

# mRNA CDMO service

Elixirgen Scientific Japan is the leading mRNA CDMO service provider supporting drug discovery with affordable and on-time GMP mRNA



## Service Range

### Research ~ Clinical trial

Design Process mRNA API Dossier API Mfg. Dossier Mfg.

Focusing on API development and manufacturing:

- Structure design and modification
- Process and analytical methods development
- ug ~ g scale manufacturing capability
- Support with documentation and dossier under cGMP

### **Delivery:**

For research grade,

Scope definition : 0.5 to 1.0 month mRNA Synthesis\* : 1.5 to 2.0 months

\* Depending on the scope, if customers provide plasmid template, we can deliver mRNA within 1.0 month after receiving the template.

### **Quality:**

We have already delivered over 350 mRNAs.

Customer feedback:

"We are strongly satisfied with your service, because you completed the project and delivered high quality mRNAs in a short period."

# **Delivery record**

# We have delivered mRNAs for pharmaceutical industries or academic institutions in Japan and the US



Contact

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### **Facilities**

**cGMP-compliant manufacturing:** Process design based on Quality by Design

Document system with following 21 CFR-Part 11

Manufacturing in Japan: Reasonable lead time and quick customer service

Manufacturing in clean environment: Manufacturing mRNA with ISO class 7/Grade C

Aseptic filling: Isolator with ISO class 5

**Quality Control:** Analyzing mRNA is performed in compliance with GLP

mRNA for Research		mRNA for Clinical Trial
CoA	Documentation	cGMP-compliant
ISO class7	Manufacturing area	mRNA: ISO class7 Aseptic filling: ISO class5
Traceable, supplier management	Supply chain	Traceable, supplier management
200 μg to 100 mg	Capacity	100 mg to over 10 g

#### News



## License Agreement for CleanCap®

- We has entered into a license agreement with TriLink BioTechnologies LLC to strengthen our support for drug discovery services using CleanCap®.
- We have become the first CDMO service provider to partner with TriLink in the APAC area.
- We can deliver mRNA with CleanCap® M6, CleanCap® AG 3'Ome, and CleanCap® AG
  cap analogs for manufacturing services, from pre-clinical through Phase III programs.

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