The Process to Commercialize a Medical Device for Scale, Quality, Performance and Profit

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Emerging Technology Commercialization

Abstract

It is often mistaken that the commercialization process begins with a design, a lab prototype and experimental testing. So often entrepreneurs and companies come with design, prototype and validation in hand without a customer or an understanding of their needs, consideration for manufacturing and quality nor any evaluation of a supply base. This presentation challenges this thinking and presents an alternative process that starts with an idea accompanied by the end customer's specifications, a thorough review of the method for manufacturing, definition of a quality plan and an understanding of your validation requirements at the component and device level. There should also be a consideration of your potential supply base and their capabilities. Furthermore, a plan should be developed for the path through the FDA approval process. Once this is complete, an iterative design is developed with a constant reassessment of performance, manufacturing, quality, validation and FDA approval. During the design phase, a core building block of technology should be developed such that it can be easily replicated in derivative products keeping as much of the design as possible the same (usually only the customer interfaces changing). This enables high volume production of identical components and features lowering cost. The resulting prototype is then closely representative of a production device that can then be fine-tuned through 2-3 design validations off tools capable of low volume production. Also in the design phase, testing is completed to understand the ranges in performance and failure as it relates to expected capability in materials, dimensions, manufacturing and environmental exposure. Scaling is then accomplished by adding capacity through tool replication and automation that is validated in the pilot phase with limited fine tuning. This process will be demonstrated through two case studies.

David DiPaola - DiPaola Consulting, LLC

Inspiration - Design - Commercialization

Sensors, MEMS / Nano, Electromechanical Products, Conservation





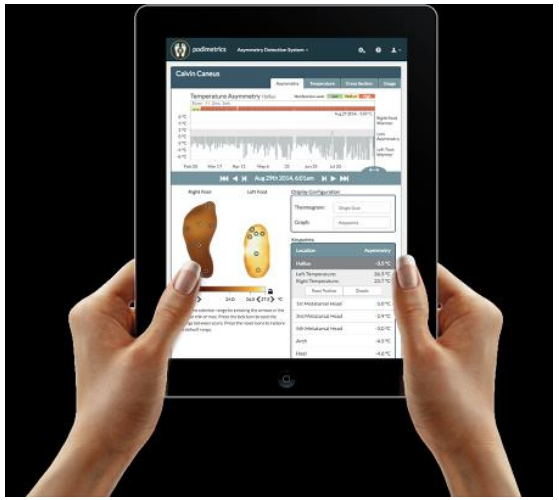

Background – Medical Device Commercialization

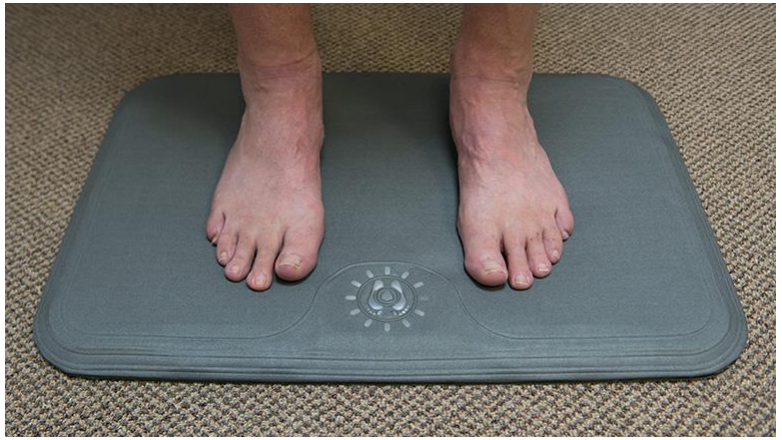
- This is what I so often see:

Idea  → Design → Prototype → Validation → FDA Approval → Commercialize at Scale

Example - Podimetrics - RTM System

- Remote Temperature Monitoring System
- A system that monitors temperature differences between multiple locations on the same foot and between feet to detect a future diabetic foot ulcer before it occurs.
- Actionable information is provided via a smart device to patients and doctors

