



REGULATORY LOCALIZATION

BEST PRACTICES GUIDE

Essential Strategies for Compliance-Driven Translation
In Dermocosmetics, Skincare, and Life Sciences

By Dr. Viveta Gene

Head of Global Localization Solutions & Innovation
Intertranslations S.A.

GALA Board Member | Postdoctoral Researcher

Executive Summary

Regulatory localization represents a specialized discipline at the intersection of translation expertise, regulatory science, and compliance strategy. Unlike general content translation, regulatory localization for dermocosmetics, skincare, and life sciences products demands deep understanding of jurisdiction-specific frameworks, ingredient classification systems, and claim substantiation hierarchies.

This guide addresses the most critical challenges facing regulatory affairs managers, localization directors, and compliance officers as they navigate global market expansion:

- Understanding how regulatory frameworks shape localization requirements across EU, FDA, and Asia-Pacific markets
- Building compliant workflows that accelerate submissions without compromising accuracy
- Implementing terminology management systems that ensure consistency across Product Information Files, safety assessments, and labeling
- Establishing quality assurance protocols that catch compliance-critical errors before submission
- Selecting and managing localization vendors with genuine regulatory expertise

Based on 20 years of specialized experience and ongoing postdoctoral research in translation technology, this guide provides actionable frameworks, decision trees, and validation checklists that regulatory teams can implement immediately.

Key findings and recommendations:

- Most regulatory submission delays stem from localization providers treating compliance documentation as general translation rather than regulatory strategy
- Terminology inconsistencies across Product Information Files and CPNP notifications represent the most common cause of compliance queries
- Organizations that implement centralized knowledge bases for ingredient nomenclature and regulatory language reduce submission revision cycles by an average of 40%
- Vendor selection based purely on translation credentials rather than regulatory domain expertise is the primary predictor of market entry delays

This guide equips compliance and localization professionals with the strategic frameworks needed to transform regulatory localization from a bottleneck into a competitive advantage in global market expansion.

1. Understanding Regulatory Frameworks and Localization Requirements

Effective regulatory localization begins with comprehensive understanding of how different jurisdictions structure compliance requirements and how these structures directly impact translation and terminology decisions.

1.1 The EU Cosmetics Regulation Framework

EU Regulation (EC) 1223/2009 establishes the primary compliance framework for cosmetics and dermocosmetics throughout the European Economic Area. Understanding this regulation's structure is essential for accurate localization because terminology choices must align with specific regulatory concepts.

Critical Documentation Requirements

The Product Information File (PIF) serves as the central compliance document. Localization of PIF components requires specialized expertise because each section has distinct regulatory implications:

- **Product Description and Intended Function:** Must align with Annex VII labeling requirements and claim substantiation evidence. Translation errors here can invalidate the entire PIF.
- **Safety Assessment:** Requires precise terminology for toxicological endpoints, exposure scenarios, and margin of safety calculations. Inconsistent translation of ingredient names between safety assessment and product formulation creates compliance failures.
- **Manufacturing Method and GMP Compliance:** Must accurately reflect process validation terminology and quality control procedures. Generic translation misses regulatory-specific quality systems vocabulary.
- **Proof of Claimed Effect:** Localization must preserve the evidentiary hierarchy between in vitro, in vivo, and clinical study data while adapting claim language to each market's regulatory interpretation.

Annexes and Ingredient Classification

The regulation's annexes define critical ingredient categories that demand absolute terminology precision:

Annex	Category	Localization Implications
Annex II	Prohibited Substances	Must use exact INCI nomenclature. Synonym variations can result in incorrect compliance determinations.
Annex III	Restricted Substances	Concentration limits and conditions must be precisely translated. Ambiguity in usage conditions creates compliance risk.
Annex IV	Colorants	Requires CI number precision and field-of-application accuracy. Product category terminology affects colorant compliance.
Annex V	Preservatives	Maximum concentration values must match exactly across all languages. Measurement unit consistency is critical.
Annex VI	UV Filters	SPF claim terminology and concentration levels require regulatory-specific translation. Generic sunscreen terminology is insufficient.

1.2 CPNP Notification Requirements

The Cosmetic Products Notification Portal (CPNP) requires specific data submission in structured formats. Localization must preserve this structure while adapting content to each market member state's language requirements.

Data Accuracy Requirements

CPNP submissions demand absolute consistency between:

- Product category classification and intended function statements
- Frame formulation ingredient listings and full INCI declarations
- Labeling information and consumer-facing product claims
- Contact information for the Responsible Person across all notification languages

1.3 FDA and International Framework Differences

While EU regulations provide the most comprehensive cosmetics framework, other major markets impose distinct requirements that affect localization strategy:

United States FDA Requirements

The FDA regulates cosmetics under different statutory authority than the EU, creating terminology divergences:

- **Drug vs. Cosmetic Classification:** Claims language determines regulatory category. Statements about treating acne, reducing wrinkles, or affecting body structure trigger drug classification requiring entirely different documentation.
- **Color Additive Certification:** FDA uses different nomenclature than EU CI numbers for many colorants. Direct translation of EU color declarations can result in non-compliant US labeling.
- **Voluntary Cosmetic Registration Program:** While voluntary, VCRP submissions require specific formatting and ingredient reporting that differs from CPNP standards.

