The Evolution of Modern Aesthetic Medicine:

From Surgery to Smart Injectable Solutions

Modern aesthetic medicine is undergoing a profound transformation. What was once dominated by invasive cosmetic surgery is now being reshaped by **minimally invasive injectable treatments** that combine science, innovation, and artistry to deliver natural-looking, rejuvenated results.

In today's fast-paced world, there is a growing demand for **non-surgical solutions** that enhance appearance without the downtime or risks associated with traditional surgery. As a result, injectables—ranging from **dermal fillers** to **skin boosters**—have become one of the most dynamic and competitive segments in the global aesthetics market.

The Rise of Injectable Treatments in Aesthetic Medicine

Injectable treatments are designed to **restore volume, enhance facial contours, and reduce visible signs of aging**. Unlike surgery, they can be performed quickly—often within minutes—and allow patients to return to their daily activities almost immediately. Their appeal lies in their **convenience, safety profile, and impressive aesthetic outcomes**.

Among the most popular injectable categories are:

- **Dermal fillers** – primarily used to restore lost volume, contour facial features, and smooth wrinkles.
- **Skin boosters (biorevitalizers)** – formulations designed to improve skin quality, including texture, hydration, and elasticity.
- **Regenerative injectables** – emerging formulations that use ingredients such as **polynucleotides** or **collagen stimulators** to promote tissue regeneration and overall skin health.

These treatments can target specific areas of the body—such as the **face, neck, décolleté, or buttocks**—offering personalized results that enhance the natural harmony of each treated region.

The Science Behind Injectables: Key Ingredients and Formulations

The **composition and concentration** of each injectable determine its functionality and clinical effect. The most commonly used active ingredients are **naturally occurring, biocompatible molecules**, including:

- **Hyaluronic Acid (HA):** Responsible for maintaining skin hydration and plumpness. Modified HA is used in dermal fillers to restore volume and smooth lines.
- **Polynucleotides:** Chains of nucleotides that improve skin elasticity and promote tissue regeneration.
- **Collagen:** A structural protein that provides firmness and tone. Some injectables stimulate natural collagen production for longer-lasting results.
- **Vitamins and Antioxidants:** Added to boost cellular metabolism and protect against oxidative stress.

Each product's **chemical structure, cross-linking technology, and concentration** influence its viscoelastic properties and durability. Generally, dermal fillers provide **temporary results (6–12 months)**, as their ingredients gradually break down and are naturally absorbed by the body. Depending on the formulation, injectables may serve volumizing, revitalizing, or regenerative purposes.

Navigating Regulation: Injectables Under the EU Medical Device Regulation (MDR)

Injectable products that do not have a medical purpose—such as those intended purely for aesthetic enhancement—are regulated under **Annex XVI of the EU Medical Device Regulation (MDR 2017/745)**.

This annex covers six categories of products, including substances intended for **facial or dermal filling by injection**.

Conducting a **clinical investigation** remains the most straightforward way to collect data on the safety and performance of such devices for CE marking. However, clinical data can also derive from **scientific literature, previous clinical experience, or real-world use of similar devices**.

For CE-marked products, **post-market clinical follow-up (PMCF)** and **post-market surveillance (PMS)** are essential to monitor product performance and detect potential risks. As part of PMCF, a clinical investigation may be required to validate the claims reported in the **Instructions for Use (IFU)**.

Manufacturers must also ensure **traceability, quality documentation, and vigilance reporting** in compliance with MDR requirements.

The Value of Real-World Data and Post-Market Activities

Beyond clinical trials, **real-world evidence (RWE)** plays a crucial role in confirming the long-term effectiveness and safety of aesthetic injectables.

Post-market activities—such as retrospective surveys, case collections, or physician-reported outcomes—offer valuable insights into patient satisfaction and product behavior in everyday practice.

These data not only strengthen regulatory compliance but also support marketing and business objectives by demonstrating **transparency, reliability, and ongoing commitment to quality**.

1MED: Supporting Innovation and Compliance in Aesthetic Medicine

With years of specialized experience in **aesthetic medicine and medical device regulation**, **1MED SA** supports manufacturers at every stage of their journey—from concept to clinical validation and post-market monitoring.

Our approach combines **scientific rigor, regulatory expertise, and technological innovation** to make minimally invasive aesthetic treatments **safer, more effective, and more accessible worldwide**.

1MED's team of experts designs, manages, and executes **clinical investigations tailored to injectable aesthetics**, ensuring compliance with **ICH E6 (R3), ISO 14155:2020, MDR Annex XVI**, and global regulatory requirements.

We also support **real-world data collection** through **1Survey**, a proprietary 1MED digital tool that helps manufacturers proactively collect and analyze data on the real-life use of their products.

Looking Ahead: The Future of Aesthetic Injectables

As aesthetic medicine continues to evolve, the future lies in **personalization and biotechnological innovation**. From bio-stimulating materials to data-driven treatment planning, the convergence of science and technology is shaping a new era of **safer, smarter, and more sustainable aesthetic solutions**.

With trusted partners like 1MED guiding manufacturers through complex regulatory pathways, the goal remains clear: **to deliver safe, innovative injectables that enhance beauty, restore confidence, and improve quality of life**.