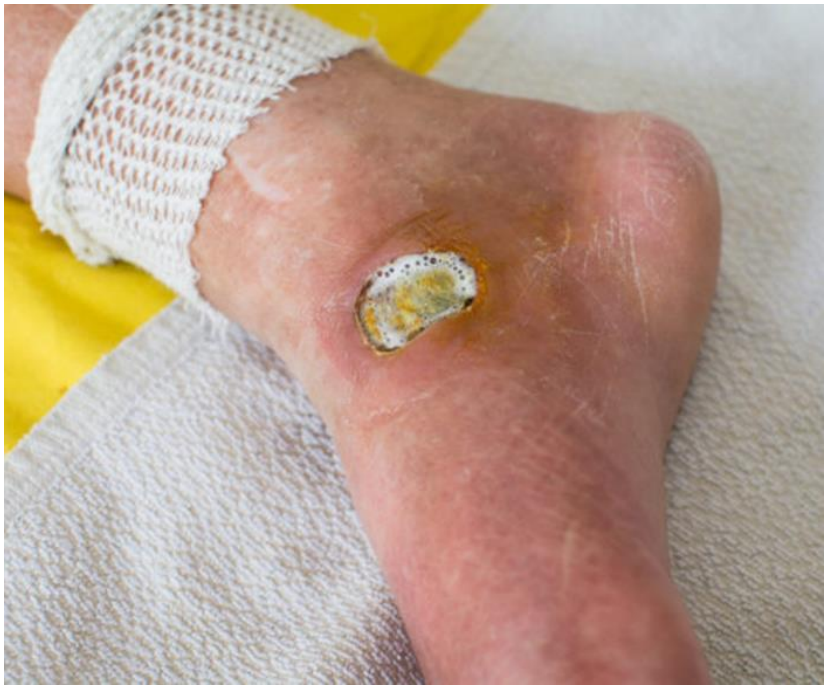




Photos courtesy of Podimetrics - https://www.podimetrics.com/

Podimetrics - RTM System

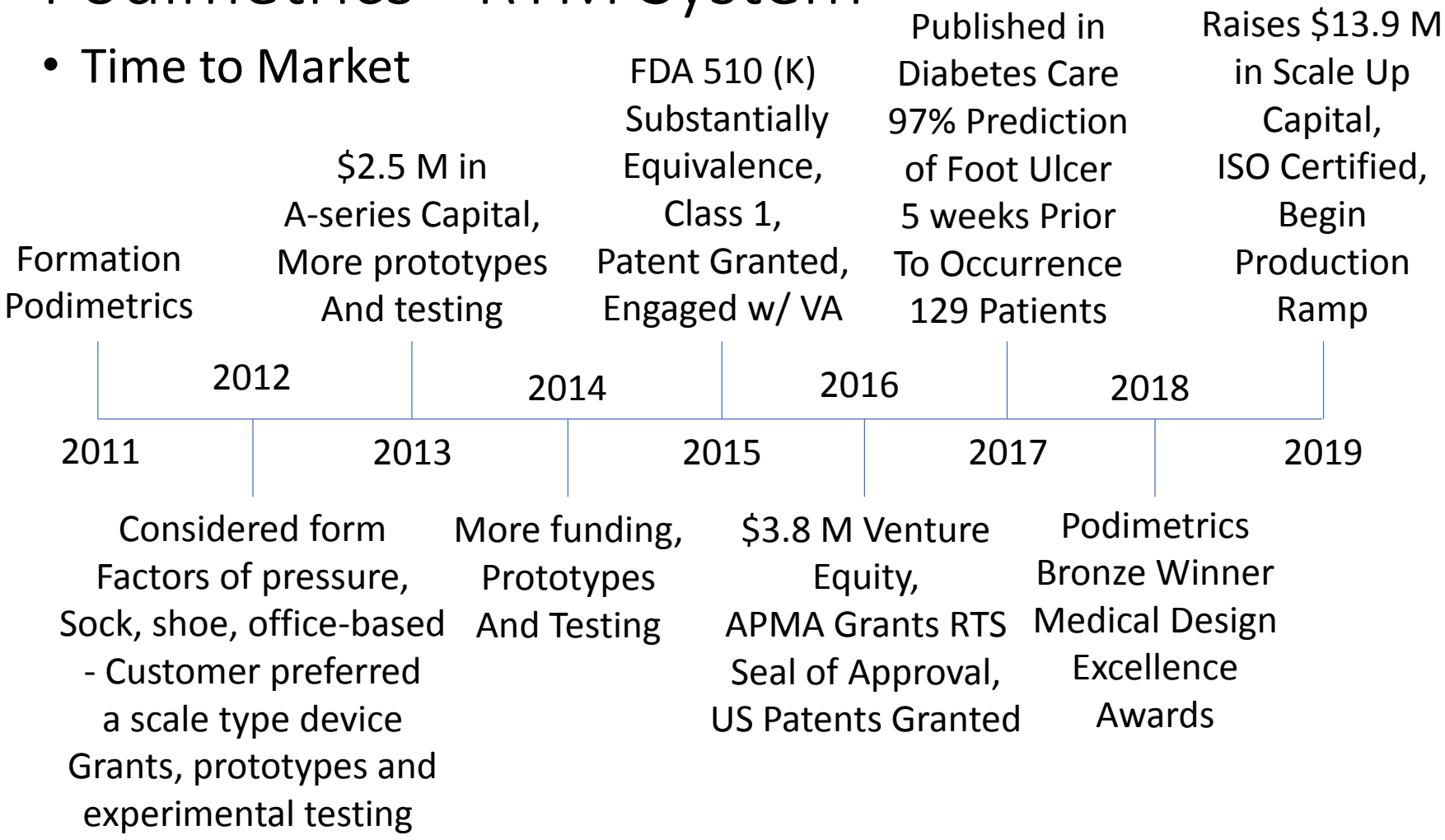
- Need for Remote Temperature Monitoring System
  - Diabetics are at risk of developing neuropathy (numbness in the extremities) resulting in uneven foot pressure distribution and ulcers
  - Foot ulcers effect 3.6 Million diabetics in the US alone (CDC)
    - https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5245a3.htm
  - Cost of treatment for a foot ulcer, the leading cause of below knee amputations, is $30,000 post initial two years or $10.9 billion annually in US alone for diabetic foot care management and treatment (NCBI)
    - https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5761954/
  - Detection of foot ulcers requires daily foot inspection by patients and is not straight forward for a podiatrist with limited visits



