EXECUTIVE SUMMARY ........................................................................................................ ES-1
i. Injection/Infusion Drug Delivery Systems ......................................................... ES-1
ii. Transdermal Drug Delivery Systems .............................................................. ES-4
iii. Inhalation Drug Delivery Systems................................................................. ES-6
iv. Methodology ..................................................................................................... ES-9

Exhibit ES-1: Injection/Infusion Drug Delivery Systems, Market Share,
by Product Segment, 2014 and 2019 ................................................................. ES-3
Exhibit ES-2: Patch-Based Pharmaceutical Products, Market Share,
by Product Segment, 2014 and 2019 ................................................................. ES-7
Exhibit ES-3: Inhalation Drug Delivery Products, Market Share,
by Product Segment, 2014 and 2019 ................................................................. ES-10

1. INJECTION/INFUSION DRUG DELIVERY SYSTEMS ...................... 1-1
   1.1 Products and Technologies .............................................................. 1-1
      1.2.1 Syringe Products .............................................................................. 1-2
         1.2.1.1 Multipurpose Standard Syringes ............................................ 1-5
         1.2.1.2 Multipurpose Safety Syringes ................................................. 1-5
         1.2.1.3 Insulin Syringes ......................................................................... 1-7
         1.2.1.4 Market Analysis ......................................................................... 1-8
         1.2.1.5 Competitive Analysis ............................................................... 1-8
      1.2.2 Injection Pen Products ........................................................................ 1-11
         1.2.2.1 Market Analysis ........................................................................ 1-13
         1.2.2.2 Competitive Analysis ............................................................... 1-13
      1.2.3 Needleless Jet Injector Products ........................................................ 1-16
         1.2.3.1 Market Analysis ........................................................................ 1-18
         1.2.3.2 Competitive Analysis ............................................................... 1-18
      1.2.4 Infusion Pump Products ...................................................................... 1-21
         1.2.4.1 Volumetric Pumps ..................................................................... 1-23
            1.2.4.1.1 Market Analysis ................................................................. 1-26
            1.2.4.1.2 Competitive Analysis ......................................................... 1-30
         1.2.4.2 Syringe Pumps ............................................................................. 1-30
            1.2.4.2.1 Market Analysis ................................................................. 1-32
            1.2.4.2.2 Competitive Analysis ......................................................... 1-33
         1.2.4.3 Ambulatory Pumps ...................................................................... 1-33
            1.2.4.3.1 Market Analysis ................................................................. 1-37
            1.2.4.3.2 Competitive Analysis ......................................................... 1-38
1.2.4.4 Disposable Pumps ........................................ 1-38
  1.2.4.4.1 Market Analysis................................. 1-43
  1.2.4.4.2 Competitive Analysis......................... 1-44

1.2.4.5 Implantable Pumps........................................ 1-48
  1.2.4.5.1 Market Analysis................................. 1-50
  1.2.4.5.2 Competitive Analysis......................... 1-50

1.2.4.6 Insulin Pumps........................................ 1-50
  1.2.4.6.1 Market Analysis................................. 1-55
  1.2.4.6.2 Competitive Analysis......................... 1-56

1.2.4.7 Enteral Pumps and Gravity Systems................. 1-60
  1.2.4.7.1 Market Analysis................................. 1-61
  1.2.4.7.2 Competitive Analysis......................... 1-62

1.2.4.8 Intravascular Gravity Infusion Systems .......... 1-62
  1.2.4.8.1 Market Analysis................................. 1-66
  1.2.4.8.2 Competitive Analysis......................... 1-69

1.2.5 Vascular Access Products.................................. 1-69
  1.2.5.1 Short Peripheral Catheters......................... 1-71
    1.2.5.1.1 Market Analysis................................. 1-74
    1.2.5.1.2 Competitive Analysis......................... 1-77

  1.2.5.2 Midline Catheters .................................. 1-77
    1.2.5.2.1 Market Analysis................................. 1-79
    1.2.5.2.2 Competitive Analysis......................... 1-79

  1.2.5.3 Peripherally Inserted Central Catheters .......... 1-79
    1.2.5.3.1 Market Analysis................................. 1-82
    1.2.5.3.2 Competitive Analysis......................... 1-83

