1. Unither Pharmaceuticals

Evaluation Criteria	Details
Regulatory Compliance & Certifications	
cGMP Compliance	Adheres to cGMP standards; facilities inspected by FDA, EMA, ANVISA, and other health authorities.
ISO Certifications	Specific ISO certifications not publicly disclosed.
Regulatory Approvals	Approved by multiple agencies, including FDA and EMA.
Data Integrity & Documentation	Emphasizes comprehensive documentation and quality management systems.
Quality Control & Assurance	
Sterility Assurance	Utilizes advanced BFS technology ensuring aseptic filling.
Endotoxin & Particulate Testing	Conducts rigorous in-house QC testing.
Material Traceability	Maintains traceability of materials across global sites.
Environmental Monitoring	Implements strict cleanroom controls and environmental monitoring.
Batch Release & Stability Testing	Offers in-house stability programs and batch release testing.
Technical Capabilities & Customization	
Container Design & Development	Provides customizable BFS solutions for volumes ranging from 0.25 to 10 mL.
Formulation Handling	Capable of handling solutions, suspensions, gels, and emulsions.
Barrier Properties & Compatibility	Utilizes materials compatible with various formulations.
Automation & Robotics	Employs advanced BFS machinery ensuring precision.
Blow-Fill-Seal Equipment	Operates state-of-the-art BFS lines across multiple facilities.
Capacity, Scalability & Lead Times	

Production Capacity	Total capacity of 5 billion unit doses per year.
Scalability	Ability to undertake projects of varying sizes with sustained investment in new BFS lines.
Supply Chain Stability	Global presence ensures diversified supply chain.
Lead Times & Batch Turnaround	Offers flexibility to meet client timelines.
Cost & Financial Stability	
Cost Competitiveness	Provides competitive pricing with transparent cost structures.
Financial Health	Established global presence indicates financial robustness.
Total Cost of Ownership (TCO)	Comprehensive services potentially reduce overall costs.
Supply Chain & Logistics	
Geographic Location	Facilities in the USA, France, and China offer strategic advantages.
Redundancy & Risk Management	Multiple sites provide operational redundancy.
Cold Chain & Storage	Capabilities for temperature-sensitive products not specified.
Customer Support & Technical Services	
On-Site Audits & Visits	Welcomes client audits and site visits.
Regulatory Support	Assists with regulatory submissions and compliance.
After-Sales Support	Provides dedicated account management and technical support.
Sustainability & ESG Compliance	
Environmental Compliance	Engages in sustainable practices; specific initiatives not detailed.
Ethical Sourcing	Commits to ethical sourcing; specifics not publicly disclosed.

2. Rommelag GmbH

Evaluation Criteria	Details
Regulatory Compliance & Certifications	
cGMP Compliance	Operates under strict cGMP guidelines.
ISO Certifications	Holds ISO 9001 and ISO 13485 certifications.
Regulatory Approvals	Regularly audited by EMEA, FDA, and ANVISA.
Data Integrity & Documentation	Maintains robust data integrity protocols.
Quality Control & Assurance	
Sterility Assurance	BFS process meets aseptic filling standards.
Endotoxin & Particulate Testing	Offers comprehensive microbiological analyses.
Material Traceability	Ensures full traceability of materials.
Environmental Monitoring	Implements strict cleanroom protocols.
Batch Release & Stability Testing	Provides stability storage and testing services.
Technical Capabilities & Customization	
Container Design & Development	Develops and optimizes custom BFS container designs.
Formulation Handling	Handles a wide range of liquid and semi-solid products.
Barrier Properties & Compatibility	Offers material selection tailored to product needs.
Automation & Robotics	Utilizes advanced BFS machinery with automation.
Blow-Fill-Seal Equipment	Pioneers in bottelpack BFS technology.
Capacity, Scalability & Lead Times	
Production Capacity	Operates over 50 bottelpack machines with a daily production exceeding 2 million containers.