Diabetic Foot Ulcers: Why You Should Never Ignore Them, Cleveland Clinic - Diabetes & Endocrinology, April 24, 2018, https://health.clevelandclinic.org/diabetic-foot-ulcers-why-you-should-never-ignore-them/

Podimetrics - RTM System

- Time to Market



Podimetrics - RTM System

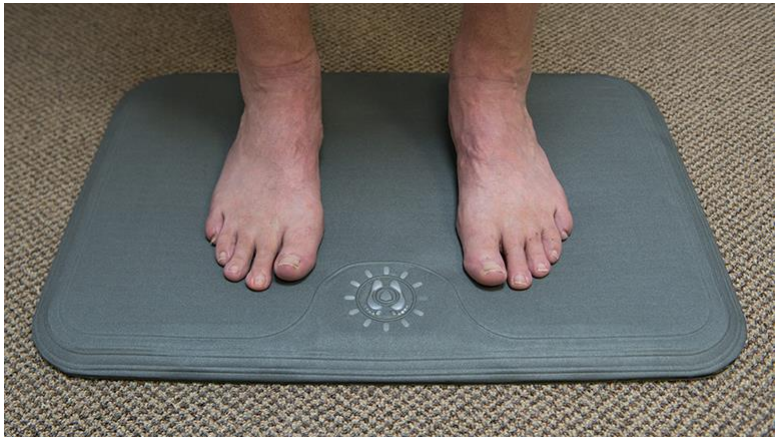
- Design for Manufacture and Quality
  - Manufacturing partner brought into game very late (8 years after start)
    - Production variation may effect performance beyond acceptable limits and could result in an expensive design change or yield loss
  - A quality system may have been developed prior to FDA determination of substantially equivalence but Podimetrics did not receive ISO certification until 2019
    - Control plan, FMEA, dimensional capability studies, manufacturing test methods, design and pilot validations
    - Is there a method to test and diagnose system without disassembly?
  - Some changes in product system after clinical studies
    - Every time a change is made you risk introducing a new variable that changes performance or can introduce a quality problem
    - Better to get to final production design as soon as possible