  1.2.5.4 Central Venous Catheters ......................... 1-83
    1.2.5.4.1 Market Analysis................................. 1-86
    1.2.5.4.2 Competitive Analysis......................... 1-87

  1.2.5.5 Implantable Ports .................................. 1-87
    1.2.5.5.1 Market Analysis................................. 1-90
    1.2.5.5.2 Competitive Analysis......................... 1-92

Exhibit 1-1: Injection/Infusion Drug Delivery Systems,
  Combined Market Forecast, 2014-2019 .......................... 1-3

Exhibit 1-2: Multipurpose and Insulin Syringes, Market Forecast, 2014-2019 . . . . 1-9

Exhibit 1-3: 2014, Multipurpose and Insulin Syringes Market,
  Share by Supplier ........................................... 1-12
U.S. Markets for Drug and Fluid Delivery Devices

Exhibit 1-4: Insulin Pen Products, Market Forecast, 2014-2019 .................. 1-14
Exhibit 1-5: 2014, Insulin Pen Products Market, Share by Supplier ............ 1-17
Exhibit 1-7: 2014, Needleless Jet Injectors Market, Share by Supplier ........ 1-22
Exhibit 1-10: 2014, Volumetric Pumps and Disposables Market, Share by Supplier .............................................................................................................. 1-31
Exhibit 1-11: Syringe Pumps and Disposables, Market Forecast, 2014-2019 ...... 1-34
Exhibit 1-12: 2014, Syringe Pumps and Disposables Market, Share by Supplier .............................................................................................................. 1-36
Exhibit 1-14: 2014, Ambulatory Pumps and Disposables Market, Share by Supplier .............................................................................................................. 1-41
Exhibit 1-16: 2014, Disposable Infusion Pumps Market, Share by Supplier .... 1-47
Exhibit 1-17: Implantable Infusion Pumps, Market Forecast, 2014-2019 ...... 1-51
Exhibit 1-18: 2014, Implantable Infusion Pumps Market, Share by Supplier .... 1-53
Exhibit 1-20: 2014, Insulin Pumps and Disposables Market, Share by Supplier .. 1-59
Exhibit 1-24: 2014, Intravenous Gravity Infusion Systems Market, Share by Supplier .............................................................................................................. 1-70
Exhibit 1-26: Short Peripheral Catheters, Market Forecast, 2014-2019 .......... 1-75
Exhibit 1-27: 2014, Short Peripheral Catheters Market, Share by Supplier .... 1-78
Exhibit 1-29: 2014, Midline Catheters Market, Share by Supplier ............... 1-81
Exhibit 1-30: Peripherally Inserted Central Catheters, Market Forecast, 2014-2019 ...................................................................................................................... 1-84

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Exhibit 1-31: 2014, Peripherally Inserted Central Catheters Market, Share by Supplier ................................................................. 1-85
Exhibit 1-32: Central Venous Catheters, Market Forecast, 2014-2019 ................. 1-88
Exhibit 1-33: 2014, Central Venous Catheters Market, Share by Supplier .......... 1-89
Exhibit 1-34: Implantable Ports, Market Forecast, 2014-2019............................. 1-91
Exhibit 1-35: 2014, Implantable Ports Market, Share by Supplier ..................... 1-93

