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Launching your medical device: A strategy and execution cross-functional guide

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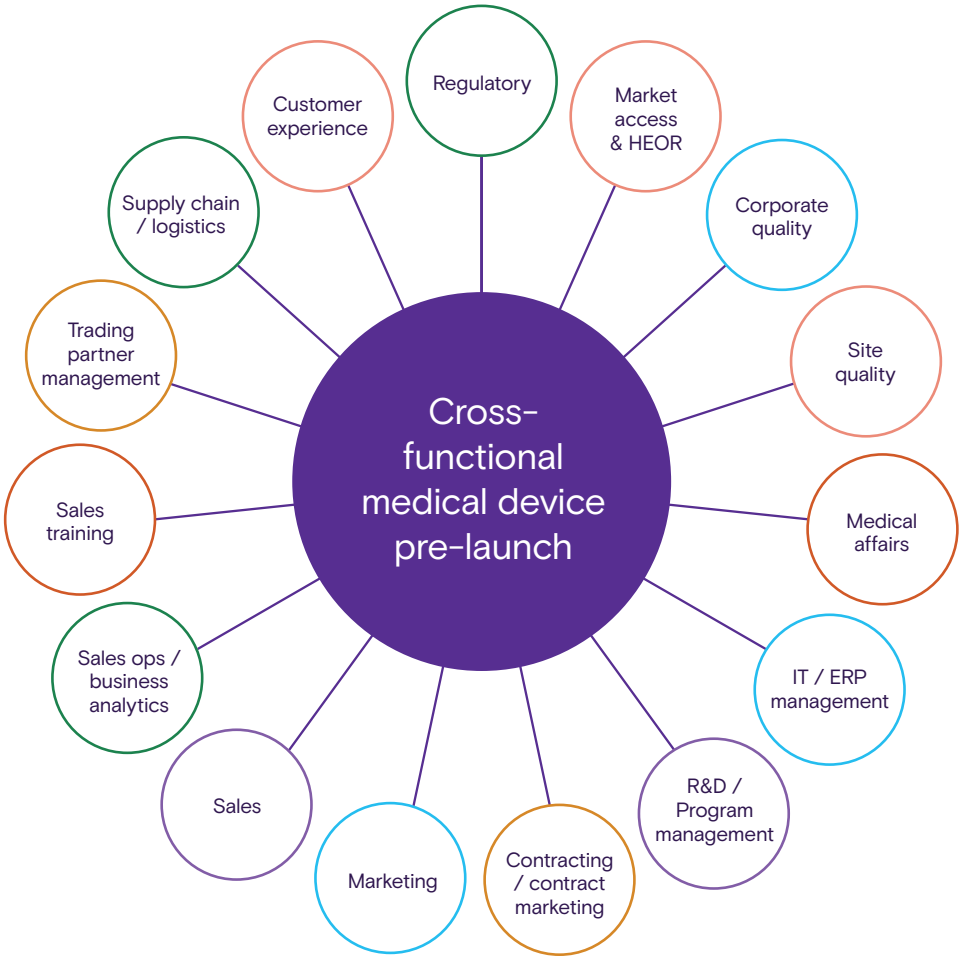
Introduction

Bringing a new medical device to market can be a lengthy and complicated process. Whether you've already received your PMA or 510(k) clearance or are awaiting FDA approval, there are several important considerations and tasks to accomplish across the organization to successfully bring your device to market, focusing primarily on the 36-48 month time frame before launch.

This guide can serve as a roadmap for your organization to follow as you progress through the development journey to commercialization. Each section will detail several of the important decisions you need to consider and includes a useful checklist you can use to remember and track your progress. While the capacity to complete each action item will be determined by your organization's budget, resources, staff and time, completing each task can be a necessary step in successfully bringing your device to market.



Disclaimer: We do not provide actionable items on manufacturing operations, validation, or documentation nor the details of the regulatory environment. The type of filing, applicable FDA guidance and feedback should be used for direction.

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The green checklist items are activities which Definitive Healthcare can provide added value throughout your journey.

Securing funding or budget approval for your medical device

Navigating the funding process for pre-revenue organizations

If this is the first device your organization is bringing to market, then developing your go-to-market strategy will depend on how much funding you've raised. Funding can be a difficult while your organization is still pre-revenue, but this guide can help you determine where funds are spent to ensure that your device launch is as successful as possible.

