Insight Brief

IQVIA Labeling Compliance Solutions

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Introduction

Label compliance is the process of verifying that a product label fulfills all health authority (HA) regulations, industry standards, and is error-free.

Drug labeling includes the data from clinical information and core safety information (Company Core Data Sheet – CCDS) of a drug product. This core label information is frequently implemented as a regional label, including product information, patient information leaflets, and artworks (primary container labels and cartons).

Regulatory labeling compliance is crucial to ensure the safe and effective use of drugs and devices. The challenge is that regulatory labeling requirements vary country by country, and new regulations are implemented regularly to update labeling documents.

To ensure seamless and risk-free regulatory implementation of labeling, it is essential that the company has a strategy for 'core-to-carton' compliance.

Compliance errors can lead to the following risks for a patient and a company:

- Patient safety and misuse of the drug
- Product recalls
- Costs of drug recall and fines
- Damage to the brand image
- Resource and time loss

"Regulatory labeling compliance is crucial to ensure the safe and effective use of drugs and devices."

Labeling strategy and preparation

Our labeling subject matter experts (SME) conduct an initial assessment of labels to evaluate requirements and assist customers in understanding labeling standards and best industry practices.

IQVIA has specialized roles and expertise for labeling requirements across the globe.

Our labeling experts can support creating first-to-file labels, CCDS from Investigator Brochures (IBs), regional label implementations, harmonizing the CCDS with local labels, and gap assessments for legal entity changes, including divestments, marketing authorization transfers, and mergers and acquisitions.

For first-to-file labels, knowledge of competitors and same-class drugs plus regional knowledge is of high importance to develop the strategy for label creation and submission.

IQVIA's innovative technology and labeling expertise go hand in hand to offer a robust strategy to the customer to ensure compliance of the highest standard.

Our labeling subject matter experts (SME) conduct an initial assessment of labels.

Figure 1: A global labeling resourcing model

• **Global Labeling Lead (GLL)**	Manages authoring and coordinates the review of core and local labels, manages HA queries, works with local RA and labeling working group to provide guidance on local exceptions or deferrals to CCDS
• **Global Labeling Assistant (GLA)**	Responsible for dispatch and tracking of approved CCDS to local countries, maintenance of labeling systems, and QC/formatting of RSI and local labels
• **Labeling compliance specialist**	Supports inquiries/audits from third parties, tracks and reports global labeling metrics, and dependency/deferral requests/reminder emails on submission due dates for GL tracking events
• **Global regulatory operations specialist**	Supports and coordinates labeling operations such as SPL, coordination for translations, artwork proofreading and QC as per QRD and artwork management
• **Labeling subject matter experts**	Provides support for ad hoc labeling projects such as labeling consulting, labeling intelligence, and strategic consulting, and review of labels or artwork, promotional materials, etc.

THE IQVIA LABELING INTELLIGENCE HUB

Using natural language processing (NLP) and artificial intelligence (AI), the IQVIA Labeling Intelligence Hub can help in understanding and analyzing the labels for a class or group of drugs within FDA drug labels, EMA drug labels, and French and Spanish labels to arrive at a target product profile or first-to-file label and helps in competitor label analysis.

Key features of the Labeling Intelligence Hub:

- Quickly screen labels for a class or group of drugs within one source or across sources.
- Effective search for labels for products with similar attributes, such as mechanisms of action or pharmacokinetics.
- Extracts adverse reactions and normalizes them for analysis.
- Identifies label content to help in the development of label strategies for improved regulatory acceptance.
- Side-by-side comparison of labels to quickly understand competitive products, accelerate approvals and develop new labels.

The IQVIA Labeling Intelligence Hub can help in understanding and analyzing the labels for a class or group of drugs.

