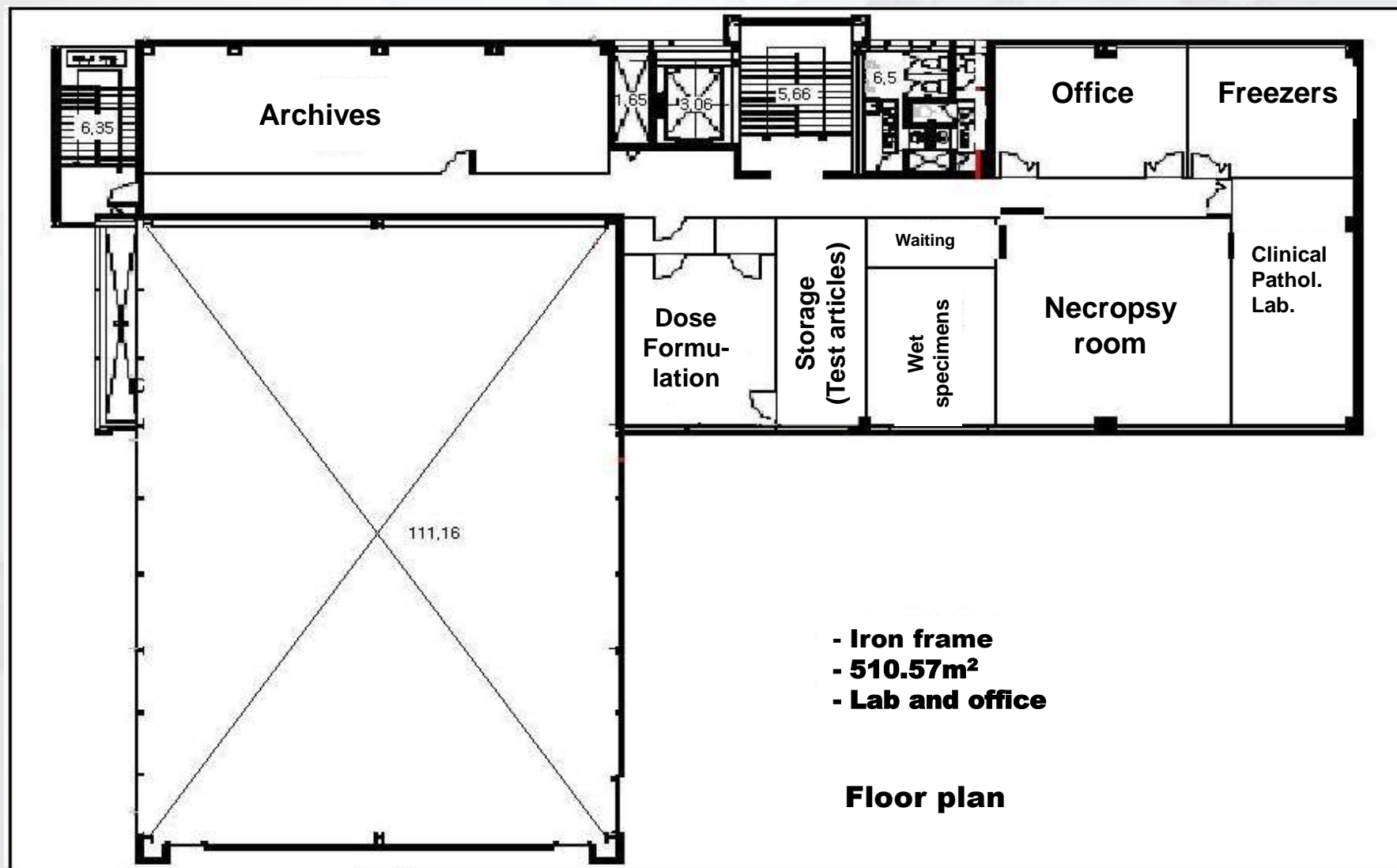
Temperature : 23±3℃
Humidity : 55±15%
Ventilation : 10-20 times/hr
Light : 12 hours(8 am ~ 8 pm)
Illuminance : 150-300 Lux

Storage



Facilities (Yongin) Research building #1

3rd Floor





Before taken into the barrier, all items are autoclaved, sprayed, UV-irradiated, submerged in disinfectant, or Gamma-ray irradiated according to the character of the item.

