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PETITION FORM
CERTIFICATION IN GOOD PRACTICES OF MANUFACTURING

ADVANCED THERAPY PRODUCTS

FOR USE BY THE RECEIVING AUTHORITY.

01	ÿ **Initial certification** ÿ **Renewal** **(Establishment previously certified by Anvisa by the same applicant company)**

02	ÿ **International company** ÿ **National company**

03	ÿ **Active Pharmaceutical Ingredient (API)** ÿ **Production line**

04	**CLASSES OF ADVANCED THERAPY PRODUCTS THAT WILL BE SUBJECT TO CERTIFICATION:**	
	***In vivo* gene therapy**	ÿ **Tissue engineered product**
	ÿEx ***vivo* gene therapy**	ÿ **Combined products**
	Advanced cell therapy	

05	**DATA FROM THE LATEST CERTIFICATION RESOLUTION (if it is a renewal):**
	RESOLUTION RE No. **OFFICE HOURS:** **DATE OF PETITION:**

06	**IDENTIFICATION OF THE REQUESTING COMPANY**	
	COMPANY NAME	
	CNPJ	

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	OPERATING AUTHORIZATION (AFE)			
	SPECIAL AUTHORIZATION (AE)			ÿ **N/A.**
	TEL:		**FAX:**	
	NAME OF THE PERSON RESPONSIBLE FOR INSPECTION SCHEDULING:			
	EMAIL OF THE AREA RESPONSIBLE FOR INSPECTION SCHEDULING: Note: If possible, please provide more than one email address.			
	I certify that the email address provided above is periodically checked by the company and I assume responsibility for it. Please be aware that inspection appointments will be handled by GIMED via email. PROVIDED.			

	IDENTIFICATION OF THE FOREIGN COMPANY TO BE INSPECTED		
	ÿ **NOT APPLICABLE**		
	UNIQUE REGISTRATION NUMBER		ÿ **UNIQUE REGISTRATION NUMBER STILL NOT AVAILABLE**
	Note: Consult https://consultas.anvisa.gov.br/#/empresas/empresasInternacionais/		
	COMPANY NAME		
07	**ADDRESS** (as per CBPF of the country of origin)		
	COORDINATES GEOGRAPHIC	Latitude: Longitude:	
	FEI (FDA) No. If the company is not registered with the FDA, enter "N/A".		
	Note: See https://datadashboard.fda.gov/ora/cd/inspections.htm		
	No. MIA (EMA) If the company is not registered with EMA, fill in “N/A”.		
	Note: See http://eudragmdp.ema.europa.eu/inspections/mia/searchMIA.do		

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	OCCURRENCE OF CORPORATE TRANSACTION	NO SIM **IF YES, PLEASE INFORM:** **SUCCESSOR COMPANY:** **SUCCESSOR COMPANY:** **TYPE OF CORPORATE TRANSACTION:** **DATA:**

	NAME OF THE EMPLOYEE ASSIGNED TO THE COMPANY FOREIGNER DESIGNATED TO RECEIVE THE INSPECTION			
	TEL:		**E-mail**	

I confirm that the address provided above corresponds exactly to the one described in the CBPF. FROM THE COUNTRY OF ORIGIN AND I ACKNOWLEDGE THAT THIS ADDRESS WILL BE USED BY ANVISA IN ALL THE RELATED PUBLICATIONS. THE ADDRESS MAY DIFFER FROM THE UNIQUE REGISTRATION DUE TO Updates made by the issuing health authority.

