

Prefillable Biological Drug Delivery Systems

Devices, Markets, Therapeutics,
Strategies, & Forecasts

Report Brochure

Greystone
Research Associates



Greystone Research Associates is pleased to announce the publication of a new market study. **Prefillable Biological Drug Delivery Systems** is a comprehensive evaluation and analysis of the technology, products and participants providing the driving force behind this evolving segment of the healthcare sector.

The study is designed to provide drug company decision makers, drug delivery developers, device designers, healthcare marketers, and supply chain participants with a detailed understanding of the economics, technologies, disease segments, and commercial opportunities for prefillable biological drug delivery systems. Provider organization business managers, healthcare administrators and investors will also benefit from this study.

Device Evolution and Increasing Patient Care Flexibility

Specialty prefilled injection devices - a group that includes pen injectors and autoinjectors – are creating new opportunities for drug developers and marketers. These devices provide the ability to create product differentiation in the age of direct-to-consumer marketing.

Because biological drugs most often target chronic conditions, dosing strategies and treatment protocols must be developed for long-term use, often for self-administration by patients who may have limitations directly related to their condition. The shift in as-supplied packaging from single and multi-use vials to prefilled injection devices will accelerate over the next five years as drug developers move to empower an increasing number of chronically ill patients. The powerful physiological effects of antibodies, hormones and other biological drugs also increase the need for safety and compliance.

Report Value Matrix

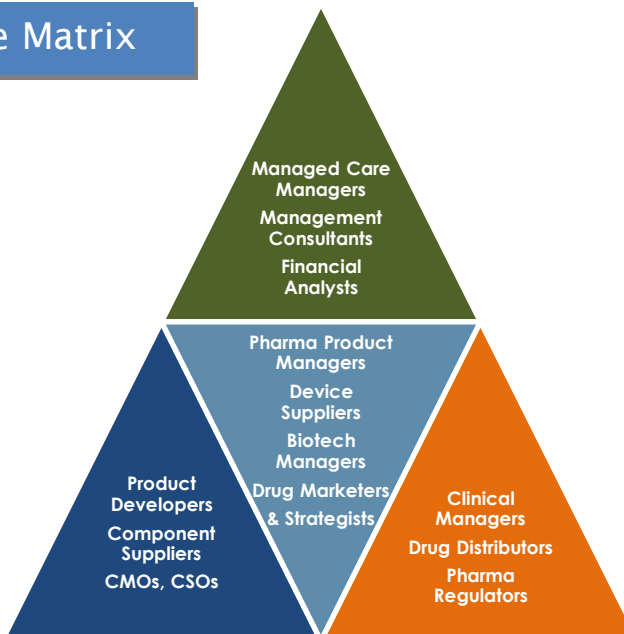


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Therapeutic Monoclonal	Wearable Devices
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Product Specific Prefillable	Hepatitis
Autoinjectors Summaries	Hematopoietics
Device Design Factors	Hormone Replacement
Material Selection Issues	Osteoporosis
Part Counts and Device Cost	Market Factors
Safety Features	Regulatory Issues
Needle Insertion Depth	Device Branding
Failsafe Activation	Patient Adherence & Ease of Use
Dose Inspection/Injection	Healthcare Economics
Confirmation	Company Profiles
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Human Engineering/Ergonomics	

What You Will Learn

- What are the market factors driving commercial activity in the biologicals drug delivery segment?
- What are the major factors driving as-supplied product development decisions within biological drug development organizations?
- How does the availability of patient support resources influence the prescribing decision for biological drugs?
- How important are drug developer-formulation technologist relationships in the biological drug packaging segment?
- What are the key influencers regarding as-supplied packaging in the biological self-administration market segment?
- What are the significant economic, technology, and regulatory factors affecting the selection criteria for self-administered biological drugs?

Report Format and Availability

This report is available electronic format. A site license for a single physical location and a global license are also available. Custom licensing options to address specific company user requirements are available by calling client services at 603-440-5710, 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 demand and future market activity are derived using standard modeling and statistical techniques.

About Greystone Associates

Greystone 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.

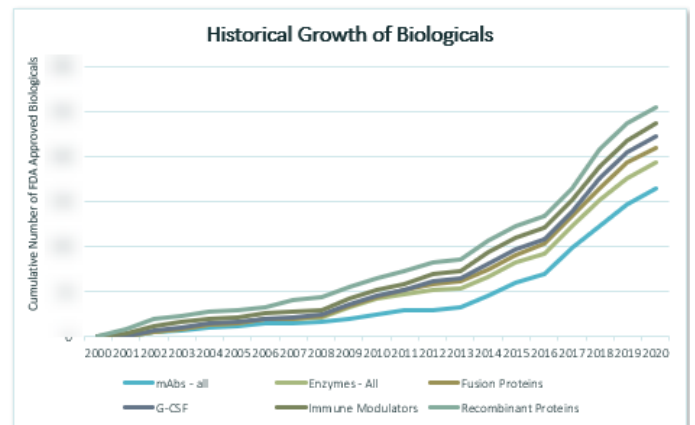
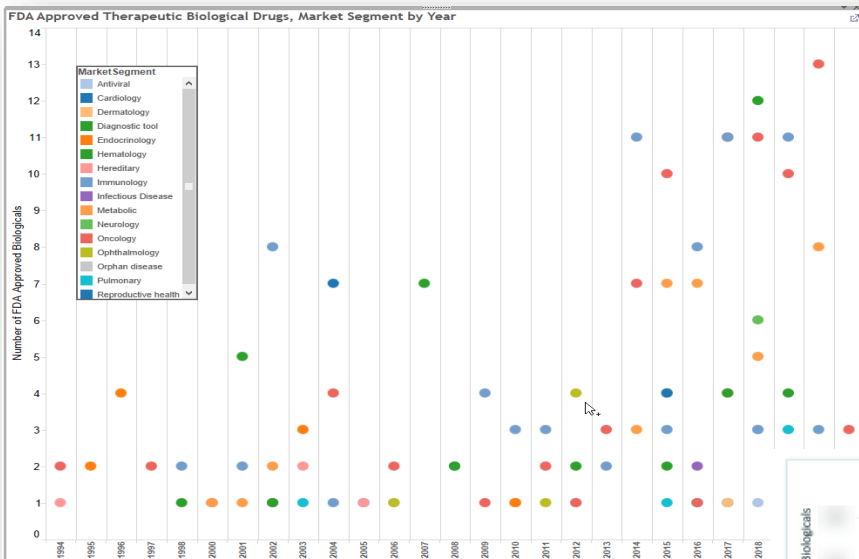
Our market research publications are designed, researched and written to provide timely and insightful information and data on focused market segments, with the aim of providing market participants with the essential knowledge to refine and execute their marketing plans and financial targets.

Clear & Concise Graphics & Visualizations

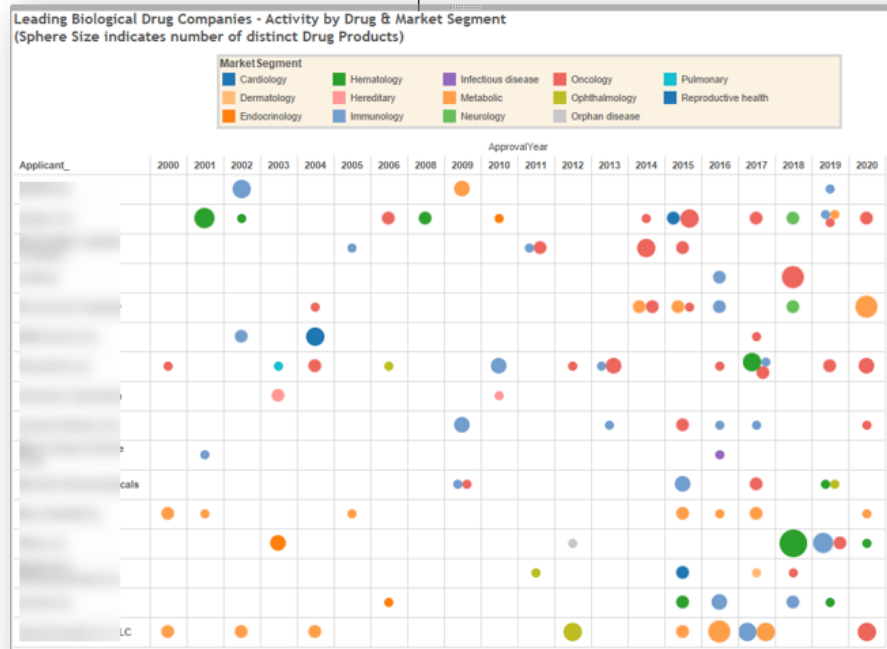
Global Biologicals Manufacturing Activity