Podimetrics - RTM System

- Design for Manufacture and quality

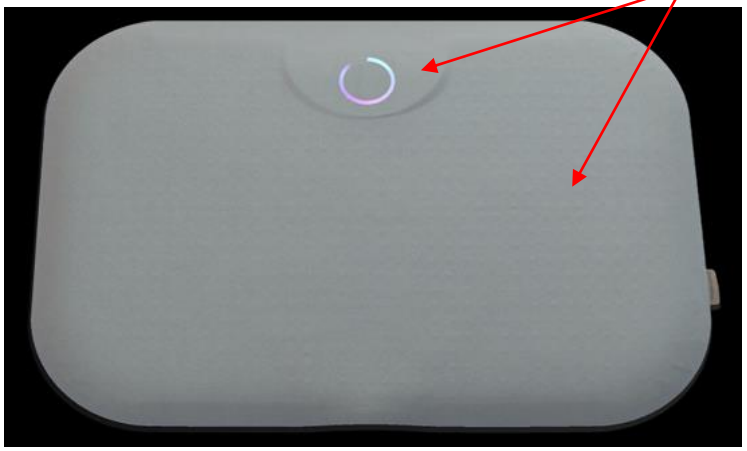
Chance for Quality issues

Prototype design



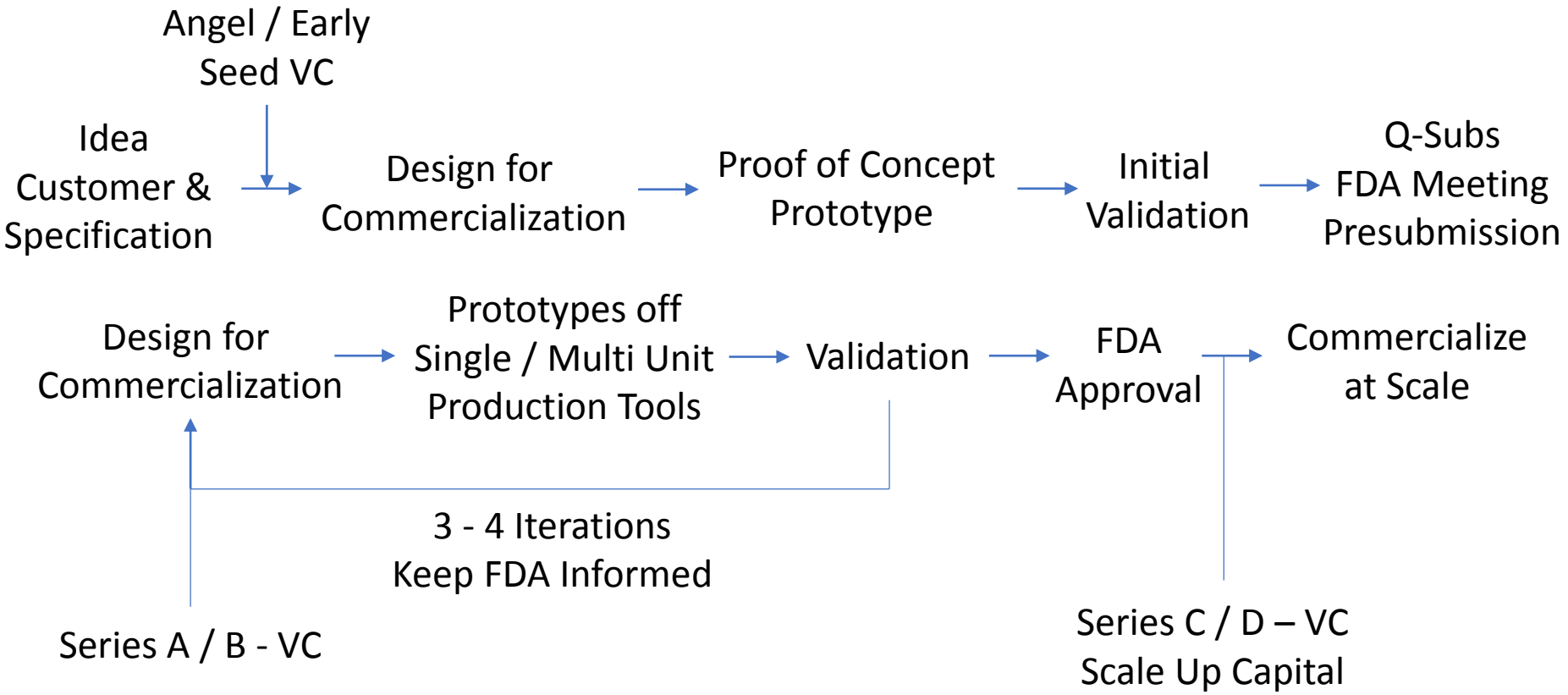
Medgadget: https://www.medgadget.com/2017/07/podimetrics-system-helps-prevent-diabetic-foot-ulcers-interview.html

