Considerations for Product Development

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ACTIV SURGICAL

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<u>Education</u>

B.S. Computer Engineering, University of Massachusetts

M.S. Mechanical Engineering, University of Massachusetts

<u>Career Highlights</u>

5 Startups (3 successfully exited or on going, 2 not so much)

Built and Lead teams of high performers at each company

>75 Robotic System Releases

8 Product Releases

7 FDA 510(k) Clearances

EDISON AWARDS™ WINNER 2017

RED HERRING N. AMERICA 100 WINNER

MEDICAL DESIGN EXCELLENCE AWARDS® 2016 BEST IN SHOW

POPULAR SCIENCE THE FUTURE NOW

RTS

Medrobotics

Expanding the reach of surgery®

Why I am passionate about product development

- Feasibility, Custom One-Off, Consumer, and Medical/Regulated – Each have their own path and all are fun
- Product Development is a team sport, and it takes all types to be successful
- The outcome of your hard work will change someone's life
- Often small, dedicated teams can out perform and out maneuver large structured teams

Understanding who and what you are is difficult and very important

Helps architect and layout the team

Questions to Ask

- Do you require quality engineers for a QMS or a PM to interact with the customer?
- Will your team grow through the project as you tackle milestones or is your team, “the team”? Is that team’s skillset broad enough to progress all fronts of design (software, electrical, mechanical, INTEGRATION)
- Do you need to complete compliance testing for your product. Have you asked the question to your customers? Things like UL, CE, TUV, FDA clearances and marks are easier to achieve when the tests are known at the beginning

Helps define milestones and funding strategies

- Early development can be done on the cheap (friends and family as resources), but PARTS COST MONEY!
- If testing is required, costs can quickly ramp to 10s of thousands
- Funding milestones aren’t always along designs critical path

Product/Market fit is even MORE important…

- Who's going to buy it? Really.

This is a hard question, we all love our idea, what do the naysayers and people that don't hold back say? How can you respond with logic, not emotion.

- Price in the market is important as an input, but don't sweat it.

Know that a solution exists in a range that the customer/market can bear.

- Understand user facing interfaces and why the competitive products made their decisions.

Assume best intentions with smart people. Things like space requirements, battery life requirements, etc.