You can also use this guide to develop a business plan to raise additional funds. Definitive Healthcare offers customizable solutions for your business needs at this stage in your commercialization journey.

Gaining project/budget approval for experienced organizations

If your organization has already launched one or more medical devices in the past, you know that earning project or budget approval for new device pipeline means having a complete understanding of the market and quantifying your return on investment.

This checklist, coupled with our healthcare commercial intelligence, can help you gain budget approval, demonstrate the business case and perform the tasks necessary to bring your device to market.

Regulatory

Regulatory is one of the most important roles in medical device organizations as they will ensure compliance with all FDA regulations and be the liaison between the company and the FDA. Regulatory should be highly involved with manufacturing operations, corporate and site quality, medical affairs and marketing.

By this stage, regulatory personnel should know if the device is considered Class I, II, or III and understand if your device will require a 510(k) or premarket application (PMA). Substantial equivalent products, if applicable, should be researched and information should be gathered. If you've determined that 510(k) is the most relevant pathway, you should also understand if you're filing a traditional, special or abbreviated application. The tactical action items for your device from a regulatory perspective will be nuanced based on the aforementioned factors and the best direction is to ensure you are adhering to specific FDA guidelines.

This list is not all-encompassing as there are strict, tactical FDA requirements for regulatory that must be adhered to and may vary depending on device classification and submission/approval pathway. The following checklist is intended to convey a small handful of considerations for the function. You should always follow FDA guidance, feedback and recommendations when formulating your regulatory processes.

- ◯ **Post 510(k) clearance or PMA, complete product registration**
- ◯ **Determine process for complaint submission in conjunction with quality**
- ◯ **Establish CAPA procedure in conjunction with quality and manufacturing operations for investigating product complaints and implementing correction or corrective actions**
- ◯ **New organizations: Identify and map process for issuing product recalls in conjunction with manufacturing, site quality, and corporate quality**
- ◯ **Review marketing materials for clinical claims & supporting evidence**

For more information about FDA guidance please visit the following resources:

- → Overall FDA device development process
- → FDA 510(k) guidance
- → FDA PMA guidance
- → FDA De Novo classification request

Market access & HEOR

Reimbursement strategy is important depending on your device because this will determine if your device is reimbursable and the amount that an insurer is willing to pay for a device. You will need to prove economic and clinical value through a health technology assessment. HEOR typically lives within a market access department.

Market access and reimbursement strategy development can easily take five to seven years, so it's important that you have a strategy in place well before your FDA submission. Because of the clinical evidence requirements that payors require, you may need to do more than what the FDA requires, depending on the device classification and submission pathway.

Definitive Healthcare can provide payor mix to the granular level based on your patient population so that you can identify CMS versus any commercial payors. Using those insights can guide your determination of which organizations you should engage with regarding reimbursement strategy. Additionally, institution, medical and prescription claims from Definitive Healthcare can help you identify physician's performing the highest volume of applicable procedures so that you can develop KOL relationships to be a voice for your payor story, either through partnership of clinical evidence development or as a product advocate. Just because you have FDA clearance, doesn't mean that you can launch. At what level you participate and at what level access and adoption will be important to determining your success.

This checklist should provide a starting point for important actions to consider when preparing to launch a new device:

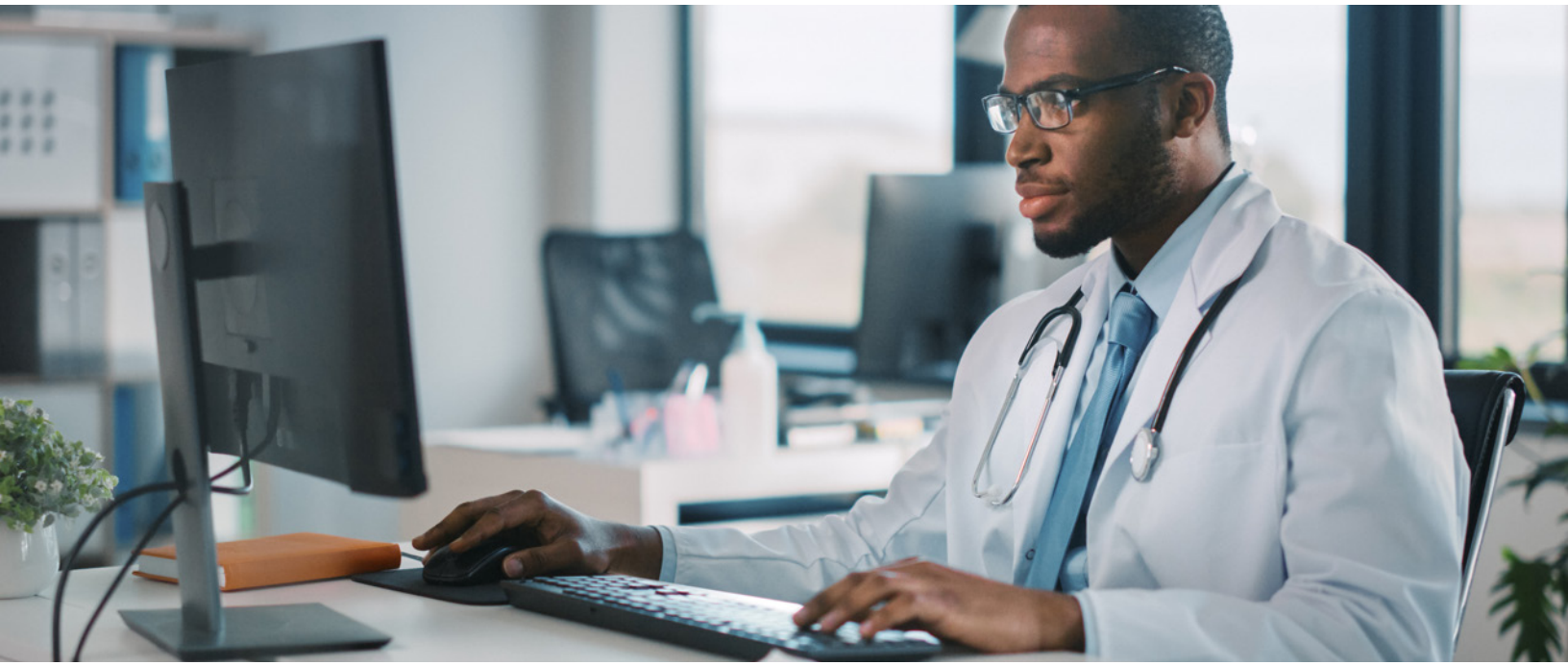
- ◯ **Perform an initial assessment to identify relevant payors to include in your reimbursement strategy. (Delineate between CMS and commercial payors)**
- ◯ **Understand payor approval processes**
- ◯ **Investigate code development:**
  - → Why is a new code needed?
  - → Why does your organization want a new code?
  - → Is there a significant difference in the product or technique?
- ◯ **Determine code development process if there is substantial reason and differentiation.**
- ◯ **Tee up clinical evidence generation with R&D, regulatory and medical to meet both FDA requirements and payor requirements.**
- ◯ **Reimbursement amount should also be used to inform pricing strategy with contracting and marketing**

Understanding common procedure terminology (CPT) is essential to your market access strategy

Physician services are billed using the CPT coding system, a proprietary product of the American Medical Association (AMA). Use of CPT is mandated under U.S. law and regulations for a defined set of services:

- Physician services
- Physical and occupational therapy services
- Radiological procedures
- Clinical laboratory tests
- Other medical diagnostic procedures
- Hearing and vision services
- Transportation services including ambulance

CPT is maintained by the AMA's CPT Editorial Panel, a 17- member group that includes 11 representatives of national specialty societies, four physicians representing Blue Cross Blue Shield, America's Health Insurance Plans, the American Hospital Association and the federal Medicare agency and two physicians from the AMA's advisory board of subspecialty societies.



CPT codes come in three categories:

1. Category I codes are permanent and carry Relative Value Unit (RVU) assignments; RVUs translate directly into payment amounts in the Medicare physician fee schedule and provide guidance to private insurers in their fee setting. The creation of a Category I code requires final FDA approval (if relevant), multiple peer-reviewed publications, and "widespread clinical utilization". The recommendation of the relevant national medical specialty society is for practical purposes the most important determinant of the acceptance or rejection of an application for a new CPT Category I code or for revision of an existing code.

2. Category II codes are permanent and used for tracking purposes and quality metrics. They have no RVU assignments and do not represent payable services.