Asia-Pacific Market Variations

China, Japan, South Korea, and ASEAN markets each maintain distinct regulatory frameworks with unique localization challenges:

- **China NMPA (National Medical Products Administration):** Requires Mandarin documentation with specific terminology for the China Inventory of Existing Cosmetic Ingredients (IECIC). Translation must distinguish between general use, imported special cosmetics, and domestic ordinary cosmetics.
- **Japan MHLW Standards:** Differentiates between cosmetics and quasi-drugs (medicated cosmetics). Claim language and ingredient concentration reporting follow distinct requirements for each category.
- **South Korea MFDS:** Functional cosmetics category requires clinical substantiation with Korean-language documentation. Terminology for functional claims must align with approved categories.

2. Building Compliance-Driven Localization Workflows

Successful regulatory localization requires process design that treats compliance as a workflow driver rather than a quality check at the end. The following framework establishes regulatory accuracy as foundational to every project phase.

2.1 Pre-Project Regulatory Assessment

Before initiating translation, conduct a comprehensive regulatory context analysis to identify compliance-critical elements that will drive terminology, formatting, and validation requirements.

Document Classification and Risk Assessment

Categorize documentation by regulatory function and compliance risk level:

Risk Level	Document Types	Validation Requirements
Critical	Product Information Files, Safety Assessments, CPNP Notifications, Ingredient Declarations	Subject matter expert review, regulatory affairs validation, automated terminology checking, parallel reference verification
High	Product Labels, Instructions for Use, Claim Substantiation Documentation, Manufacturing Procedures	Regulatory reviewer validation, automated claim checking, formatting compliance verification
Medium	Marketing Materials with Claims, Technical Data Sheets, Training Documentation	Terminology consistency checking, claim alignment with substantiation, standard linguistic QA
Standard	Internal Communications, General Marketing Content, Non-Claim Product Descriptions	Standard translation QA, brand consistency checking

2.2 Terminology Preparation and Validation

Terminology accuracy represents the single most critical factor in regulatory localization success. Establish centralized terminology resources before beginning translation to ensure consistency across all documentation.

Building Regulatory Termbases

Regulatory termbases must extend beyond standard glossaries to include compliance context:

- **Ingredient Nomenclature:** INCI names, CAS numbers, EC numbers, and market-specific identifiers linked in each entry
- **Regulatory Status Flags:** Annex classifications, concentration restrictions, usage conditions, and prohibited contexts
- **Approved Claim Language:** Pre-validated claim statements with substantiation tier mapping and market-specific variants
- **Forbidden Terminology:** Blacklisted terms that trigger regulatory issues (e.g., medicinal claims in cosmetics contexts)
- **Context Dependencies:** Terms with different regulatory meanings based on product category or intended use

3. Terminology Management for Regulatory Compliance

Inconsistent terminology across regulatory submissions represents the primary cause of compliance queries, approval delays, and post-market surveillance issues. Effective terminology management requires treating regulatory language as structured data rather than simple translation equivalents.

3.1 Knowledge Graph Approaches to Regulatory Terminology

Traditional terminology databases struggle with regulatory complexity because they model terms as isolated pairs rather than interconnected regulatory concepts. Knowledge graphs provide superior architecture for regulatory terminology because they preserve relationships between ingredients, classifications, restrictions, and market-specific requirements.

Core Knowledge Graph Components

An effective regulatory knowledge graph connects:

- **Ingredient Entities:** INCI names linked to CAS numbers, EC numbers, chemical synonyms, and trade names across all languages
- **Regulatory Classification Nodes:** Annex categories, substance lists, functional classifications, and product category definitions
- **Restriction Relationships:** Maximum concentrations, prohibited combinations, usage conditions, and labeling requirements linked to specific ingredients and product types
- **Market-Specific Variations:** Regional naming conventions, alternative ingredient listings, and jurisdiction-specific compliance requirements
- **Claim Substantiation Links:** Approved claim language connected to required evidence types and validation methodologies

4. Quality Assurance and Validation Protocols

Regulatory quality assurance extends far beyond standard linguistic review. Validation must verify regulatory accuracy, compliance with submission requirements, and consistency across all related documentation.

