



**KriSan Biotech Co., Ltd.**

**International  
CDMO Expert  
in  
GMP Drug Substance**

- Established in August, 2015.
- Accredited Contract Development and Manufacturing Organization  
**Pharmaceutical Research Company (approved by Taiwan MOEA)**  
**Small Molecule, Complex Drug Substance,**  
**Peptide, Oligonucleotide.**
- Six GMP production lines.
- Taiwan FDA GMP certificate for pilot plant.
- Japanese Accreditation of Foreign Manufacturers (AFM) certificate.



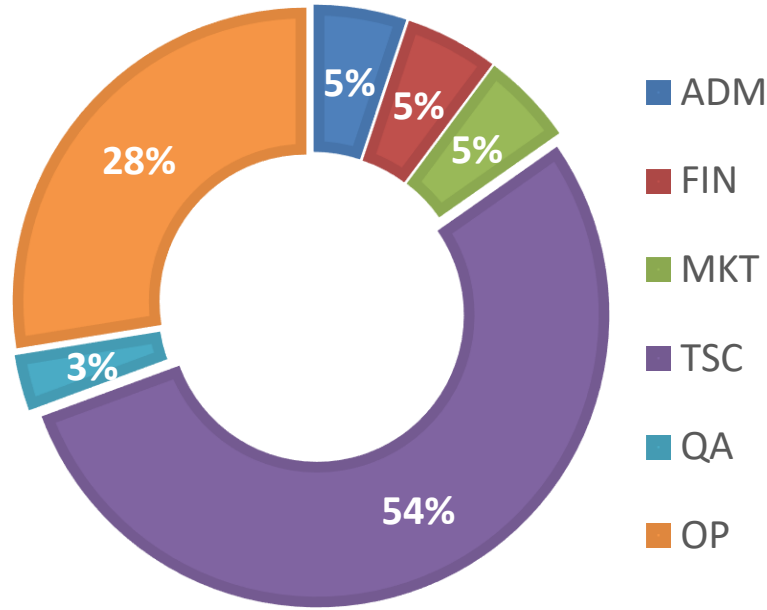
**Southern Taiwan  
Science Park  
4F, 5F**



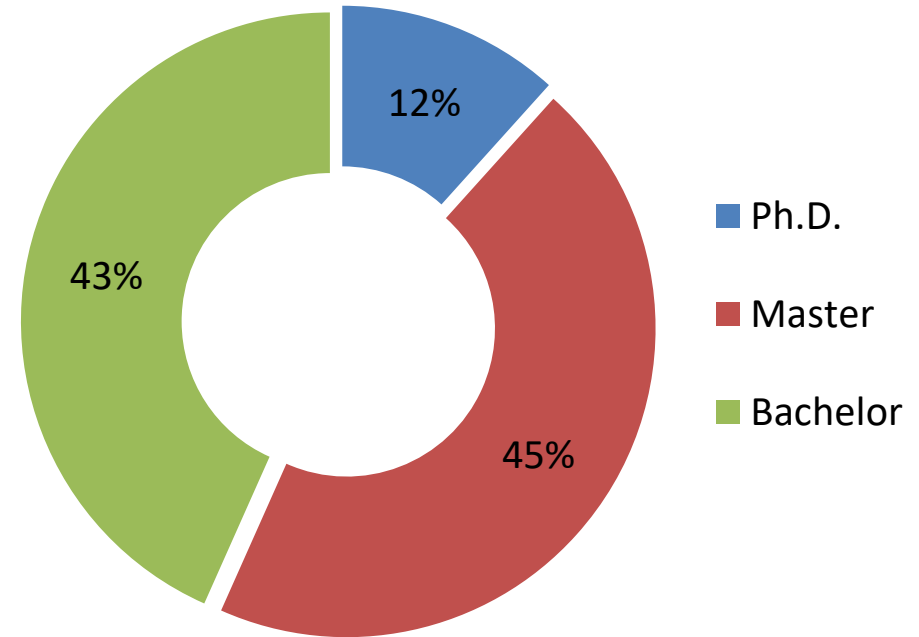
Name	Title	Seniority	Expertise
Jessen Chang	President	10 years	Management
Bret Wu	PTS Director	15 years	<b>Small molecules &amp; PEG-drug conjugate</b> <b>Peptide &amp; Oligonucleotides</b> Process R&D, optimization, scale-up and validation Impurity standards preparation and characterization
Long Hu Wang	PTS Manager	16 years	
SW Lee	PTS Manager	13 years	
CY Liu	ATS Associate Director	15 years	<b>Small molecules &amp; PEG-drug conjugate</b> <b>Peptide &amp; Oligonucleotides</b> Analytical method development and validation
Emma Wang	ATS Manager	16 years	
Janet Hsu	ATS Manager	11 years	
Kenny Hung	QA Senior Manager	13 years	Familiar to ICH guidance and PIC/S GMP
Tina Yen	RTS Manager	10 years	Pharmacist Familiar to CMC, DMF, IND, ANDA filing and Business Development
William Lo	Production Manager	14 years	GMP Facility Management Process R&D, optimization, scale-up and validation
Ming Shen	Engineering Supervisor	11 years	Supporting System Management