Corridor

Differential air pressure must be maintained between the Room / Anteroom / Corridor / Outdoor. The timer should be checked periodically to synchronize with real time.



Emergency lantern

Anteroom

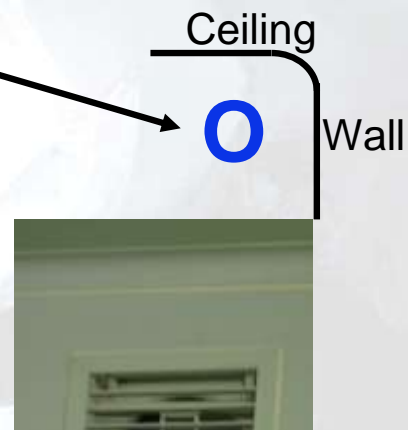


- Supplies in Anteroom for Cleaning
- Sterilized water supply/Drain
 - Sink
 - Disinfectant
 - Mop

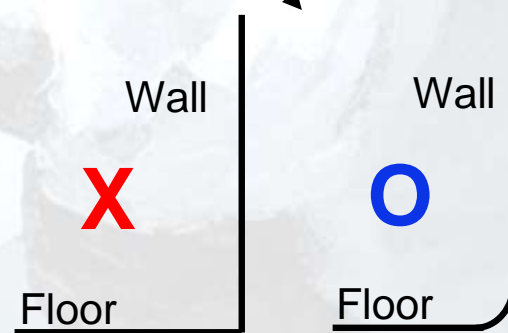
Animal room



- 1. Air exhaust
- 2. Sentinel animal
- 3. Door to anteroom



Round finish



Animal room



Mechanical High/Low thermometer and Humidity meter are installed to back-up Computer-based automatic sensors.

Dose Formulation Lab



Necropsy Room



Clinical Biochemistry Lab



Facilities (Yongin) Research building #2



Conference room
Electrophysiology (hERG assay)
QAU
Histopathology lab
Office of management, Histopathology expert, Study directors, Administration, Project manager
Restaurant

Research Building #1

Histopathology Lab



New 3rd Building for a New start

Efficacy
Animal Tox
 Rodents, Rabbits, Dogs, Minipigs
Genetic Tox
Environmental Tox
hERG assay
Telemetry
Mechanics
Archives
Office



Facilities (Yongin) Research building #3

Yongin Facility

240 Nampyeong-ro, Yangji-Myeon, Cheoin-Gu,
Yongin, Gyeonggi-Do, 17162, Korea



Facilities (Suwon)



Suwon Facility (909.9m²)

10 & 15F, Gyeonggi Bio-Center, 147 Gwanggyo-ro Yeongtong-Gu, Suwon, Gyeonggi-Do, 16229, Korea

10F

Genotoxicity Lab 2 Genotoxicity lab 3
Cell Culture Lab Genotoxicity Lab 1

B1

Rodent Room 4, 5 Rodent Room 1, 2, 3
Cleaning Room & Entrance

10F

Efficacy Lab 1 Efficacy Lab 3
Efficacy Lab 1

15F

Analysis Lab QAU
Archive Room

5 UPLC systems (will be 7 in 2017)
5 LC-MS/MS systems (will be 6 in 2017)

Facilities (Suwon)



Analysis Lab

15F



GeneTox Lab

10F



Capacity – overall



Yongjin Facility

Species	No. Room	Max. Capacity
Rodent	20	5,800~12,000*
Beagle Dog	7	206
Guinea Pig	2	600
Rabbit	3	234

