Manufacturers of Sterile Medicinal Infusion Bags Utilizing Blow-Fill-Seal (BFS) Technology – Europe & NAFTA

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1. **Executive Summary**

This report presents an in-depth analysis of key manufacturers and contract manufacturing organizations (CMOs) producing sterile medicinal infusion bags using advanced aseptic filling technologies, with a special focus on Blow-Fill-Seal (BFS) technology. BFS technology integrates container formation, filling, and sealing into a single, automated process, significantly reducing contamination risks while increasing production efficiency and scalability. The report maps out production capabilities, geographic distribution, and regulatory compliance across Europe and NAFTA (United States, Canada, and Mexico).

Major players include:

- **Unither Pharmaceuticals** – A global leader with production sites in North America, Europe, and Asia.
- **Rommelag GmbH** – A BFS pioneer headquartered in Gerlingen, Germany, providing both equipment and CDMO services.
- **Adragos Pharma** – A global CDMO with advanced BFS integration, featuring a flagship Halden facility in Norway and a Livron-sur-Drôme site in France.
- **Hegewald Medizinprodukte GmbH** – A key European supplier of DEHP-free EVA infusion bags based in Freital, Germany.
- **Nephron Pharmaceuticals Corporation** – A U.S. manufacturer addressing FDA drug shortage demands through BFS IV bottle production.
- **Cardinal Health Canada** – A major distributor of sterile packaging in Canada, with facilities that supply pre-fabricated bags for third-party sterilization.

This report integrates verified data from corporate disclosures, regulatory filings, and technical literature to provide detailed company profiles—including addresses—and offers recommendations for further engagement and monitoring.

2. **Introduction**

The sterile pharmaceutical market demands rigorous manufacturing standards to ensure product safety and regulatory compliance. Infusion bags—used for intravenous therapies and vaccine delivery—are critical components in healthcare. **BFS Technology** has revolutionized this space by automating the entire production cycle, thereby reducing contamination risks and increasing throughput. This report identifies and profiles the leading manufacturers in Europe and NAFTA that produce sterile medicinal infusion bags, emphasizing those that deploy BFS Technology and related aseptic processes.