08	**The situation of the foreign company regarding Good Manufacturing Practices (GMP) in its country of origin.**	
	ÿ **NOT APPLICABLE**	
	AUTHORITY SANITARY RESPONSIBLE FOR THE GMP CERTIFICATION	
	HEALTH AUTHORITY MEMBER OF PIC/S	
	Frequency with which the company is inspected IN ACCORDANCE WITH THE LAW OF THE COUNTRY OF ORIGIN	
	IDENTIFICATION OF THE LEGISLATION MENTIONED IN THE ITEM ANTERIOR	
	DATE OF THE MOST RECENT INSPECTION CARRIED OUT BY HEALTH AUTHORITY OF THE COUNTRY OF ORIGIN	
	INSPECTION CONCLUSION	
09	**Did the inspection and certificate issued by the local health authority cover the production line where products exported to the Brazilian market are manufactured?** . If so, the company must forward attached is a statement from the manufacturing company that The inspection and certificate issued by the local health authority covered the production line where products exported to [country name] are manufactured. Brazil.	

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10	**Company data with ANVISA (Brazilian Health Regulatory Agency)**		
	RELATING TO EXISTENCE FROM PETITIONS TO OTHERS LINES IN THIS SAME ENTERPRISE	**LINE**	**OFFICE HOURS**
	RELATE AS CERTIFICATIONS AWARDED BY ANVISA FOR THIS ENTERPRISE	**RE N.º** **DOU de** **RE N.º** **DOU de** **RE N.º** **DOU de** **RE N.º** **DOU de**	ÿ **N/A.**
	Relate the dates of the last 3 INSPECTIONS CONDUCTED BY ANVISA IN THIS COMPANY (Regardless of the applicant and scope considered).	**OFFICE HOURS:** **DATA:** **RESULT:**	ÿ **N/A.**

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		OFFICE HOURS: **DATA:** **RESULT:**	
		OFFICE HOURS: **DATA:** **RESULT:**	

11	**Data from the health authority of the country of origin.** **If you are a domestic company, you do not need to fill out this table.**			
	NAME			
	ADDRESS			
	TEL:		**FAX:**	
	E-mail			

12	**DATA ON THE AIRPORTS NEAREST TO THE COMPANY**	
	NAME	
	IATA CODE (Three-letter code that identifies the airport)	
	NAME	
	IATA CODE (Three-letter code that identifies the airport)	

13	**AVAILABILITY TO RECEIVE INSPECTION (Fill in with 3 possible weeks within the period between 3 and 9 months after filing, with a minimum interval of one month between the suggested periods, to assist in scheduling the inspection). Completing this form does not guarantee that the inspection will take place on the indicated dates, but the dates will be prioritized. The production line for the** **The company for which certification is being requested must be operational and there must be no holidays during the suggested period.**	
	Period 1	
	Period 2	

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	Period 3	

	FINAL DECLARATION	
	I declare, aware that presenting false documentation to a public official is a crime, As provided for in Chapter III of the Brazilian Penal Code - Decree Law No. 2848, of 7 December 1940, that all the information present in this petition form They represent the truth.	
	ÿ **I CONFIRM THAT I HAVE COMPLETED ANNEXES I, II and III.**	
14	**RESPONSIBLE TECHNICAL** **CPF** **CLASS COUNCIL**	**SIGNATURE**
	RESPONSIBLE LEGAL **CPF**	
	DATA	**SIGNATURE**

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ANNEX I – DESCRIPTION OF ADVANCED THERAPY PRODUCTS

Complete Annex I for each advanced therapy product that the company seeking certification exports or intends to export to Brazil.

MEDICINE		PHARMACEUTICAL INPUT	
COMMERCIAL NAME		NAME OF ACTIVE SUBSTITUTE ACCORDING TO DCB	
PHARMACEUTICAL FORM (Fill in accordingly) Controlled Vocabulary of Pharmaceutical Forms		DCB No. (IF NOT YET AVAILABLE, PLEASE INFORM ON CAS No.)	
REGISTRATION NUMBER/PROCESS NUMBER			
CATEGORY IN ACCORDANCE PRODUCT REGISTRATION			
PRESENTATION			
Is it registered in the country of origin?			
EXPORT METHOD			
START DATE EXPORT			
NUMBER OF LOTS EXPORTED PER YEAR			
NUMBER OF LOTS EXPORTED PER YEAR			