2. TRANSDERMAL DRUG DELIVERY SYSTEMS................................. 2-1

2.1 Technology .................................................................................. 2-1

2.1.1 Passive Transdermal Transport Systems........................................... 2-3

2.1.2 Active Transdermal Transport Systems ............................................. 2-5

2.2 Clinical Applications ..................................................................... 2-6

2.2.1 Cardiovascular Disease Management ............................................. 2-10

2.2.1.1 Products .................................................................................. 2-12

2.2.1.2 Market Analysis ....................................................................... 2-12

2.2.1.3 Competitive Analysis ................................................................. 2-12

2.2.2 Central Nervous System Disorder Management ......................... 2-14

2.2.2.1 Products .................................................................................. 2-17

2.2.2.2 Market Analysis ....................................................................... 2-18

2.2.2.3 Competitive Analysis ................................................................. 2-18

2.2.3 Hormone Replacement Therapy ..................................................... 2-20

2.2.3.1 Products .................................................................................. 2-23

2.2.3.2 Market Forecast ....................................................................... 2-23

2.2.3.3 Competitive Analysis ................................................................. 2-24

2.2.4 Pain Management ....................................................................... 2-26

2.2.4.1 Cancer-Related Pain ................................................................. 2-26

2.2.4.2 Post-Herpetic Neuralgia ............................................................. 2-29

2.2.4.3 Products .................................................................................. 2-30

2.2.4.4 Market Analysis ....................................................................... 2-32

2.2.4.5 Competitive Analysis ................................................................. 2-34

2.2.5 Urologic Disorder Management ..................................................... 2-34

2.2.5.1 Products .................................................................................. 2-37

2.2.5.2 Market Analysis ....................................................................... 2-38
Exhibit 2-1: Patch-Based Pharmaceutical Products, by Application, Combined Market Forecast, 2014-2019 ................................................................. 2-8
Exhibit 2-3: 2014, Patch-Based Clonidine and Nitroglycerin Products Market, Share by Supplier ................................................................. 2-15
Exhibit 2-4: Patch-Based Central Nervous System Disorder Treatment Products, Market Forecast, 2014-2019 ................................................................. 2-19
Exhibit 2-5: 2014, Patch-Based Central Nervous System Disorder Treatment Products Market, Share by Supplier ................................................................. 2-21
Exhibit 2-6: Patch-Based Estrogen Replacement Products, Market Forecast, 2014-2019 ................................................................. 2-25
Exhibit 2-7: 2014, Patch-Based Estrogen Replacement Products Market, Share by Supplier ................................................................. 2-27
Exhibit 2-8: Patch-Based Pain Management Products, Market Forecast, 2014-2019 ................................................................. 2-33
Exhibit 2-9: 2014, Patch-Based Pain Management Products Market, Share by Supplier ................................................................. 2-35
Exhibit 2-10: Patch-Based Urologic Treatment Products, Market Forecast, 2014-2019 ................................................................. 2-39

3. INHALATION DRUG DELIVERY SYSTEMS ................................................................. 3-1
3.1 Chronic Respiratory Disorder Management ......................................................... 3-1
   3.1.1 Bronchial Asthma .................................................................................. 3-1
   3.1.2 Chronic Obstructive Pulmonary Disease ................................................ 3-3
   3.1.3 Cystic Fibrosis ....................................................................................... 3-4
   3.1.4 Obstructive Pulmonary Disorder Management ........................................ 3-5
      3.1.4.1 Allergy-Blocking Agents ............................................................. 3-5
      3.1.4.2 Anti-Inflammatory Agents ............................................................ 3-7
      3.1.4.3 Bronchodilators ............................................................................ 3-8
3.2 Diabetes Management ..................................................................................... 3-8
3.3 Emerging Applications .................................................................................... 3-10
   3.3.1 Alkermes ............................................................................................... 3-10
   3.3.2 Aradigm ................................................................................................. 3-11
   3.3.3 MannKind ............................................................................................ 3-12
   3.3.4 Nektar Therapeutics ................................................................................ 3-13
EXECUTIVE SUMMARY
Pharmacotherapy represents the first-line treatment in the management of most chronic and transient medical conditions warranting therapeutic intervention in the United States (U.S.).

This report covers the device-based drug delivery modalities that offer the best available combination of functional characteristics required for effective pharmacologic therapy. The drug delivery technologies analyzed in this report include injection/infusion systems [e.g., syringes, pens, jet injectors, infusion pumps, and vascular access devices (VADs)]; transdermal systems for cardiovascular, central nervous system (CNS), hormone replacement therapy (HRT), pain management, and urologic applications; and inhalation systems [e.g., metered dose inhalers (MDIs), dry powder inhalers (DPIs), and nebulizers] for the treatment of acute and chronic respiratory disorders as well as diabetes.

i. Injection/Infusion Drug Delivery Systems
Despite its relative invasiveness and technological maturity, instrument-based infusion and injection of pharmaceutical preparations commonly is regarded as the most accurate, effective, reliable, and reproducible method of therapeutic drug and fluid delivery. A variety of drug infusion/injection techniques are used at hospitals and alternate care sites for the management of patients with acute and chronic medical conditions warranting or responsive to pharmacologic therapy.

Major clinical applications of drug and fluid infusion and injection tools include anesthesia delivery, antibiotic/antiviral therapy, bone marrow and organ transplant support therapy, cardiovascular disease management, chemotherapy, diabetes management, hydration therapy, nutritional support, pain management, and transfusion therapy.