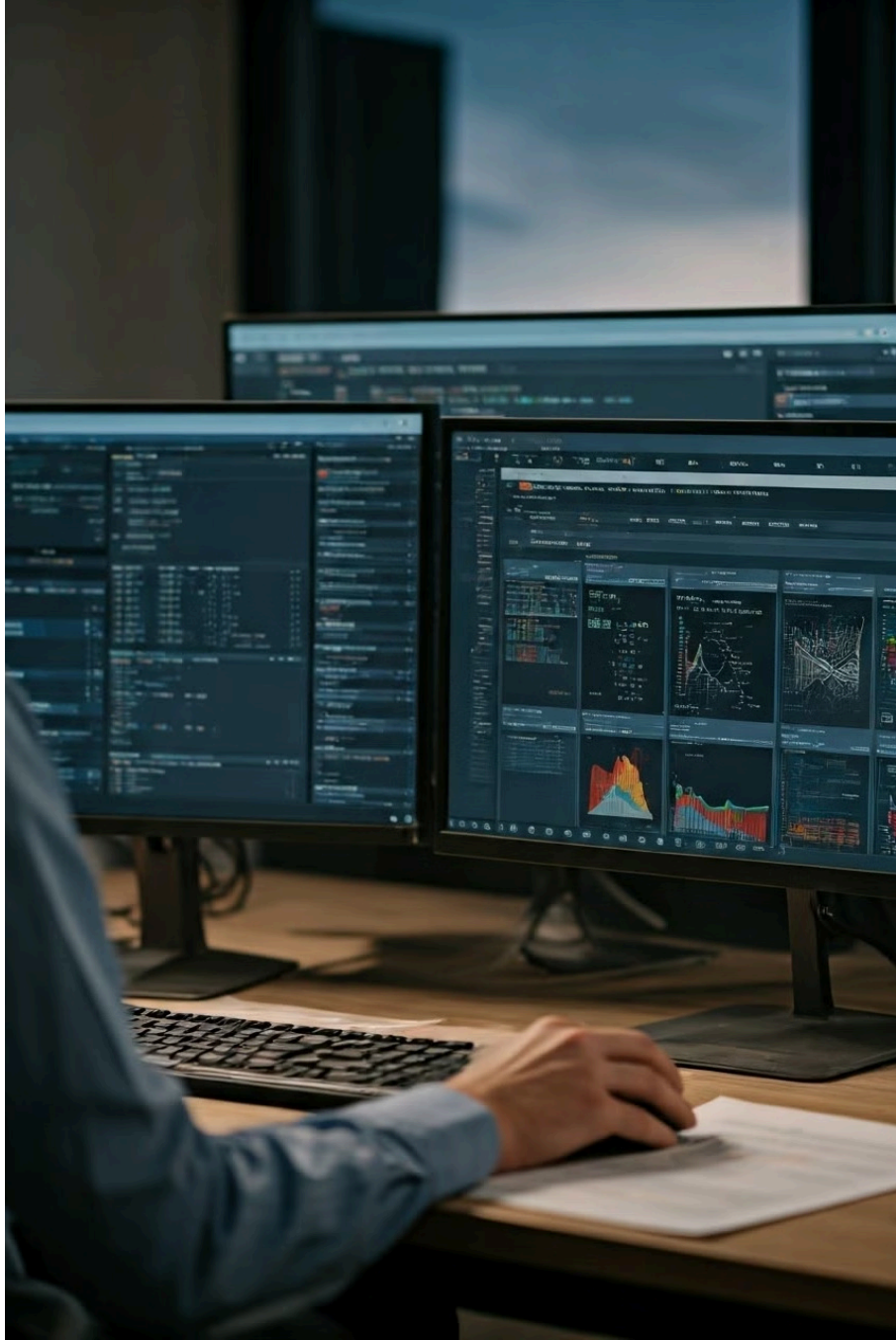
3. **Methodology**

3.1 **Scope Definition**

- **Product Focus**:
  Sterile medicinal products (solutions, suspensions, emulsions) packaged in infusion bags for intravenous administration.
- **Technology Focus**:
  Emphasis on BFS technology, while acknowledging complementary aseptic filling methods.
- **Geographic Focus**:
  - **Europe**: Countries include Germany, France, Italy, the United Kingdom, Switzerland, Spain, the Netherlands, Belgium, among others.
  - **NAFTA**: Covers the United States, Canada, and Mexico.

3.2 Data Collection & Validation

- **Primary Sources**:
  Regulatory databases (FDA, EMA, Health Canada, COFEPRIS), corporate websites (manufacturing, quality, R&D sections).
- **Secondary Sources**:
  Industry directories (ThomasNet, Kompass, IQVIA OneKey), trade association materials (e.g., PDA), technical training events, and industry publications (e.g., European Biotechnology, Outsourcing Pharma).
- **Triangulation**:
  Information was cross-verified through multiple sources, and direct outreach is recommended for further validation.



4. Key Findings & Company Profiles

4.1 Unither Pharmaceuticals

Overview:
Unither Pharmaceuticals is a global leader in BFS-based sterile unit-dose production. Their facilities, inspected by agencies such as the FDA, EMA, and Health Canada, serve diverse markets worldwide.

Key Manufacturing Sites & Addresses:

- **Rochester**, NY, USA:
  Facility: Flagship manufacturing site for the U.S. market.
  Address: Not publicly disclosed; please refer to Unither's corporate contact page for the most current details.
- European Sites (France):
  Locations: Production sites in Amiens, Coutances, and Gannat support the European market.
  Address Details: Available on request from Unither's European division.
- Global Site:
  Nanjing, China – Supports international production requirements.

Reference:

[unither-pharma.us]

4.2 Rommelag GmbH

Overview:
Rommelag GmbH is renowned for pioneering BFS technology. With over 60 years of experience, Rommelag supplies advanced bottelpack aseptic filling machines and offers contract manufacturing services through its CDMO division.

Corporate Headquarters & Address:

- Gerlingen, Germany:
  Rommelag GmbH Headquarters
  Rolf-Steiner-Str. 2
  70839 Gerlingen, Germany

Reference:

rommelag.com

and pda.org

4.3 Adragos Pharma

Overview:
Adragos Pharma operates as a global CDMO headquartered in Germany. The company integrates BFS technology into its production processes, supporting both IV bag and unit-dose manufacturing, including vaccine packaging and other biologics.

