Genovior Biotech Corporation

Corporate Presentation

Q1 2022

www.genovior.com.tw

Genovior Biotech Corporation

About Genovior

Date Founded：2015/4/23
DUNS No. ：658871895

Headquarters：
4F., No.50-8, Keyan Rd., Zhunan Township, Miaoli County 35053, Taiwan (R.O.C.)

No. of Employees：163

Leadership Team

Dr. Steve J. P. HSU

(Chairman and CEO)

Over 30 years in Pharma Industry
Founder of Savior Lifetec Corporation, VP of RD,
ScinoPharm Taiwan, Sr. Engineer of **Merck & Co., Inc**.
Ph.D. ChE, Massachusetts Institute of Technology, USA

Mr. Kai-Der KO

(Chief Strategy Officer)

Over 25 years in Hi-Tech & Biotech Industry.
Researcher, **Taiwan Biotech Co., Ltd.**,
EMBA, National Chengchi University,
M.S. in Pharmacy, College of Medicine, **National Taiwan University**

Mr. Wen-Hsien CHEN

(Vice President of Quality Systems)

Over 20 outstanding years of experience in Pharmaceutical Industry. Master degree of Chemical Engineering from the Cleveland State University in Ohio, USA

Dr. Sam CHANG

(Sr. Director of Quality Management Center)

Over 30 years in Pharma/Biotech Industry
Pfizer Biotech Corporation, Maxigen Biotech Inc., Scinopharm Taiwan,
Sandoz/Novartis Pharmaceuticals,
Ph.D. Chemistry, University of Missouri-Rolla, USA

Mr. Gary Wong

(Quality Center Director/ Head of QA, Zhunan site)

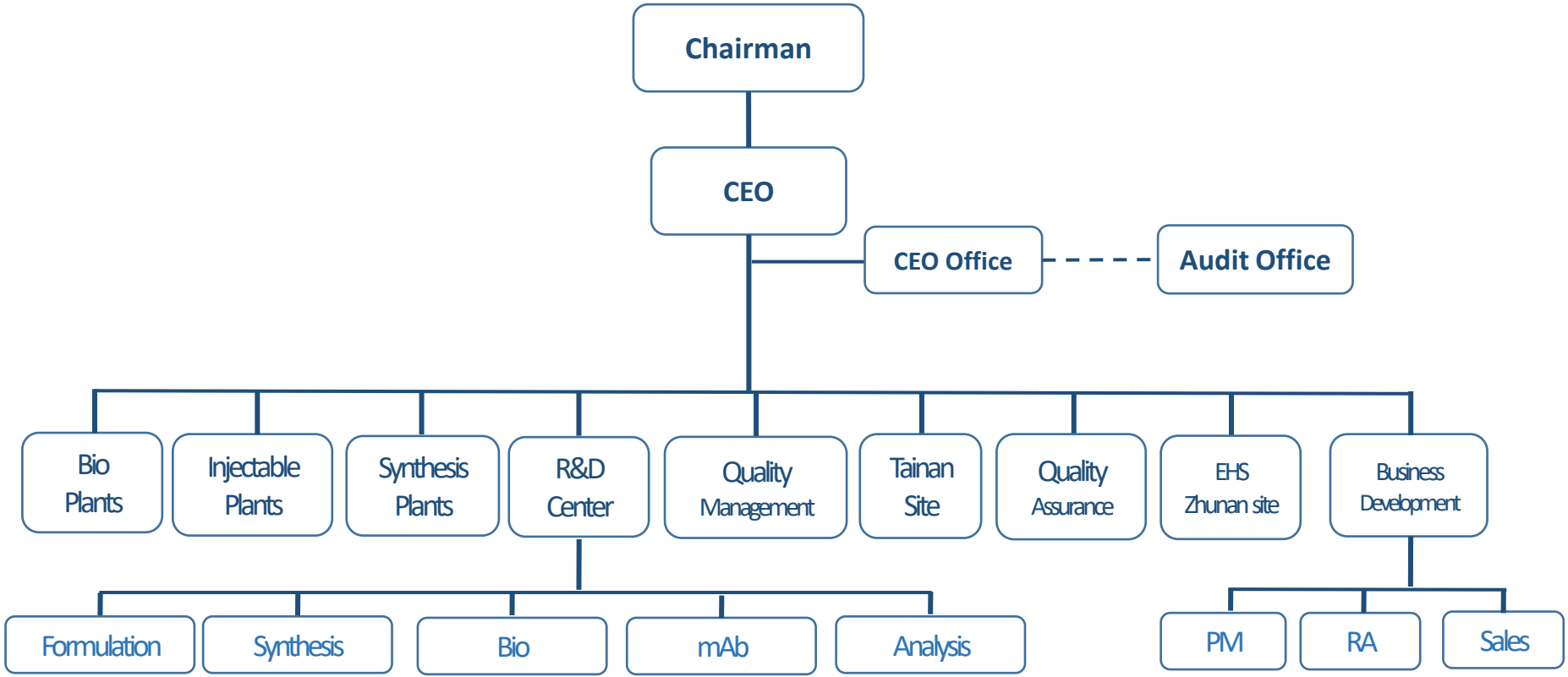
Over 27 years in Pharma/Biotech Industry
Rich experience in MAA and MAH inspections, such as Taiwan FDA, US FDA, EU QP (Germany, UK...etc.), KFDA, PMDA, France IPSEN, US Thermo Fisher, Canada Baxter, SQA, UniLab, etc.
Quality Management Director, Centapharm Healthcare Group