Production design



Photograph courtesy of Podimetrics

Alternative Proven Approach:



What is Design for Commercialization

- Start with an idea, specification and a customer
- Before you design your medical device consider the following questions:
  - How will it be manufactured?
  - How will it be tested (validation, production and returns from field)?
  - How will dimensional analysis be completed?
  - What controls are need to ensure quality?
  - Who will be the suppliers of the components and what are their capabilities?
  - What is your path for FDA approval?
  - What are the customer specifications and how will it be validated?
  - What are potential failure modes and how can they be mitigated?
  - How can this core technology be used as a building block for derivative products once in production?
    - Can the core technology of the product be easily replicated in derivative products keeping as much of the design as possible the same (usually only the customer interfaces changing)

Example: GBS Inc. – Saliva Glucose Biosensor

- First non-invasive, saliva-based glucose test for diabetes management

Place Saliva Glucose Biosensor in contact with saliva

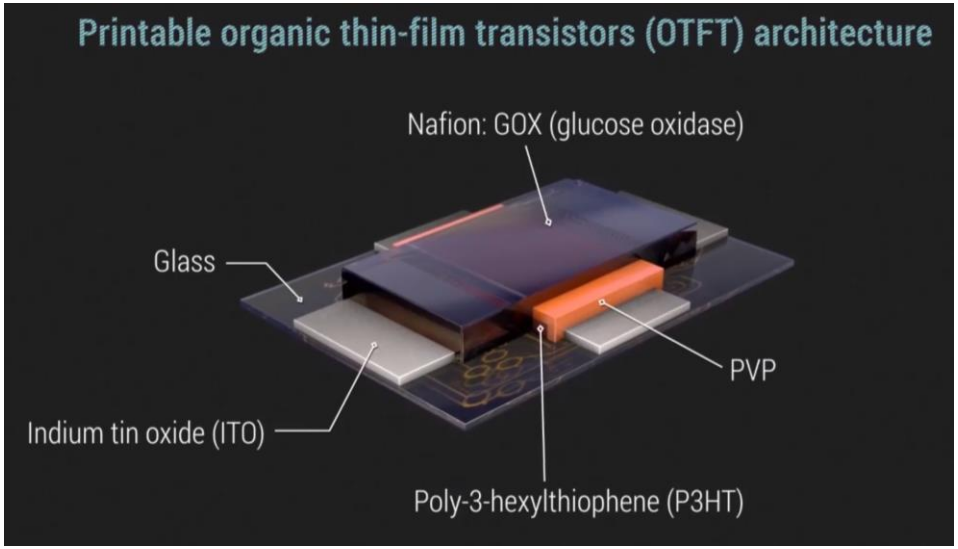
With biosensor nearby, the digital app displays glucose measurement

App provides real time comparison and flags attention when needed

Photos courtesy of GBS Inc. - https://glucosebiosensor.com/saliva-glucose/

GBS Inc. – Saliva Glucose Biosensor

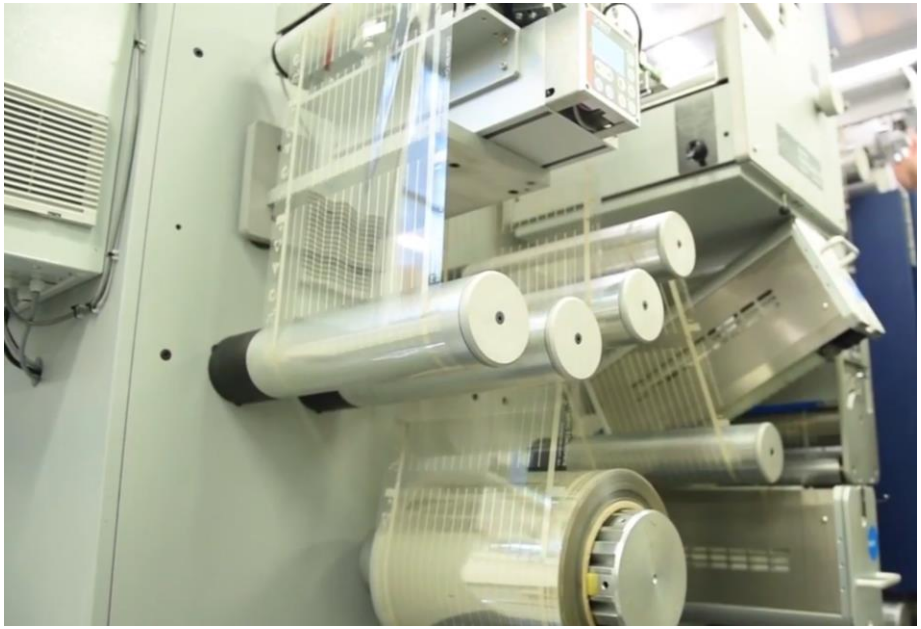
- Started with an idea and specification (can glucose be detected as good or better than blood)
- Who is the customer – 422 million people with diabetes (WHO)
- Proof of Concept Prototype



