

Insist on more.

**QUALITY**



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. When you choose Mallinckrodt for your APIs, you get the peace of mind that comes from working with a trusted source. We want you to expect more – in fact, we insist on it.

## Quality Update: Manufacturing Quality Record

At Mallinckrodt, our inspection record speaks for itself: Our API production facilities passed 11 consecutive United States Food and Drug Administration (FDA) inspections without an FDA Form 483 Inspectional Observation for plant concerns. That's because we see our products as more than just chemicals. They're pharmaceutical-grade APIs produced in facilities designed for such important products. By purchasing your API products from Mallinckrodt, you benefit from our commitment to continuous improvement and our impeccable domestic and international inspection record across all of our facilities.

### Regulatory Inspection Record

- As both an API supplier and finished dosage manufacturer, we understand your needs for a high-quality ingredient supplier. We work directly with our customers to ensure we have the appropriate regulatory inspections to support your product applications. For instance, at the request of customers, both our p-Aminophenol and Acetaminophen facility and our Directly Compressible Acetaminophen and Ibuprofen plant successfully completed European Union inspections resulting in the issuance of EU Good Manufacturing Practice Certificates. Neither plant received a FDA Form 483 observation during their most recent inspections.
- We feature an experienced quality team at each of our facilities, and all of our quality managers possess finished-dosage experience to ensure our plants meet the high standards of our customers.
- Our experienced technical staff will work directly with you to ensure our API products meet your standards. For instance, we have customized quality agreements with many customers in order to support the quality initiatives of their production facilities.

### Continuous Improvement

- We're dedicated to continuous improvement. We evaluate and upgrade both equipment and processes in our production facilities to ensure you receive the highest quality products for your investment. Mallinckrodt continues to invest in its manufacturing capabilities for our p-Aminophenol and Acetaminophen, and Controlled Substances, Stearates and Inorganics facilities.
- All of our production facilities take part in Mallinckrodt's worldwide Quality Improvement Program. Each year, the quality systems and culture of our production facilities undergo a rigorous audit. Our 12 plants around the world share best practices as we constantly strive to improve our performance.

Mallinckrodt's commitment to the highest international standards for quality and investments in our API production facilities mean you receive exceptional uniformity and reliability from our products. We look forward to servicing your business as your supplier of choice.