



Project Scope Document

LGO Fellow: Aaron Wubshet

Internship Company and Site: Amgen @ Thousand Oaks, CA

Project Title: Closing the gap: Evaluate On Body Injectors (OBIs) technologies available in the market and their readiness to commercialization.

Academic Advisors: Jacob White & Negin Golrezaei

Company Supervisor: Marcela Molezzi

Areas of Research: Product/Process Development

The project scope document defines the business problem the company is trying to solve and the scientific approach the student will be using. The scope needs to be appropriate to be able execute during the six-month on-site and subsequent analysis thesis generation. The content needs to be aligned to meet the engineering department of the student. The scope document will serve as the basis of the thesis proposal.

Section 1: Business Problem - What is the main problem that the business is trying to solve?

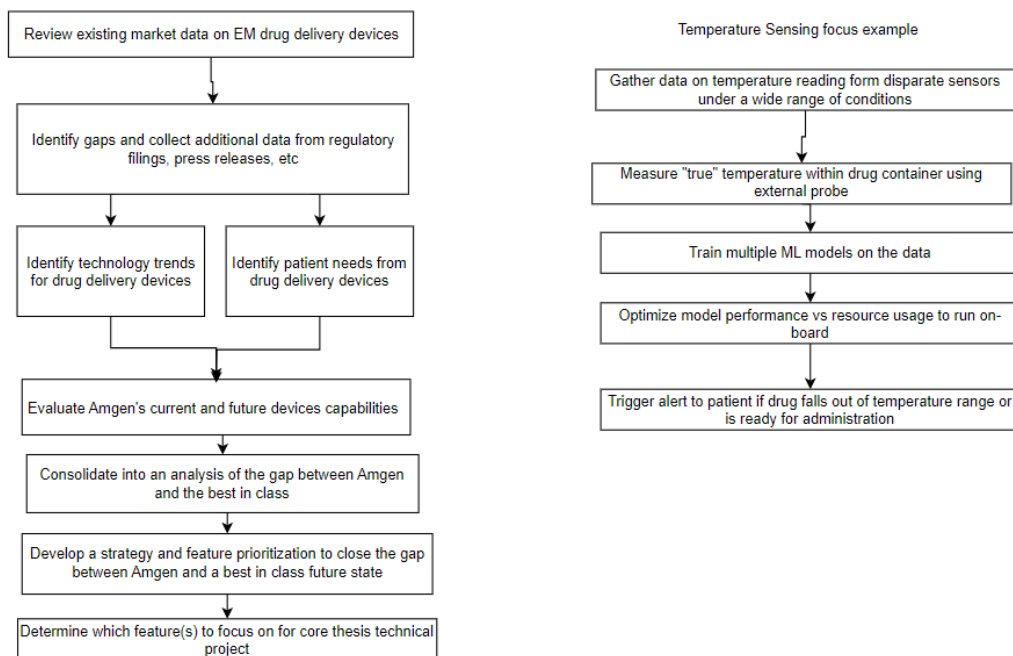
Today there is a gap between Amgen's drug delivery devices and the best-in-class options available on the market. Furthermore, there are believed to be technology and patient use trends that are driving the market of devices forward that Amgen is not responding to appropriately as there is a lack of patient and market driven product strategy and roadmap. This hinders the readiness to deliver certain drugs that have higher volume, concentration and viscosities than what our existing mechanical Auto Injectors can delivered reliably. This thesis will demonstrate potential pathways for Amgen to determine what is the best OBI technology available while closing the gap between Amgen delivery devices and the gold standard.