Planning, the necessary evil

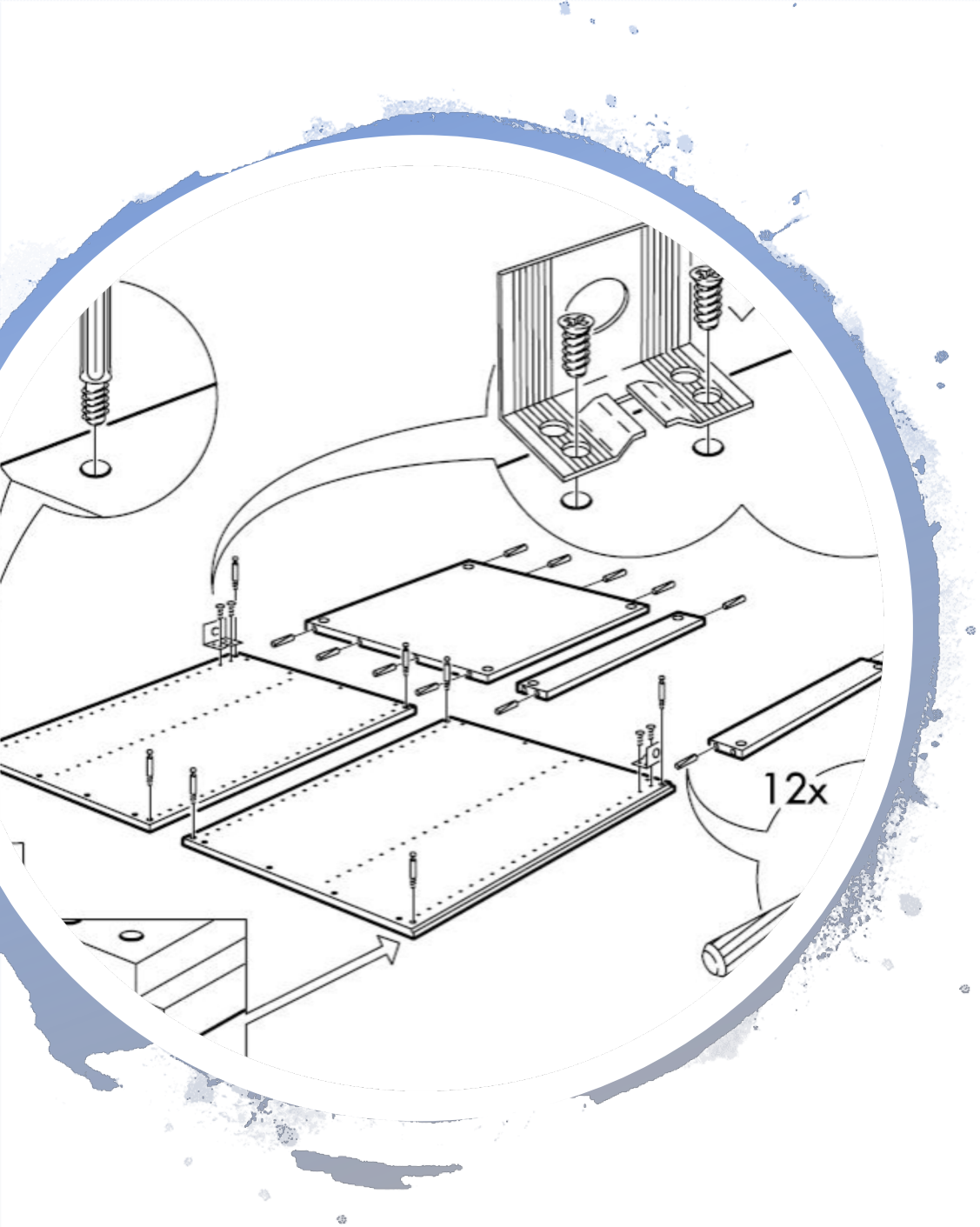
- Development Plans – Product (who is responsible for what), Software (development, testing, release) – Tons of available strategies. Spend some time and think it through early on.
- Lifecycle Plans – Who’s going to sell it? Who’s going to maintain it?
- Release Planning – How and when? How do you get customers attention? If you are not embarrassed by the first version of your product, you've launched too late. – Reid Hoffman

Building the dream team

- Recruitment and retainment is Job #1 – Make it fulfilling and fun to come to work
- Experience vs fire in the belly – I'll pick fire in the belly every time
- Mix of personalities drives a well-rounded office – Sports fans vs video game fans vs music fans

Design and Development, The fun stuff!

- Integrate early and often – Drives collaboration and cross discipline empathy
- Drive toward demonstrations, even if they're internal
- Keep a system running and in plain sight
- Make it fun! – Rubber chicken for critical path, Celebrate just as hard for failures



Making more than one (transfer to manufacturing)

- Write your initial build steps down, you'll use them over and over again.
- Keep those that will be responsible in the loop.. Even if it's too early. They'll understand the design decisions

My favorite resources

- FDA Design Control Guidance

https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070642.pdf

- Greenlight Guru white papers

https://www.greenlight.guru/medical-device-resources

- Podcasts – Masters of Scale, Startup

ACTIV SURGICAL

- Located in South Boston, Across from Murphy's Law
- Invented by surgeon at CNMC in Washington, DC
- Initially funded for 7 years (>$13M in Grants)
- Raised seed round from Bay Area VC's in 2017

Mission: Empower surgeons to complete complex minimally invasive tasks with the utmost precision, knowledge, and confidence.

Thank You

Please Reach Out:

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