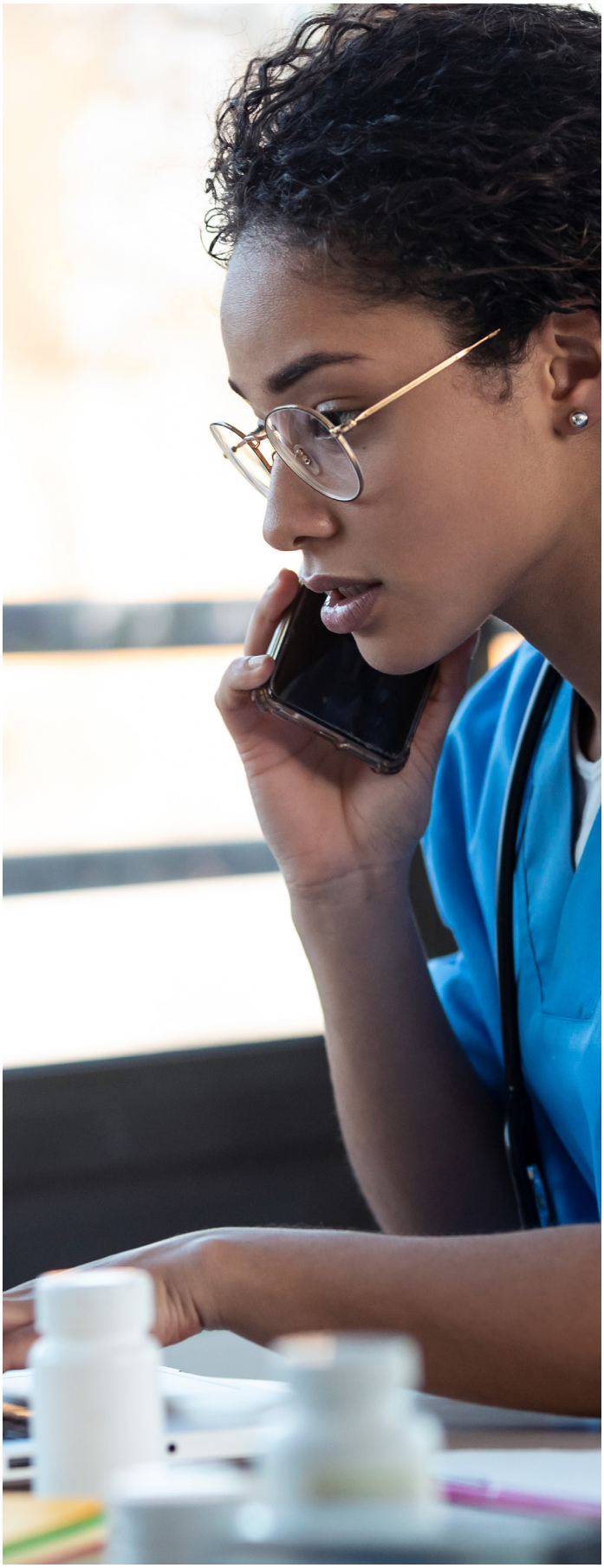

Figure 2: Text mining of drug labels

Regulatory labeling

Informed and data-driven life cycle management of existing product portfolio for key country labeling. Ensure products can be used safely by patients. Align global and local regulatory strategies to meet regulatory and business requirements

Safety

Drug labels contain summaries of drug-related adverse events from preclinical and clinical development and post-market surveillance. This landscape of safety data is valuable for safety teams to understand the context of any particular signal, enable predictive risk models, compare ADRs for drugs in same class, and more

Medical

Medical affairs teams communicate the real-world benefits and use of product to prescribers, where label information can be combined with real-world evidence, published research, and safety information for a holistic view

Brand and therapy area

Understand efficacy, evidence, safety, administration, patient age, and specific populations factors that affect prescribing behaviors and feed insights into therapy area strategy, evidence planning, label authoring, and expansion

Regional labeling management

The major challenge while implementing local labels is defining proper key performance indicators (KPIs) and ensuring an excellent-quality document, e.g., regulatory-compliant documents within the stipulated timelines.

IQVIA has expertise in understanding the KPIs and knowledge of clock start and clock stop at each step. The major KPIs tracked by IQVIA are:

- Timely completion of CCDS review and update
- Timely implementation of CCDS update in local labeling
- Timely update of customer/internal tracking systems
- Timely implementation of updates of artworks
- Tracking of Deferrals and Local Label Deviations
- Notifying the changes to relevant stakeholders

The IQVIA team works well in advance, taking the end-to-end process into consideration, e.g., from core to carton implementation, to ensure risk-free/error-free supply chain continuity.

In the case of labeling variations and label updates, ensuring supply chain continuity is the major challenge because supply chain planning must be done well in advance to avoid out-of-stock situations in a market. IQVIA's regulatory intelligence tools help customers understand the various aspects of supply chain continuity (e.g., approval timelines/sales bans/import bans of old stocks) to ensure the availability of the drug product in different markets in case of label updates.

IQVIA's regulatory intelligence tools help customers understand the various aspects of supply chain continuity.

Gap analysis and review of labeling documents

Gap analysis and label mapping is one of the critical activities for periodic updates of CCDS, implementation of CCDS updates in local labels, and performing an impact analysis of HA queries.

Performing a manual mapping, comparison, gap analysis, and QC of labeling documents in multiple languages can be tiresome.

