EASA Part 21J Third Country Approval From 0 to 36 Months

Sofema Aviation (www.sofemaaviation.com) Considers the Journey to obtain EASA Part 21J Approval

Introduction

In this document we will Identify the steps necessary to obtain third country EASA Part 21J approval from a zero position & provide a typical timeline. Starting from a "zero position" to achieve a third-country (non-EU) EASA Part 21J Design Organisation Approval (DOA) is a massive regulatory and operational undertaking. It typically requires 24 to 36 months of continuous development, rigorous documentation, and significant financial investment.

Organisation Approval

Because EASA delegates design privileges directly to your firm rather than individually certifying your engineers, you are effectively building an internal mini-regulator.

The Ground Rules for Third-Country Applicants

Before spending a dime on development, you must clear two massive gating hurdles that apply specifically to non-EU applicants:

The BASA Conflict: If your company is located in a country with a robust Bilateral Aviation Safety Agreement (BASA) with the EU—such as the United States (FAA), Canada (TCCA), or Brazil (ANAC)—EASA will typically **reject** a direct 21J application.

- They expect you to obtain approval through your local authority and use the validation path. You must be located in a non-BASA state or prove an exceptional, highly specific business case.

The Direct Need Rule: EASA will not issue a DOA "just to have it on the shelf." Your application must be formally tied to a concurrent type investigation project, such as a Supplemental Type Certificate (STC), Major Change, or European Technical Standard Order (ETSO).

The Macro Project Timeline

The journey from a zero position to certification is divided into six distinct phases.

Phase 1: Feasibility, Strategy & Core Recruitment - Months 1–6

Establish your specific business justification for EASA. Recruit or designate your core management team. Perform a gap analysis comparing your current engineering practices against EASA Part 21 Subpart J requirements, including recent Safety Management System (SMS) integration mandates.

Phase 2: Formal Application & Intake - Months 7–9

Submit EASA Form FO.DOA.00080 along with your certification project application. Secure funding for EASA's initial investigation fees. EASA evaluates your eligibility on a case-by-case basis and assigns a DOA Team Leader (DOATL).

Phase 3: Building the Design Assurance System (DAS) - Months 10–18

Draft the foundational architecture of your design ecosystem. Write the first complete draft of your Design Organisation Handbook (DOH) and build underlying procedures for tracking configurations, managing subcontractors, and monitoring airworthiness data.

Phase 4: Desktop Review & Personnel Training - Months 19–24

Engage in iterative review cycles with your EASA DOATL. Train your engineering staff on EASA regulations, safety management, and your specific handbook procedures. Address high-level structural findings raised by the Agency.

Phase 5: Implementation & Shadow Projects - Months 25–30

Put your written procedures into active daily practice. Run a "sample certification project" under close internal observation. Activate your Independent System Monitoring (ISM) function to perform internal audits and identify internal non-compliances.

Phase 6: EASA Audits & Issuance Months 31–36

EASA conducts comprehensive on-site or deep-dive virtual audits of your facilities. They interview your key personnel and check your sample projects. Close out any regulatory findings to receive your official EASA Part 21J DOA certificate.

The Core Compliance Architecture (Four Pillars)
To pass inspection, your zero position must be transformed to support four structural pillars of a Part 21J organization:

The Design Assurance System (DAS): This is the organizational quality management engine. It must coordinate everything from initial design concepts to final compliance data verification, and it must feature an integrated Safety Management System (SMS) to track risk indicators and safety data.

Key Nominations (EASA Form 4 Holders): You must appoint four specific individuals who hold ultimate regulatory accountability. EASA will vet these people heavily via interviews:

- **Chief Executive:** The Accountable Manager who controls the budget and takes ultimate legal responsibility.
- **Head of Design Organisation (HDO):** Holds direct authority over all design and engineering processes.
- **Chief of the Office of Airworthiness (COA):** The direct liaison to EASA; handles change classifications (minor vs. major) and ensures continued airworthiness.

