

Global Medical Device Registration & Renewal: 12 Critical Compliance Checks You Should Never Miss

1. FDA Annual Registration Status Verification

- Confirm annual FDA establishment registration is active
- Verify renewal payment completion
- Review registration ownership details

2. FDA Device Listing Accuracy Review

- Check all active device listings
- Verify product codes and listing details
- Ensure discontinued devices are updated properly

3. Country-Wise Renewal Deadline Validation

- Review renewal dates for each market
- Confirm submission lead times
- Validate local authority timelines

4. Expiry Tracking vs Submission Logs

- Match actual submission records against renewal deadlines
- Identify missing or delayed submissions

5. Authorized Representative Validity Check

- Verify EU and international authorized representative agreements
- Confirm current contact information and contracts

6. Registration Record Consistency Check

- Compare registration records across countries
- Identify mismatched device names or model numbers

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7. Labeling vs Registration Alignment Review

- Ensure labeling claims match approved registrations
- Verify IFU and product descriptions remain aligned

8. Post-Market Update Compliance Check

- Review whether reportable changes require registration updates
- Confirm complaint and vigilance impacts were assessed

9. Regulatory Change Impact Assessment

- Evaluate recent regulatory changes affecting renewals
- Review country-specific update requirements

10. Audit Readiness Documentation Review

- Verify renewal evidence is organized
- Confirm traceability for submissions and approvals

11. Multi-Country Portfolio Visibility Review

- Ensure centralized visibility across all markets
- Confirm ownership responsibilities for each region

12. Internal SOP & Escalation Process Check

- Verify renewal SOPs are current
- Confirm escalation paths for high-risk renewals