
accenture
Accenture
Regulatory
Capabilities

Accenture Life Sciences Regulatory Practice

Our Regulatory Practice at Accenture is comprehensive, including innovative consulting experience, proven-digital/technology capability, and industry-leading operations services

Strategy / Consulting

- Technology / Data strategy and roadmap
- Operating model optimization
- Diagnostic process and business assessment
- Program and change management
- Regulatory compliance assessment and remediation programs (CMC, Labeling)
- IDMP assessments and data collation
- Defining AI & automation strategy
- Training strategy & execution
- Perspective on digital thread

Technology

- Data hub and analytics transformation
- Technology strategy road mapping
- RIM system implementation and maintenance
- Regulatory automation engineering
- Authoring templates (StartingPoint)
- Generative AI-based large language model submission authoring

Operations

- Major and LCM submission management and production
- Regulatory Affairs submission/strategy consulting
- CMC and Labeling management (incl. authoring, change coordination)
- Document formatting
- Data management services
- Medical writing
- Staff augmentation ….

Providing solutions for 23+ years

Over 200+ clients

Experience in 90+ countries

4 Global Delivery Centers

Emerging Markets Strategy & Consulting *(Generative AI, Cell Gene Therapy Workforce for the future etc.)*

250+ skilled Regulatory Professionals

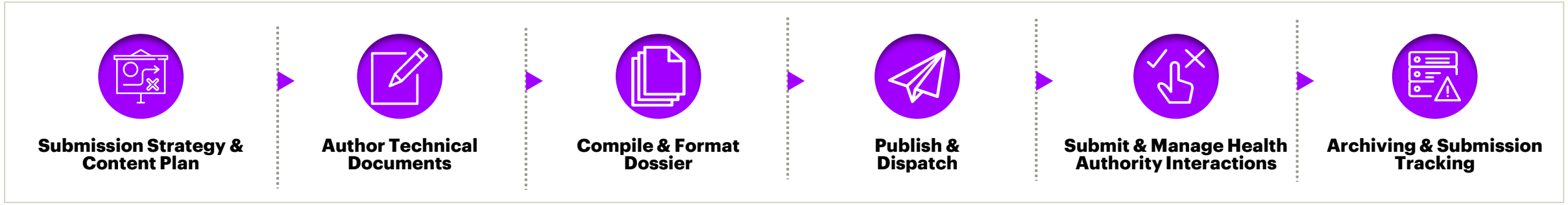
Experience in major Technologies – Veeva RIM Partner

Active Professional Membership Participation

Regulatory Offerings for Biopharma

Providing Regulatory services for 23+ years

Regulatory Process, Tools & Experience



StartingPoint® TrackWise DIGITAL evermap ViewPoint® SAP PLM LORENZ eValidator

LIQUENT InSight® eCTDmanager™ LORENZ docuBridgeFIVE <oXygen/> XML Editor BLUE Veeva