**Qualified Employees**

**60 employees**



**54%**  
**CMC Services**



**57%**  
**Experienced Graduate Degree**

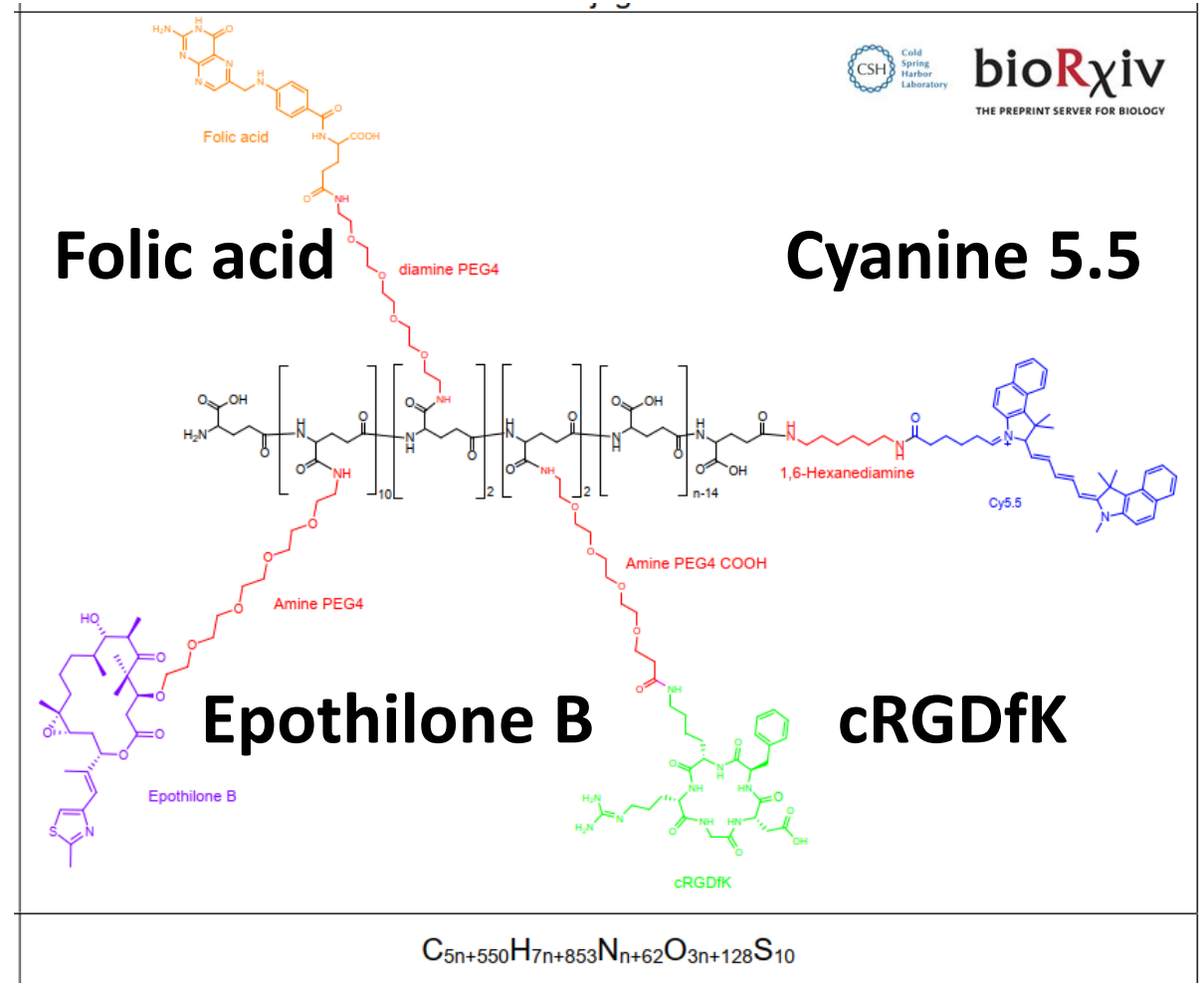
Parthanatos-inducing zinc agent C010DS-Zn elicits  
Anti-tumor immune responses involving T cells and macrophages *in vivo*

**Small Molecule**

**Oligonucleotide**

**Complex  
Drug Substance  
(Conjugate)**

**Peptide**



## PIC/S GMP and ICH Compliance

**Research**

**Preclinical Study**

**IND Application**

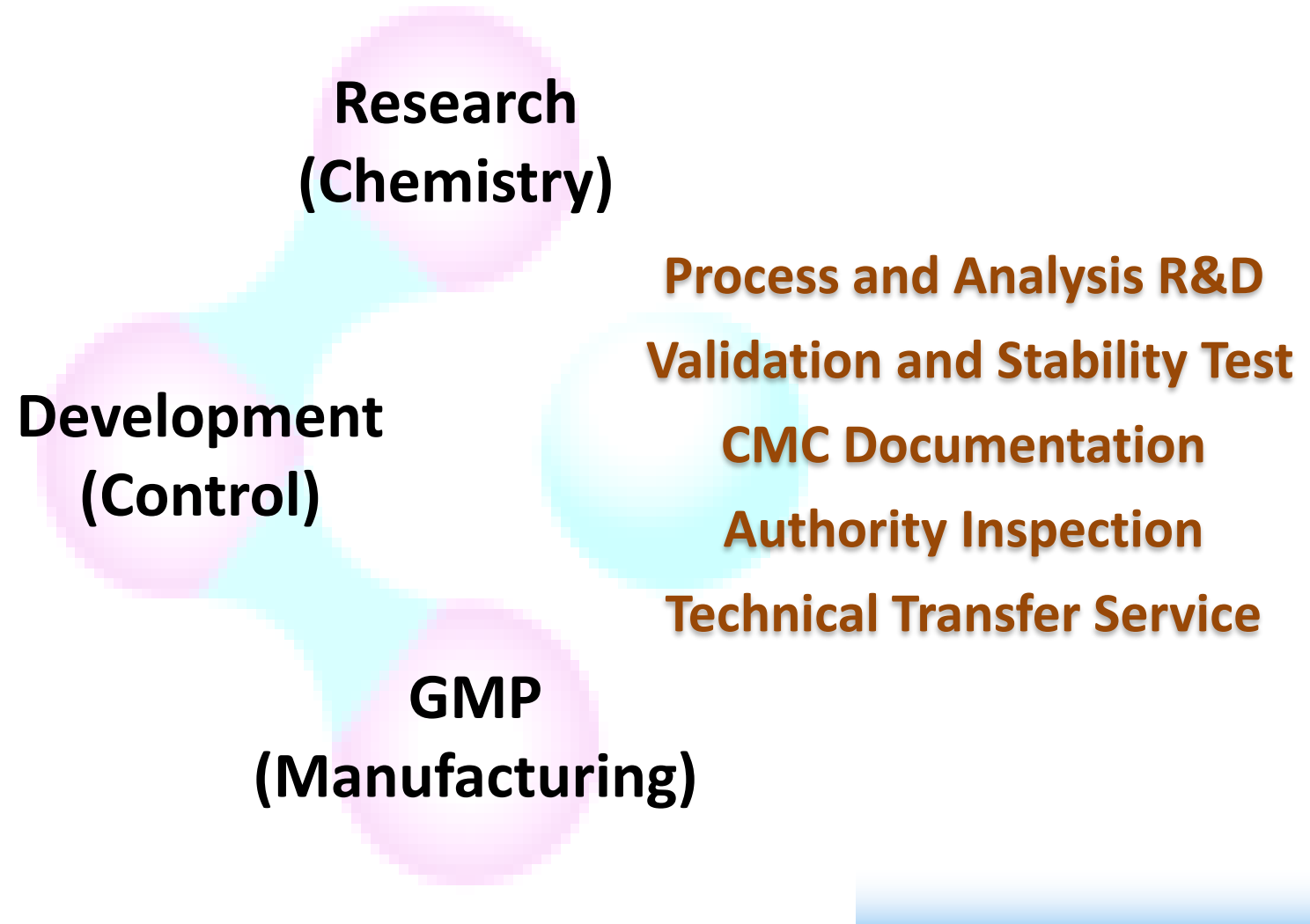