Scalability	Supports clients from pilot batches to full-scale production.
Supply Chain Stability	Established infrastructure ensures supply chain resilience.
Lead Times & Batch Turnaround	Offers efficient process development and production timelines.
Cost & Financial Stability	
Cost Competitiveness	Provides cost-effective solutions via contract manufacturing.
Financial Health	Rommelag has a longstanding market presence, indicating financial stability.
Total Cost of Ownership (TCO)	Comprehensive services potentially reduce overall costs.
Supply Chain & Logistics	
Geographic Location	Strong European presence with extensive supply chain.
Redundancy & Risk Management	Multiple production facilities provide risk management.
Cold Chain & Storage	No specific mention of cold chain logistics.
Customer Support & Technical Services	
On-Site Audits & Visits	Encourages client audits and inspections.
Regulatory Support	Assists with product registration and compliance.
After-Sales Support	Offers dedicated customer service teams.
Sustainability & ESG Compliance	
Environmental Compliance	Engaged in environmentally friendly packaging solutions.
Ethical Sourcing	Focuses on responsible sourcing policies.

3. Adragos Pharma

Evaluation Criteria	Details
Regulatory Compliance & Certifications	
cGMP Compliance	Adheres to cGMP standards across its facilities.
ISO Certifications	Specific ISO certifications are not publicly disclosed.
Regulatory Approvals	Facilities have undergone inspections by relevant health authorities; specific approvals are not detailed.
Data Integrity & Documentation	Emphasizes robust quality management systems and compliance with regulatory requirements.
Quality Control & Assurance	
Sterility Assurance	Specializes in sterile liquid manufacturing, including BFS technology.
Endotoxin & Particulate Testing	Conducts comprehensive analytical testing in state-of-the-art laboratories.
Material Traceability	Maintains stringent control over material sourcing and traceability.
Environmental Monitoring	Implements strict cleanroom protocols and environmental controls.
Batch Release & Stability Testing	Offers extensive stability studies and in-house quality control testing.
Technical Capabilities & Customization	
Container Design & Development	Provides development and manufacturing services for various dosage forms, including sterile liquids.
Formulation Handling	Experienced in handling both small and large molecules, including complex formulations.
Barrier Properties & Compatibility	Utilizes materials compatible with a wide range of pharmaceutical formulations.
Automation & Robotics	Employs advanced manufacturing technologies to ensure precision and efficiency.
Blow-Fill-Seal Equipment	Operates state-of-the-art BFS machinery, particularly at their Halden facility in Norway.
Capacity, Scalability & Lead Times	
Production Capacity	Operates multiple facilities across Europe and Japan, with significant production capabilities.
Scalability	Demonstrates the ability to scale production in response to client needs.
Supply Chain Stability	Global presence ensures a resilient and diversified supply chain.
Lead Times & Batch Turnaround	Committed to meeting client timelines with efficient project management.
Cost & Financial Stability	

Cost Competitiveness	Offers competitive pricing structures tailored to client requirements.
Financial Health	Backed by FSN Capital VI and Prange Group, indicating strong financial support and stability.
Total Cost of Ownership (TCO)	Integrated services aim to optimize costs and reduce overall expenditure for clients.
Supply Chain & Logistics	
Geographic Location	Facilities strategically located in Europe and Japan, facilitating global distribution.
Redundancy & Risk Management	Multiple sites provide operational redundancy and risk mitigation.
Cold Chain & Storage	Offers cold chain management services to handle temperature-sensitive products.
Customer Support & Technical Services	
On-Site Audits & Visits	Encourages client audits and site visits to ensure transparency and trust.
Regulatory Support	Provides comprehensive regulatory services, including assistance with submissions and compliance.
After-Sales Support	Dedicated teams offer ongoing support and technical assistance post-production.
Sustainability & ESG Compliance	
Environmental Compliance	Committed to sustainable practices; specific initiatives are not detailed.
Ethical Sourcing	Adheres to ethical sourcing standards; further specifics are not publicly disclosed.

