



Realize your cytotoxic agent's
unique potential.

BioPharma Solutions

Connect to the resources you need.

Baxter

Baxter Cytotoxic Services.

EXPERIENCE YOU CAN TRUST.

Parenteral cytotoxic agents are among the most highly sensitive drugs to handle and produce. As a global parenteral drug leader with more than 75 years of experience, Baxter knows how to get your product to market with proven efficiency and reliability.

Integrated, state-of-the-art resources dedicated exclusively to cytotoxic and high-potency product manufacturing ensure your molecule moves smoothly from development and clinical trials right through full-scale commercial manufacturing.

Discover how we can help you outsource with confidence.

Specialized technology.

BARRIER ISOLATORS: THE BENEFITS OF CLOSED-SYSTEM MANUFACTURING.

From weighing and solutions makeup to closing procedures, the Halle facility's leading barrier-isolator technology ensures your cytotoxic product is manufactured under precisely controlled temperature, relative humidity, and pressure conditions- in a clean-room Class 100 environment.

- Minimized contamination risks
- High-quality product development/manufacture
- Increased batch yield for optimized efficiency
- Employee and environmental safety
- Regulatory compliance



FACILITY DESIGN: MAXIMIZE MANUFACTURING VALUE.

The Halle facility is uniquely designed to deliver high-quality products with optimum efficiency and speed to market.

DEDICATED PRODUCTION AREAS:

- Provide state-of-the-art cGMP manufacturing for high potency and cytotoxic compounds
- Eliminate the risks of cross-contamination between products and product classes

FULLY INTEGRATED MANUFACTURING RESOURCES:

- Reduce variability and production delays
- Accelerate turnaround times
- Increase batch yields and optimize use of valuable API
- Ensure market demands are met-with an exceptional track record of on-time delivery

Cytotoxic contract manufacturing with Baxter.

CYTOTOXIC SERVICES

More than 50 years of cytotoxic manufacturing experience at the Germany facility.

Core services

- Chemical synthesis (API)
- Process development and scale-up through full commercialization for parenteral products
- Stability storage
- Validation
- Documentation

Equipment

- Isolator technology
- 4 production lyophilizers, shelf capacity:
- 14 m² clinical and 90 m² commercial (3 x 30 m²)
- 3 aseptic filling suites
- 2 packaging lines
- Dedicated cytotoxic production area
- Scale-up laboratory/center
- Cold storage 2°C-8°C

Cytotoxic capabilities per year

- Lyophilization: up to 5 million vials
- Aseptic powder filling: up to 23 million vials
- Aseptic liquid filling: up to 22 million vials
- Sterile crystallization: up to 12.5 tons

Supporting services

- Purchasing
- Production planning
- Packaging design
- Quality control/assurance
- Microbiology
- Technical services
- Cost accounting and finance
- Warehousing and distribution

Capacity

- More than 1,900 meters²/20,000 ft.² total cytotoxic capacity
- 3,770 m²/40,580 ft.² storage



We invite you to learn how our cytotoxic expertise can help ensure your product's success. For more information, contact your Baxter representative at 1-800-4-BAXTER, or visit us on the Web at www.baxterbiopharmasolutions.com.

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