E2E Project Management and Oversight

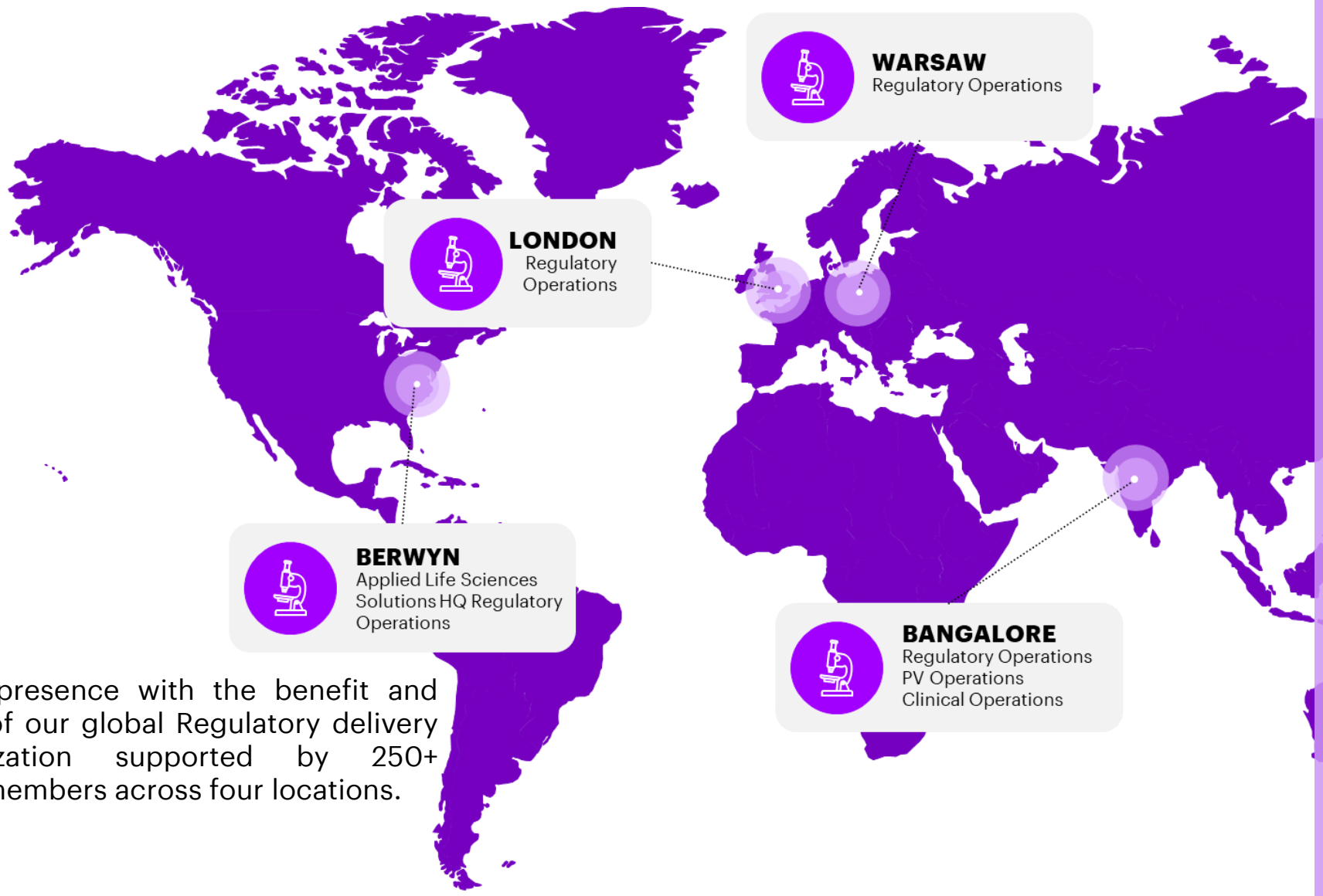
- HA meeting and information requests
- Submission planning
- Gap analysis
- Meeting support
- Change assessment

- CMC management (incl. gap assessment, authoring, review, change coordination)
- Labeling management (incl. gap assessment, authoring, review, change coordination)
- StartingPoint Templates

- Regulatory document authoring, submission document formatting & publishing
- Medical Device application management (compilation, formatting & publishing, dispatch, archiving & tracking)
- Clinical Trial Regulations (CTIS | CTIM)

- Structured Product Labeling (SPL) services
- Major (original) and lifecycle submission management (Variations, Annual Reports and License Renewals) for US and ROW markets
- Regulatory IDMP

Our Global Footprint



Local presence with the benefit and scale of our global Regulatory delivery organization supported by 250+ team members across four locations.