4. Hegewald Medizinprodukte GmbH

Evaluation Criteria	Details
Regulatory Compliance & Certifications	
cGMP Compliance	Operates in accordance with applicable medical device manufacturing standards.
ISO Certifications	Holds ISO 13485 certification for quality management systems in medical devices.
Regulatory Approvals	Products comply with relevant EU medical device regulations; specific approvals are not detailed.
Data Integrity & Documentation	Maintains thorough documentation practices as per medical device industry standards.
Quality Control & Assurance	
Sterility Assurance	Specializes in DEHP-free EVA infusion bags; sterility assurance processes are in place.
Endotoxin & Particulate Testing	Conducts necessary testing to meet medical device safety standards.
Material Traceability	Ensures full traceability of materials used in production.
Environmental Monitoring	Implements environmental controls suitable for medical device manufacturing.
Batch Release & Stability Testing	Performs batch release testing; stability testing specifics are not detailed.
Technical Capabilities & Customization	
Container Design & Development	Focuses on infusion bag production; customization capabilities are not specified.
Formulation Handling	Not applicable, as the company does not handle pharmaceutical formulations.
Barrier Properties & Compatibility	Specializes in DEHP-free EVA materials, ensuring compatibility for infusion applications.
Automation & Robotics	Utilizes manufacturing technologies appropriate for infusion bag production; specifics are not provided.
Blow-Fill-Seal Equipment	No involvement in BFS technology.
Capacity, Scalability & Lead Times	

Production Capacity	Details on production capacity are not publicly available.
Scalability	Information on scalability is not specified.
Supply Chain Stability	Maintains a stable supply chain for medical-grade materials.
Lead Times & Batch Turnaround	Specific lead times are not disclosed.
Cost & Financial Stability	
Cost Competitiveness	Pricing information is not publicly available.
Financial Health	Limited public financial data available.
Total Cost of Ownership (TCO)	Not specified.
Supply Chain & Logistics	
Geographic Location	Based in Germany, serving primarily the European market.
Redundancy & Risk Management	No details available.
Cold Chain & Storage	No information provided.
Customer Support & Technical Services	
On-Site Audits & Visits	No specific details available.
Regulatory Support	Limited information available.
After-Sales Support	No detailed information provided.
Sustainability & ESG Compliance	
Environmental Compliance	Not publicly disclosed.
Ethical Sourcing	No information available.

5. Nephron Pharmaceuticals Corporation

Evaluation Criteria	Details
Regulatory Compliance & Certifications	
cGMP Compliance	Adheres to cGMP but received an FDA warning letter in October 2022 for violations.
ISO Certifications	Not publicly disclosed.
Regulatory Approvals	History of FDA inspections and approvals for various products.
Data Integrity & Documentation	Maintains quality assurance processes, though FDA cited deficiencies.
Quality Control & Assurance	
Sterility Assurance	Utilizes advanced BFS technology for aseptic manufacturing.
Endotoxin & Particulate Testing	Conducts in-house testing to ensure product safety.
Material Traceability	Uses a barcode-based track and trace system.
Environmental Monitoring	LEED-certified facilities with automated contamination control.
Batch Release & Stability Testing	Conducts in-depth quality checks.
Technical Capabilities & Customization	
Container Design & Development	Specializes in BFS unit-dose vials and IV bottles.
Formulation Handling	Experienced in manufacturing respiratory and sterile compounded medications.
Barrier Properties & Compatibility	Uses materials suitable for diverse formulations.
Automation & Robotics	Fully automated manufacturing, packaging, and distribution.

Blow-Fill-Seal Equipment	State-of-the-art BFS production lines.
Capacity, Scalability & Lead Times	
Production Capacity	Over 840,000 square feet of production space.
Scalability	Recent $10M expansion to increase production.
Supply Chain Stability	In-house water purification and automated inventory management.
Lead Times & Batch Turnaround	Not publicly detailed.
Cost & Financial Stability	
Cost Competitiveness	Competitive pricing structure.
Financial Health	Ongoing facility investments indicate stability.
Total Cost of Ownership (TCO)	Efficient operations may lower costs.