* Rats or Mice



Suwon Facility

Species	Flat	Capacity
Rodent(Rat)	5	3,200

Current SOPs

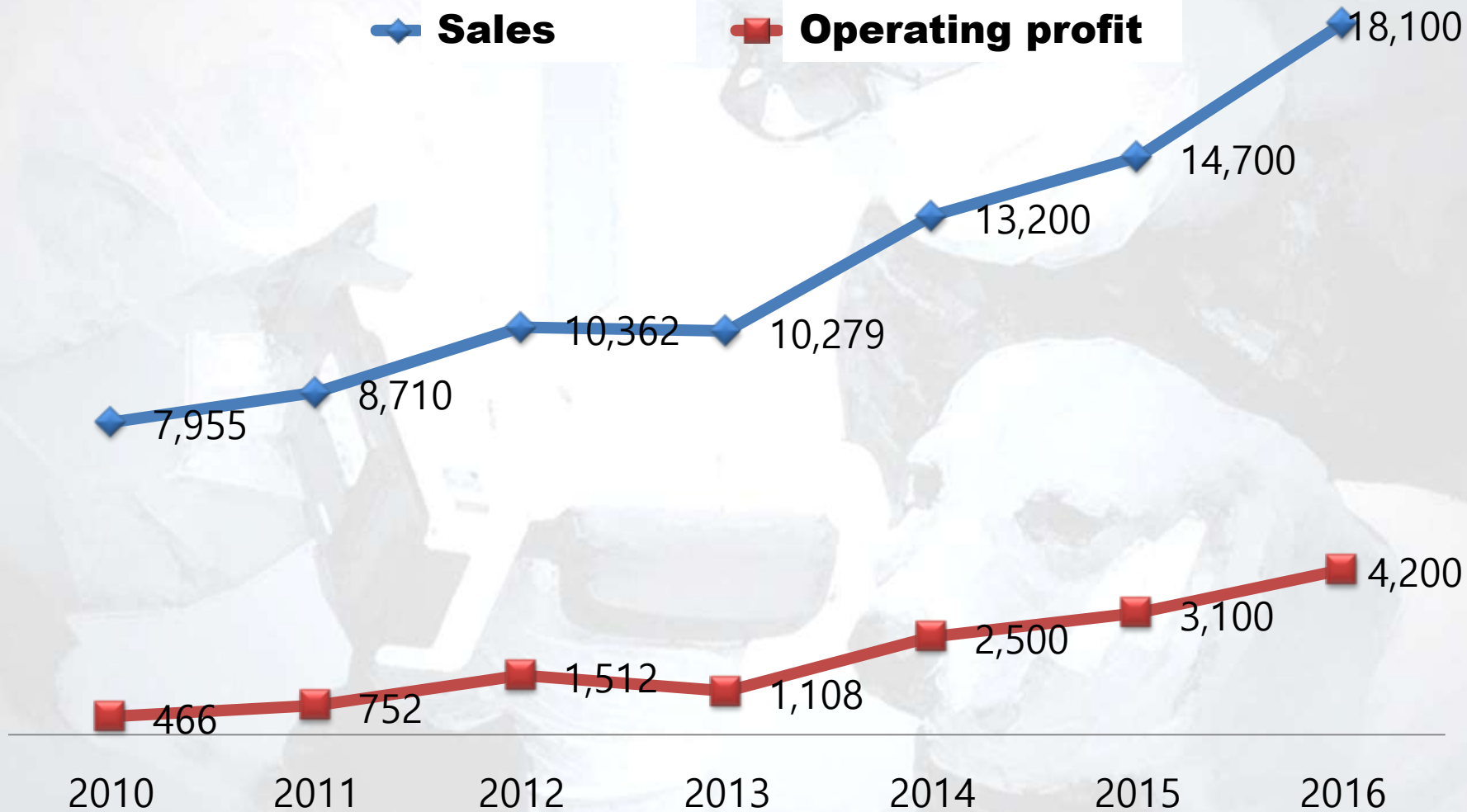
Categories (Code)	#SOP	Categories (Code)	#SOP
Documentation and general affairs (TO)	16	General pharmacology (GP)	13
Quality assurance (QA)	7	Safety pharmacology (SP)	4
Laboratory animal care (BM/BE)	24	Quarantine (QT)	9
Animal experiments (AT)	19	Local toxicity test (LT)	7
Storage and preparation of test article (TA)	9	Analysis of test article (AS)	7
General toxicity tests (GT)	10	Toxicokinetic study (TS)	6
Genetic toxicity tests (MT)	31	Instrument operation (IO)	200
Clinical pathology (BL)	11	Instrument maintenance (IM)	7
Histopathology (PA)	14	Instrument calibration (IC)	26
Facility Maintenance (FA)	17	Laboratory safety (LS)	5
Statistics (ST)	4	Veterinary Care (VC)	5
Reproductive toxicity test (RT)	16	Computer data input (CO)	4
Immunological toxicity test (IT)	8	Archives (AC)	8
Carcinogenicity test (CA)	6	Total	508