Regulatory Affairs Submission/ Strategy Consulting

- Clinical development strategy
- Global drug registration strategy
- Scientific advice and agency meetings
- Lifecycle Management (LCM) strategy
- Regulatory intelligence

Regulatory Compliance & Data Management

- CMC and Labeling management (including Reference creation, gap analysis, authoring, change control coordination data remediation, and maintenance)
- EMA Article 57 and EMA Policy 70 compliance
- IDMP Readiness Assessment & Compliance
- Labeling and Artwork review

Major & LCM Submissions Management and Production

- Full spectrum of pre-authorization and post-authorization submissions for all global markets
- Product registrations for consumer goods.
- Submission activities include:
  - Submission planning and project management
  - Authoring and collating documentation
  - Compiling a submission package
  - Document-level publishing
  - Submission-level publishing
  - eCTD/NeeS/PDF/paper format preparation, dispatch, archiving, and tracking

Overall Regulatory Services – Factsheet

2,650+
SPL transactions
(Jan. 2012 to date)

Provided strategic registration advice to
~50 companies

23+
Years
of Regulatory Operations Experience

250+
skilled Regulatory professionals

26+
therapeutic areas

4,000+
xEVMPD messages
(Sept. 2013 to-date)

1,000+
CMC dossier
baselines established

~1,500
Product renewals submissions annually across the globe

10,000+
Health Authority Submissions annually

5+ Enterprise-scale RIM Implementations for Tier-1 clients

1,000+
original filings
(IND, NDA, BLA, MAA, etc.)

120K+
Artwork / Labels reviewed

54K+
Products registered

10+
Languages Supported
for consumer goods' product labeling compliance

Zero
Regulatory Inspection Findings

Submissions experience in
90+
countries

Our Regulatory Operations Services

Submission Management

Creation and **management of Dossier Plan(s) / Submission Packages** in line with regulatory strategy, providing regulatory guidance during the drug development process to enable on-time and compliant submissions **by liaising with multiple stakeholders across functions.**

Document Publishing

Document Publishing / Submission Readiness services include **formatting of Word files and publishing (bookmarking and hyperlinking)** for all eCTD document types (Clinical, Safety, Regulatory, CMC), and Clinical eCRF documents as well as handling of Regulatory Data Management Systems, in compliance with Regulatory guidelines.

Submission Publishing

Our services include submissions to global regulatory authorities during the drug development, approval and post-approval phases in **eCTD, CTD, or NeeS formats** using **in-house /external industry-leading publishing tools** and technology that adhere to regional and ICH standards.

Structured Product Labeling (SPL)

Structured Product Labeling services include Human Prescription, **Drug Labeling Conversion and updates, Bulk Product Listing, Establishment Registration, Deregistration**, No Change Notification, NDC Labeler Code Request, Blanket No Change Notification, Lot Distribution Reports along with publishing and dispatch to the Health Authority.

Clinical Trial Data Transparency / Redaction Services (EMA Policy 0070 & HC PRCI)

Accenture provides redaction services to our clients as per HA guidelines for **EMA and HC PRCI** regions. This includes **draft redaction markings** for client / HA review and feedback, final redaction of documents, deletion and insertion of replacement pages, cover letter, Justification table, and anonymization report.

Our Regulatory Affairs Services

Chemistry, Manufacturing and Controls (CMC)

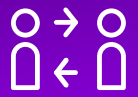
CMC authoring, review and submission of **quality modules** for pre-clinical/ investigational, marketing authorizations (New & Generic Drug Applications) and post-approval lifecycle management of marketed products across globe.

Lifecycle Management (LCM)

Supports pharmaceutical and biotech companies in keeping the **registered dossier up to date** as per country and region-specific regulatory requirements throughout the **product lifecycle** through Annual Reports/Renewals and Supplements/Variations submissions and line extensions etc.

Labeling

Labeling management services include preparation of Company **Core Data Sheet (CCDS)/ Company Core Safety Information updates** and management of labeling changes to safety, local product and lifecycle management procedures.



