



American Society of Regenerative Medicine Cell and Gene Therapy Laboratory Accreditation

Accreditation Application Form for Cellular and Gene Therapy Labs

Section 1: General Information

1. Lab Name:

○ _____

2. Address:

○ _____

○ _____

3. Contact Person:

○ Name: _____

○ Title: _____

○ Phone: _____

○ Email: _____

4. Type of Lab:

○ Cellular Therapy

○ Gene Therapy

○ Both

5. Date of Application:

○ _____

Section 2: Organizational Structure

1. Organizational Chart:

○ Attach a current organizational chart detailing the hierarchy and reporting relationships.

○ [Attach File]

2. Leadership Team:

○ Provide names and titles of the leadership team:

▪ CEO/Director: _____

▪ Quality Assurance Manager: _____

▪ Lab Manager: _____

▪ Other Key Personnel: _____



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Section 3: Facility Information

1. Facility Description:

- Provide a brief description of the facility, including size, layout, and key features:

- _____
- _____
- _____

2. Clean Room Certification:

- Attach clean room certification documents.
- [Attach File]

3. Environmental Monitoring Records:

- Attach recent environmental monitoring records.
- [Attach File]

Section 4: Quality Management System (QMS)

1. QMS Manual:

- Attach a copy of the Quality Management System (QMS) manual.
- [Attach File]

2. Quality Policies:

- Provide a summary of the lab's quality policies:

- _____
- _____
- _____

3. Internal Audit Reports:

- Attach the most recent internal audit reports.
- [Attach File]

Section 5: Standard Operating Procedures (SOPs)

1. List of SOPs:

- Provide a list of all Standard Operating Procedures (SOPs) relevant to the lab's operations.

- _____
- _____
- _____



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2. Sample SOPs:

- Attach sample SOPs for the following processes:
 - Cell Collection: [Attach File]
 - Cell Processing: [Attach File]
 - Gene Editing: [Attach File]
 - Quality Control Testing: [Attach File]

Section 6: Personnel Information

1. Staff Qualifications:

- Attach resumes, certifications, and training records for key personnel.
- [Attach File]

2. Training Programs:

- Provide details of ongoing training programs:

- _____
- _____
- _____

3. Staffing Levels:

- Provide a summary of current staffing levels and plans:

- _____
- _____
- _____

Section 7: Equipment and Facilities

1. Equipment List:

- Provide a comprehensive list of all equipment used in the lab.

- _____
- _____
- _____

2. Calibration and Maintenance Records:

- Attach calibration and maintenance records for critical equipment.
- [Attach File]



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Section 8: Regulatory Compliance

1. Regulatory Licenses and Certifications:

- Attach copies of all relevant regulatory licenses and certifications.
- [Attach File]

2. Regulatory Compliance Records:

- Provide evidence of compliance with local, national, and international regulations.

- _____
- _____
- _____

3. Ethical Approvals:

- Attach documentation of ethical approvals for procedures and protocols.
- [Attach File]

Section 9: Additional Information

1. Description of Therapies:

- Provide a detailed description of the types of cellular and gene therapies offered.

- _____
- _____
- _____

2. Clinical Trials:

- Provide information on any clinical trials being conducted or planned.

- _____
- _____
- _____

3. Research and Development:

- Provide details of ongoing research and development activities.

- _____
- _____
- _____



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Section 10: Declarations

1. Conflict of Interest:

- Declare any conflicts of interest:

- _____
- _____
- _____

2. Certification:

- By signing below, I certify that the information provided in this application is accurate and complete to the best of my knowledge.
 - Name: _____
 - Title: _____
 - Signature: _____
 - Date: _____
-

Instructions for Submission

- Ensure all required sections are completed and all supporting documents are attached.
- Submit the completed application form and supporting documents to the accrediting body by email or through their online portal.