- **Chief of Independent System Monitoring (ISM):** Effectively the Quality Manager for design; must remain independent from data creation to objectively audit the system.
- **The Compliance Verification Engineer (CVE) System:** CVEs are the cornerstone of EASA's delegated trust. They are highly experienced engineers granted the authority to sign off on compliance documents. They must maintain strict independence, meaning **a CVE cannot verify design data that they created or directly supervised.**
- **The Design Organisation Handbook (DOH):** This is your operational bible. It details your organizational chart, names your CVEs, maps out your engineering processes, and specifies how you manage configuration controls, record keeping (minimum 5-year retention past product retirement), and operational suitability data.

The EASA Certification Sequence

Once your strategy is set and your application is submitted, you will enter EASA's formal initial investigation process. This procedural workflow follows a strict sequence:

Application Validation

EASA Intake - Submit your Form FO.DOA.00080 alongside your business case and upcoming project details. EASA checks for regional jurisdictional conflicts and issues an acknowledgment of receipt once they accept the business justification.

The Kick-Off Meeting - Cologne, Germany or Virtual

Your assigned EASA Team Leader (DOATL) hosts an official kick-off. Your company presents its high-level organizational plan, corporate setup, and targeted technical scope. EASA establishes their specialized DOA Team (DOAT) to match your technical discipline.

Iterative Desktop Investigation - Document Review

Submit your drafted Design Organisation Handbook (DOH) and associated procedural documents to EASA. Expect multiple rounds of feedback.

- The agency reviews your manuals to ensure they perfectly align with Part 21 requirements before anything is verified in practice.

Sample Project Run & Trial Phase

System Testing - Execute a mock or live sample project using your new DOH rules. Your engineers generate data, and your CVEs review and sign it off using your new independent checking protocols. Your ISM function must audit this exact process to prove internal oversight is functional.

The Main EASA Audit – On-site Inspection

The EASA team spends several days evaluating your facility. They will conduct deep-dive technical interviews with your HDO, COA, ISM chief, and selected CVEs to verify that your staff understand your procedures and possess the requisite technical competency.

Finding Management & Approval - Final Closeout

EASA issues an audit report detailing any non-compliances (Level 1 or Level 2 findings). You must submit a root-cause analysis and corrective action plans. Once EASA signs off on your closures, they compile the final investigation report and issue your EASA Part 21J DOA certificate.

Crucial Advice for a "Zero Position" Start

- **Do Not Skimp on the Office of Airworthiness (COA):** Many startups treat the COA role as administrative paperwork. In reality, EASA expects the COA to be a sharp regulatory gatekeeper who understands airworthiness codes inside and out. Hiring an experienced aviation certification engineer for this role will save you months of delays.
- **Map out your CVE Matrix Early:** You must demonstrate that you have a qualified CVE for every single technical discipline within your requested scope (e.g., structures, electrical systems, software, cabin safety). If you lack in-house expertise for a specific discipline, you must establish external CVE interface agreements early in Phase 3.
- **Control Your Subcontractors:** If you plan to outsource drafting, simulation, or testing, your DOH must include robust subcontractor control procedures. You are fully responsible for their output; EASA will audit how you vet and control your suppliers just as tightly as they audit your internal staff.

CVE – Overview

Criteria and procedural framework required by EASA to qualify and maintain internal and external Compliance Verification Engineers (CVEs).

Under EASA Part 21 Subpart J, the Compliance Verification Engineer (CVE) is the absolute cornerstone of the delegated trust model. Unlike regulatory systems that rely on individual designees personally appointed by the aviation authority, EASA grants design privileges directly to the organization (21.A.263).

Consequently, your Design Organisation (DOA) bears the entire regulatory burden of vetting, authorizing, and monitoring its CVEs. EASA does not individually approve your CVEs; instead, they audit your system for managing them.

The following criteria and procedural framework are required to build, implement, and maintain a compliant CVE network.

Core Qualification Criteria (The Baseline)

To qualify an engineer for CVE status, your Design Assurance System (DAS) must evaluate them across four distinct dimensions. These criteria must be explicitly documented within your Design Organisation Handbook (DOH).