Section 2a: Approach (brief description of how you will proceed)

The initial steps involve accurately and quickly assessing Amgen's current drug delivery device capabilities as well as planned growth trajectory, focusing on OBIs. Effectively I will need to understand what features and technologies exist today in Amgen, what features are planned and needed for future drug product releases, what time horizon will these features be realized and what were the driving factors in prioritizing those features. From there a similar analysis is needed for the market. I need to identify who are the major players for OBIs, what OBJ products exist commercially available today, what trends can be seen historically but also moving forward when it comes to features (e.g., volume, viscosity, connectivity, etc.). Moreover, a patient needs analysis will help supplement market trends to understand where the gap exists between Amgen today and where the market and patients' needs Amgen to be in the future. This will help develop

the appropriate prioritization criteria for feature enhancements to Amgen's OBI drug delivery platforms. I will also – evaluate if the Amgen OBI platforms (Onpro and West OBI) already meet a significant portion of patient and market needs, or whether Amgen should invest in a new technology. From there, I will investigate what the best technology should be for the future Amgen drug product portfolio, including potential drivers for investment in new technologies while also increasing product-market fit. My initial hypothesis of these drivers are higher volume, higher viscosities, lyophilization capabilities, temperature sensing and modeling, lower cost, and reliable manufacturability. Addressing lyophilization capabilities would greatly increase the flexibility of the Amgen OBI platform for current and future drugs. Having robust temperature modeling built into the OBI would allow for more temperature sensitive drugs to use the platform with alerts for the patient of when the drug is ready to be injected, modifying injection profile based on drug temperature, etc. Finally, if the Amgen OBI platforms were lower cost more drug platforms would be able to adopt it. This will require working with vendors and establishing the potential for higher volumes.

Section 2b: Process Image – Provide a high-level image or chart of your process / approach



Section 3: Related work

There is prior work starting the scan of market available devices and trends. It will require a refresh and deeper dive. There are existing lyophilization and drug temperature sensing approaches in drug delivery devices on the market today which can serve as the basis for a significant portion of the work. There are some OBIs that come prepared with the drug product inside. This technology should also be evaluated with specific attention to sterilization as that is critical for our patients. The drug temperature sensing would require more ML modeling efforts while the lyophilization efforts would focus on feasibility analysis working Amgen approved CMOs. However there have been multiple papers exploring the use of dual chamber lyophilization techniques which will be key to adding that feature to Amgen OBI platform.

Section 4: Data Sources and Data Types and Format

The majority of the market scan data will be from regulatory agencies, press releases, and other 3rd party market research documents and reports. The lyophilization feasibility, temperature sensing and sterilization efforts would require testing capabilities in a lab setting. The data collection for the temperature sensing focus would for example be a series of temperature readings under a wide range of conditions.

Section 5: Expected outcomes, including knowledge transfer (what are the deliverables from your project? how will the knowledge and learnings from the internship be transferred to the organization?) (

The primary outcomes will be a strategy document and feasibility assessment / proof of concept. The strategy document will summarize the gap between Amgen's devices and what the market needs. It will also outline how to update the product roadmap and strategy moving forward for Amgen OBI devices. It will likely live within the devices team access. If necessary, it could be added to the CDOCs secure version controlled document management system that Amgen uses. The feasibility assessment / proof of concept's exact form will depend on the results of the market scan and strategy analysis, but in the case that the temperature sensing project moves forward, the handoff would be to the senior engineer on the team to begin the final implementation stages of the prediction model (assuming in testing the model's performance was sufficient).

Section 6: Evaluation plan and assessment (what is the basis or metrics for determining whether or not your project is a success?)

The project would be deemed a success if the strategy document outlined an achievable set of short and long term goals and a clear recommendation for what OBI technology Amgen should be focused on within the next 2 years. The primary indicator of success in the immediate future would be getting executive buy-in and funding to evaluate available technologies or OBI devices that could be used in Amgen production. Furthermore, having Amgen drug products endorse the use of the recommended platform would go a long way to proving that the project was successful.

Section 7:

Project plan with schedule and milestones (this should outline the major tasks, durations and dependencies for the internship). Expected to change and evolve through the course of the internship. Format is flexible – table, spread sheet, project plan SW.

Evaluate On Body Injectors (OBIs) technologies available in the market and their readiness to commercialization.