Dr. Toby Fan

(Associate Director, Head of PM Department)

Over 15 years of relevant experience in the biotech/pharmaceutical industry.
Focus on CDMO/CMO business,
Ph.D., Chemistry from National Tsing Hua University

Organization



Milestone

2016
R&D Center
Bio Pilot Plant
Injectables Pilot Plant

2017
Zhunan Oncology Plant
Tainan Commercial Plant

2018
Peptide Plant

PIC/S GMP Taiwan FDA
Pilot Injectable

2019
mAb RD Lab

PIC/S GMP Taiwan FDA
Oncology API*1
Multi-purpose Injectable

2020~2021
Additional mAb RD Lab
Additional Bio/Peptide Plant
Additional Oncology API/Injectables Plant
Additional Multi-purpose Injectables Plant

PIC/S GMP Taiwan FDA
Oncology Injectable (Lyo)
Oncology API*3
Peptide API*1

Pmda
Commercial Injectable
(Accreditation of Foreign Manufacturers)

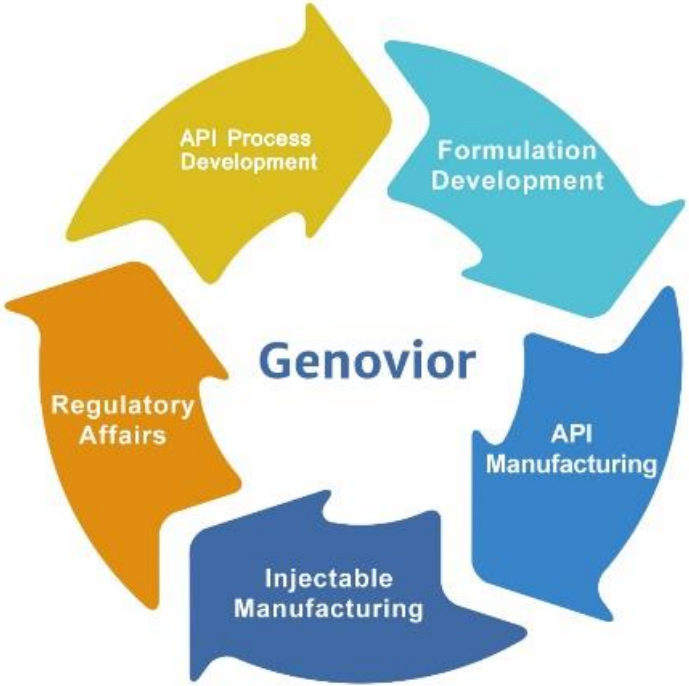
CDMO/CMO Services

Development

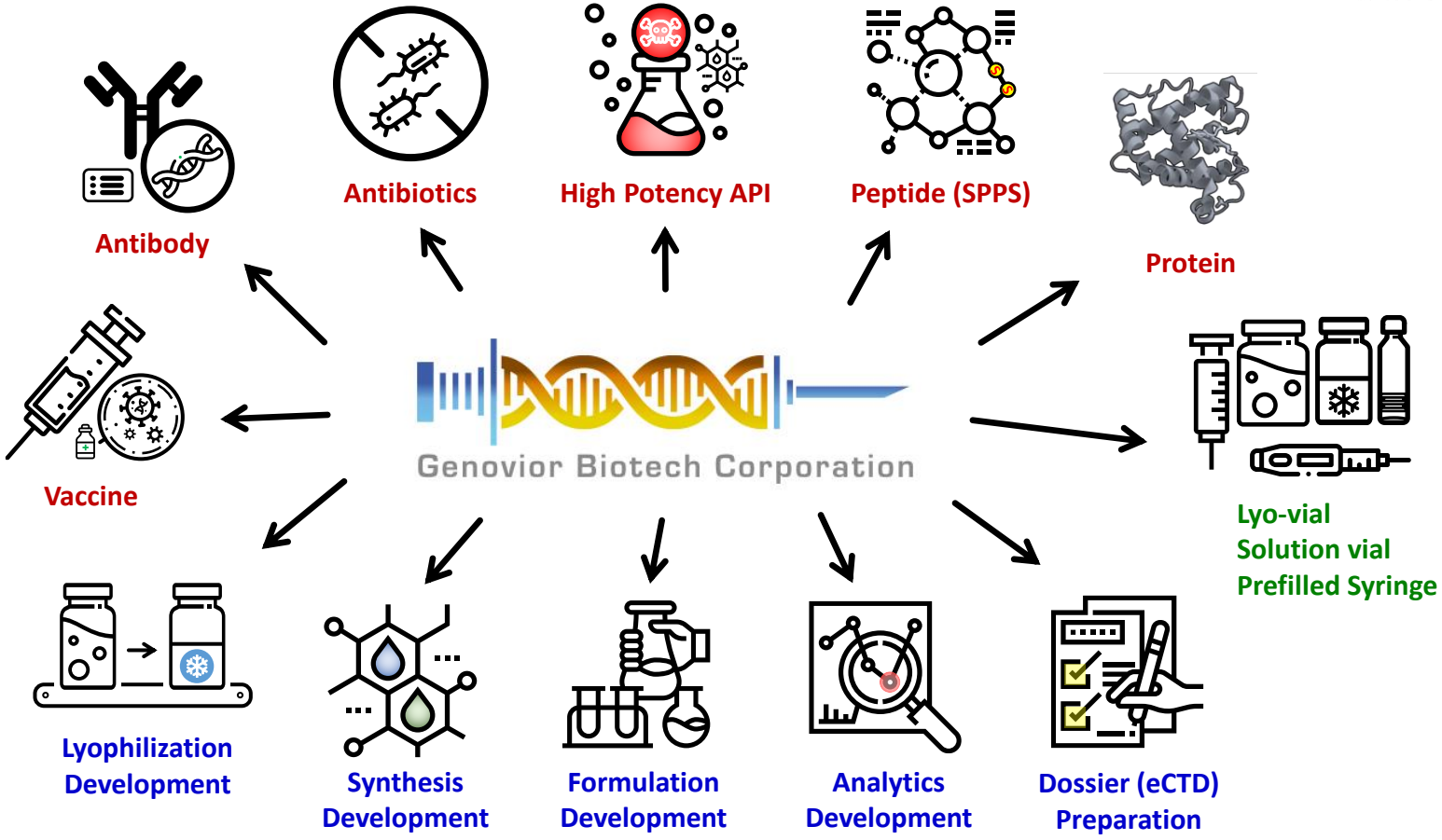
- **Process** development & optimization
- **Method** development & validation
- Pre-formulation/ **formulation development**

Manufacturing

- **From Biologic/API to injectable**
- Flexible batch size from preclinical to commercial scale
- Fill and finish
- Analytical services
- Regulatory support



One Stop Service


Antibody
Antibiotics
High Potency API
Peptide (SPPS)
Protein
Vaccine
Genovior Biotech Corporation
Lyo-vial
Solution vial
Prefilled Syringe
Lyophilization Development
Synthesis Development
Formulation Development
Analytics Development
Dossier (eCTD) Preparation

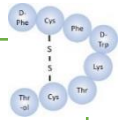
From API/Biologic to Injectables

Genovior Biotech Corporation

Drug Substance

- **Small Molecular**
  - Oncology/Others

- **Peptide**
  - Chemical Synthesis



- **Protein**
  - Microbial/ Mammalian Cell

Drug Product

- **Solid Form**
  - Lyophilisate

- **Liquid Form**
  - Solution
  - Cartridge (for pen injector)
  - Pre-filled Syringe