4.1 Multi-Layer Validation Framework

Implement sequential validation layers that address distinct quality dimensions:

Layer 1: Automated Terminology Validation

Deploy automated checking for:

- INCI name accuracy against approved ingredient databases
- Consistency of ingredient names across PIF, CPNP, and labeling
- Forbidden terminology detection (medicinal claims, unapproved efficacy language)
- Measurement unit accuracy and decimal separator compliance
- Cross-reference validation between sections

Layer 2: Regulatory Affairs Review

Subject matter experts validate:

- Claim language alignment with substantiation documentation
- Compliance with market-specific regulatory frameworks
- Accuracy of regulatory classification statements
- Correct interpretation of Annex restrictions and usage conditions
- Completeness of safety assessment translations

Layer 3: Linguistic Quality Assurance

Professional linguists verify:

- Grammar, syntax, and target language fluency
- Stylistic appropriateness for regulatory documentation
- Cultural adaptation where appropriate without altering regulatory meaning
- Formatting compliance with submission requirements

Multi-Layer Validation Framework

Regulatory Localization Quality Assurance Process

- 9 -

1

Automated Terminology Validation

Deploy automated checking for:

- ✓ INCI name accuracy against approved ingredient databases
- ✓ Consistency of ingredient names across PIF, CPNP, and labeling
- ✓ Forbidden terminology detection (medicinal claims, unapproved efficacy language)
- ✓ Measurement unit accuracy and decimal separator compliance
- ✓ Cross-reference validation between sections

2

Regulatory Affairs Review

Subject matter experts validate:

- ✓ Claim language alignment with substantiation documentation
- ✓ Compliance with market-specific regulatory frameworks
- ✓ Accuracy of regulatory classification statements
- ✓ Correct interpretation of Annex restrictions and usage conditions
- ✓ Completeness of safety assessment translations

3

Linguistic Quality Assurance

Professional linguists verify:

- ✓ Grammar, syntax, and target language fluency
- ✓ Stylistic appropriateness for regulatory documentation
- ✓ Cultural adaptation where appropriate without altering regulatory meaning
- ✓ Formatting compliance with submission requirements

✓ **Submission-Ready Documentation**

Regulatory compliant, linguistically accurate, audit-ready

5. Selecting Regulatory Localization Partners

Vendor selection represents one of the highest-impact decisions in regulatory localization. Choosing partners based purely on translation credentials rather than regulatory domain expertise is the primary predictor of market entry delays and compliance issues.

5.1 Essential Qualification Criteria

Regulatory Domain Expertise

Verify that potential vendors demonstrate:

- Documented experience with EU Regulation 1223/2009 and jurisdiction-specific equivalents
- In-house regulatory affairs reviewers or established partnerships with regulatory consultants
- Track record of successful submissions with first-time approval rates
- Understanding of PIF structure, CPNP workflows, and safety assessment requirements
- Familiarity with ingredient databases (CosIng, INCI nomenclature, Annex classifications)

Terminology Management Infrastructure

Assess vendors' terminology capabilities:

- Centralized terminology management systems with regulatory metadata
- Pre-built glossaries for cosmetics ingredients, regulatory terms, and claim language
- Automated terminology validation integrated into translation workflows
- Capacity to build and maintain client-specific regulatory termbases
- Knowledge graph or similar advanced terminology architecture

5.2 Risk Assessment Questions

During vendor evaluation, ask specific questions that reveal regulatory competence:

- How do you ensure INCI name consistency across PIF sections, CPNP notifications, and product labeling?
- Describe your process for validating that translated claim language aligns with substantiation evidence tiers.
- What automated checks do you perform to detect prohibited ingredients or concentration violations?
- How do you handle situations where EU and FDA terminology diverge for the same ingredient or claim?
- Who on your team reviews safety assessment translations, and what regulatory credentials do they hold?
- Provide examples of how you have identified and prevented compliance issues before submission.

6. Common Pitfalls and Prevention Strategies

Analysis of regulatory submission delays and rejections reveals recurring failure patterns. Understanding these pitfalls enables proactive prevention rather than reactive correction.

6.1 Ingredient Name Inconsistencies

The Problem:	The same ingredient appears with different names across PIF sections, CPNP notification, and product labeling. Common variations include INCI name vs. chemical name, trade name vs. generic name, or inconsistent use of prefixes and suffixes.
Prevention:	
	1. Establish a master ingredient list with approved INCI nomenclature before translation begins
	2. Lock terminology for all ingredient names in translation memory and terminology systems
	3. Implement automated cross-document verification that flags any deviation from master list
	4. Require that translators use CosIng database as definitive reference for EU submissions

6.2 Claim Language Over-Translation

The Problem:	Translators adapt claim language for cultural fluency or marketing appeal, inadvertently creating claims that exceed substantiation evidence or trigger medicinal classification.
Prevention:	
	1. Classify claims by substantiation tier and restrict translation freedom accordingly
	2. Provide translators with claim substantiation documentation to understand evidentiary basis
	3. Maintain blacklists of prohibited terminology that triggers regulatory classification changes
	4. Require regulatory affairs review of all efficacy and performance claim translations