**Phase I**

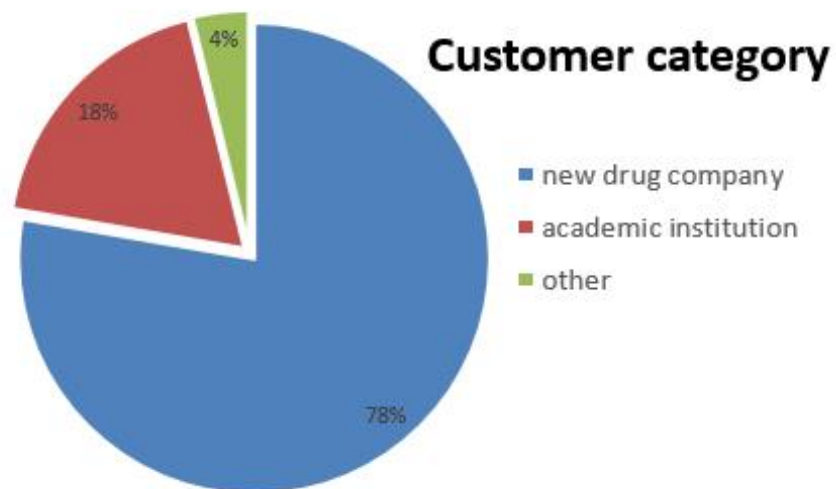
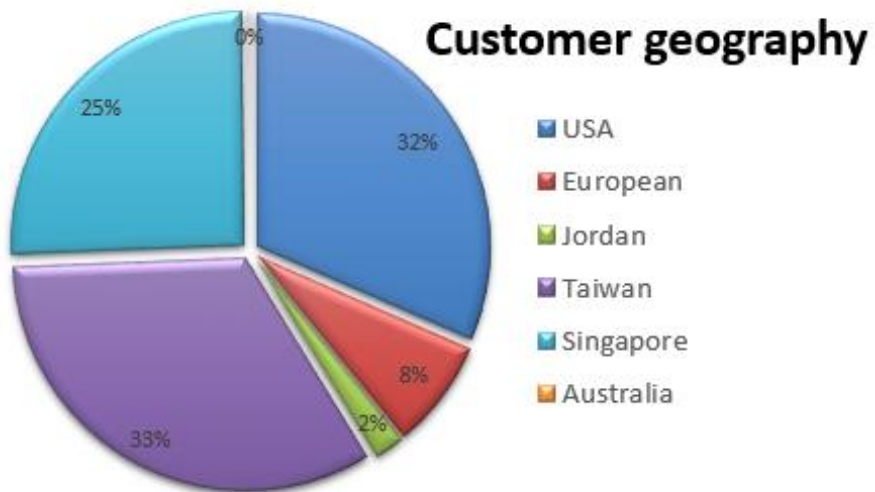
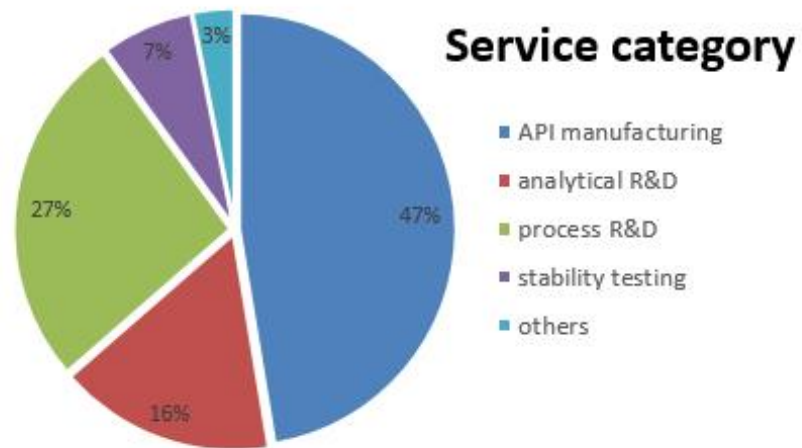
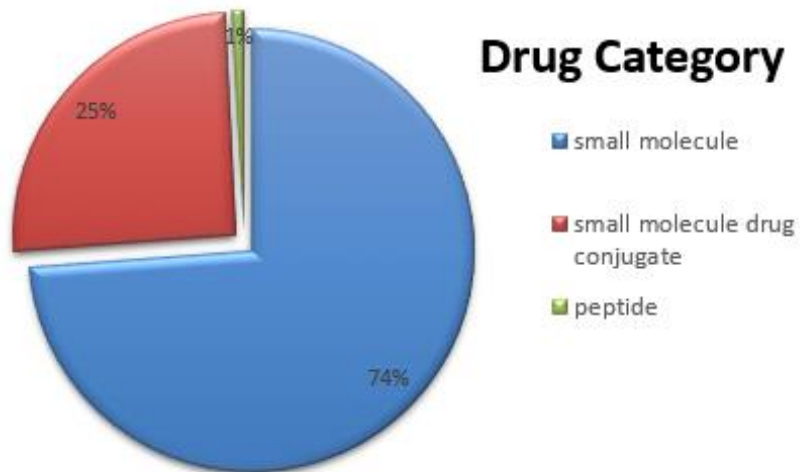
**Phase II**