Dimension	Minimum Regulatory & Operational Expectation
Education	A degree in a relevant engineering discipline (Aeronautical, Mechanical, Electrical, etc.) from a recognized university. Equivalent long-term technical experience may be accepted but requires exhaustive, documented justification.
Technical Experience	Typically a minimum of **5 to 7 years** of hands-on engineering experience in the specific technical discipline (e.g., cabin safety, structures, avionics). A significant portion of this must involve the actual demonstration of compliance with airworthiness codes.
Regulatory Knowledge	Deep familiarity with relevant **EASA Certification Specifications (CS-23, CS-25, CS-27, etc.)** and Environmental Protection requirements. Candidates must prove they know how to interpret Acceptable Means of Compliance (AMC) and Guidance Material (GM).
Systemic Competency	Full operational understanding of Part 21 Subpart J regulations, your company's internal DOH procedures, and your integrated Safety Management System (SMS) reporting lines.

The Core Sentinel Rule: Independence

Per **AMC 21.A.239(b)**, the independent checking function is absolute. The signatory flow within your engineering department must guarantee a clean operational separation:

The Separation Rule: A CVE can never verify compliance data that they created, compiled, or directly supervised as a lead designer.

While a CVE can sit in the same workspace and collaborate with design engineers during the early phases of a project, their verification signature must represent a completely uninfluenced technical check. Your processes must show that the CVE is free from commercial or timeline pressure, answering strictly to the Head of Design Organisation (HDO) and the Chief of the Office of Airworthiness (COA) on airworthiness matters.

Procedural Framework for Initial Qualification

To move an internal or external candidate from an unauthorized state to active status, you must execute a formal, multi-step internal process:

Candidate File Assembly

The candidate compiles a comprehensive qualification dossier. This file is a legal record and must contain:

- A detailed CV mapping specific past modifications, STCs, or repairs they worked on.
- A capability matrix pairing their experience directly with specific **ATA Chapters** or EASA technical disciplines.
- Certificates of training for Part 21, SMS, human factors, and specialized technical courses.

Technical & Regulatory Assessment

The HDO and COA conduct a formal interview and file review. They assess the candidate's understanding of:

- The precise boundary between minor and major changes.
- How to properly apply and defend specific Means of Compliance (MoC 0 through MoC 9).
- How to systematically address unexpected test failures or non-compliances.

The Trial / Shadow Phase

Before full authorization is granted, the candidate must enter a supervised trial period.

- They review active project documentation and draft compliance statements.
- An established, fully authorized CVE reviews their work and co-signs the document.
- The candidate's files are tagged as "under supervision" to ensure unapproved signatures do not leak into final certification packages.

Formal Authorization & Scope Mapping

Once the trial phase is successfully completed, the HDO issues a formal internal CVE Authorization Document. This document defines their exact Scope of Approval, specifying:

- Eligible aircraft types, weights, or product categories.
- Specific technical disciplines (e.g., CS-25 Subpart D: Design and Construction).
- Permitted document types they can sign (e.g., Test Programmes, Compliance Reports, Flight Manual Supplements).

Special Provisions for External (Contract) CVEs

Third-country DOAs frequently utilize external, contract CVEs to cover specialized technical fields or scale up during peak project loads. To maintain compliance, you must implement an enhanced administrative framework:

- **The Design Organisation Interface Document (DOID):** You must execute a formal interface agreement with the external CVE or their primary employer. This contract must legally state that when the external CVE is performing verification tasks for your DOA, they are operating solely under your design privileges and answer directly to your HDO.

- **Procedural Integration:** External CVEs cannot simply sign off using their own methods. They must be thoroughly trained in your DOH procedures, your document templates, and your configuration control systems.
- **Availability and Capacity Tracking:** EASA will look closely at a contract CVE's workload during audits. You must maintain an active log showing how many hours or percentages of their capacity are legally dedicated to your organization, proving they have the bandwidth to perform deep-dive data reviews rather than just "rubber-stamping" files.