Systemic or local injection/infusion of medical preparations is an invasive form of drug therapy used in cases in which other delivery routes are considered inadequate, ineffective, or unfeasible due to pharmacologic incompatibility or patient intolerance and noncompliance. Drug and fluid administration via the injection/infusion route typically involves the use of various combinations of the following hardware components:
• access devices such as catheters, needles, or ports, which are intended to penetrate natural protective barriers and simultaneously establish the endpoint for the delivery of drugs, fluids, and nutrients into the vascular system or other anatomic sites;

• administration sets, with or without filters or additional ports, which provide an interfacing conduit for transporting drugs or fluids from a container to the access device;

• pumping instruments (e.g., gravity bags, hand-driven syringe plungers, or mechanical pumps) intended to maintain a sufficient positive pressure gradient and desired drug flow into the patient's bloodstream or targeted intracorporeal sites; and,

• separate or built-in containers for drugs or solutions ranging from standard bags, bottles, and vials to proprietary cassette reservoirs used with ambulatory infusion pumps and elastomeric balloon-like containers for disposable pumps.

In 2014, combined U.S. sales of injection/infusion drug delivery systems totaled approximately $6,917.9 million; of this, infusion pumps and disposables accounted for an estimated 51.7% of sales, followed by syringes with 23.9%, VADs with 15.4%, gravity infusion systems with 8.5%, injection pens with 0.4%, and needleless jet injectors with 0.1%. Over the forecast period covered by this report, total sales of injection/infusion drug delivery systems in the U.S. are expected to increase at a compound annual rate of 3.7%, reaching an estimated $8,300.6 million in the year 2019. Robust growth in this market will continue to be driven primarily by the ongoing transition to more expensive safety-enhancing pumping instruments and needleless technologies in all major groups of disposable drug delivery devices used in injection/infusion therapy. Anticipated healthy expansion in the niche needleless jet injector segment will have only nominal impact on the growth dynamics of the overall infusion/injection products market.

Exhibit ES-1 presents the U.S. market share, by product segment, for injection/infusion drug delivery systems for the years 2014 through 2019.
Notes: Syringes include multipurpose syringes (including standard and safety syringes) and insulin syringes. Injection pens include insulin pens and insulin pen needles. Infusion pumps and disposables include ambulatory pumps, disposable pumps, implantable pumps, insulin pumps, syringe pumps, volumetric pumps, and enteral nutrition pumps and associated disposables. Vascular access devices include central venous catheters, implantable ports, midline catheters, peripherally inserted central catheters, and short peripheral catheters.

Source: Medtech Insight
Exhibit 1-2: (Continued)

Multipurpose and Insulin Syringes, Market Forecast, 2014-2019

Source: Medtech Insight
Selected suppliers of ambulatory pumps in the U.S. include:

- **CME America**—products (distributed in the U.S. by B. Braun Melsungen) include the BodyGuard multipurpose continuous/bolus infusion therapy system and the CMExpress continuous infusion pump featuring piggyback mode to allow secondary line infusion, automatic display cycling, and an integrated free-flow protection valve;

- **Hospira**—products include the GemStar line of color-coded, compact, application-specific instruments with remote access capabilities for arterial, epidural, or IV infusion in ambulatory, home, or hospital settings;

- **Moog**—products (distributed in the U.S. by B. Braun Melsungen) include the Curlin 6000 CMS ambulatory infusion pump featuring integrate free-flow protection and the Curlin PainSmart IOD pump featuring Information On Demand to enable users to view clinical information while the pump is running;

- **Smiths Medical**—products include the CADD line of infusion systems, available in the Legacy, MS3, Prizm PCS, Prizm VIP, and Solis models; and,

- **WalkMed Infusion**—products include the WalkMed line of infusion systems, available in the WM 350 VL and WM 350 LX models.

### 1.2.4.3.1 Market Analysis

Over the past 15 years, the U.S. demand for ambulatory pumps has been increasing, reflecting a cost containment-driven market and the continuing migration of noncritical infusion caseloads to more economical alternate and home care settings. At the end of 1990s, some extra impetus to market growth was generated by the introduction of ambulatory pumps with telecommunication peripherals (for remote pump programming and therapy monitoring) that provided ample opportunities for savings on personnel time and labor, accounting for up to 65% of outpatient infusion therapy costs.