6.3 Concentration and Measurement Unit Errors

<p>The Problem:</p>	<p>Decimal separator conventions differ between markets (period vs. comma), percentage vs. fraction notation varies, and concentration units require precise conversion. Translation errors in numerical values create immediate compliance failures.</p>
<p>Prevention:</p>	
	<p>1. Establish market-specific formatting guides for numerical values and measurement units</p>
	<p>2. Implement automated validation that flags inconsistent decimal separators within documents</p>
	<p>3. Require parallel verification where source and target numerical values are checked independently</p>
	<p>4. Lock numerical values in CAT tools to prevent inadvertent modification during translation</p>

7. Implementation Checklists

The following checklists provide actionable frameworks for implementing regulatory localization best practices within your organization.

7.1 Pre-Project Regulatory Assessment Checklist

Complete this assessment before initiating any regulatory localization project:

- Identify all target markets and confirm regulatory framework for each jurisdiction
- Classify all documents by regulatory risk level (Critical, High, Medium, Standard)
- Compile master ingredient list with INCI names, CAS numbers, and regulatory status
- Map all product claims to substantiation documentation and evidence tier
- Identify market-specific terminology requirements and naming conventions
- Determine formatting and submission requirements for each regulatory authority
- Establish validation workflow appropriate to document risk classification
- Confirm availability of regulatory affairs reviewers for target markets
- Verify that terminology resources exist for all critical regulatory concepts
- Document all compliance-critical dependencies and cross-references between files

7.2 Vendor Qualification Checklist

Use this checklist to evaluate potential regulatory localization vendors:

- Request client references for cosmetics/dermocosmetics regulatory submissions
- Verify credentials of regulatory affairs reviewers (education, certifications, experience)
- Review sample terminology databases to assess regulatory metadata and structure
- Request documentation of quality assurance protocols for regulatory translation
- Confirm ISO 17100 certification or equivalent quality management standards
- Evaluate technology infrastructure (CAT tools, terminology systems, validation automation)
- Assess capacity to scale for multiple markets and product lines simultaneously
- Verify understanding of CPNP workflows and PIF structure requirements
- Request submission success rate data (first-time approvals vs. revisions required)
- Confirm availability for urgent regulatory queries and post-submission support

7.3 Pre-Submission Validation Checklist

Complete this validation before submitting regulatory documentation:

- Verify all ingredient names match CosIng database exactly (EU) or appropriate national database
- Confirm ingredient order matches formulation declaration across all documents
- Check that concentration values use correct decimal separators for target market
- Validate that all claims align with substantiation documentation language
- Confirm no medicinal or therapeutic claims appear in cosmetics documentation
- Verify restricted ingredient concentrations do not exceed Annex III limits
- Check that required warnings and usage instructions are complete and accurate
- Confirm Responsible Person contact information is consistent across all filings
- Validate formatting compliance with submission platform requirements (CPNP, etc.)
- Conduct final regulatory affairs review by qualified subject matter expert

Conclusion: From Compliance Burden to Strategic Advantage

Regulatory localization, when executed with domain expertise and systematic rigor, transforms from a compliance obligation into a competitive advantage that accelerates global market entry and reduces operational risk.

Organizations that implement the frameworks outlined in this guide achieve measurable improvements:

- Faster time-to-market through first-submission approval rates exceeding 95%
- Reduced compliance risk from systematic terminology management and validation protocols
- Lower total cost of ownership through prevention rather than correction of compliance issues
- Scalability to support simultaneous multi-market expansion without proportional resource increases
- Enhanced regulatory relationships built on consistent, high-quality submissions

The distinction between commodity translation and regulatory localization expertise becomes evident at the point of submission. Organizations that recognize this distinction early gain months of market advantage over competitors still treating compliance documentation as general content.

Next Steps

Implementing regulatory localization best practices requires organizational commitment, process design, and partnership with vendors who possess genuine regulatory domain expertise.

Immediate actions to strengthen your regulatory localization program:

1. Audit current localization workflows using the risk classification framework in Section 2
2. Assess vendor regulatory expertise using the qualification checklist in Section 7.2
3. Build master ingredient termbase with INCI nomenclature and regulatory metadata
4. Establish validation protocols appropriate to document risk levels
5. Implement automated terminology checking for compliance-critical documents

For organizations seeking expert guidance in regulatory localization strategy:

Viveta Gene Intertranslations S.A.

Global Localization Solutions for Regulated Industries

Email: v.gene@intertranslations.com

Web: www.intertranslations.com

Schedule a consultation to discuss your regulatory localization requirements: