Drug Delivery Systems
Understanding the Competitive Landscape

Prepared by Fletcher/CSI for:

PHARMA CI
CONFERENCES

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Agenda

- Evolution and continuing developments in DDS
- Regulatory changes
- Understanding the processes and players in an effective development strategy
- Boiling the Ocean: tools and resources to help identify a development program’s best DDS candidates
About Fletcher/CSI

Over 30 years experience in providing competitor intelligence research and strategic consulting to Life Science companies

- Pharmaceutical
- Biotech
- Consumer Health

Customized Research & Consulting Services
- Deep Dive & Ad-hoc Research
- Benchmarking & Due Diligence
- Strategy Workshops & CI Consulting
- Market Monitoring
- Conference Coverage
- Secondary Newsletters

- MDD Manufacturers
- Medical Equipment Manufacturers
- Laboratory Services & Devices
Drug Delivery Systems (DDS) relevant experience

Fletcher/CSI has completed multiple, broad based engagements in DDS for leading global pharma and medical device organizations. Our knowledge base spans:

**Pharmaceutical Companies**
- DDS systems used in Oncology, Immunology, Endocrinology, CV and others TAs
- DDS development processes
- Organizational DDS decision processes
- External device development partner assessments and benefit analyses

**Medical Device Companies**
- Several specific drug delivery system studies
- DDS market landscape analysis
- War Gaming and Strategy Planning Workshops for several WW organizations

**All types of Devices**
- Syringes
  - Auto/Pen Injectors
- Inhalers
- Infusion systems
- Wearables
- Pumps
- Patches

**Primary Insights**
- Device Design Houses
- Device Manufacturers
- Pharma
- Smart Technology Cos.
- Device Experts/KOLs
- Hospitals/HCPs
- Trial Leaders
- Regulatory
Example: Evolution of DDS

Ongoing Evolution and Innovation

First Generation
(late 80’s to late 2000’s)
- Dual chamber pen injectors
- Insulin pens
- First TNF inhibitor auto-injectors

Second Generation
(2010’s to 2017)
- Improved audio/visual cues
- Electronic auto-injector
- Wearable Bolus Injector

Future of Biologic Drug Delivery
(2018 to 2022, and beyond)
- Flexible viscosities/volumes
- Smart/connected technology
- Accelerometers
- Orientation indicators
Some innovative devices in development

- Autoinjectors
- Wearables
- Smart Pills
- Smart Inhalers
- Smart Pumps
- Implants
- Microneedles
- Needleless
- Hydrogels
- Transdermal
- Microchips

## Emerging Patient Needs

Many organizations struggle to find a balance between affordability and patient-centric devices.

<table>
<thead>
<tr>
<th>Patients Want</th>
<th>Innovation Category</th>
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<tbody>
<tr>
<td>Less frequent injections</td>
<td>Larger Volumes: Doses over 3 mL</td>
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<tr>
<td>Patients want comfort, confidence and feel attracted to device</td>
<td>Less Anxiety: Needle shield or a hidden needle, less noise, true end of dose indicators (audible, visual, or tactile), aesthetic appeal</td>
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<td>To feel at ease with device</td>
<td>Both Anxiety and Ease of Use: Ergonomic device/patient comfort</td>
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<tr>
<td>Patients want quick and straightforward injection experiences</td>
<td>Ease of Use: Less steps (injection process), accelerometer, orientation indicator, smart design and packaging</td>
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<tr>
<td>Ability to keep track of their medication regimens</td>
<td>Medication tracking, reminders, and communication with HCP: Bluetooth connectivity</td>
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<tr>
<td>Little to no adverse effects</td>
<td>Reduced Toxicity: Targeted, direct to organ or therapeutic site</td>
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Evolving Drug Delivery Systems (DDS)

The market for advanced drug delivery technology is growing, and is poised to play a greater role in future innovations that improve patient outcomes.

- **Novel DDS are evolving, with >1,100 in development:**
  - Ongoing need for more effective delivery methods for biologics with unique product characteristics
  - Potential implications of ‘smart’ or ‘connected’ technology (IoT)
  - Nano-technology advances

- **New DDS have the ability to:**
  - Deliver targeted therapies and control drug release rates
  - Improve safety and efficacy
  - Increase compliance
  - Provide a better patient experience
### Emerging DDS Trends

<table>
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<td>New platforms face regulatory hurdles, higher costs, and longer development timelines, therefore companies are trying to work with add-ons to existing primary containers and PFS</td>
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<td>Smart technology has the potential to provide advantages across the entire pharma network</td>
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<td>Smart Technologies are positioned to improve compliance, provide insights to stakeholders, improve patient satisfaction, and realize better patient outcomes and lower revenue losses.</td>
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<td>The need for larger volumes in auto-injectors has been gaining traction given the growing patient need for less frequent injections.</td>
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<td>Many device manufacturers are engaging and promoting some form of human factors engineering (HFE) expertise (mostly in-house)</td>
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How the right DDS creates competitive advantage

Options in DDS offer patient choice based on dosing schedule preferences, improved comfort, and lifestyle considerations

**Reduced time to infusion, from IV to SC**

- **Herceptin trastuzumab**
  - For HER2+ Breast Cancer
  - From hospital setting IV, 30-90 minutes, every week/three weeks

**MyDose** device, providing SC drug delivery in ~5 minutes

- Reduced time from IV to SC for HER2+ Breast Cancer

**Adapting delivery systems to target patient demographics, evolving patient needs/wants, and potential utility in ‘smart’ connectivity**

- **Cimzia (certolizumab pegol)**
  - For RA, PsA, AS, CD
  - PFS: designed in partnership with OXO Good Grips

**AutoClicks:** Prefilled pen

- Prefilled pen device

**ava:** re-usable electronic injection device
Development timelines may be dynamic and iterative

- **Discovery & Ideation**
- **Invention & Prototyping**
- **Pre-Clinical**
- **Clinical**
- **Regulatory Decision**
- **Product Launch**
- **Post-Market Monitoring**

**Iterative Development Cycle**
- Investigational Phase
- Design-Development Phase

**Existing Platform**
- No modification
- 12-18 month

**New Platform – Some Innovation**
- 28 to 36 months

**Innovative – Novel Device**
- 3 to 5 years

- **Months**
  - 0
  - 12
  - 24
  - 36
  - 48
  - 60
The new directive will significantly affect pharmaceutical manufacturers supplying drug/device combinations

- 2020 – full directive in place
- 3 year transition period
  - Life cycle approach to approval - Current
  - CE certificate valid until reissue date unless changes made to device
  - Recertification by NB needed thereafter
- Make approval stricter
- Greater focus on clinical trials
- Safety/performance requirements
- New ISO standards
- More detailed regulations
- New classifications

Notified Bodies issue certificates Max. 5 years validity
Leveraging tools and strategies to identify an optimal drug/device match, while also keeping abreast of competitive developments

Example:

- **>7,800 medical device products**
- **<1,150 target products**
- **227 target products**
- **78 target products**

To advance to design phase, the top 2-3 products are selected.

**Fletcher/CSI’s Comprehensive CI Solutions**

- Secondary searches proprietary databases & non-proprietary sources
- Market monitoring of device developments via secondary collaboration/reporting tools
- Collection of intelligence at Pharma and device trade shows
- Primary interviews with device companies, design houses, CMOs, technology partners, KOLs, and others

**Scenario Planning and Competitive Simulation Workshops**
Understanding the process and players involved in an effective development strategy

From concept to final assembly, device development programs may be conducted all or in part with specialized vendor partners.

**Concept**
- With input from or collaboration with design houses or contract engineers

**Design & Engineering**

**Components Assembly**
- With input from or collaboration with device manufacturers, technology and component partners

**Final Assembly & Fill/Finish**

**Possible Internal Stakeholders/Decision Makers**

1. Drug R & D
2. Device Strategy & Development & Human Factor Engineers
3. Project and Process Managers
4. Manufacturing, Packaging, QC & Finished Goods
5. Global Commercial Lead
How CI can be part of the decision process

1. Understand internal DDS decision process, and people and departments involved

2. Work to identify information needs and appropriate timing

3. Establish information collection process and tools needed

4. Provide strategic insight to select right partners, device, and regulatory filing processes
Thank you.
We look forward to supporting your strategic business needs

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