US Agent Services

US Agents and Liaison services for Health Authority communications on behalf of Sponsor/Client projects with the FDA. Our agents facilitate communications between sponsor/client and FDA teams, and provide regulatory strategy support, including **regulatory guidance** for market authorization and post-market approval development of global regulatory submissions.

Clinical Trials Regulation (CTR) Services

With **CTR now in full force** for all initial clinical trials submitted in the EU, Accenture can help you with your clinical trial submission across the board starting with assisting with your regulatory filing strategy, authoring key documents for the clinical trial submissions, right through to navigating the new **Clinical Trial Information System (CTIS)** and setting up your organization with the requisite user roles.

Identification of Medicinal Product (IDMP)

Helps pharma and emerging biopharma companies in assessing their **IDMP readiness** across data management of CMC, clinical, non-clinical and supply chain by applying global data standards as per ISO 11616, 11238, 11239 and 11240, data governance, technology implementation, process, and change management.

Our Medical Writing Services

Clinical Writing

Clinical Protocols
- Strategic Study Design, Synopsis, Protocol writing
- Informed Consent Form

Clinical Study Reports
- Full, Abbreviated, Interim, and Synoptic
- CSR Appendices compilation

eProgrammed Patient Narratives
- Authoring and peer review using AI Tools
- Data QC and Medical review

Lay summaries
- Content and Infographics

Strategic Consultancy

Investigator's Brochures
- First Version IBs, Periodic updates, and Amendments

Briefing Documents
- Regulatory authority meetings
- Scientific advice

Pediatric investigation plans
- EU PIP
- USA PSP

Orphan Drug Designation
- EU/US
- Sections A to E

Applications for special consideration
- Breakthrough Therapy Designation
- Fasttrack Designation

Regulatory Writing (Dossier support)

Clinical Overviews and **Summaries** (Module 2.5 and 2.7)

Non-Clinical Overviews and **Summaries** (Module 2.4 and 2.6)

ISS and **ISE** (Integrated analyses)

Labels
- CCDS, CCSI, SPC, PI, PIL, Medication Guide
- Label Harmonization

Renewals and Variation filings
- Standalone CO, NCO
- Clinical Expert Statements

Real World Studies

PMS Studies
- Phase IV protocols and reports
- PASS protocols and reports
- REMS Protocols and Assessments

Outcomes Research Studies
- Disease Burden studies
- Drug Utilization Pattern studies
- Switching and Dosing Studies

Scientific Communications

Manuscripts and Review Articles
- Primary publication
- Meta-analysis and Systematic Review
- Resubmissions and Responses to reviewers