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INFORM THE MEDICINE MANUFACTURING CHAIN (If there are differences in the manufacturing chains of the medications, please report separately)			
COMMERCIAL NAME/ **IFA**			
STAGE OF THE FLOW OF MANUFACTURING	**SUB-STAGES OF MANUFACTURING**	**NAME OF MANUFACTURING UNIT/CITY-COUNTRY**	**Resolution number and date of publication in the Official Gazette of the Certification Resolution.**
PRODUCTION OF INPUT/ PRODUCT Note: If the company is not responsible for all stages of production of the biological input, please specify which stages each company is responsible for. ÿ **N/A**			
PRODUCTION FINISH ÿ **N/A**	**FORMULATION**		
	PACKAGING PRIMARY		
	PACKAGING SECONDARY		
PRODUCTION OF THE DILUENT ÿ **N/A**			
STUDY OF STABILITY ÿ **N/A**			
PLACE OF STORAGE OF FINISHED PRODUCT NO. COUNTRY OF ORIGIN AND IN BRAZIL ÿ **N/A**			

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ANNEX II – DESCRIPTION OF PHARMACEUTICAL FORMS IN THE PRODUCTION LINE

Fill in the information relating to EACH production line submitted for Good Manufacturing Practices certification.

The listed pharmaceutical forms comply with the Controlled Vocabulary of Pharmaceutical Forms of Anvisa (Brazilian Health Regulatory Agency).

Mark PA if ASEPTIC PREPARATION is used in the production of the medicine subject to certification.

Mark ET if the TERMINAL STERILIZATION method is used in the production of the medicine subject to certification.

Mark LP if PARAMETRIC RELEASE is used in the production of the drug subject to certification. A separate petition is required for these cases.

STERILE PRODUCTS

Small volume parenteral emulsions	ÿPA ÿET ÿLP ÿ OTHER:
Large volume parenteral emulsions	ÿPA ÿET ÿLP ÿ OTHER:
Gels	ÿPA ÿET ÿLP ÿ OTHER:
Implants	ÿPA ÿET ÿLP ÿ OTHER:
Ointments	ÿPA ÿET ÿLP ÿ OTHER:
Post	ÿPA ÿET ÿLP ÿ OTHER:
Freeze-dried powders	ÿPA ÿET ÿLP ÿ OTHER:
Solutions	ÿPA ÿET ÿLP ÿ OTHER:
Small volume parenteral solutions	ÿPA ÿET ÿLP ÿ OTHER:
Large volume parenteral solutions	ÿPA ÿET ÿLP ÿ OTHER:
Small volume parenteral suspensions	ÿPA ÿET ÿLP ÿ OTHER:
Large volume parenteral suspensions	ÿPA ÿET ÿLP ÿ OTHER:
Suspensions	ÿPA ÿET ÿLP ÿ OTHER:
Others	ÿPA ÿET ÿLP ÿ OTHER:

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ANNEX III – ASSESSMENT OF THE COMPLEXITY OF THE MANUFACTURING COMPANY

Fill in the information regarding ALL production processes of the manufacturing company, regardless of the scope of the certification.

Nº			
1	ÿ Number of employees ÿ 50	ÿ Number of employees between 51 and 149	ÿNumber of employees ÿ 150
2	ÿDedicated production equipment		ÿ Multi-product production equipment
3	ÿNational Circulation		ÿNational and/or International Circulation
4	Product portfolio ÿ 20	Product portfolio between 21 and 49	Product portfolio ÿ 50
5	ÿ Does not act as a service provider. manufacturing (third party)		ÿ Acts as a service provider of manufacturing (third party)
6	ÿ Productive operations in systems open	ÿ Productive operations restricted to closed systems	ÿ Productive operations that allow for the dispersion of parts of the API/product into the environment.
7	ÿ No use of third parties for production stages or analyses of Release of the finished product.		ÿ Using third parties for production stages or analyses of Release of the finished product.