Overall Status



OWNER: AARON WUBSHET
TEAM MEMBERS: MARCELA MOLEZZI

Future/Recent Milestones		Plan	Forecast
Complete review of existing materials		6/26	6/26
Complete individual meetings with team members		7/19	7/19
Create draft summary of existing analysis for review		7/22	7/22
Build out technical details and trends summary		7/26	7/26
Create KIQ and SOW draft for Dan G./Fletcher		8/9	8/9
Collect temperature monitoring / sensing data		9/27	9/27
Update technical details, trends, and market landscape summary (using information from Fletcher + own research)		10/11	10/11
Scan market to determine initial lyophilization feasibility		10/18	10/18
Build temperature prediction model		10/31	10/31
Investigate sterilization challenges and solutions		11/15	11/15
Get initial results from deep dive on lyophilization via Flex feasibility study		11/22	11/22
Build out strategy / prioritization to "close the gap"		11/29	11/29
Consolidate results and analysis for handoff/codify		12/10	12/10
Prepare materials for final presentation		12/15	12/15

Escalations: None

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AMGEN
May 14, 2024

Section 8: include Official Company Approval Process for reference

Amgen Final Publication Review (FPR) Approval Process – End Program Deliverables

- LGO student should maintain close contact with their Amgen Supervisor throughout the process.
- Once Amgen Legal and the assigned ED and/or VP reviews the content and provides comments, the LGO student will make edits and return their final draft to their Amgen Supervisor. **It is the Amgen Supervisor's responsibility to ensure the recommended edits are implemented prior to the student submitting the final document(s) to MIT.**

Timeline&	2024 Dates (Final Thesis Deliverables)	Action	Owner
	March 1	LGO student emails Amgen supervisor initial draft of thesis (Note – This is strongly recommended by the MIT LGO program office, but not required.)	LGO student
Day 0	April 1	LGO student emails documents (thesis, presentation, and use case summary) for Amgen Supervisor to review.	LGO Student
Day 1 – Day 3	April 2 – 4	Amgen Supervisor reviews documents and emails LGO student with required edits and comments.	Amgen Supervisor
Day 4	April 5	Amgen Supervisor notifies aligned Executive Director and VP of FPR timeline and responsibilities prior to official FPR submission.	Amgen Supervisor
Day 4 – Day 6	April 5 – 9	Amgen Supervisor submits documents for FPR through internal system on behalf of the LGO student.	Amgen Supervisor
Day 7	April 10	FPR team routes through the system to Amgen Legal and appropriate Amgen Executive Director and VP for review. A confirmation email with a Pub ID# is sent to the Amgen Supervisor within one business day.	FPR Team
Day 8 – Day 17	April 11 – April 24	Amgen Legal and appropriate Amgen Executive Director and VP reviews the content and provides comments. LGO student makes edits and emails final documents to Amgen Supervisor.	Amgen ED and/or VP Amgen Legal LGO student
Day 18-19	April 25 – 26	Approval notification is submitted to Amgen Supervisor through the FPR system. Amgen Supervisor to notify LGO student to proceed with final submission to MIT.	Amgen Supervisor
Day 20	April 29	Final deadline for students to submit their thesis, presentation, and use case summary to MIT.	LGO Student
	May 3	MIT LGO Knowledge Review	

*Note: Timeframes are estimated and in business days

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Approved by:

LGO INTERN (print name):

Aaron Wubshet

ENGINEERING FACULTY ADVISOR (print and sign name):

SLOAN FACULTY ADVISOR (print and sign name):

COMPANY SUPERVISOR (print and sign name):

COMPANY AUTHORIZED OFFICIAL (print and sign name):

DATE:

Note: Signature approval via e-mail is valid only if it is made clear that the content document is approved without further edits

From: Nikki nikki.golrezaei@gmail.com
Subject: Re: MIT LGO Project Scope Approval
Date: July 30, 2024 at 10:07 AM
To: Wubshet, Aaron awubshet@amgen.com
Cc: white@mit.edu, Molezzi, Marcela mmolezzi@amgen.com, Aaron Wubshet aaron24wubshet@gmail.com



I approve of Aaron Wubshet's Project Scope Document.