Abstracts, Posters, Oral Presentations

Newsletters

Slide Kits

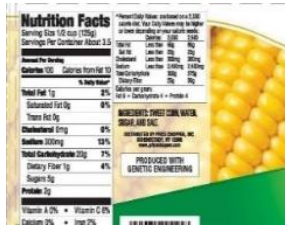
Product monographs

Product brochures

Web content

R&D Offerings for Consumer Products

Accenture provides robust set of R&D Services for Consumer Goods Clients



ANVISA
Agência Nacional de Vigilância Sanitária

FDA

Labeling	Artwork	Registrations	Supplier	Spec Data Mgmt.	Cosmetovigilance
• This is the process of entering data to create the label as part of the Labeling process for the client products • Raw material and formula/recipe entry in client tools • Provide inputs to create master specification for foods and refreshment products • **Nutrition Label Reform –** updates to the nutrition facts panel based on new regulations	• Artwork is the translation of the brand key into a visual representation of what the consumer will see on the shelf, designed and owned by Client • Principal display panel (PDP), Information Panel & Alternate Principal PDP are reviewed against master specification • If the Artwork is compliant, high resolution Artwork Files are created for Printout and Approvals	• The Registration Process is a process of Product registration, which requires a set of documents to be submitted to authorities. It is a mandatory premarket approval abiding by laws and regulation in the country of sale • Document Collection, Reception & reviewing of documents • Filling online / manual registration forms • Dossier Preparation & Submission & receiving registration number	• Process includes reviewing of ingredient data, information and documents from suppliers to determine if ingredients are approved for use within a country • Verifying that mandatory information is provided by suppliers in accordance with the requirements • Review / verification is the confirmation that data entered into the Client template is consistent with the corresponding Client SOP and supporting documents	• Centralized Spec data management services to ensure ongoing maintenance and monitoring of data quality in the following data domains: product, supplier, packaging • Product / BOM: Ensures alignment of BOM across network • Supplier: Ensure quality of ingredient information from suppliers • Packaging: Ensures quality of packaging data	• Accenture provides end-to-end Individual Case Safety Reports (“ICSR”) management services, including Case Processing in safety database and further follow-ups and query mgmt. • Accenture offers authoring and review of various Aggregate reports • Accenture handles Product Enquiries / Medical Enquiries and Product Quality Complaints (PQC) received from call center and other sources (Client websites, email etc.)

Supported by Quality Management System

Regulatory Submissions Support – seamless project ramp-up and noiseless delivery

A top multinational biopharma company was in the market for a Regulatory submissions support vendor able to handle higher submission volumes along with a higher focus on quality delivery and better customer service.

Accenture provided an integrated regulatory submission service supporting product lifecycles from early Pre-IND planning phase through the submission of marketing application, along with post-marketing support for the client's global portfolio. We process 1000+ electronic regulatory submissions annually, managing large fluctuations in volume and accommodating mid-stream updates, while maintaining SLAs.

We established workflow management, cross-skilled & cross-certified the pool of resources for handling global submission to HAs and integrated a Quality Management System with continuous learning to ensure constant upskilling of workforce. We were able to streamline the process by proactively identifying the pain points and mitigations strategy for seamless delivery.

100%
For TAT compliance

<1%
Errors calculated monthly

1000+
Submissions annually

13+
Unique countries supported so far, and growing

2
Accenture Delivery Centers – Berwyn & Bangalore

Regulatory Submissions Support – seamless end-to-end submission process with high compliance

A top multinational biotechnology company, with a portfolio of 48 compounds/products, was in the market for a partner with higher quality delivery and better customer service, within stringent timelines.

Accenture provides an integrated regulatory submission service supporting product lifecycles from the early Pre-IND planning phase through the submission of a marketing application and post-marketing support for a diverse global portfolio. We process over 500 regulatory submissions annually in all formats as per predetermined timelines.

We collaborated with all stakeholders to prepare submission forecasts, and established workflow management to facilitate better planning and execution of submission-related activities. We implemented a robust quality system that ensured continued compliance and efficiency of 100% to client's SLA during the contractual period.

99.9%
For TAT compliance

<1%
Errors calculated monthly

500+
Submissions annually

60+
Unique countries supported so far, and growing

4
Accenture Delivery Centers – Berwyn, Bangalore, London & Warsaw

Regulatory Renewals – Seamless end-to-end Regulatory Project Management Support

A top multinational pharmaceutical company, with a portfolio of ~1400+ renewal submissions annually, was in the market for a partner with higher quality delivery and better customer service.

Accenture provides dedicated Staff Augmentation regulatory project management as part of lifecycle, which includes planning and coordination of renewal submissions for their marketing application(s) for a diverse global portfolio.

We collaborated with all stakeholders to prepare and complete submissions based on advanced forecasts, and established workflow management to facilitate better planning and execution of renewal submission-related activities. We implemented a robust quality system that ensures continuous compliance and efficiency of 100% to client's SLA.