**Phase III**

**NDA Application**

**Exclusive Launch**





➤ **45 Customers :**

USA, Japan, European, Singapore,  
Middle East and Taiwan

➤ **90 Products Delivered :**

Small Molecule: **66 Products** ◦

Complex Drug Substance: **14 Products** ◦

Peptide: **8 Products** ◦

Oligonucleotide: **2 Products** ◦

➤ **11 Clinical Phase Products :**

1 Phase III, 6 Phase II, 4 Phase I

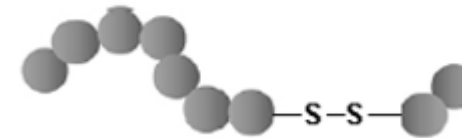
Linear peptide



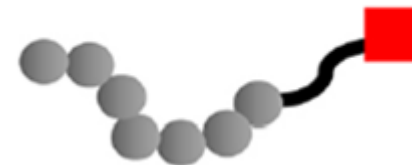
Small cyclic peptide



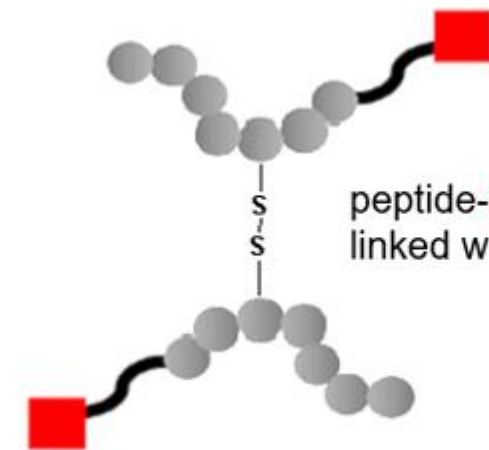
Peptides linked with disulfide



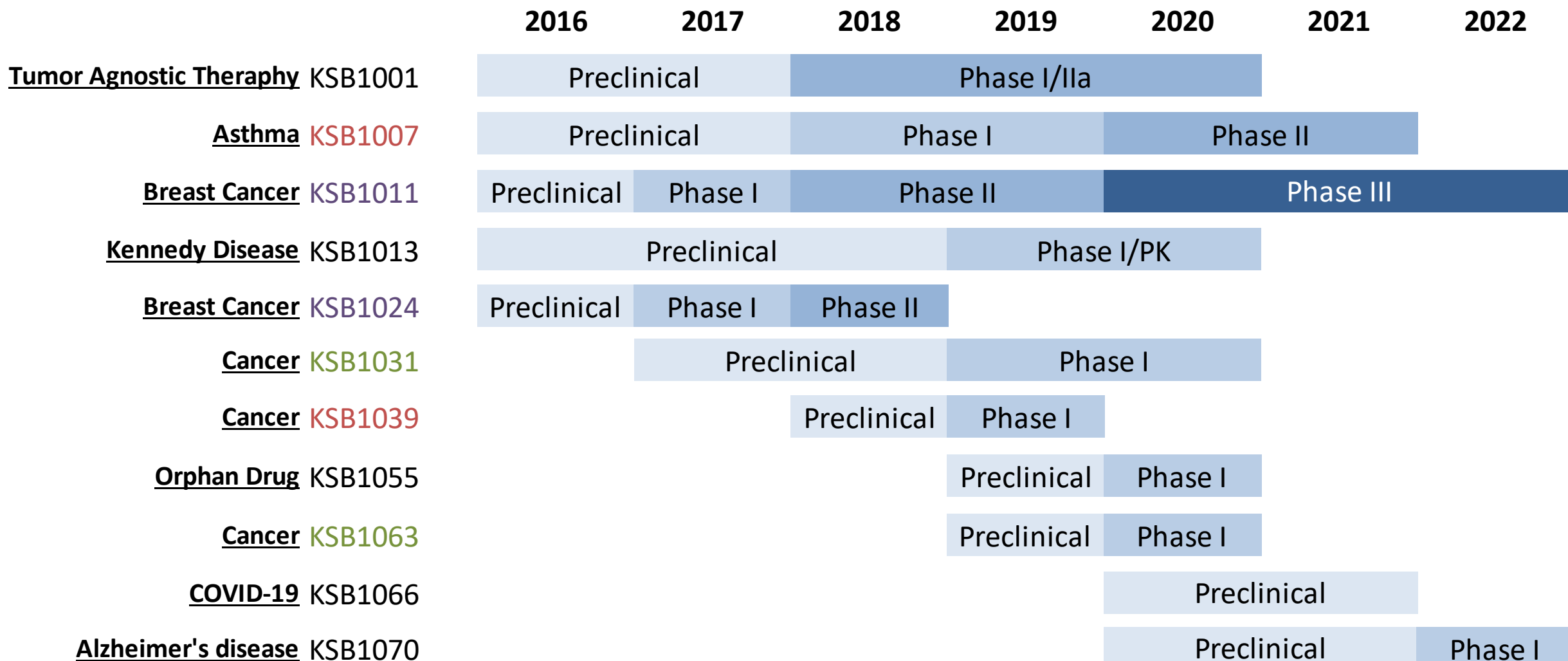
peptide-drug conjugation



peptide-drug conjugation  
linked with disulfide







## Quality Control

- ❁ **Raw & Starting Materials**
  - ✧ Method Development / Validation
  - ✧ Sample Testing
  - ✧ Establish Specification
- ❁ **Standard**
  - ✧ API, intermediate, Impurity Ref. Std. Qualification
- ❁ **In Process Control**
  - ✧ IPC Method Development /Validation
  - ✧ IPC Sample Testing
  - ✧ Key Intermediates Testing
- ❁ **API**
  - ✧ API Method Development / Validation
  - ✧ Cleaning Method Development / Validation
  - ✧ Cleaning Sample Testing
  - ✧ API Testing / COA Issuance
  - ✧ Establish Specification
- ❁ **Stability**
  - ✧ Stability Study Conditions:  
-20 °C, 5 °C, 25 °C, 30 °C, 40 °C

