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EMBELIA, first European distributor to obtain ISO 15378 certification

ISO 15378 is the most exacting quality standard specifically intended for primary packaging suppliers to the pharmaceutical industry. EMBELIA, a major player in packaging, active in the design, development, distribution of complete primary packaging solutions: containers, closure accessories, decorations and associated services, is the first distributor in Europe to obtain this certification. Beyond the pharmaceutical industry, this level of know-how and requirement will benefit all EMBELIA's customers whatever their sector of activity, cosmetics, beauty, wellness, food supplements, CBD, parapharmaceuticals, etc.

The aim of the ISO 15378 is to ensure patient safety. Certified companies must demonstrate their ability to consistently provide products and services that comply with customer requirements and applicable legal and regulatory requirements, by engaging in a continuous improvement process which aims for excellence.

Its scope covers the design, manufacture (GMP) and logistics of primary packaging items for medicinal products.

It includes criteria concerning manufacturing batches and their traceability, control of environmental conditions (cleanliness and hygiene), validation of critical processes and risk management.

The pharmaceutical industry expects their primary packaging suppliers to comply with this standard.

A long-term commitment to quality

Stéphane Hourdin, Quality Manager at EMBELIA explains:

"The project was initiated in 2019 based on the quality system in place: ISO 9001. The additional requirements were gradually deployed to all our processes both in terms of infrastructure, traceability, organization, training, and most of all using a risk-based approach."

Stéphane Vlgier, General Manager of EMBELIA, says:

"The ISO 15378 standard is very exacting. This certification rewards the magnificent work done by our teams on a daily basis. It is a guarantee for all our customers beyond those of the pharmaceutical industry and for all our customers' customers, be they patients or critical consumers. We bring them real and lasting security. The fact that we are the first in our field to obtain this certification is naturally a source of pride for the whole team."

About EMBELIA:

EMBELIA is a major European player in the field of primary packaging. It designs, develops, and distributes complete solutions including containers - bottles, jars, cans, etc. -, closure accessories and associated services such as decoration, sterilization, etc., in all the materials traditionally used in packaging - glass, plastic, aluminum.

EMBELIA accompanies its customers' projects in fields as varied as Beauty, Health, Home Care, Food or Chemistry.

EMBELIA is a subsidiary of the [SGD PHARMA group](#)

EMBELIA in figures

- 80 years of passion celebrated in 2018,
- 38 million euros of which 20% are exported,
- 4 commercial agencies
- More than 2500 active customers,
- Deliveries in more than 50 countries,
- 8 500 M2 of storage space,
- 1 500 items in stock

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