Integrated Devices for Reconstituting Injectables
Devices, Markets, Players, Strategies and Forecasts

Greystone Research Associates
Patient-friendly Drug Reconstitution

The inherent instability of biological drugs is a limitation that has a direct impact on the drug delivery sector. Therapeutic proteins must either be stored under special conditions or formulated to retain their efficacy from the time of manufacture until they are dispensed. Liquid protein drugs require refrigeration until dispensed. Alternatively, proteins can be formulated as powders (lyophilization) and must be reconstituted prior to injection. Historically, this was accomplished by including a disposable syringe and diluent vial for manual reconstitution. As the number of drugs developed for self-administration has grown, devices that integrate a reconstitution step with the injection step have gained traction. As biological drugs continue to grow in terms of therapeutics and total prescriptions, the impact of specialty devices will increase.

Market-driven Product Strategies

A longer life span is expected to translate to a growing number of patients diagnosed with chronic conditions. To counteract the financial and medical infrastructure implications of this trend, pressure from the public sector and managed care organizations will place a premium on therapeutic self-administration, an expectation that is creating an increased interest in routes of administration that are patient-friendly and cost-effective. Pharma company decision makers have come to the realization that for many products, success no longer only depends on the medication itself but also on achieving a consumer-compatible form of packaging and application.
Currently only a small number of lyophilized drugs are supplied in integrated reconstitution devices - most lyophilized drugs for injection are typically sold in vials packaged with a diluent syringe - but this number is expanding with the growing number of branded injectables that cannot be stored as liquids at room temperature. The simplicity and patient acceptance of integrated reconstitution devices is becoming an accepted method for differentiating injectables in an increasingly competitive market.
Our reports are carefully researched and written to provide timely and insightful analysis of key factors and developments shaping the commercial marketplace. The focused nature of our publications is designed to allow readers to identify emerging demand and growth opportunities in selected markets. Numerous charts, tables and graphs complement the text, with evaluations and assessments of current and probable future market developments, technology issues and business factors - information necessary to compete effectively in the global marketplace.

**What You Will Learn**

- What is the impact of lyophilized injectable drugs on today’s therapeutic market, how are they packaged, and who markets them?
- Who are the suppliers of integrated reconstitution devices, and what is their market impact?
- What are the major factors driving the demand for integrated devices for injectable drug reconstitution?
- What is the relative impact of integrated reconstitution systems to OEM or standalone reconstitution devices and how will this change by the end of the decade?
- What are the essential design factors, material selection issues, technologies and market development issues for drug reconstitution systems and devices?
- What is the role of integrated drug reconstitution systems on drug life cycle management?
- What are the significant economic, technology, and regulatory factors affecting the market for injectable drugs and reconstitution systems in particular?

**Report Value Chain – Who Should Read this Report**

---

**Development**
- Drug Developers
- Device Suppliers
- CMOs
- Components/APIs
- Testing/Validation
- Clinical Trial Mgmt

**Industry**
- Pharma Managers
- Biotech Managers
- Drug Marketers
- Industry Strategists
- Financial Analysts
- Management Consultants

**Market**
- Clinical Managers
- Drug Distributors
- Pharma Regulators
- FDA Consultants
- Managed Care Managers
Greystone Research Associates

*The Power of Insight*

Find us on the Web: www.greystoneassociates.org

---

**Report Format and Availability**

This report is available electronic format. A single user license as well as licenses for multiple users are available. Custom licensing options to address specific company user requirements are available by calling client services at 603-595-4340, or by emailing clientservices@greystoneassociates.org.

**Methodology**

Research methodology is based on primary research in the form of in-depth interviews with key market participants, technology developers, distributors, industry experts, and market influencers, a list that includes regulatory officials, industry trade groups, and materials standards organizations.

Primary data is evaluated and normalized against secondary sources including trade journal articles, technical literature, industry publications, company data sheets and published information, and statistical data from government agencies and trade associations. Forecasts and projections of market

---

**Greystone Research Associates**

*Greystone Research Associates is a medical technology consulting firm focused on the areas of medical market strategy, product commercialization, venture development, and market research. We assist medical and healthcare market participants in achieving their business objectives through the creation of detailed development strategies, product commercialization programs, and comprehensive market and technology research and analysis. Our market research publications are designed, researched and written to provide timely and insightful information and data on focused market segments, with the aim of providing market participants with the essential knowledge to refine and execute their marketing plans and financial targets.*
Orders may be placed via postal mail, e-mail or fax. Orders not accompanied by a purchase order must contain a telephone number for verification, and clearly indicate the physical shipping address. Orders which are not prepaid must indicate the billing address. There is no charge for handling and shipping for destination addresses within the continental US.

**Payment**

We accept the following forms of payment:

- **Company Check**: Please make checks payable to ‘Greystone Associates’
- **Credit Cards**: We accept MasterCard, Visa and American Express
- **Wire Transfers**: See ‘Wire Transfers’ below for more information

**Orders Outside the U.S.**

Orders must be prepaid via credit card, company check in US funds and drawn on a US bank, or wire transfer.

<table>
<thead>
<tr>
<th>Wire Transfers:</th>
<th>TD Banknorth</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>300 Franklin Street</td>
</tr>
<tr>
<td></td>
<td>Manchester, NH 03103</td>
</tr>
<tr>
<td></td>
<td>(Call for Account Information)</td>
</tr>
</tbody>
</table>

**Mailing Address:**

Greystone Research Associates
Client Services
P.O. Box 1362
Amherst, NH 03031

---

Integrated Devices for Reconstituting Injectables
*Devices, Markets, Players, Strategies and Forecasts*

<table>
<thead>
<tr>
<th>Select</th>
<th>Format</th>
<th>License</th>
<th>Price (U.S. funds)</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>PDF</td>
<td>Single User</td>
<td>$2,850.00</td>
<td></td>
</tr>
<tr>
<td>[ ]</td>
<td>PDF</td>
<td>Site License</td>
<td>$5,500.00</td>
<td></td>
</tr>
<tr>
<td>[ ]</td>
<td>PDF</td>
<td>Global License</td>
<td>$7,500.00</td>
<td></td>
</tr>
</tbody>
</table>

**Total Payment (U.S. funds)**

Method of Payment: ___ Company Check     ___ [ ] Check     ___ [ ] Wire Transfer

Card Number:__________________________ Name on Card ______________________________________
Expiration Date: ____________ Card CVV_______

**Billing Information**

- Name:
- Title:
- Company:
- Street Address:
- City, State/Province:
- Country/Postal Code:
- Phone:
- Fax:
- Email:

**Shipping Information**

- Click here if same as Billing Information
- Name:
- Title:
- Company:
- Street Address:
- City, State/Province:
- Country/Postal Code:
- Phone:
- Fax:
- Email:

Fax to: 603-218-7020
or email to clientservices@greystoneassociates.org