Maintenance of Competence & Continuous Oversight

An authorization is not a lifetime appointment. To ensure your CVE network remains compliant during regular EASA surveillance audits, your Independent System Monitoring (ISM) and Office of Airworthiness must execute a continuous maintenance framework:

- **Currency Thresholds:** Your DOH must define a minimum level of active participation. For example, a CVE must verify a minimum of two compliance packages or log a set number of hours in their technical discipline every 24 months to maintain currency.
- **Mandatory Recurrent Training:** CVEs must undergo scheduled recurrent training covering updates to EASA basic regulations, new ED Decisions, safety mandates, and insights derived from your internal SMS data.
- **ISM Sampling Audits:** Your internal quality assurance (ISM) function must regularly sample compliance documents signed off by your CVEs. The auditor checks that the CVE didn't just sign the cover page, but actually reviewed the underlying raw data, test logs, and engineering calculations.

All qualification files, trial project records, recurrent training logs, and active scope matrices must be kept completely up to date. During an EASA initial or surveillance audit, the DOATL will randomly pull these files and interview your CVEs on the spot to ensure the integrity of your Design Assurance System.

Design Organisation Handbook

Provide a comprehensive standard table of contents and structural breakdown for an EASA Part 21J Design Organisation Handbook (DOH).
An EASA Part 21J Design Organisation Handbook (DOH) must be structured to directly address the acceptable means of compliance outlined in AMC 21.A.243. It serves as the definitive legal framework defining your design privileges, processes, and lines of accountability.

Following recent EASA regulatory updates, a modern DOH must explicitly weave an integrated Safety Management System (SMS) throughout its operating procedures rather than treating it as an isolated quality manual.

The standard master structure and comprehensive Table of Contents required for an EASA-approved Part 21J Design Organisation are detailed below.

Part 0: Administration and Control

This introductory section establishes the legal validity of the manual and defines the mechanism for keeping the documentation synchronized with evolving EASA regulations.

0.1 Corporate Commitment

- Accountable Manager Statement: Signed declaration committing the organization to work strictly in accordance with Part 21 Subpart J and the procedures contained within the DOH.

0.2 Management of the Handbook

- Procedure for DOH amendment, revision control, and tracking.
- Process for identifying and notifying EASA of significant vs. non-significant changes to the Design Assurance System (DAS).

0.3 Distribution List and Master Document Control

- Physical/digital access control lists (including mandatory copy distribution to the assigned EASA DOATL).

0.4 Definitions, Abbreviations, and Acronyms

Part 1: Organisation and Management

- This section establishes the physical footprint, the human infrastructure, and the authorized scope of your engineering privileges.

1.1 Scope of Approval & Privileges

- Detailed matrix of technologies, aircraft categories (e.g., CS-23, CS-25, CS-27), and technical disciplines (e.g., Avionics, Structures, Cabin Safety).
- Definition of privileges held under 21.A.263 (e.g., approval of minor changes, classification of major changes).

1.2 Terms of Approval

- Cross-reference to official EASA Form 3X certificates.

1.3 Management Structure and Key Personnel

- Corporate and operational organization charts detailing the independence of System Monitoring and Airworthiness from commercial structures.
    - Credentials, roles, and responsibilities of EASA Form 4 holders:
        - Head of Design Organisation (HDO)
        - Chief of the Office of Airworthiness (COA)
        - Chief of Independent System Monitoring (ISM)

1.4 Human Resources and Competence Management

- Credentials, initial/recurrent training, and authorization processes for staff.
- The CVE Authorization System: selection, trial phases, and scope management.

1.5 Facilities and Equipment

- Description of engineering facilities, software tool validation (e.g., FEM, CAD packages), and testing environments.

Part 2: The Design Assurance System & Operational Procedures

This is the core execution chapter. It details how engineering concepts are moved safely from initial design to certified reality.

2.1 The Certification Process Flow

- Inception of a design project, structural layout, and initial safety assessments.

2.2 Classification of Changes and Repairs (21.A.91 / 21.A.431A)

- Criteria and internal guidelines for categorizing modifications into Minor or Major.
- Procedure for processing and justifying classification decisions.

2.3 Preparation of the Certification Programme

- Defining the Type Certification Basis (TCB), establishing special conditions, and identifying relevant environmental/noise standards.
    - Mapping the compliance matrix using Means of Compliance (MoC 0–9).