On Tue, Jul 30, 2024 at 12:47 PM Wubshet, Aaron <awubshet@amgen.com> wrote:

Hi all,

@Jacob, Negin: Marcela will be taking over for Azita as my supervisor for the project for the foreseeable future! The project's path forward has solidified into a focus on two key enhancements to the AutoTouch platform (temperature monitoring/feedback and lyophilization capabilities) in an effort to improve the platform's attractiveness to other drugs.

Please see the attached Project Scope document for approval. This document outlines a high-level breakdown of the project's motivation, goals, and approach. It is meant to serve as the precursor to the Thesis Proposal.

If you have comments or suggestions I can make adjustments as needed! Otherwise, in order to submit the document to MIT I need your signatures or simply a reply to this email saying "I approve of Aaron Wubshet's Project Scope Document"

Cheers,

Aaron Wubshet

From: Wubshet, Aaron <awubshet@amgen.com>
Subject: FW: Aaron LGO Project Check-in
Date: August 5, 2024 at 9:19 AM
To: Aaron Wubshet aaron24wubshet@gmail.com



From: Molezzi, Marcela <mmolezzi@amgen.com>
Sent: Friday, August 2, 2024 11:25 AM
To: Wubshet, Aaron <awubshet@amgen.com>; white@mit.edu; golrezae@mit.edu
Subject: Re: Aaron LGO Project Check-in

Hello Everyone,

The project description summary looks great. I approve it! This will significantly help our future portfolio needs.

Please let me know if I need to do anything else.
Marcela

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From: Wubshet, Aaron <awubshet@amgen.com>
Sent: Friday, August 2, 2024 10:53:47 AM
To: white@mit.edu <white@mit.edu>; golrezae@mit.edu <golrezae@mit.edu>
Cc: Molezzi, Marcela <mmolezzi@amgen.com>
Subject: Aaron LGO Project Check-in

Hi all,

Just wanted to provide a quick update on the direction of the project and slightly updated scope document after some helpful advice!

The focus will still be on developing a strategy to close the gap between Amgen and the gold standard of electromechanical drug delivery device, but the focus will be on body injectors more so than autoinjectors. The case studies of features to be added to Amgen's OBI portfolio will focus on temperature sensing and modeling, lyophilization, and sterilization along with analysis of increasing volume / viscosity capabilities, lowering costs, and ensuring reliable manufacturing. The main technical component will be writing and training an ML model to predict drug temperature.

From: Wubshet, Aaron <awubshet@amgen.com>
Subject: FW: Aaron LGO Project Check-in
Date: August 15, 2024 at 9:20 AM
To: Aaron Wubshet aaron24wubshet@gmail.com



From: Jacob K White <white@mit.edu>
Sent: Thursday, August 15, 2024 8:59 AM
To: Molezzi, Marcela <mmolezzi@amgen.com>; Wubshet, Aaron <awubshet@amgen.com>; Negin Golrezaei <golrezae@mit.edu>
Subject: Re: Aaron LGO Project Check-in

EXTERNAL: Use caution with unknown senders

All,

I apologize for being late, I didn't realize I had to approve the project changes.

So, I approve the project description changes.

Best,
Jacob

From: Molezzi, Marcela <mmolezzi@amgen.com>
Date: Friday, August 2, 2024 at 2:25 PM
To: Wubshet, Aaron <awubshet@amgen.com>, Jacob K White <white@mit.edu>, Negin Golrezaei <golrezae@mit.edu>
Subject: Re: Aaron LGO Project Check-in

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To: white@mit.edu <white@mit.edu>; golrezae@mit.edu <golrezae@mit.edu>
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