

10-Stage

Pre-Commercialization Audit

For Med Device & Med Tech CEOs

In commercialization, there is one leap between idea and successful launch – **action**.

However, many companies plunge into commercialization with their innovative Medical Devices, MedTech, and AI-Enhanced Products only to falter without knowing the proper steps, skewed data, or a misaligned plan in place.

Even revolutionary health tech that ought to set off a tidal wave of interest in every OR suite can fail or stall due to lack of funding as even the most dedicated leadership run into roadblocks too late in the pre-commercialization phase.

To help more revolutionary products reach the patients and providers who need them the most, this **10-Stage Pre-Commercialization Audit** is a must-have guide for CEOs and executive teams to develop the steps necessary to meet the real-world demands of Commercialization.

Print and complete this pre-commercialization checklist with your team to close the gap between idea and execution, and balance regulatory compliance with market momentum.

1

Market Analysis:

- ☐ Have you identified healthcare provider segments with the most urgent unmet needs that [insert technology here] can fulfill?
- ☐ Is your value proposition crystal clear, emphasizing clinical benefits, workflow improvements, and cost or time savings?

Ask yourself:

"Does our market research go beyond surface-level TAM and CPT code data to truly understand customer pain points?"

"Do we have feedback from the field, real-time? If not, how can we gather that feedback?"

2**Value Proposition Refinement:**

- ☐ How is your technology different? What unique challenges does it solve? Why does it matter that we solve that challenge? What do our competitors solve and where are their gaps?
- ☐ How does stand out from the competition in addressing one or two specific healthcare challenges?

Ask yourself:

"Have we validated our value proposition with real feedback from providers, staff, and administrators in the field?"

3**Route to Market:**

- ☐ Do you have a preferred route to market? Have you budgeted for your own sales team or are you looking to go through a partnership with another organization or distributors? What have you budgeted and what budget do we have to work with?

Ask yourself:

"What people and financial resources do we have to bring this product to market?"

4**Product Market Fit:**

- ☐ Have you established a robust method for gathering and analyzing user feedback, particularly from the first 20 customers?

Ask yourself:

"Are we fixing the right problem for these users? Is the function of our product resonating with the realistic needs of the market? Who else is using this product?"

5**Regulatory Strategy Integration:**

- ☐ Is your regulatory approach designed with a commercial mindset from the onset?

Ask yourself:

"Do we have a dedicated point person to navigate regulatory conversations effectively? Who is that point person on our team? How are we equipping them with the information and resources they need?"

6

Sales and Marketing Alignment:

- ☐ Does your marketing strategy actually reflect the data and feedback from market research?

Ask yourself:

"Are sales and marketing goals based on how we want the market to respond or the current market realities and recent, real customer feedback?"

7

Sales Team Evaluation:

- ☐ What does the right sales team look like for this product, market, and company culture? What assessments do you deploy to ensure the team aligns with your product and company culture? What standards are set and who manages the meeting of those standards?

Ask yourself:

"What profile best matches that ideal salesperson? What type of personality and profile aligns with the sale of this product, and do our current team members fit this mold? Can it be taught? If so, how?"

8

Customer Support Preparation:

- ☐ How is your customer support structured? Is help on-demand, proactive, and responsive to the initial feedback post-launch? What is the anticipated response time from our actual users when they need assistance?

Ask yourself:

"What are our actual timelines and standards for customer support? How will we establish a continuous feedback loop for product enhancement?"

9

Metrics and KPI Implementation:

- ☐ What are the projected goals for this launch in time, revenue, and volume? Have you set up the appropriate metrics and KPIs to measure launch effectiveness, team performance, and market response?

Ask yourself:

"What metrics will best reflect our product's performance and user satisfaction?"

Risk Assessment and Contingency Planning:

☐ Have you done a thorough risk assessment for potential roadblocks post-launch?

Ask yourself:

"Do we have contingencies in place for unexpected market or regulatory changes after launch?"

Considered thoroughly, these steps have helped CEOs address and avoid the most common setbacks to give their products the best chance possible of successful commercial launch.

Trusted, go-to expert in Commercialization and Sales Strategy, **Steve Sapot** has led massive action for renowned companies like Hologic, Faxitron, and Perimeter Medical Imaging.

His action-forward methods, cross-functional collaboration, and command of AI and ML technology have catapulted market-entry strategies – from idea to infrastructure to launch.

Steve empowers leadership who mean to transform innovative concepts into successful, market-ready solutions that deliver on their promise of changing the healthcare landscape.

For leaders who mean to transform new and early-stage concepts that deliver on their promise of changing healthcare for good, Steve is an ideal partner to CEOs ready to prioritize action over stagnation.

Engaging Steve will assist companies reduce their exposure in going to market and in turn save the company significant dollars by not making early stage commercialization mistakes.

You can learn more by visiting his Stevesapot.com. To talk with Steve Sapot about your pre-commercialization audit, connect with him at steve@stevesapot.com or on LinkedIn.

Here's to your sustained growth and market dominance.

Cheers!

A stylized, handwritten signature in white ink that reads "Steve".