2.4 Compliance Demonstration and Verification

- Procedures for drawing control, engineering calculations, and document generation.
- Execution of compliance testing (Ground, Laboratory, and Flight Test management).
- The Independent Checking Function: Rules for the execution of document reviews by authorized CVEs.

2.5 Operational Suitability Data (OSD)

- Procedures for creating and verifying OSD constituents (Flight Crew, MMEL, Cabin Crew, Maintenance) when mandated by the scope of the change.

2.6 Approval of Minor Changes and Repairs

- Procedural flow for executing approvals entirely under internal 21.A.263 privileges.

2.7 Submission of Major Changes / STCs to EASA

- Coordination, data package aggregation, and formal submittal management via the Office of Airworthiness.

Part 3: Integrated Safety Management System (SMS)

- This section maps the specific processes that shift your design engine from passive compliance to proactive safety and risk mitigation.

3.1 Safety Policy and Objectives

- Management commitment, safety accountability, and emergency response planning lines.

3.2 Safety Risk Management

- Hazard identification processes specific to engineering design vulnerabilities.
- Risk assessment, mitigation tracking, and internal safety case management.

3.3 Safety Assurance

- Safety performance monitoring via explicit safety performance indicators (SPIs).

- Management of change: evaluating how modifications to company infrastructure or engineering tools affect structural safety risks.

3.4 Safety Promotion

- Internal safety communication channels, just-culture declarations, and safety competency training loops.

Part 4: Continuing Airworthiness & Occurrence Reporting

This section controls the post-certification lifecycle, ensuring your design organization maintains visibility of its products throughout their service lives.

4.1 Monitoring of Continued Airworthiness (21.A.3A)

- Collection, analysis, and tracking of in-service difficulties, structural defects, and maintenance malfunctions.

4.2 Occurrence Reporting Procedure

- Rules for notifying EASA, operators, and type-certificate holders of safety-critical failures within the mandatory 72-hour regulatory window.

4.3 Preparation of Airworthiness Directives (AD) / Service Bulletins (SB)

- Drafting, verifying, and distributing mandatory continued airworthiness instructions and corrective actions to the fleet.

4.4 Instructions for Continued Airworthiness (ICA)

- Authoring, updating, and validating maintenance manual supplements and structural repair manuals.

Part 5: Document Control, Configuration, and Subcontractor Management

5.1 Configuration Management

- Establishing the engineering baseline, managing design iterations, tracking weight and balance variations, and controlling effectivity.

5.2 Record Keeping and Data Retention

- Archiving compliance documentation, raw test logs, and design calculations.
- Retention rule: Keeping data accessible for a minimum period of 5 years after the specific aircraft model has been permanently retired from service.

5.3 Subcontractor and Supplier Control

- Processes for auditing, selecting, and integrating external engineering providers or test labs.
- The Design Organisation Interface Document (DOID) workflow for managing contract CVEs.

Part 6: Independent System Monitoring (ISM)

This functions as the internal audit protocol, providing the HDO and EASA with verification that the DOH is being actively followed.

6.1 ISM Scope and Independence

- Establishing the mandate of the ISM chief to audit all elements of Parts 1 through 5 without operational interference.

6.2 Audit Scheduling and Performance

- The annual audit plan matrix covering all procedural elements of the DAS.

6.3 Finding Management and Corrective Actions

- Recording non-compliances, executing root-cause analyses, tracking implementation deadlines, and escalating un-cleared findings to the Accountable Manager.

Part 7: Appendices and Reference Data

- **Appendix A:** EASA Form 4 Holder Biographies and Accepted Positions.
- **Appendix B:** Master Register of Authorized CVEs (including individual scope limits and signature templates).
- **Appendix C:** Cross-Reference Matrix (Direct mapping of every Part 21 Subpart J regulation section to its exact corresponding procedure paragraph in this handbook).
- **Appendix D:** Standard Document Templates (Compliance Reports, Test Programmes, Minor Change Approval Sheets, Ground Test Logs).