Closing the gap: Evaluating On Body Injector technologies and their readiness for commercialization

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AMGEN

Agenda

- Project Background and Objective
- Approach
- Project Summary
- Next Steps

Amgen is a biotechnology company, focusing on discovering, developing, manufacturing, and delivering therapeutics.

- They were **founded in 1980 in Thousand Oaks, CA** where their HQ is located.
  - **Singapore and Puerto Rico** are two of their larger drug manufacturing plants
- **$28.2 billion** in revenue and **over 26,000 employees** globally
- Amgen focuses on four main therapeutic areas: **oncology, inflammation, general medicine and rare disease.**
- Amgen invests heavily in R&D, developing **biologic and synthetic medicines** many of which are administered with **drug delivery devices.**

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This project aims to evaluate the gap between existing drug delivery devices and market / patient needs

Background | Approach | Project Summary | Next Steps

Background

- Amgen has two **primary electromechanical (EM) devices** for drug delivery: Onpro and AutoTouch
  - **AutoTouch**: reusable autoinjector used with Enbrel to treat rheumatoid arthritis
  - **Onpro**: on body injector used with Neulasta to boost white blood cell
- Key Question: What strategies can be implemented to **make delivery devices more appealing to patients?**
- To narrow scope of the discussion of EM drug delivery devices, on-body injectors (OBI) will be the primary focus

Identify and evaluate the gap

- **Hypothesis to test:** Drug delivery devices have a wide range of features serving different markets and patients with varying success
  - Market participants must **respond appropriately to technology and patient use trends** to ensure the best possible technology is available to patients
- Incorporating **patient and market dynamics** into **product strategies and roadmaps is difficult and complex**
  - **Multiple stakeholders contribute across the value chain**
  - **Successful implementations** are likely **accelerate product development**

Focused enhancements studies

- Demonstrate potential **pathways to determine what is the best OBI technology across different market and patient needs**
- Conduct **case studies** on value of different features and **prototype features**
- Consolidate investigation results into a **transparent strategic document** to **align devices and drug product teams** on best **path forward for patients** when it comes to drug delivery

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Reviewing the OBI market landscape will require understanding patient needs, various product offerings / features, and trends

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Market overview

- Electromechanical drug delivery mechanisms are designed to **precisely** and in a **controlled manner administer drugs to patients** using **actuators** and **sensors** to **improve the experience**
- Different categories include: autoinjectors, **on-body injectors,** smart inhalers, infusion pumps
- Major distinction within OBIs is insulin vs non-insulin
  - **Non-insulin offerings make up about 40% of the market**
  - Relatively new market compared to other devices

Trends, competitors, features

- Major players in the OBI space include companies like West and BD with Enable, LTS, and Sensile more recently entering the market
- Key specifications include max **volume, viscosity** capabilities, **reusability,** connectivity, dose type, and **lyophilization**
- Early trends identified such as **larger volume, platform capabilities**, stronger pumps (to support higher viscosities), and partial reusability
  - Connectivity is still viewed as a nice to have if it doesn't complicate the process

Initial potential patient needs

- Wearability
  - Comfort
  - Size
  - Weight
- Sterilization process and avoiding infection
- Audio / visual cues
  - Progress tracking
  - Error notification
- Dose accuracy
- Simplicity / ease of use

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Multiple case studies and feature enhancements will be explored

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Increasing volume / viscosity

- A significant portion of biologics are administered through intravenously (IV) when initially released
  - High bioavailability
  - Well understood approval processes
- **Expanding to subcutaneous (SC) or intramuscular (IM) injections** comes with the benefit of reaching more patients
- However, the **lower bioavailability** means more drug product is required
  - **Higher volume and/or higher concentration resulting in higher viscosities**

Lyophilization reconstitution

- Freeze drying certain medications allow for longer shelf life
- The resulting **drug product is usually stored in a sealed vial of powder with a separate diluent**
- The reconstitution of the diluent and powder creates a solution to be administered
- **Enabling that reconstitution to happen at home in autoinjectors and OBIs is a highly sought after and difficult feature**

Temperature

- Temperature is a key variable that impacts **drug efficiency, injection comfort, and shelf life**
- Drug product often is required to reach room temperature before administration
- Some drugs even require being above room temperature and must be warmed
- While **extending drug shelf life usually requires lower temperatures especially for biologics during transportation and storage**

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Temperature sensing and modeling enhancements to autoinjector platforms provide blueprint that can be replicated for OBIs

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Collect temperature data

- 4 sources of temperature data can be provided to the microprocessor
- Modifying the firmware to collect the data is likely too slow of a process, so instead **external wire based temperature probes used to gather data**
- Different environmental chambers used to **test temperature trend from baseline to room temperature**

Train & evaluate ML models

- Time based model to estimate equilibrium time
- **Survey of different potential approaches to compare complexity and accuracy**
- Linear models, time-series models, and potentially neural nets to be tested
- Concern will be **memory capacity required to execute a prediction efficiently** due to portable nature of the device

Determine implementation

- Firmware on the microprocessor written and handled by **external CMO partner**
- Initial model and training will be written in a higher level language (e.g., Python), but **implementation will have to be in C most likely**
- Coordination with that partner to ensure additional functionality (i.e., machine learning model implementation) can fit within the **timing, memory, and bandwidth constraints**

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Develop actionable, strategic initiatives backed up by enhancement study results to share with key stakeholders

- Strategic initiatives
  - Leverage market landscape study, case studies, and feature prototyping experience to **ideate key initiatives to meet various market and patient needs**
  - **Circulate initiatives** and gather input on relative prioritization and impact
- Identify primary relevant stakeholders
  - **Near term and long term drug product teams** with patient needs that align with available and soon-to-be available technologies
  - **Business development partners** to aid in identifying partnerships and acquisition targets to help achieve relevant initiatives
  - **Executive sponsors** to champion specific initiatives
- Lay out execution plan for key initiatives

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