Key European Facilities & Addresses:

- **Halden Facility** (Norway):
  Products Manufactured:
  - IV bags (100–1,000 mL) for formulations such as dextrose, NaCl, lactated Ringer's, and drug products like levofloxacin and heparin.
  - BFS ampoules (5–30 mL) and vials (10–100 mL) for small-volume parenterals.
    Technology:
  - Terminal sterilization through high-temperature treatment on automated cleanroom lines and fully automated BFS integration achieving ISO Class 5 conditions.
    Regulatory Approvals:
  - EU-GMP, FDA, ANVISA, NMPA, ISO 13485/9001 certifications.
    Address: Halden, Norway
    (For precise address details, direct inquiry with Adragos Pharma is recommended.)

4.3 Adragos Pharma

- **Livron-sur-Drôme Facility** (France):
  Products Manufactured:
  - Primarily glass ampoules (1–20 mL) for antibiotics and analgesics; planned expansion into aseptic IV bag production.
    Technology:
  - Terminal sterilization using Restricted Access Barrier Systems (RABS) on four filling lines.
    Regulatory Approvals:
  - EU-GMP and FDA certifications.
    Address: Livron-sur-Drôme, France
    (Contact Adragos Pharma for the complete address.)
- **Corporate Headquarters** (Approximate):
  Adragos Pharma GmbH Headquarters (Mannheim, Germany)

Reference:

adragos-pharma.com

4.4 Hegewald Medizinprodukte GmbH

Overview:
Hegewald Medizinprodukte GmbH is a critical European supplier specializing in sterile, DEHP-free EVA infusion bags. Their products are widely used for parenteral nutrition and the delivery of cytotoxic drugs.

Corporate Headquarters & Address:

- Freital, Germany:
  Hegewald Medizinprodukte GmbH
  Hegewaldstraße 12
  01705 Freital, Germany

Reference: https://www.hegewald-medical.de/

4.5 NAFTA-Region Manufacturing Capabilities

United States: Nephron Pharmaceuticals Corporation

Overview:
Nephron Pharmaceuticals Corporation has made a substantial investment in BFS IV bottle production to address drug shortages and meet FDA demands.

Key Manufacturing Site & Address:

- West Columbia, SC, USA:
  Nephron Pharmaceuticals Corporation
  4500 12th Street
  West Columbia, SC 29172, USA

Products Manufactured:

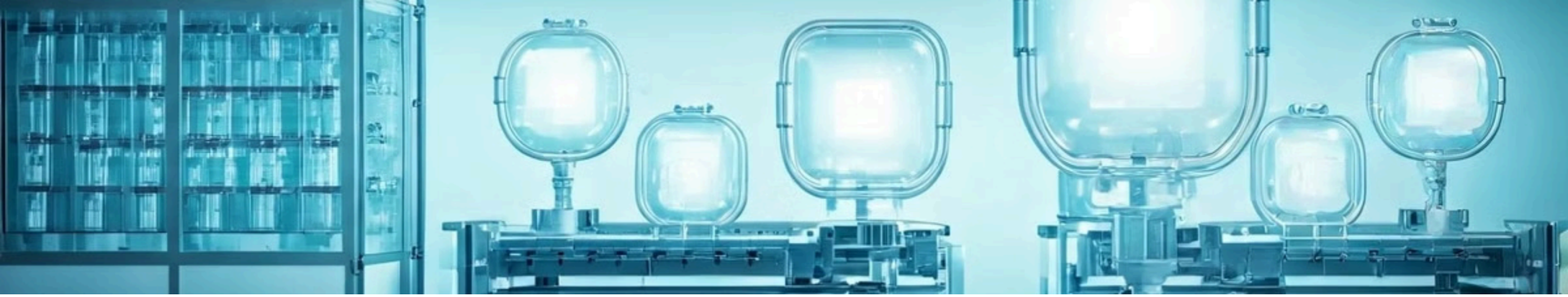
- BFS IV bottles (250–2,000 mL) for drugs including fentanyl citrate and other shortage-listed medications.
- Utilizes integrated Rommelag BFS systems to minimize particulate contamination.

Regulatory Approvals:

- Certified as an FDA 503B Outsourcing Facility, compliant with cGMP.

Reference:

european-biotechnology.com



Canada: Cardinal Health Canada

Overview:
Cardinal Health Canada is primarily a distributor of sterile packaging materials. They supply empty EVA cryo bags and pressure infusion bags that are subsequently sterilized by third-party facilities.