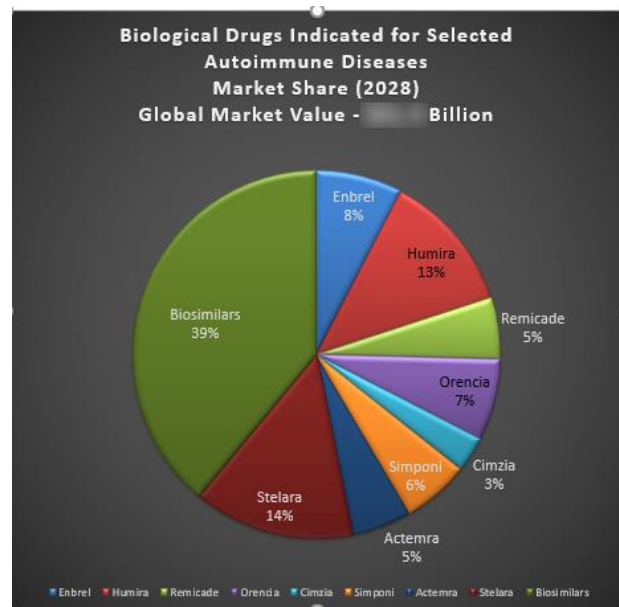
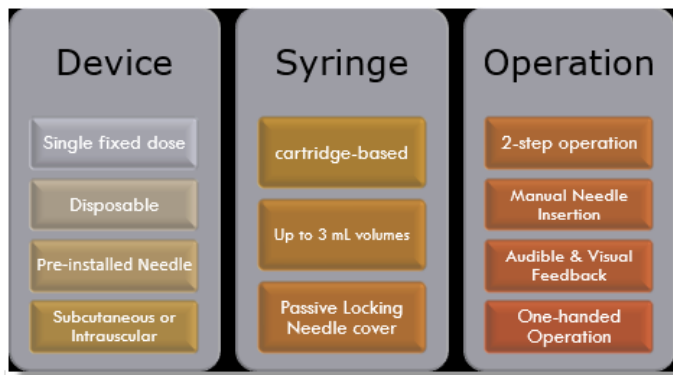
FDA-approved Biological Drug Activity



Biological Drug Activity by Company, Year and Market Segment



Product Summary

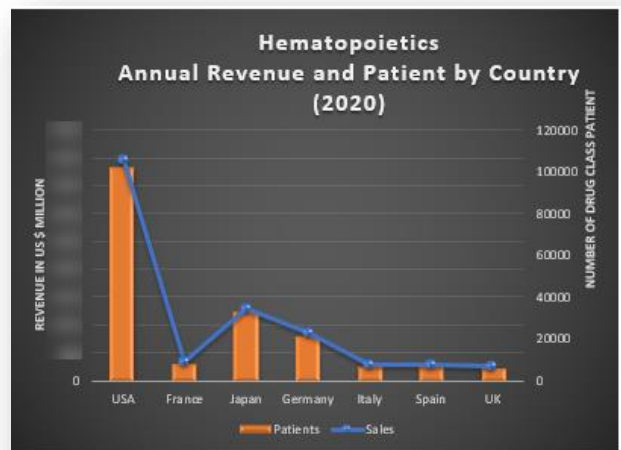


Device Summary	
Device Design	Mechanical
Device Type	Disposable
Primary Container	Type 1 Glass
Injection Event	Automatic
Injection Volume	Preset bolus injection volume
Injection Rate	Preset injection rate
Drug Viscosity	100 cps
Drug Volume	2 – 10 mL
Drug Fill	Prefilled
Safety/Feedback	Passive needle safety
Integrations	BD <u>Neopak</u>
Partners	
<u>Harro Hofliger</u>	Clinical/pre-production quantities