Generic/Biosimilar Pipeline for Licensing/Supply

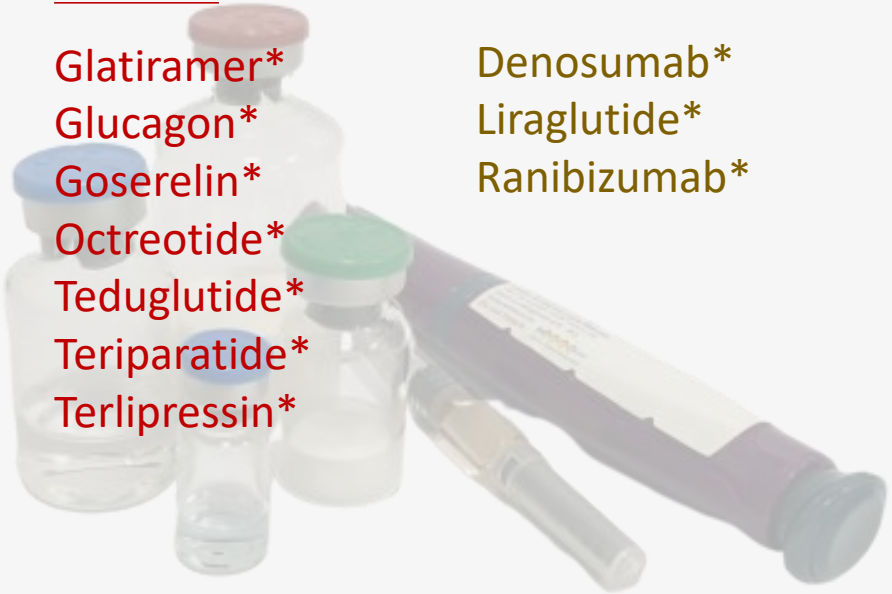
Genovior Biotech Corporation

ONCOLOGY

Azacitidine*
Bortezomib*
Carboplatin
Docetaxel
Epirubicin
Fulvestrant*
Gemcitabine
Irinotecan
Oxaliplatin
Pemetrexed*
Ponatinib*

PEPTIDE

Glatiramer*
Glucagon*
Goserelin*
Octreotide*
Teduglutide*
Teriparatide*
Terlipressin*



BIO

Denosumab*
Liraglutide*
Ranibizumab*

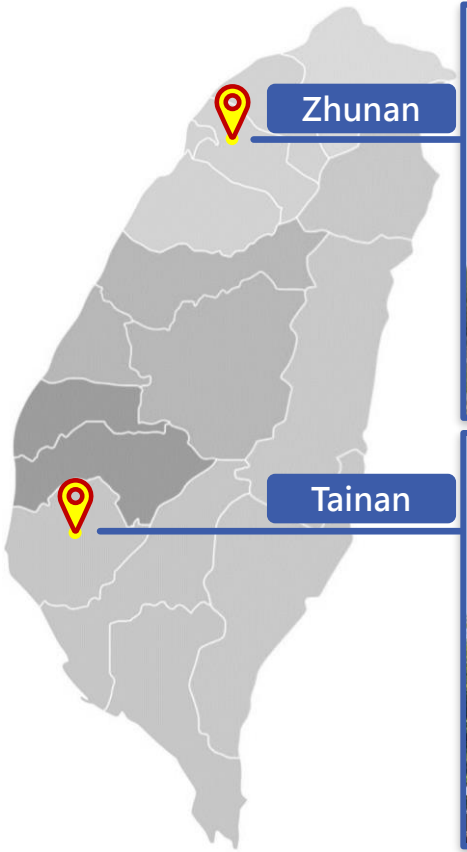
OTHERS

Dexmedetomidine*
Ganciclovir
Levetiracetam
Palonosetron
Valproate

* Manufacturing of API for in-house use

Capabilities

Capabilities-2 sites in Taiwan



Zhunan site

- ✓ HQ/R&D Center
- ✓ Bio & Oncology Plant
- ✓ Commercial Plant
  - Fermentation/Purification
  - Oncology injectable
  - Lyo/Solution/Peptide/
  - API synthesis