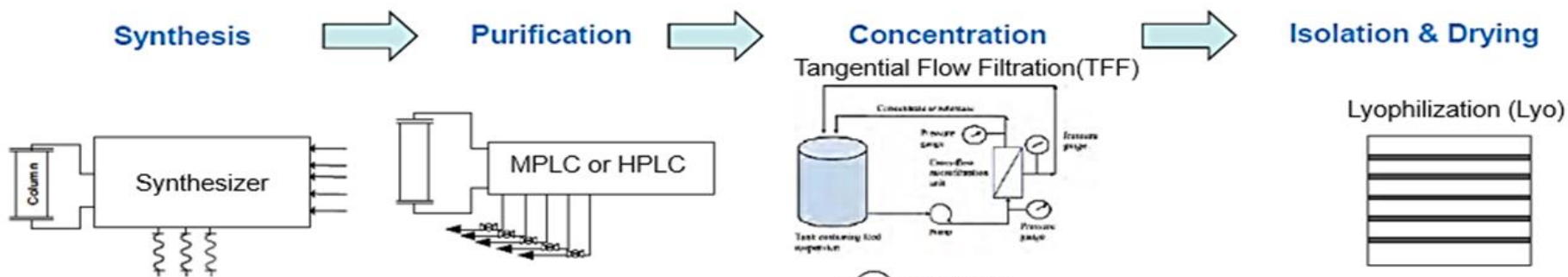
## Quality Assurance

- Product Release
- **Change Control**
- Investigation & Deviation Management
- **CAPA Program Management**
- Complaint Handling
- **Document Control**
- Review & Approval of GMP Documentations
- **Internal Audits**
- Handling Customer Audits and Regulatory Inspections
- **Vendor Audits**
- Training Coordination/ GMP Training

<b>Date</b>	<b>Customer region</b>	<b>Project No.</b>
July, 2016	US	KSB1011
August, 2016	TW	KSB1006
November, 2016	EU	KSB1007
December, 2016	TW	KSB1002
May, 2017	TW	KSB1030
May, 2017	TW	KSB1006
July, 2017	US	KSB1011/KSB1024
May, 2019	EU	KSB1007
July, 2019	TW	KSB1055
September, 2019	US	KSB1011/KSB1024
March, 2021	EU	KSB1007
October, 2021	TW	KSB1055

Chemical Property Determination	Physical Property / Spectroscopic Analysis	Stability Study
<ul style="list-style-type: none"> <li>➤ HPLC / UPLC               <ul style="list-style-type: none"> <li>- UV</li> <li>- PDA</li> <li>- Refractive Index</li> <li>- Fluorescence</li> </ul> </li> <li>➤ GC / Headspace GC</li> <li>➤ Auto-titration</li> <li>➤ Total Organic Carbon</li> </ul>	<ul style="list-style-type: none"> <li>➤ DSC</li> <li>➤ TGA</li> <li>➤ Polarimeter</li> <li>➤ Particle Size Analyzer</li> <li>➤ Karl Fischer               <ul style="list-style-type: none"> <li>- Volumetric</li> <li>- Coulometric</li> <li>- Thermoprep (oven)</li> </ul> </li> <li>➤ Melting Point</li> <li>➤ FT-IR</li> <li>➤ UV-Vis</li> <li>➤ ICP-MS / Microwave digestion</li> <li>➤ Vacuum Oven</li> <li>➤ Conductivity Meter</li> </ul>	<ul style="list-style-type: none"> <li>➤ Stability Chamber               <ul style="list-style-type: none"> <li>-20 °C</li> <li>5 °C</li> <li>25 °C / 60%RH</li> <li>30 °C / 65%RH</li> <li>40 °C / 75%RH</li> </ul> </li> <li>➤ Suntest</li> </ul>
		Outsourcing
		<ul style="list-style-type: none"> <li>➤ Dynamic Vapor Sorption (DVS)</li> <li>➤ NMR</li> <li>➤ Mass (LC-MS, GC-MS, MS-MS)</li> <li>➤ X-Ray diffraction</li> <li>➤ Microbiological Examination</li> <li>➤ Specific Microorganisms</li> </ul>

