



Insist on more.

SUPPLY CONTINUITY

As your Active Pharmaceutical Ingredient (API) supplier, Mallinckrodt is dedicated to your complete satisfaction with everything we do. Our promise to customers is reflected in our four core values: quality, performance, supply continuity and customer service. Our global reach is unequalled in the industry, allowing us to deliver a continuous and uninterrupted supply of APIs. We want you to expect more – in fact, we insist on it.

Supply Continuity Update: Controlled Substance Raw Material Diversity

Our more than 125 years of experience in the controlled substance API business offers our customers peace of mind. Extensive experience with domestic and international regulatory agencies, trusted and diverse sources of raw materials and a depth of industry knowledge ensure you receive the products you need when and where you need them. This, coupled with our risk mitigation strategy around sourcing, helps us to deliver a continuous and uninterrupted supply of controlled substance APIs.

Industry Experience

- With a portfolio of more than 30 controlled substance APIs, Mallinckrodt provides supply chain security. Our extensive experience working with regulatory bodies around the world including the United States (US) Food and Drug Administration (FDA), the US Drug Enforcement Administration (DEA) and the European Medicines Agency help us access critical raw materials and navigate changing international regulations to ensure consistent supply.
- Manufacturing controlled substance APIs requires strong regulatory knowledge/background on both sides of the supply chain. We communicate directly with government officials in countries such as India and Turkey to be one of a limited number of companies that can secure the raw materials needed to ensure consistent supply for you. Mallinckrodt is also the only company in the U.S. processing raw opium.
- Our strong regulatory knowledge/background and experience predicting industry demand help us plan innovative solutions to sourcing challenges. In 2008, we anticipated an increase in morphine demand and a corresponding inequity in the supply-and-demand balance in the coming years. Thus, working with the DEA, we increased our sourcing of other alkaloids to ensure our customers received the API products they needed without disruption.

Diversity of Supply

- We have a substantial, diverse pool of trusted suppliers, and work closely with them to improve extraction processes, provide market trend analyses and assist them in planning appropriate production. This planning process ensures we can receive the quality and quantity of raw materials we need to meet your needs.
- Multiple sources of raw materials in both hemispheres and our flexible use of available alkaloids enable us to mitigate the risk of weather and other natural catastrophes, ensuring we have a steady, reliable supply throughout the year.
- Mallinckrodt also operates multiple manufacturing facilities for controlled substance APIs, allowing us to customize our production lines to best meet customer needs.

At Mallinckrodt, our proven, diverse methods of controlled substance raw material sourcing provide us with a structured, reliable system that best ensures we can manufacture the supply to meet your demand. We look forward to servicing your business as your supplier of choice.