THE JACIE ACCREDITATION PROCESS
From Application To inspection
Contents

1. Before submitting an application.
2. The application process.
3. The required pre-inspection documentation.
4. The actual inspection.
Before submitting an application
Keep improving

Learn from inspection findings

Prepare and go through the JACIE inspection

Have a Quality Management / Risk Assessment approach

Start working under the current edition of the FACT-JACIE Standards
Before applying

INDICATORS

DOCUMENTATION

TRAINING

QM TEAM

STANDARDIZATION

AUDITS
Accreditation scope
The application process
Documents needed

Application form

- Scope
- Structure
- Size
- Team organization

Checklist

First-time Applicants Only!
The Checklist
### Part B: Clinical

<table>
<thead>
<tr>
<th>IEC</th>
<th>07 ref</th>
<th>7 standard</th>
<th>Applicant’s assessment</th>
<th>Source of evidence and explanatory text</th>
<th>Inspector’s Assessment</th>
<th>Inspector’s Comments (support your answers with additional information)</th>
<th>Accreditation Committee comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>B1</td>
<td>GENERAL</td>
<td></td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
<td>BLANK CELL</td>
</tr>
<tr>
<td>B1.1</td>
<td></td>
<td>The Clinical Program shall consist of an integrated medical team that includes a Clinical Program Director(s) housed in a defined location(s).</td>
<td>Compliant</td>
<td>REF - SOP - 001 01</td>
<td>Compliant</td>
<td></td>
<td></td>
</tr>
<tr>
<td>B1.1.1</td>
<td></td>
<td>The Clinical Program shall demonstrate common staff training, protocols, Standard Operating Procedures, quality management systems, clinical outcome analyses, and regular interaction among all clinical sites.</td>
<td>Compliant</td>
<td>REF - SOP - 001 01</td>
<td>Non-compliant</td>
<td>Missing SOP</td>
<td></td>
</tr>
<tr>
<td>B1.2</td>
<td></td>
<td>The Clinical Program shall use cell collection and processing facilities that meet FACT-JACIE Standards with respect to their interactions with the Clinical Program.</td>
<td>Partially compliant</td>
<td>REF - SOP - 001 01</td>
<td>Partially compliant</td>
<td>SOP not complete</td>
<td></td>
</tr>
<tr>
<td>IEC</td>
<td>B1.2.1</td>
<td>If the Clinical Program or an intermediary facility receives cellular therapy products directly from a third-party provider, the following responsibilities shall be defined, at a minimum, by a written agreement:</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Next steps

Quotation
Agreement signed
Invoice
Pre-audit documentation
The required pre-inspection documentation
Pre-inspection documents

- SOPs
- Staff training and qualifications
- Licences and authorizations.
- QM Manual.
- QMS evidence.
- Transplant activity.
- Consent forms.
- Sample labels.
- Plans or maps.
- Third party agreements.
The actual inspection
The inspectors

- LANGUAGE AND AVAILABILITY
- NO CONFLICT OF INTEREST
- TEAM LEADER
Inspection team

- Clinical Adults
- Collection
- Clinical Paed
- Processing
- Quality Management
- Observer
- Facilitator
Inspection duties

The applicant
- Logistics
- Staff
- Private meeting rooms
- Possible process demo
- Documentation available

The inspectors
- Teleconference
- Interviews
- Prepare documentation
- Timetable
- Start working on the checklist
Logistics

- Travel agency preferred
- Arrival time
- Perdiem 80 euros per day (3 days)
- Inspector availability
Timeline

Application: 4-6 months
Inspection: 3-4 months
Post Inspection: 4-8 months
Accreditation: 12-18 months
Time variables

- Amount of applications received
- Inspector availability
- Timely replies of inspectors
- Report turnaround and quality of reports
- Timely replies and corrections from the centre
Accreditation fees

Fee per area
- 1 area
- 2 areas
- 3 areas

Supplementary fee
- Additional clinical site
- Additional Collection site
- Additional Processing site
- Administration of IEC

Discount
- EBMT Members 50%
- 1 active inspection 15%
- > 1 active inspector 20%
Summary

- Before applying
- Timeline and stages
- Roles and responsibilities before and during inspection