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Building an AI-Powered

CDSCO Regulation Readiness Agent

for a Medical Device Distributor



PROBLEM STATEMENT

Regulatory evidence sat across product records, licenses, supplier documents, and other supporting records. Teams had to interpret the applicable CDSCO requirements, check each record against them by hand, and chase suppliers for what was missing. Gaps such as missing, expired or expiring documents were hard to spot early, which put application preparation, renewals, imports and inspection readiness at risk

CHALLENGES

- **Fragmented Documentation** - Regulatory evidence is spread across product records, licences, supplier documents and other supporting records.

- **Complex Regulatory Requirements** - Teams must identify and interpret applicable CDSCO requirements for their products and business activities. Undetected documentation gaps can delay application preparation, renewals, imports or inspection readiness.

- **Manual Document Verification** - Reviewing records against regulatory requirements takes considerable time and effort.

- **Supplier Coordination** - Obtaining missing evidence and following up on outstanding documents involves multiple stakeholders.

Solution

1

Regulatory Requirement Mapping
Identifies applicable CDSCO requirements based on products, licences and regulatory activities.

2

Documentation Assessment
Maps requirements against product records, licences, registered premises, responsible personnel and supporting evidence.

3

Gap Identification and Remediation
Flags missing, incomplete, expired or expiring documents, including those lacking required notarization or attestation, and defines the actions needed to close each gap.

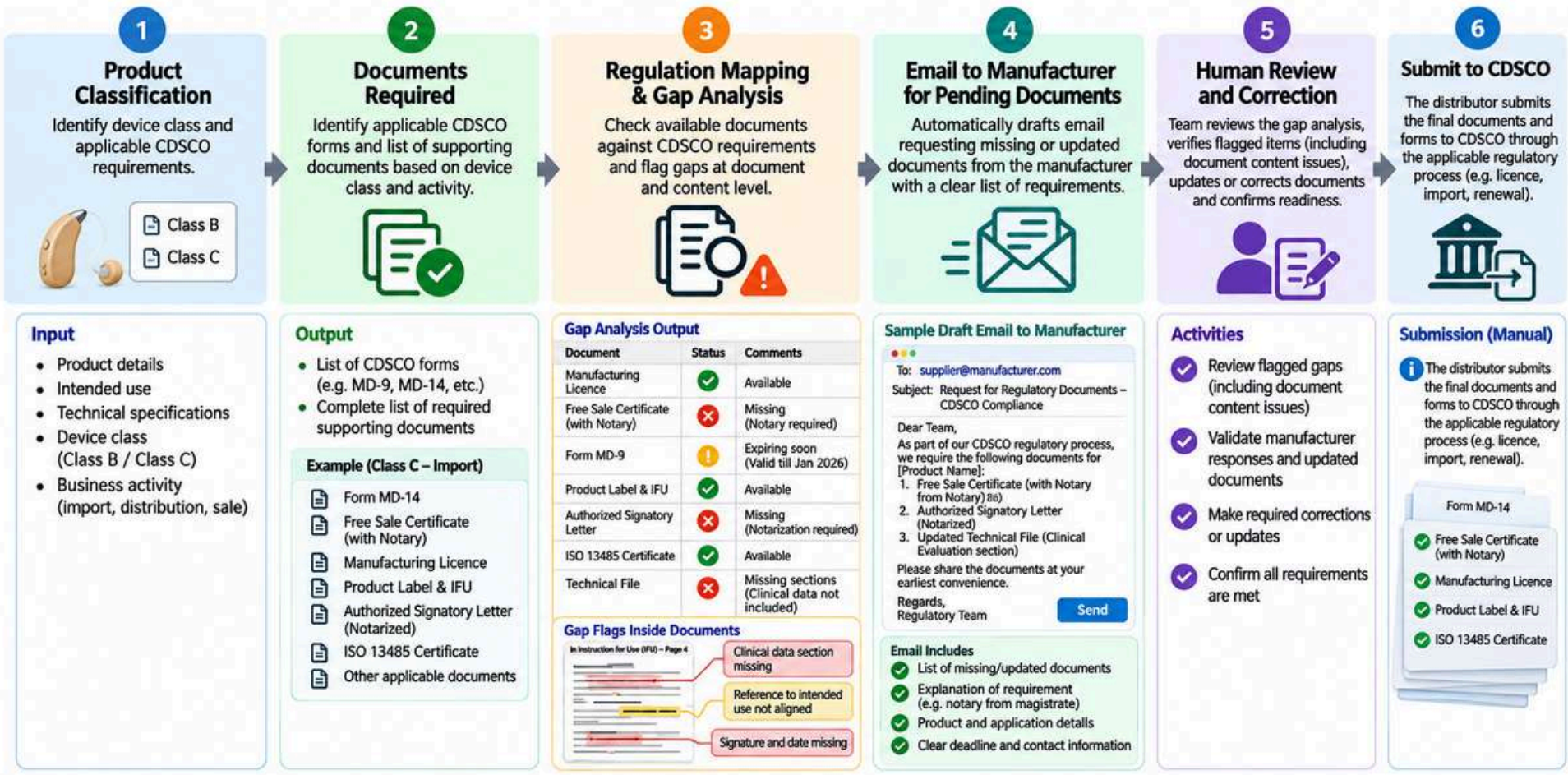
4

Evidence Collection and Tracking
Supports requests for missing documents and tracks evidence collection and remediation progress.

5

Regulatory Readiness Visibility
Helps teams monitor outstanding requirements and prepare for relevant applications, renewals, imports and inspections.

Solution Architecture



Impact

60%

Reduction in Manual Regulatory Documentation Review Effort

Faster Identification of Regulatory Documentation Gaps

70%

50%

Reduction in Time Spent on Evidence Follow-ups and Coordination



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