Tainan site

- ✓ R&D Center
- ✓ Multi-purpose Plant
- ✓ Commercial Plant
  - Multi-purpose Injectable
  - Lyo/Solution/PFS/Cartridge

Capabilities-R&D Center

Genovior Biotech Corporation

Formulation | Synthesis | Bio | mAb | ARD

- Formulation development

  30+ injectables projects in pipeline/completed

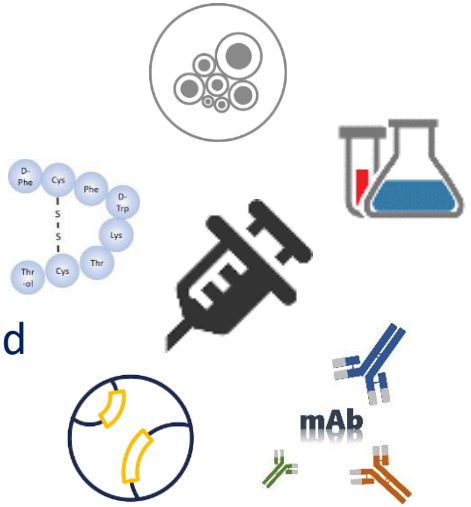
  Lyophilizer capacity : 315~1,998 vials per batch (2R~50R)

- API development

  20+ projects (Oncology, Peptide, Bio) in pipeline/completed

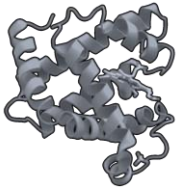
- 2 bio labs and each lab equips with 3L/30L fermenters and GE AKTA Pure (E. coli platform)

- 1 Monoclonal antibodies (mAbs) lab (CHO platform)



Capabilities-manufacturing

Genovior Biotech Corporation

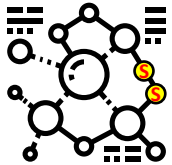


1. Bio Plant

Two production lines (up- & downstream)
Fermenters W/V: 5L/50L/320L
Purification: GE AKTA Pure

2. Oncology API Plant (High-Potency API)

Reactors from 5L to 500L



3. Peptide Synthesis Plant

Reactors from 5L to 500L

4. Injectables Plant

Lyo: 400 vials (20R) ~ 1,000 vials (2R)
Solution: 1.5L ~ 50L
PFS (5mL) 360 pcs/hr

5. Oncology Injectables Plant

Lyo: 6,400 vials (50R) ~ 41,209 vials (2R)
Solution: 1.5L ~ 200L

6. Multi-purpose Injectables Plant

Cartridge 3.0 mL ≧ 2000 pcs/hr
PFS (1 mL ~ 2.25mL) 6K ~ 10K pcs/hr
Solution: 1.5L ~ 500L
Lyo: 18,000 vials (10R) ~ 41,209 vials (2R)

GMP Inspection Plan

(APPROVED)

	Production Line	TFDA PIC/S GMP (Estimated)	EU, US FDA Inspection (Estimated)	PMDA **(AFM)**
Small Scale Plants	1. **Biologic** (Drug Substance)			**accredited**
	2. **Injectables (Sol/Lyo vial, PFS)**	**Approved(Lyo vial)**		
Oncology Plants	3. **HPAPI**	**Approved**	**EU QP audited**	
	4. **Injectables (Lyo, Solution vial)**	**Approved**	**UK Audit (rescheduled)**	
General Plants	5. **Peptide Synthesis API**	**Approved**		
	6. **Multi-purpose Injectables (Solution/Lyo vial, PFS, Cartridge)**	**Approved**	**EU QP audited*1 (Teriparatide)**	**Accredited (Lyo form)**

GMP Inspection Plan

(EXPECTED IN 2022/2023, DEPENDS ON BUSINESS NEGOTIATION)

	Production Line	EU, US	Japan
Small Scale Plants	1. Biologic	(TBD)	GMP
	2. Injectables (Sol/Lyo vial, PFS)		
Oncology Plants	3. HPAPI	EU, US	
	4. Injectables (Lyo, Solution vial)	EU, US	AFM(Lyo)
General Product Plants	5. Peptide Synthesis API	EU, US	
	6. Multi-purpose Injectables (Solution/Lyo vial, PFS, Cartridge)	EU(Cartridge)+US(Cartridge +Lyo +PFS)	GMP

衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: September 22, 2020

Issued following an inspection in accordance with Article 57 of the Pharmaceutical Affairs Law and relevant Regulations of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:
The manufacturer: Genovior Biotech Corporation (Tainan Site)
Site address: 3F-2 / 4F-1 / 4F-2 No.5, 4F-1 No.9, Nanke 2nd Rd., Xinshi Dist., Tainan City 74147, Taiwan (R.O.C.)
Manufacturer's licence number: (AP)0458149

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage forms:
-Sterile products: 1) Liquid dosage forms: injections (aseptic preparation-small volume liquids); 2) Solid dosage forms: freeze-dried powder/lyophilisate (aseptic preparation).

From the knowledge gained during inspection performed on July 21-23, 2020, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) and Good Distribution Practice (PIC/S GDP) for medicinal products.

This certificate is valid until October 25, 2022.
This certificate may be revoked at anytime as warranted.

Signed by

Shou-Mei Wu

Shou-Mei Wu, Ph.D.
Director-General
Food and Drug Administration
（http://www.fda.gov.tw/TC/index.aspx）

Under the delegated authority of
Shih-Chung Chen, D.D.S.
Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

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衛 生 福 利 部
MINISTRY OF HEALTH AND WELFARE

CERTIFICATE OF GOOD MANUFACTURING PRACTICE

Issue Date: May 21, 2021

Issued following an inspection in accordance with Article 57 of the Pharmaceutical Affairs Law and relevant Regulations of the Republic of China (Taiwan).

The competent authority of the Republic of China confirms the following:
The manufacturer: Genovior Biotech Corporation
Site address: No. 50-3/4F., No. 50-5/4F., No. 50-8/3F., No. 50-8/4F., No. 50-8/5F., No. 50-9/5F., Keyan Rd., Zhunan Township, Miaoli County 35053, Taiwan (R.O.C.)
Manufacturer's licence number: (AP)0455153

is the manufacturer of medicinal products for human use that has been inspected with the following pharmaceutical dosage forms:
-Sterile products: Solid dosage forms: freeze-dried powder (aseptic preparation).
and following types of specifically toxic and hazardous substances: Cytotoxics
-Sterile products: 1) Liquid dosage forms: injections (aseptic preparation-small volume liquids); 2) Solid dosage forms: freeze-dried powder (aseptic preparation).

From the knowledge gained during GMP inspection performed on April 7-8, 2020, and September 1-3, 2020, it is considered that the manufacturer complies with the Pharmaceutical Inspection Convention/Co-operation Scheme Guide to Good Manufacturing Practice (PIC/S GMP) and Good Distribution Practice (PIC/S GDP) for medicinal products.

This certificate is valid until November 16, 2022.
This certificate may be revoked at anytime as warranted.

Signed by

Shou-Mei Wu

Shou-Mei Wu, Ph.D.
Director-General
Food and Drug Administration
（http://www.fda.gov.tw/TC/index.aspx）

Under the delegated authority of
Shih-Chung Chen, D.D.S.
Minister
Ministry of Health and Welfare
Republic of China (Taiwan)

07185

DEPO PACK

DEPO-PACK S.R.L.

Telefono 02.9604896 – Telefax 02.98705060
E-mail: info@depopack.it

QUALIFIED PERSON'S DECLARATION EQUIVALENCE TO EU GMP FOR INVESTIGATIONAL MEDICINAL PRODUCTS MANUFACTURED IN THIRD COUNTRIES[1] (ARTICLE 13(3)(b) OF DIRECTIVE 2001/20/EC)

EudraCT number(s)	Name of the IMP(s)
2019-002586-35	Teriparatide Injection Pen_0.600mg/2,4ml

Manufacturing and/or Importation Authorisation (MIA) number[2] under which this declaration is made:

Depo-Pack S.r.l. - Via Morandi 28, 21047 Saronno (VA)-ITALY- Authorization N.aAMM-35/2021

Part A

Name of the IMP(s)	Manufacturing site(s) (Name and address where the activity is performed)	Activity performed at this site (including packaging, labelling and testing)
Teriparatide Injection Pen _0,600mg/2,4ml	**Genovior Biotech Corporation** Address: 3F-2 / 4F-1 / 4F-2 No. 5, 4F-1 No. 9, Nanke 2nd Rd., Xinshi Dist., Tainan City 74147, Taiwan (R.O.C.) Country: Taiwan	-manufacturing, -primary and secondary packaging -testing,

[1] Countries other than EU Member States or contracting states of the European Economic Area (EEA).
[2] If no number is issued please state the name of the authorisation holder.

