



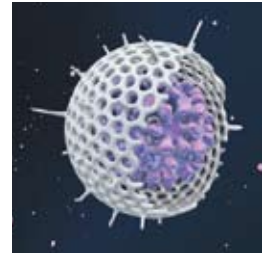
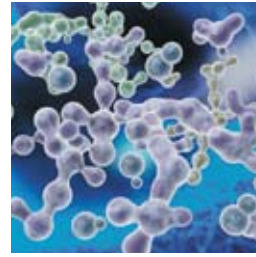
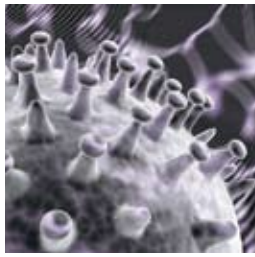
## Testing Facility for Biological Safety (TFBS)

Protein drugs, or biopharmaceuticals, are among the fastest growing products in the pharmaceutical industry. It is important to ensure the quality and safety of emerging biopharmaceutical products in addition to its efficacy. Testing Facility for Biological Safety (TFBS) is committed to assisting its clients in assuring the quality of their biopharmaceutical products and most importantly, meeting the global biological safety requirements for regulatory approval worldwide. Our biological safety studies are conducted in compliance with Good Laboratory Practice (GLP) for Nonclinical Laboratory Studies. The aims of these studies are twofold:

- 1.) Ensuring the quality of biological drug producing cells and other microbes, by verifying that these source materials are free of undesired microbial or viral pathogens;
- 2.) Identifying and characterizing the aforementioned biological materials in biopharmaceutical drug production.

Based on testing platforms established at Development Center for Biotechnology (DCB) and Animal Technology Institute Taiwan (ATIT), TFBS now offers a consolidated testing service for biological safety with the following features:

1. Global Quality Standard: ICH, US FDA, EMA and JP
2. GLP Quality Systems: In Compliance with GLP (TFDA, US FDA, OECD)
3. ISO 17025 Certified Assays
4. Quick Response and Timely Delivery
5. Availability of Customization
6. Regulatory Consultation and Submission Experience
7. Alliances with Reputable Institutes
8. Affiliations with the cGMP Biopharmaceutical Pilot Plant Facility and Center for Toxicology and Preclinical Science.



## Available Services

<p><b>Molecular Biology</b></p>	<ul style="list-style-type: none"> <li>&gt; Genetic Stability</li> <li>&gt; Determination of Copy Numbers</li> <li>&gt; DNA Sequencing</li> <li>&gt; Host Cell DNA / Protein Clearance Studies</li> </ul>		
<p><b>Virology</b></p>	<ul style="list-style-type: none"> <li>&gt; Process Virus Clearance Validation</li> <li>&gt; Adventitious Virus Detection</li> <li>&gt; Retrovirus Detection</li> <li>&gt; TEM</li> <li>&gt; Virus Seed Lot Characterization</li> </ul>		
<p><b>Cell Bank Characterization</b></p>	<table border="0"> <tr> <td data-bbox="533 1182 884 1413"> <ul style="list-style-type: none"> <li>&gt; Prokaryotic</li> <li>• Identity of Host Organism</li> <li>• Analysis of Plasmid</li> <li>• Microbial Contamination</li> <li>• Genetic Stability</li> </ul> </td> <td data-bbox="932 1182 1347 1469"> <ul style="list-style-type: none"> <li>&gt; Eukaryotic</li> <li>• Identity</li> <li>• Purity</li> <li>• Viral / Microbial Contamination</li> <li>• Genetic Stability</li> <li>• Tumorigenicity / Oncogenicity</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>&gt; Prokaryotic</li> <li>• Identity of Host Organism</li> <li>• Analysis of Plasmid</li> <li>• Microbial Contamination</li> <li>• Genetic Stability</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Eukaryotic</li> <li>• Identity</li> <li>• Purity</li> <li>• Viral / Microbial Contamination</li> <li>• Genetic Stability</li> <li>• Tumorigenicity / Oncogenicity</li> </ul>
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<p><b>Lot Release Test</b></p>	<ul style="list-style-type: none"> <li>&gt; Residual Host Cell DNA</li> <li>&gt; Residual Host Cell Protein</li> <li>&gt; Endotoxin</li> <li>&gt; Sterility</li> </ul>		
<p><b>Bioassay</b></p>	<table border="0"> <tr> <td data-bbox="533 1787 740 2018"> <ul style="list-style-type: none"> <li>&gt; Method</li> <li>• Development</li> <li>• Validation</li> <li>• Optimization</li> <li>• Transfer</li> </ul> </td> <td data-bbox="932 1787 1203 1917"> <ul style="list-style-type: none"> <li>&gt; Other</li> <li>• Immunogenicity</li> <li>• Customized Assays</li> </ul> </td> </tr> </table>	<ul style="list-style-type: none"> <li>&gt; Method</li> <li>• Development</li> <li>• Validation</li> <li>• Optimization</li> <li>• Transfer</li> </ul>	<ul style="list-style-type: none"> <li>&gt; Other</li> <li>• Immunogenicity</li> <li>• Customized Assays</li> </ul>
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### Contact Us

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