Line No.	API Batch	Equipment	Temperature °C	Filter Dryer (Hastelloy C276)	Isolator	Status
1	1 kg	10 L and 30 L Reactor (Glass)	-60 to 150	10 L	Glove Box	Qualified
2	3 kg	20 L Reactor (Glass) 60 L Reactor (Glass-lined)	-25 to 150	10 L	Glove Box	Qualified
3	4 kg	30 L Reactor (Glass) 63 L Reactor (Glass-lined)	-25 to 150	20 L	Glove Box	Qualified
4	100 g <ul style="list-style-type: none"> <li>· Oligonucleotide</li> <li>· Peptide</li> </ul> · Complex Drug Substance <b>Preparation Purification</b>	<b>Oligonucleotide Synthesizer</b> (AKTA OligoPilot 100) <b>20L Filter Reactor</b> (Glass) <b>DAC Column Purification</b> (HPLC Grade Column $\varnothing$ 150* 450 mm)	NA	NA	Glove Box	Qualified
5	10 L <ul style="list-style-type: none"> <li>· Oligonucleotide</li> <li>· Peptide</li> </ul> · Complex Drug Substance <b>Purification Lyophilization</b>	<b>Plate type lyophilizer</b> (0.67 m <sup>2</sup> effective shelf area vacuum < 0.01 mbar) <b>Semiauto-Ultrafiltration</b> (filtration area from 0.5 to 5 m <sup>2</sup> )	-70 to 80	10 L (5 tray lyophilizer)  100 L (TFF Tank)	Glove Box	Qualified
11	10 kg	250 L and 160 L Reactor (Glass-lined)	-25 to 150	40 L	Glove Box	Qualified



**AKTA Oligo 100**

1  $\mu$ mol to 9 mmol



Ø 150\*450 mm



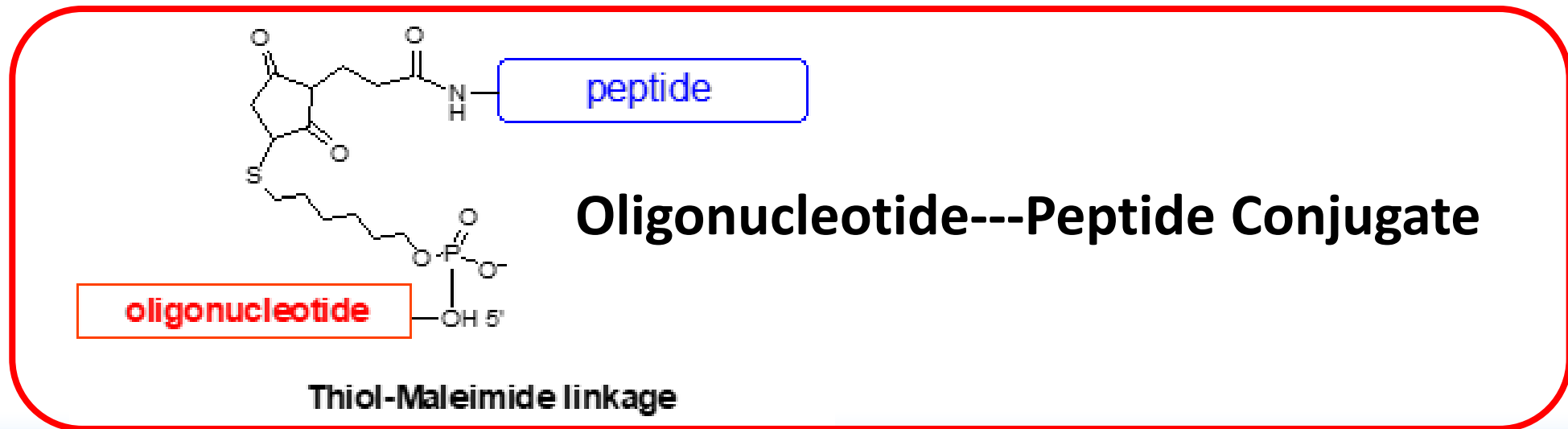
100 L Tank

**Glove box  
(under Nitrogen)**



10 L (5 Trays)

- **Type 1:** Oligonucleotides (start from Feb. 2022)
- **Type 2:** Antigenic Epitope Peptides
- **Type 3:** Customized synthetic molecules (Conjugate)
- **Type 4:** Natural Products (Purification)



# Acknowledgement

**Key relationship in Science and novel Biotech**