More recently, the U.S. ambulatory pumps market registered extra gains from a coupling of its core infusion instrument technology with patient safety- and data management-oriented informatics, although the scope and scale of such a coupling are still rudimentary compared to those observed in acute care settings. Over the
3. INHALATION DRUG DELIVERY SYSTEMS

Inhalation drug therapy traditionally has targeted acute and chronic pulmonary disorders, and has been the mainstay palliation and treatment modality for asthma and chronic obstructive pulmonary disease (COPD) for the past four decades.

Over the years, extensive and reasonably successful attempts have been made in utilizing the pulmonary route for the delivery of nonrespiratory systemic medications, such as antibiotics, insulin, interferons, vaccines, and some novel macromolecular peptide- and protein-based biopharmaceuticals.

An overview of established and emerging applications of inhalation pharmacotherapy and corresponding pulmonary drug delivery technologies is provided in the following sections.

3.1 Chronic Respiratory Disorder Management

Chronic respiratory disorders encompass a broad range of acquired or congenital medical conditions that result in transient or permanent pulmonary insufficiency characterized by impairment of the perfusion or ventilation function of the lungs. Drug inhalation therapy is used widely in the management of pulmonary insufficiency associated with severe airway obstruction due to bronchial asthma as well as chronic bronchitis and emphysema (which comprise the COPD group of respiratory conditions). The pulmonary route of drug administration also commonly is used in the treatment of chronic lung impairment associated with a genetic disease known as cystic fibrosis (CF).

3.1.1 Bronchial Asthma

Bronchial asthma—a chronic inflammatory respiratory disease characterized by recurrent episodes of airway obstruction due to bronchoconstriction or bronchospasm—is a complex disorder involving autonomic, biochemical, endocrine, immunologic, and infectious factors. Typical symptoms of an asthma attack include anxiety, breathlessness, coughing, increased heart rate, rapid breathing with prolonged expiration, tightness of the chest, and wheezing due to vibrations in the narrowed airways. An attack may last from a few minutes to a few hours or even days, and may be relieved spontaneously or as a result of therapy. In extreme
### Exhibit 3-2: Advantages and Disadvantages of Inhalation Drug Delivery Devices

<table>
<thead>
<tr>
<th>Device Type</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dry Powder Inhalers</td>
<td>For prophylactic and rapid relief applications; Available with a grip attachment (for patients with arthritic or restricted finger movement) and a whistle adapter (for indicating adequate inspiratory flow); Breath coordination not required; Easy to use; Little or no medicinal aftertaste; Multiple drug doses available; Propellant-free; Small size</td>
<td>Device loading may be cumbersome; Exhaling into the devices may affect drug delivery; No definite indicator of the remaining drug level; Not suitable for all patients due to high inspiratory flow rate requirements; Require deep, forceful inspiration; Typically more costly compared to MDIs</td>
</tr>
<tr>
<td>Medication Nebulizers</td>
<td>Available in battery-powered versions; Greater flexibility in drug dosing/mixing; May be used with a mask or mouthpiece; More comfortable to use and more efficient drug delivery with less waste than a DPI or MDI; Suitable for use in the clinic, home, or hospital</td>
<td>Eyes may be affected by nebulized drugs escaping a poorly fitted mask; Increased risk of chest infection when used with reusable attachments that are not properly cleaned; Not suitable for active patients; Relatively high initial cost; Treatment takes considerably longer to administer than other methods</td>
</tr>
<tr>
<td>Metered Dose Inhalers</td>
<td>For prophylactic and rapid relief applications; Choice of open- or closed-mouth drug delivery methods; Easily handled by most patients; Low inspiratory flow required (15L/min to 20L/min); May be used with enhancing attachments; Multiple drug doses available; Small size</td>
<td>Breath coordination may be a challenge for some patients; Less efficient with the closed-mouth method; Many devices still rely on CFC-based propellants; May be difficult to use for those with restricted hand/arm movement</td>
</tr>
</tbody>
</table>

Notes: CFC = chlorofluorocarbon. DPI = dry powder inhaler. MDI = metered dose inhaler.

Source: Medtech Insight