It is quite easy to miss information when processes are manual and repetitive, which are prone to mistakes and QC errors. The higher the volume, the higher the chances of such mistakes and QC errors.

IQVIA'S LABEL COMPARE FOR COMPLIANCE (LCC)

LCC digitizes the labels and maps them against a base component structure, making it easy to compare multilingual and multiregional labels in one view. Using NLP and AI, along with Multilingual, Multiregional, and Multilabel (3M) comparison attributes, the LCC tool will help to reduce the risk of compliance error to near zero.

IQVIA's Label Compare for Compliance digitizes the labels and maps them against a base component structure.

TEXT PROOF

Text Proof can compare Word documents, PDF documents, RTF documents, or OpenOffice documents with each other.

Key features of Text Proof:

- **Text flow**
  Text Proof ensures that the text in both documents is always in the same order and that no text, letters, or characters are incorrectly placed.
- **Text attributes**
  Text Proof finds and lists formatting changes such as bold, italic, underline, superscript, subscript, font, etc.
- **Pictograms**
  During comparison, pictograms are recognized and classified.
- **Text areas excluded**
  Text Proof can automatically exclude non-relevant areas from the comparison (e.g., bullets, hyphenation, page numbers, quotation marks, etc.).
- **Comparison workflows**
  Text Proof can perform multiple comparison workflows, flow text, QRD documents, and one-to-one and one-to-many comparison.
- **Languages**
  Text Proof supports all Unicode languages.
- **Reports**
  Users can comment on all errors found during the comparison. Once the process is complete, a standard report can be created to show any discrepancies, or an annotated PDF report can be created highlighting all notes taken during the inspection process.

PIXEL PROOF

Pixel Proof is an easy-to-use proofing system for visual version control of artwork, mockups, and print-ready packaging material.

Key features of Pixel Proof:

Applications

- Folding boxes
- Leaflets
- Labels
- Tubes
- Foils
- Booklets
- Artwork
- Multiple printed panels
- Impositions

Features

- Workflow-based software (process-driven)
- High performance due to multiprocessing and multi computing
- Multipage document against multi-scan
- Integration with document management systems via plugins
- Integration into different workflow systems
- Innovative, customizable reports
- Batch validation
- Multiple error processing

Functions

- Graphic text and color check
- Barcode and 2D codes analysis
- Braille content and height analysis
- Color check with spectrometers

Knowledge of current global and regional labeling requirements

Based on IQVIA's global labeling experience, it is essential to have region-specific checklists to cover local nuances of labeling. Below are a few examples of the checklists implemented by the IQVIA labeling operations team:

- Checklist as per EMA QRD conventions for the EU region
- Selected Requirements of Prescribing Information for the US FDA
- Sponsor-specific checklist for artwork management
- TGO 91 and TGO 92: Standard for labels of prescription/OTC and related medicines for the TGA

Product launch support

The labeling/artwork process plays a critical role during product launches from the day of product approval, which might be a 24x7 launch on the same day of approval, a robust launch in a week, or a standard launch in a month/ defined timeline. IQVIA provides support, with a special focus on working proactively and being compliant with the customer's product marketing strategy.

Conclusion

Using a unique blend of global labeling SMEs plus our NLP and AI technologies, IQVIA experts will review and confirm automated proofreading for formatting, content, and pixels of labels. These steps will help cover the number of given checkpoints for respective core and regional labels.

IQVIA tech-enabled labeling services are committed to “right-first-time” labels, with top-notch process efficiencies to achieve the highest patient safety.

IQVIA experts will review and confirm automated proofreading for formatting, content, and pixels of labels.

About the authors

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Ankit is IQVIA's Associate Director of Regulatory Affairs and Drug Development Solutions (RADDS) and is responsible for managing global and regional labeling projects including generating concise, accurate and well written labeling documents, strategic process consulting, regulatory labeling transformation and technology enablement.

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Rama Mohan Rao is IQVIA's Senior Director of Global Regulatory Affairs-India (GRA-India) focusing on leading the GRA-India division for Global Regulatory Services and Technology. Rama Mohan Rao acts as the business domain expert between Regulatory Affairs and IT divisions for implementing RA Life Science IT tools and driving change for global operating models by connecting technology with pharma's strategic priorities.

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As the Senior Regulatory Affairs Director for Business and Technology Transformation, Donald works with the Regulatory Affairs and Drug Development Solutions (RADDS) team at IQVIA to add and update technology solutions to RADDS's business processes. Having worked in several organizations of different sizes, he provides perspectives from sponsors, vendors and now CROs.

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