elm plastic

precision&
product safety

customer advantage series 4

From Drug Formulation to Market-Ready Delivery

Navigating Functionality, Compliance, and Global Regulatory Pathways for Dosing Devices

Be it a new, innovative drug development or an outsourced generic – once a pharmaceutical formulation enters clinical evaluation, the packaging and dosing concept becomes increasingly specific. For liquid formulations, precision dosing systems such as pipettes are critical to ensure therapeutic efficacy, patient safety, and regulatory compliance.

As a supplier of dosing devices, we support pharmaceutical manufacturers in aligning drug and device development from the earliest stages – ensuring compatibility, traceability, and regulatory readiness.

1. Functional Requirements: Where Drug Meets Device

In pharmaceutical applications, functionality is not just about operability – it's about reproducibility, precision and resilience.

Key considerations for dosing systems:

· MECHANISM & DOSING ACCURACY	Is the device consistently accurate?
· MATERIAL COMPATIBILITY	Are materials biocompatible and suitable for the specific drug formulation?
· DURABILITY & CLEANING RESISTANCE	Does the device withstand repeated use and cleaning cycles?
· USER SAFETY & ERGONOMICS	Is the system intuitive and safe for patients or healthcare professionals?

These aspects must be validated through traceable documentation, supplier audits, and risk-based testing, ensuring that the device supports the drug's intended use throughout development and commercialization.

2. Regulatory Strategy: One Drug / One Device – Many Markets

Combination products – where medical devices form an integral part or are co-packaged with a pharmaceutical – must meet the legal requirements of both fields. The relevant framework depends on the primary mode of action.

2.1. European Union (EU)

- **Article 117 MDR**
  Requires a Notified Body Opinion (NBOp) for the device part of an integral combination product, submitted as part of the Marketing Authorization Application (MAA).[1]
- **GMP + ISO 13485**
  Both pharmaceutical and device quality systems must be aligned.
- **Labeling & UDI**
  UDI may apply to co-packaged devices; drug-device combinations, the drug labeling rules prevail.[2]

2.2. United States (FDA)

- **Combination Product Office (OCP)**
  coordinates review across Center for Drug Evaluation and Research (CDER) and Center for Devices and Radiological Health (CDRH).
- **cGMP Rule (21 CFR Part 4)**
  Requires full compliance with drug GMPs and selective compliance with device quality system requirements, depending on the nature of the combination product and its primary mode of action.
- **UDI Requirements**
  UDI is generally not required for drug-led combination products (e.g., integrated dosing pipettes) if labeled with an NDC .[3,4]

2.3. Global Access & MDSAP

- **MDSAP** enables shared audits across the US, Canada, Australia, Japan, and Brazil.
- **Brazil** (ANVISA), while part of MDSAP, still requires additional local registration and documentation.
- Other key markets such as **China** (NMPA), **India** (CDSCO), **Saudi Arabia** (SFDA), **UAE** (MOHAP), or **South Korea** (MFDS) require local documentation, language translation, and in some cases local clinical data or representation.

3. Why Partner with Us: Proven Quality, Trusted Compliance

As a manufacturer of precision dosing pipettes, we support pharmaceutical companies with device solutions that meet the highest functional and regulatory standards. Our development and production processes are fully aligned with regulatory requirements for drug-device systems.

Regulatory Declaration

- Definition of essential characteristics and market eligibility
- Early alignment with pharmaceutical product profiles

Dosing Accuracy (ISO 13485)

- Validated liquid dosing tests
- Low tolerance thresholds for critical applications
- Optimized actuation force for improved usability

According to customer feedback: our pipettes outperform in precision and handling

Auditability & Transparency

- Approx. 15 customer audits annually
- Fully digitized quality management and thorough documentation
- Strong sustainability practices across the supply chain

Global Market Readiness

- Regulatory support for EU (CE marking) and US (FDA) registrations
- Extensive experience with combination product submissions and Notified Body interactions

Are you looking for a trusted partner in pharmaceutical dosing systems?

elmplastic specializes in precision pipettes for every development stage—from concept to worldwide launch. If you need support in product development or regulatory affairs, our expert team is ready to help you achieve your goals.

Ready to turn your product concept into a market-ready solution?

Contact elmplastic today to discuss your pharmaceutical packaging needs:

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Our team of experts is ready to help you develop customized solutions that ensure your pharmaceutical packaging supply chain remains resilient in the face of any challenge. Reach out today and discover how elmplastic can become your trusted partner in pharmaceutical packaging excellence.

Sources:

1. European Medicines Agency, Drug-device combination products under the MDR, June 2022
   https://www.ema.europa.eu/en/documents/presentation/presentation-ema-experience-mdr-implementation-cbouygues-pvenneugues-ema_en.pdf
2. European Medicines Agency, Guideline on quality documentation for medicinal products when used with a medical device, July 2021
   https://www.ema.europa.eu/en/documents/scientific-guideline/guideline-quality-documentation-medicinal-products-when-used-medical-device-first-version_en.pdf
3. eCFR, 21 CFR Part 830 - Unique Device Identification
   https://www.ecfr.gov/current/title-21/chapter-I/subchapter-H/part-830
4. Federal register, Unique Device Identifier Requirements for Combination Products; Draft Guidance for Industry and FDA Staff, June 2025
   https://www.federalregister.gov/documents/2025/06/26/2025-11806/unique-device-identifier-requirements-for-combination-products-draft-guidance-for-industry-and-fda

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