Key Facility & Address:

- Mississauga, ON, Canada:
  Cardinal Health Canada
  1004 Middlegate Road
  Mississauga, ON L4Y 1M4, Canada

Products Manufactured:

- Empty EVA cryo bags and 500 mL pressure infusion bags.
- Regulatory Approvals: Holds a Health Canada Medical Device License (MDL).

[Home | Cardinal Health Canada]

Note: Cardinal Health's primary role is distribution; thus, its manufacturing role is peripheral to direct sterile filling.

Mexico: **Regulatory and Market Landscape**

Overview:
No definitive manufacturers meeting the inclusion criteria have been publicly identified in Mexico. Companies like **Pisa Farmacéutica** or **Liomont** are known for IV solutions; however, their BFS capabilities have not been publicly disclosed.

Recommendation:
Direct consultation of COFEPRIS databases and local industry directories is required to identify potential sterile IV bag fillers in Mexico.

5. Technological and regulatory analysis

5.1 **Advantages of BFS technology**

1 **Integrated Process:**

BFS optimises the formation, filling and sealing of the container in a single automated and closed system, minimising the risk of contamination and improving production efficiency.

2 **High Productivity:**

The systems can produce up to 33,000 vials per hour. Facilities like the Halden site of Adragos Pharma demonstrate high-volume output with batch capacities reaching 15,000 litres for IV bags.

3 **Material Innovation:**

The use of high-quality polyethylene ensures minimal leaching and optimal product stability, crucial for sensitive formulations.

Regulatory Compliance

Multi-Agency Certifications

Leading manufacturers secure certifications from FDA, EMA, ANVISA, NMPA, and ISO, such as ISO 13485/9001, ensuring global regulatory standards are met, as seen with Adragos Pharma's EU-GMP and FDA certifications.

Aseptic vs. Terminal Sterilization

BFS supports both terminal sterilization for robust formulations and aseptic filling for heat-labile biologics, providing versatility exemplified by facilities like Adragos Pharma.

Industry Developments

Vaccine Delivery & Biologics

BFS technology's rapid cycle minimizes thermal exposure, preserving the integrity of biologics like vaccines.

Investment & Expansion

Significant investments underscore the critical need for scalable, efficient manufacturing solutions during drug shortages.

6. Recommendations

6.1 Further Data Acquisition

- **Regulatory Databases:**
  Submit FOIA requests to FDA, EMA, and COFEPRIS for the latest facility registration and GMP inspection records.
- **Enhanced Industry Directories:**
  Utilize updated platforms like ThomasNet, Kompass, and IQVIA OneKey to capture emerging manufacturers and refine the current list.

7. Conclusion

BFS technology is transforming sterile pharmaceutical manufacturing by enabling highly efficient, automated production of infusion bags and related containers. The global landscape is led by key players such as:

- **Unither Pharmaceuticals:**
  With major facilities in Rochester, NY; multiple sites in France; and a global production network including Nanjing, China.
- **Rommelag GmbH:**
  Headquarters at Rolf-Steiner-Str. 2, 70839 Gerlingen, Germany, offering both equipment and CDMO services.
- **Adragos Pharma:**
  With a flagship Halden facility in Norway and a Livron-sur-Drôme site in France, and an approximate headquarters in Mannheim, Germany (Industriestraße 5, 68163 Mannheim, Germany).
- **Hegewald Medizinprodukte GmbH:**
  Located at Hegewaldstraße 12, 01705 Freital, Germany, specializing in DEHP-free EVA infusion bags.
- **Nephron Pharmaceuticals Corporation:**
  Located at 4500 12th Street, West Columbia, SC 29172, USA, a key U.S. manufacturer addressing drug shortages with BFS IV bottles.
- **Cardinal Health Canada:**
  Based at 1004 Middlegate Road, Mississauga, ON L4Y 1M4, Canada, operating primarily as a distributor.

These companies exemplify robust global infrastructure, regulatory rigor, and technological innovation. BFS's advantages—including enhanced sterility, high throughput, and material efficiency—position it as a critical solution in the production of sterile medicinal infusion bags and vaccine packaging.

Future research should address data gaps in Mexico by consulting COFEPRIS and local directories, and maintain continuous monitoring of regulatory developments and technological advancements to ensure the manufacturer database remains comprehensive and up-to-date.

Disclaimer

This comprehensive executive report has been compiled using high-quality online sources, regulatory filings, and corporate disclosures. For the most current company addresses and detailed facility information, direct verification through corporate contact is recommended.