Curia's Approach to Regulatory Compliance in Brazil

curia
Generic APIs

Curia has strategically expanded its footprint in Brazil. As ANVISA tightens regulations under ICH/PIC-S-aligned standards, Curia positions itself as a strategic partner for customers seeking seamless access to the Brazilian market. Leveraging decades of experience in complex global regulatory environments and in collaboration with local partners, Curia swiftly adapted to the specific requests for Brazilian regulation.

Brazil's Regulatory Framework for APIs

Since 2020, Brazilian Authorities has been implementing a new regulatory framework:

1. DIFA → CADIFA System

- In 2020, ANVISA introduced the resolution RDC 359/2020 which institutes the Active Pharmaceutical Ingredient Dossier (DIFA) and the Letter of Suitability of the Active Pharmaceutical Ingredient (CADIFA).
- From August 2023, obtaining a CADIFA—or proof of CADIFA request—is mandatory prior to filing a finished product registration.
- IN 289/2024 permits reliance on approvals from Equivalent Foreign Regulatory Authorities (AREEs) to shorten review.
- ANVISA Manual updates (Feb 2025) refine module structuring, change-of-applicant rules, and duplicate CADIFA mechanisms.

2. GMP Requirements

- ANVISA GMP certificate (or equivalent evidence accepted by ANVISA policy): either an existing ANVISA certificate or proof of inspection/third-party recognized certifications, depending on case.
- ANVISA performs and requires GMP assessments for API suppliers.
- Inspection history: list of recent GMP inspections (ANVISA, FDA, EMA, PIC/S) plus copies of inspection reports and CAPA where relevant.
- Access for inspection: commitment to allow ANVISA inspections of foreign manufacturing sites, access to records and personnel.

3. Process Innovations & Fees

- Guide No. 71/2024 encourages continuous API production & lifecycle control based on ICH Q7/Q12.
- CADIFA issuance remains fee-free. Only standard fees (e.g., those associated with GMP certification) apply, not fees tied to CADIFA applications.

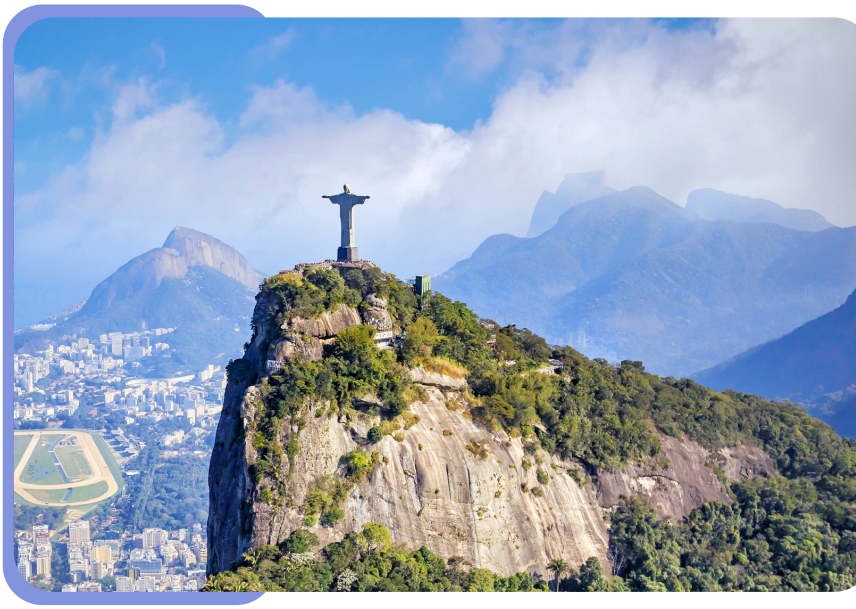
Key practical tips for API manufacturers:

- ANVISA's RDC 637/2022 mandates national registration/cadastro of APIs for companies operating in Brazil.
- API manufacturer must file a complete API dossier (AP+RP) in association with MAH at ANVISA via SOLICITA system – no eCTD.
- Method validation according ANVISA requirements.
- Stability zone: Brazil requires consideration of Zone IVb (30°C/75% RH).
- No renewal but dossier lifecycle management.
- GMP inspections / certificates: ANVISA performs its own inspections and may require foreign site audits or acceptable third-party evidence. Fee it is about 15000 € and it should be renewed every 2 years.

Curia's Journey in Brazil

Curia's APIs have been distributed supporting essential drugs in the Brazilian market since decades. Our commitment to quality and regulatory excellence is reflected in our strong track record of API registrations in the Brazilian market previous and after CADIFA system.

Testimony of this is the grant of the Certificação de Boas Práticas de Fabricação (GMP certificate) issued by ANVISA in August 2025 for our site in Spain, based on the on-site audit performed by the agency in the second quarter of 2025 joining our French and Italian sites which also hold CBPF certificate from Brazilian Authorities.



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