LIONBRIDGE

AI-POWERED READABILITY TESTING FOR FASTER, COMPLIANT SSCPs

ABOUT THE CUSTOMER

Croma-Pharma® (Croma) is a global, innovative player within the minimally invasive aesthetics market. It's a leading European manufacturer of premium-quality hyaluronic acid (HA) syringes. Since its 1976 founding in Vienna, the company has expanded into 80 markets globally and offers a cutting-edge, comprehensive aesthetics portfolio.

Additionally, Croma is a globally recognized contract manufacturer in aesthetics, orthopedics, and ophthalmology. Lionbridge has been Croma's trusted language services provider in recent years, translating various documentation into over 30 different languages.

50% FASTER TURNAROUND TIME	**10 MINUTES** TO GENERATE READABILITY REPORT	**SAVED 8–10 HOURS** OF LABOR FOR THE MEDICAL WRITING TEAM

THE CHALLENGE

Croma is required to submit and publish Summaries of Safety and Clinical Performance (SSCPs) for its aesthetic dermal filler devices. Dermal fillers are minimally invasive treatments. As such, they fall within the scope of class III implantable devices under the EU Medical Device Regulation (EU MDR) 2017/745. The SSCP plays a vital role in providing transparent, accessible, and updated information on the safety and performance of medical devices for users and healthcare professionals. Croma's dermal filler users are healthcare professionals. However, for implantable devices, information on safety and clinical performance must be accessible for consumers. Therefore, the SSCP must include a part intended for laypersons and a part for healthcare professionals. As part of Conformity Assessment of medical devices in the EU, SSCPs must be validated by a Notified Body. The Notified Body validates the SSCP for accuracy and completeness against the Technical Dossier.

Additionally, the Notified Body assesses the readability of the layperson's part of the summary. Readability is the ease with which a reader can understand a written text. It must be clear, understandable, and actionable. The layperson's part of the SSCP should contain plain language and a style reflecting the knowledge of a sixth to eighth grade reader; the recommended reading level of the Good Lay Summary Practice Guideline. The Medical Device Coordination Group (MDCG) recommends using a direct user consultation or other means to verify an SSCP's readability.

THE SOLUTION

This case study was one of a series of projects that Croma entrusted to Lionbridge for readability assessment and re-authoring of the SSCP laypersons' part. The project was for a group of facial fillers called viscoelastic implants. These gel-like implants are based on hyaluronic acid (HA) and are injected into the facial skin by a trained healthcare professional (doctor). The fillers add or restore facial volume from loss of naturally occurring HA.

For this project, Lionbridge used its innovative AI-powered readability assessment tool to speed up the readability assessment and quickly re-author the SSCP.

METHODOLOGY

Lionbridge used a three-step process to assist Croma.

STEP 1: We ran the English source SSCP through a Large Language Model (LLM) using our advanced prompt template. The LLM generated an automated readability report. Lionbridge has designed our readability prompt to train the model to comply with health literacy principles and regulated standards within terminology, style, and non-promotional language.

STEP 2: Lionbridge's in-house medical device and linguistic subject matter expert evaluated the readability assessment report. They also implemented relevant changes in the SSCP based on the LLM's analysis and proposed improvements. No LLM output were implemented during the SSCP re-authoring without an expert human-in-the-loop's approval.

STEP 3: Lionbridge issued a certificate confirming the readability assessment and that the re-authoring of the SSCP's laypersons' part was carried out according to principles of health literacy and Good Lay Summary Practices. Croma uses these certificates as evidence of readability testing towards regulatory authorities and Notified Bodies.

PLANNING

‣ Project scoping and specifications
‣ Project proposal
‣ Customized prompt template for Croma's needs
‣ Prepared material for LLM

MULTIDISCIPLINARY TEAM

‣ 1 AI Engineer
‣ 1 Subject Matter Expert

COMMUNICATION

Project Inquiry   **Email Updates**   **Delivery**

METHODOLOGY

Lionbridge successfully delivered the project to Croma ahead of schedule using its AI-powered readability tool. The tool's instant reporting, combined with its ability to promptly analyze text and propose improvements, saved valuable time for Croma's technical and medical writers. The tool helped via:

‣ Advanced prompt engineering, which trained the LLM to ensure compliant, harmonized, and consistent plain language output

‣ An instant readability assessment report to serve as a strong co-author of SSCPs and layperson content

‣ Built-in health literacy principles ensuring appropriate readability level and accessibility of medical device information for users and the public

‣ Built-in terminology to control specific or regulated definitions

‣ Built-in stylistic aspects, such as neutral, non-promotional, and active language

‣ Full human-in-the-loop reviews, which removed any risk of LLM hallucinations

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