Performance



* Study number/year (by Dec 2016), regardless of the scales of individual studies

Sales (KRW)



Reliability of Studies – Approved by Foreign Countries

Test Items and Studies performed by Chemon Inc.	Status
(Company N) Natural substance for Dementia (New drug) – Tox. (~1 month, with TK), Genetic tox.	US FDA, IND
(Company G) First Korean biological drug – Efficacy, Tox, Pharmacology, PK	US FDA, NDA
(Company Y) First Korean Botanical drug – General tox, Reprod Tox, Special tox, TK	US FDA, Phase I
(Company D) Botanical drug – General tox, Reprod tox, Special tox, TK	US FDA, Phase II
(Company V) Analgesic-related drug (Incrementally modified drug) – General tox, Reprod tox, Special tox, TK	US FDA, Phase II
(Company U) 2 items (Food ingredient) – Tox. (~3 months), General tox.	US FDA, GRAS
(Company C) 1 item (Food ingredient) – Tox. (~3 months), Genetic tox.	US FDA, GRAS
(Company H) Bio-Drug (Botox) – Efficacy, Tox. (~1 month), Immunogenicity	Europe/Australia, NDA
(Company B) Drug for hypertension – General tox (dog, 9M), Reprod tox	Mexico, NDA

- **Intracerebral administration**
- **Intra-arterial admin.**
- **Intra-articular admin. (knee joint)**
- **Intra-retinal admin.**
- **Anal sphincter**
- **Urethral sphincter**
- **Infusion (infusion pump)**
 - Tail vein
 - Jugular vein
 - Femoral vein
 - Portal vein
- ❖ **Intra-articular studies**
 - 15 rabbit studies or dog studies
- ❖ **Cell therapeutics – Human stem cells etc.**
 - 63 studies including 18 rodent studies



MFDS : Food, Pharmaceuticals and Cosmetics



Acute Toxicity, Repeated-dose Toxicity, Genetic Toxicity, Reproductive Toxicity(Seg 1, 2 & 3), Immunotoxicity, General Pharmacology, Local Irritation Test, Ocular Irritation, Photosensitization test, Phototoxicity test, Skin Irritation Test, Carcinogenicity and Safety Pharmacology (core battery)

NIER : Chemicals



Acute Oral Toxicity, Acute Skin Toxicity, Acute Skin irritation & corrosive test, Acute eye-irritation & corrosive test, Skin-sensitization test, Sub-acute Toxicity, Genetic Toxicity, Fertility & Generation Toxicity, Teratogenicity test, Carcinogenicity Test.

RDA : Agricultural Chemicals



Acute Oral Toxicity, Acute Skin Toxicity, Sub-acute Oral Toxicity, Sub-acute Dermal Toxicity, Genetic Toxicity, Chronic Toxicity, Teratogenicity test, Reproductive Toxicity, Skin-sensitization test, Skin irritation test, Eye-irritation test, Chronic/Carcinogenicity Test.



AAALAC International is a private, nonprofit organization that promotes the humane treatment of animals in science through voluntary accreditation and assessment

programs. AAALAC stands for the "Association for Assessment and Accreditation of Laboratory Animal Care." More than 790 companies, universities, hospitals, government agencies and other research institutions in 32 countries have earned AAALAC accreditation, demonstrating their commitment to responsible animal care and use. These institutions *volunteer* to participate in AAALAC's program, in addition to complying with the local, state and federal laws that regulate animal research.

Full Accreditation on March 10, 2010

- **Top 10 Global Nonclinical CRO**

- **Mission**

To the world by Maximum value creation for customers and staff

- **Strategy**

- 1) Nurturing talent
- 2) Globalization of GLP status
- 3) Establishment of integrated nonclinical services
- 4) Customized service
- 5) Cultivate teamwork

A person wearing a white lab coat, a white face mask, and safety glasses is working in a laboratory. They are holding a piece of equipment, possibly a pipette or a small container, and looking down at it. The background is slightly blurred, showing other laboratory equipment and a clean, professional environment.

Thank you

- E-Mail : webmaster@chemon.co.kr
- Tel : +82-31-329-9900, +82-31-888-6633~4
- Fax : +82-31-329-9902, +82-31-888-6640