認定番号 AG10600078
Number of accreditation

医薬品 外国製造業者認定証
Accreditation certificate of foreign drug manufacturer

氏名又は名称 Name (Name of corporation)	GENOVIOR BIOTECH CORPORATION
製造所の名称 Name of the manufacturing establishment	GENOVIOR BIOTECH CORPORATION (TAINAN SITE)
製造所の所在地 Location of the manufacturing establishment	3F - 2/4F - 1/4F - 2 No. 5, 4F - 1 No. 9, NANKE 2nd Rd., Xinshi Dist., Tainan City 74147, Taiwan (R. O. C.)
認定の区分 Accreditation categories	医薬品 無菌医薬品 (Sterile Drugs)

医薬品、医療機器等の品質、有効性及び安全性の確保等に関する法律第 13 条の 3 の規定により認定された医薬品外国製造業者であることを証明する。
It is certified that the above manufacturer is certificated foreign drug manufacturer pursuant to Article 13-3 of the Act on Securing Quality, Efficacy and Safety of Pharmaceuticals, Medical Devices, Regenerative and Cellular Therapy Products, Gene Therapy Products, and Cosmetics.

令和 2 年 6 月 29 日
2020 Year Month Day

厚生労働大臣 カロ 順藤 恵勢 仁司
Minister of Health, Labour and Welfare Kato Katsumoto

有効期間 令和 2 年 6 月 29 日 から
Valid period From 2020 Year Month Day

令和 7 年 6 月 28 日 まで
until 2025 Year Month Day

5130208016967

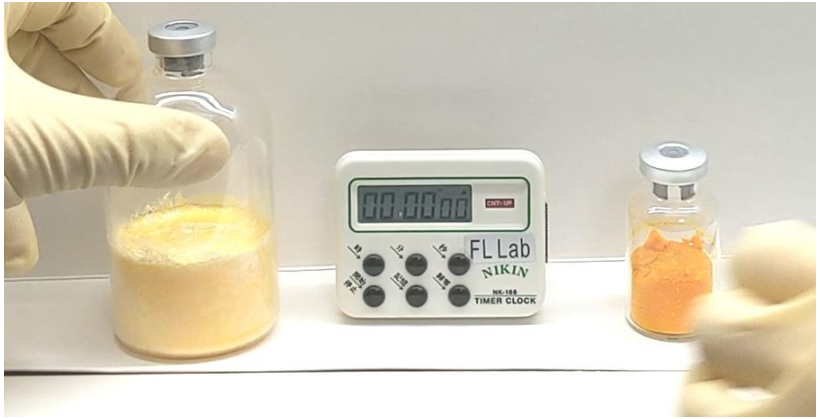
Genovior's lyophilized capabilities

Genovior's lyophilized capabilities

Genovior Biotech Corporation

	RLD	CDMO
0''		
20''		
100''		

RLD CDMO

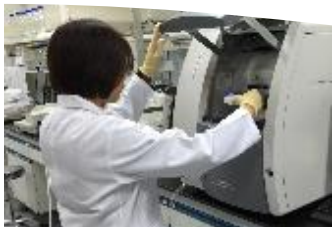


	RLD (weakness)		CDMO (improvement)
Reconstitution Time	100"	→	10"
Lyo vial size	50R vial	→	20R vial
Batch size each batch	6,000 vials	→	11,000 vials


Teriparatide injection
20 micrograms / 80 microliters
solution for injection in pre-filled pen
Do Not Freeze!

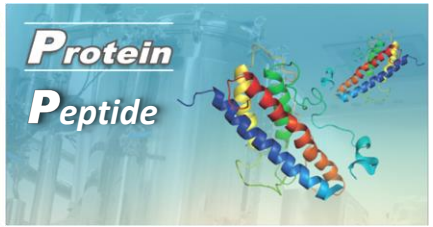

Glucagon Emergency Kit
for Low Blood Sugar

THANK YOU




Biologic


Oncology


Protein
Peptide


Injectable