Photos courtesy of GBS Inc.

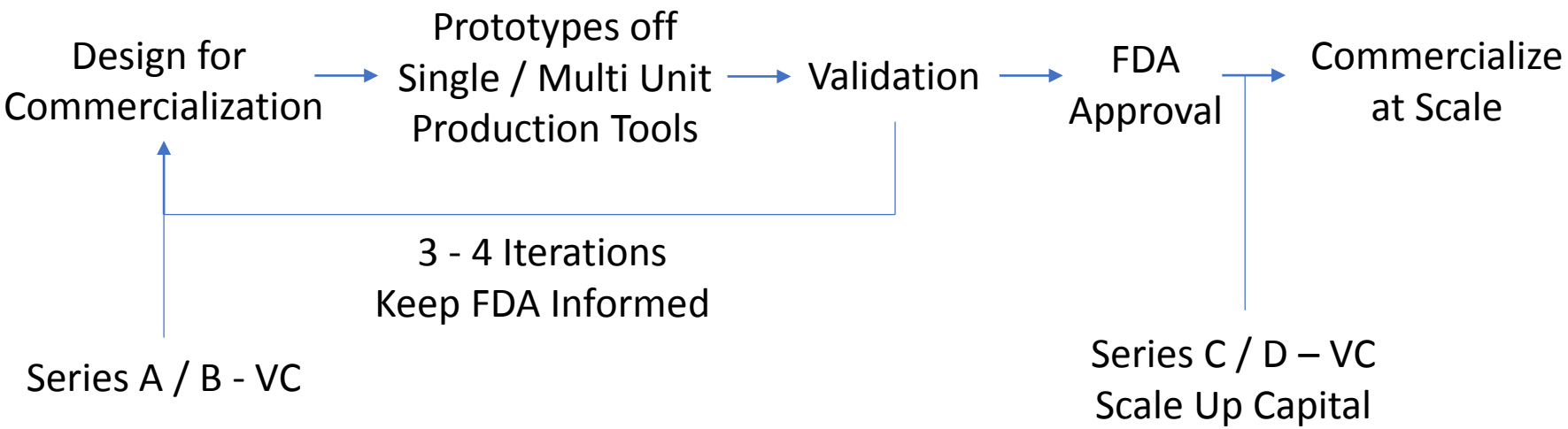
GBS Inc. – Saliva Glucose Biosensor

- Manufacturing (reel to reel printing) was at the forefront of this development in contrast to Podimetrics
  - Printable enzymatic glucose sensor based on organic thin film transistors are printed via inkjets
  - Strategy for scale manufacturing developed prior to clinical studies for regulatory approvals



Photos courtesy of GBS Inc.

Iterative Design and Validation Process:



- In the design phase, testing is completed to understand the ranges in performance and failure as it relates to expected capability in materials, dimensions, manufacturing and environmental exposure.
- Scaling is then accomplished by adding capacity through tool replication and automation that is validated in the pilot phase with limited fine tuning.