99.9%
For TAT compliance

14 FTE

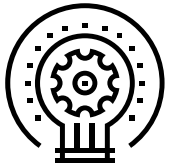
~1400+
Renewals annually

~108
Countries

Automation
driven Operations

Regulatory Innovation Services & Automation

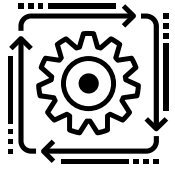
Regulatory Innovation Services



Challenging orthodoxies and shaping the future

- Breakthrough design thinking workshops
- Ideation workshops
- Prototyping workshops
- MVP and prototype development
- Ecosystem & co-development partnerships

Regulatory Automation



Transforming regulatory through automation

- Robotics capability assessment
- Process automation assessment
- Robotics operating model design
- Online labeling
- Submission content authoring using generative AI
- Patient information leaflets

Global Pharma Company: Next Generation Labeling

Business Background and Challenge

- This Next Generation Labelling capability project was initiated to improve pharmaceutical labeling and patient safety for a large global bio-pharma company.
- The project objective was to provide a smarter approach to pharmaceutical labeling, offering end-to-end traceability, and taking steps toward enabling both patients and healthcare professionals to have access to the most current, accurate, and relevant product information – faster than ever before.

How Accenture Helped

- Accenture hosted a four-day design sprint that brought industry and technology experts to reimagine the art of the possible.
- Design thinking methodology was leveraged to move from problem statement to rapid prototype.
- The prototype involved:
  - Digitizing labeling documentation into defined data fields
  - Using client data to mature the data model
  - Obtaining human-centered insights on tool functionality and system interface
  - Testing, learning and iterating on the prototype from user testing

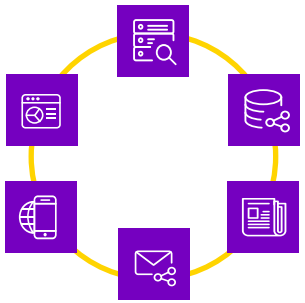
Client Value Added

- Re-imagined the art of the possible for next generation labeling that is comprised of six key components. Note: project is still ongoing to continue to build and scale.

Trigger Management
Natural language processing (NLP) and machine learning (ML) trigger review processes.

E2E Labeling Dashboards
Dashboards provide E2E visibility and traceability to cross-functional stakeholders.

Label Availability
Once approved, local label content is available to all stakeholders in the cloud.



Core Data Creation and Storage
Product information is stored as a collection of data elements. Artificial intelligence (AI) recommends updates.

Local Label Management
AI and ML recommend local label updates. Affiliates review, edit or accept the recommendation, which is shared with HQ.

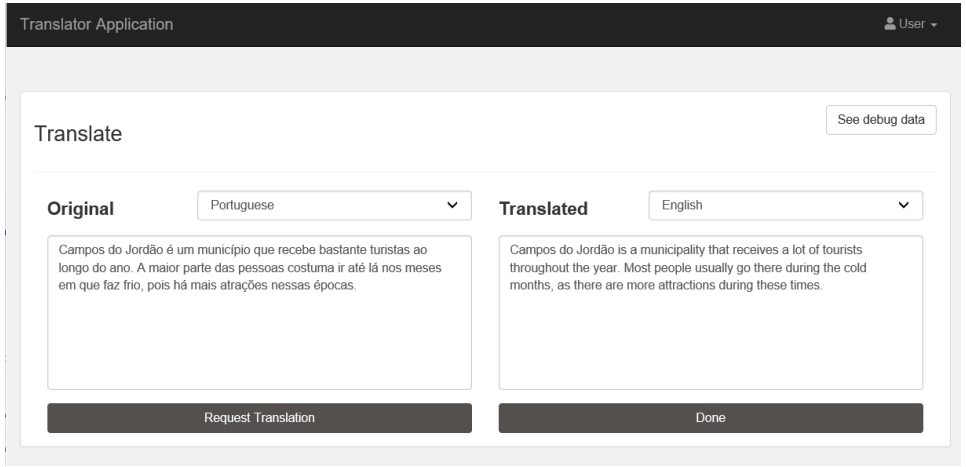
Health Authority Tracking
Robotic process automation (RPA) enters HA correspondence into registration tracking.