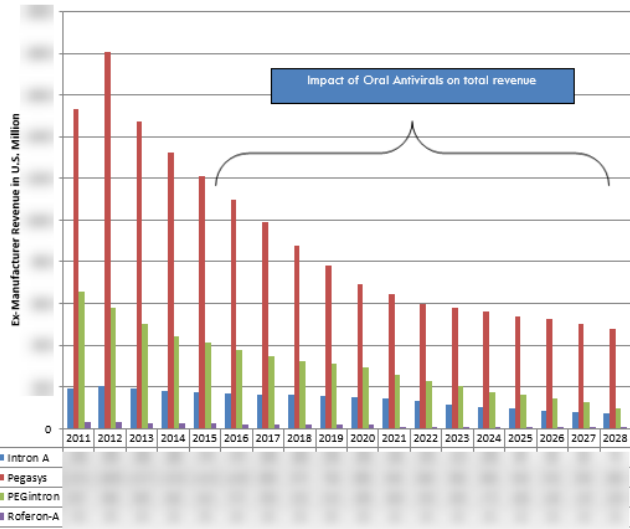
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Selected Wearable Subcutaneous Injectors

Device Design	Electronic	EM	EM	Electronic	Electronic	Mechanical	Electronic	Mechanical
Device Type	Disposable	Disposable	Semi-disposable	Semi-disposable	Semi-disposable	Disposable	Disposable	Disposable
Needle/Cannula	29 g needle	5 – 8 mm	5 – 8 mm	Automatic	Automatic	Automatic	Automatic	Automatic
Primary Container	Cyclic Olefin Cartridge	Glass Cartridge	Std Vials	Type 1 glass	Std Container	Std Container	Std Container	Type 1 glass
Injection Method	Push Button	Programmable	Programmable	Battery-driven piston	Rotary pump	Push Button	Electronic	Push Button
Capacity (mL)	3.5	2 - 10	2 - 10	2 mL	3 mL	1 – 20	3 mL	2 - 10
Drug Fill	Prefilled	Prefilled	Prefilled	Prefilled	Cartridge	Vial-to-device	Prefilled	Prefilled



Injectables Indicated for HVC Historical Global Revenue & Forecast



Biologics Indicated for Autoimmune Diseases (Supplied in Prefillable Drug Delivery Systems)

Proprietary_Name	Proper_Name	Applicant	As_Supplied	DrugClass
Abrilada	adalimumab-atzb	Pfizer, Inc		mAb
				mAb
Actemra	tocilizumab	Genentech, Inc.		mAb
Benlysta	belimumab	GlaxoSmithKline LLC		mAb
				mAb
Cosentyx	secukinumab	Novartis Pharmaceuticals		mAb
				mAb
Cytezo	adalimumab-adbm	Boehringer Ingelheim Pharmaceuticals		mAb
Erelzi	etanercept-422s	Sandoz Inc.		Fusion Protein
Erelzi Sensoready	etanercept-422s	Sandoz Inc.		Fusion Protein
Hadlima	adalimumab-buwtd	Samsung Bioepis Co., Ltd.		mAb
				mAb
Hulio	adalimumab-figp	Mylan Pharmaceuticals Inc.		mAb
				mAb
Humira	adalimumab	AbbVie Inc.		mAb
				mAb
Hyrimoz	adalimumab-adaz	Sandoz Inc.		mAb
				mAb
Kevzara	sarilumab	Sanofi-Aventis U.S. LLC		mAb
Kineret	anakinra	Swedish Orphan Biovitrum AB (publ)		Immune modulator
Siliq	brodalumab	Valeant Pharmaceuticals Luxembourg		mAb
Simponi	golimumab	Janssen Biotech, Inc.		mAb
				mAb
Taltz	ixekicumab	Eli Lilly and Company		mAb
				mAb
Tremfya	guselkumab	Janssen Biotech, Inc.		mAb

Annual Sales and Number of Patients by Injectable Drug Class and Country (2019)

	USA	France	Japan	Germany	Italy	Spain	UK
Growth Hormones							
Sales (US Billion)							
Patients (Thousands)							
Hematopoietics							
Sales (US Billion)							
Patients (Thousands)							
Autoimmune							
Sales (US Billion)							
Patients (Thousands)							
Hepatitis C							
Sales (US Billion)							
Patients (Thousands)							
Multiple Sclerosis							
Sales (US Billion)							
Patients (Thousands)							
Osteoporosis							
Sales (US Billion)							
Patients (Thousands)							

Ordering Information

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 and billing address.

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.

Email to
research@greystoneassociates.org

Wire Transfers: TD Banknorth
300 Franklin Street
Manchester, NH 03103
(Call for Account Information)

Mailing Address: Greystone Research Associates
Client Services
P.O. Box 1362
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Expiration Date: _____ Card CVV _____ Signature _____

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