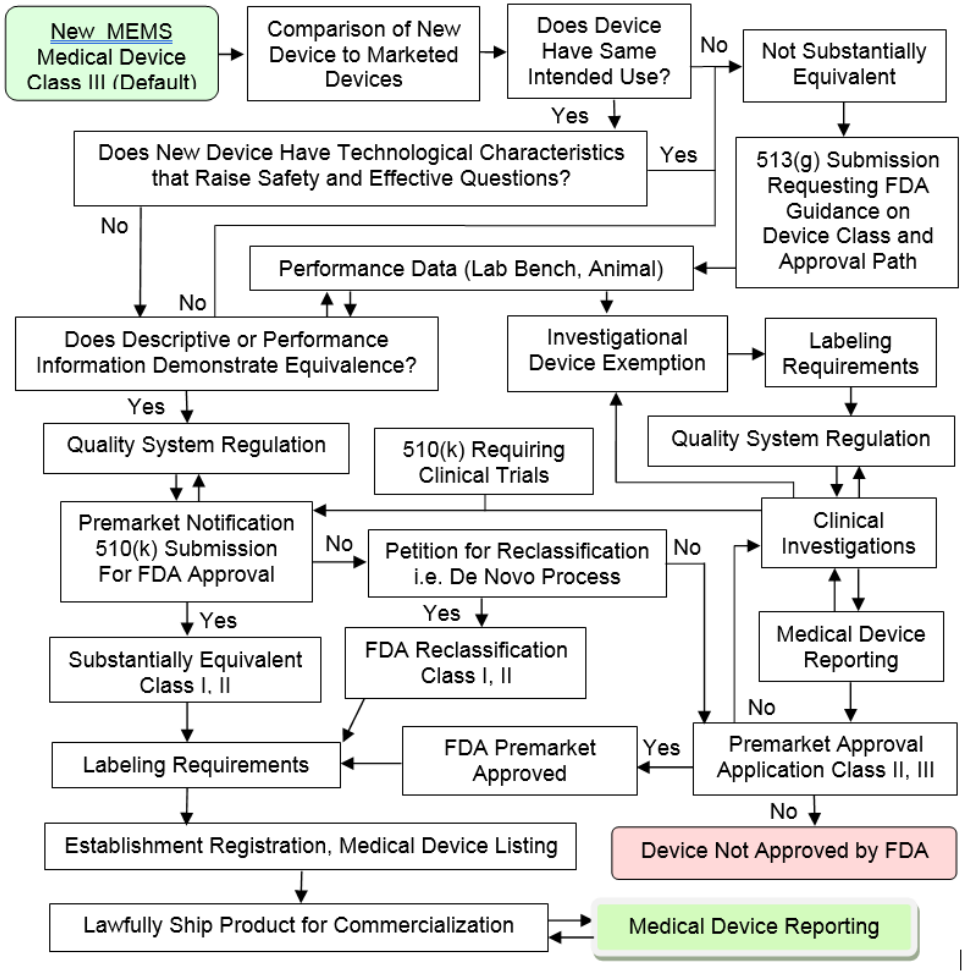
Manufacturing Line

GBS Inc. – Saliva Glucose Biosensor

- Platform technology
  - Can be adapted to detect a variety of substances that identify a range of diseases
  - Looking for substances that identify cancer, heart disease and allergies
  - Technology can scale derivatives rapidly

- Company needs to be careful of project creep and defocus of resources, draining of capital and delayed timelines
  - 6 years in development and path to regulatory approval and full commercialization unclear

What is Path for Regulatory Approval?



- Podimetrics (Temp Scale) - FDA Classification and Determination
  - Submitted a Section 510(k) premarket notification
  - FDA Determination: Substantially Equivalent Class 1, General controls
- GBS Inc. (Saliva Glucose Biosensor) - FDA Classification and Determination
  - TBD – lets hypothesize
  - FDA considers noninvasive glucose devices that are intended to measure, monitor, or predict blood glucose levels in diabetics to be high-risk medical devices. As a result, FDA requires both analytical and clinical studies to support the intended claims for these new devices.

Conclusions

- A great technical product alone is not enough to successfully launch at scale, design for commercialization is a necessity
  - Platform technology building blocks are great for derivative products and growing business
- Before you start have a clear plan of the timeline to market
  - The benchmark for FDA substantially equivalent medical devices is 3 – 5 years
  - Competitors will take advantage of your missteps and investors will get impatient
  - Not managing time to market will result in cash burn
- Manufacturing and quality should be considered at the start and developed in parallel with the core technology
  - Performance and quality issues that arise in production are extremely expensive to fix and can terminate your product
- Have a plan for regulatory approval and engage early for guidance
- Scaling is most efficient when replication and automation is implemented not changes to the design of the product
- Use these lessons to assess your own products from the very beginning to maximize your success rate

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- Oct 22, 2020 - Half day offsite tours of technical facilities in area (8 AM – 1 PM)
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