Automated Translation Tool

Fast, consistent, clinical-domain translations reduce costs

Business Challenge

Translation is mandatory and costly. Machine translation is available from many vendors, but the clinical domain is challenging for out-of-the-box machine translation solutions.



Accenture Approach

A simple translation service deployed as a modern Serverless solution using state-of-the-art Neural Machine Translation (NMT) from Google, trained using clinical text samples from existing PV cases.
NMT service learns from agent's edits to improve the service over time.

Key Outcomes / Benefits

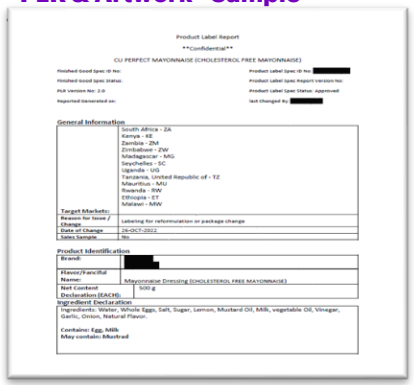
Dramatically shorten translation time in the in-case intake process. **15% reduction** in case handling time.
Consistent translation quality—**80%** of automated translations are passed on with minimal human editing.
Gateway to further automation solutions based on text mining.

iACTIVATE makes the perfect tool for transforming R&D operations into a digital platform

Business Challenge

Artwork Proofreading is the process of verifying the accuracy of the agreed graphic elements against the necessary documentation inputs (e.g., PLR), including Nutrition Values, Nutrient Names, Ingredient line, Net Weight, Grammar, Spelling, etc.

PLR & Artwork - Sample

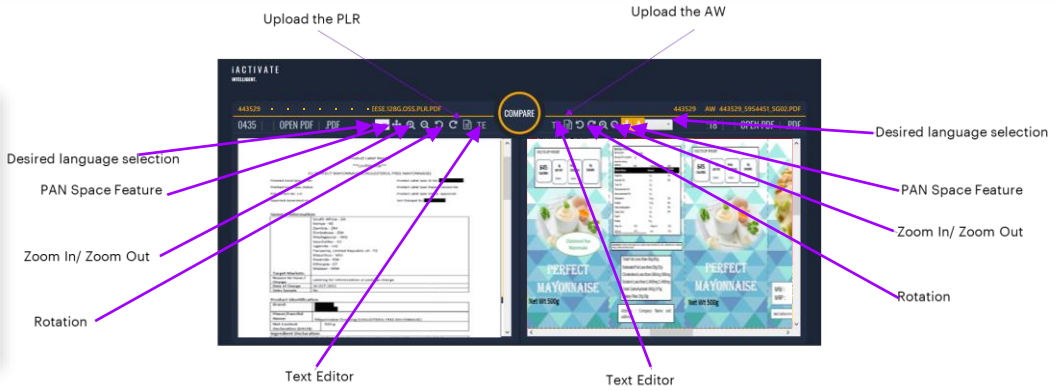


Challenges:

- Review prone to manual errors due to very miniscule & cluttered text which is difficult for human eyes to identify
- Increased processing time as reviewer would need to find deviations & errors in Artwork manually
- Multi-lingual Artworks (combination of 2 or more languages) also increases the processing time and complexities
- Critical errors would cost the client Brand erosion, Financial penalties & Product recalls

Accenture Approach

Accenture developed an AI-based tool – **iACTIVATE,** which is



Key Outcomes / Benefits

iACTIVATE:

- Improved Accuracy & faster processing time due to automated Artwork review
- 40% efficiency gain realized with the implementation of iACTIVATE
- Is a language-agnostic tool & can process multi-lingual Artworks
- Character-to-Character comparison of artwork against the PLR
- Provides summary of comparison, enabling consolidated view of edits to be performed
- Auto Compare using Pattern matching will enable you to spot differences between two images
- Overall, it leads to higher savings and better regulatory compliance for the client