3. Category III codes are temporary and are intended to describe emerging technologies or services. They are expected to expire or be converted to Category I in five years but can be renewed by the Editorial Panel. The requirements for approval are far less rigorous than for Category I: a. Recent use in humans, AND b. Any one of the following:

a. Support by at least 1 CPT or HCPAC Advisor representing practitioners who would use this procedure or service; (or)

b. Support in the English language peer-reviewed literature for actual or potential clinical efficacy; (or)

c. An approved IRB study protocol, or ongoing clinical trial, or other evidence of clinical utilization. Category III CPT codes do not receive RVU assignments. They can be used for billing purposes (assuming appropriate regulatory clearance), but do not carry payment level guidance. Until recently, insurers categorized Category III codes as "experimental" and non-covered by default; the AMA has worked to change that presumption and has made progress in that effort. It is important to understand that the Editorial Panel is famously frugalin granting new CPT codes. If a procedure can be squeezed into an existing code, or described by a combination of existing codes, or accommodated in an existing code through a minor revision, they will opt for that course. New codes, whether Category I or Category III, are only approved when the application describes a procedure that is in fact meaningfully distinct from any existing code or codes.

Corporate quality

Corporate quality is the centralized quality handling group within an organization that owns the formalized product complaint, market action, and recall processes.

Because there are strict, tactical FDA requirements that must be adhered to and which may vary depending on device classification and submission/approval pathway, this checklist is not an all-encompassing guide. The information below is intended to serve as directional considerations alongside FDA recommendations.

- ◯ **Determine process for complaint submission in conjunction with regulatory. Consider how:**
  - → Clients will report complaints
  - → The complaint is logged, reviewed, and routed for investigation
  - → Mechanism for return of product in question
- ◯ **Establish CAPA procedure in conjunction with regulatory, site quality, and manufacturing operations for investigating product complaints and implementing corrections or corrective actions**
- ◯ **New organizations: Identify and map process for issuing product recalls in conjunction with manufacturing, site quality, and regulatory**

Site quality

Like corporate quality, there are strict FDA requirements which govern site quality. These requirements may vary depending on device classification and submission/approval pathway. The information below is intended to serve as directional considerations alongside FDA recommendations.

- ◯ **Finalize design transfer with R&D/program management and manufacturing operations, including development and documentation of auditing protocols**
- ◯ **Establish CAPA procedure in conjunction with corporate quality and manufacturing operations, and regulatory for investigating product complaints and implementing corrections or corrective actions**
- ◯ **New organizations: Identify and map QMS process for issuing product recalls in conjunction with regulatory and corporate quality**

Medical affairs

Medical affairs in the pre-launch phase works closely with marketing, regulatory, market access and HEOR, as well as independently on the following activities featured in the checklist below.

Medical affairs is an evolving department in medical device that describes the team that sits between R&D and commercial. They interact with healthcare professionals (HCPs) who utilize or are involved with research related to the company's products. This team has advanced degrees that enable them to understand and effectively communicate the science behind a device and answer questions about off-label usage, publications, safety information, and overall medical usage and education.

MSLs or medical science liaisons are field based representatives who engage in scientific exchange with physicians and key opinion leaders (KOLs). The number of MSLs is growing and are required to adhere to strict policies and procedures around company communications. They should know how to respond to off-label use inquiries, grants, medical education, and investigator-initiated trial grant requests, to name a few.

While guidance from the FDA should always be the source of truth for requirements, there are some additional cross-functional activities where a medical affairs team can provide value in the successful launch of your new device. The action items in the checklist below reflect post-clinical trials or human factors assessments and are limited to product launch preparation.

Definitive Healthcare helps you to easily identify the right experts in your specific area of interest or region and utilize RWE to understand the competitive landscape. These experts could then become your key opinion leader (KOL) for your new device at conferences or event speaking engagements.

Medical affairs continued

- [ ] Closely align with HEOR or market access to ensure that all clinical evidence is gathered and available for reimbursement strategy
- [ ] Identify and engage KOLs for clinical support as needed
- [ ] Work in conjunction with marketing on clinical claims within marketing materials
- [ ] Set up internal process for answering off-label inquiries
- [ ] Review marketing materials for clinical claims & supporting evidence
- [ ] Identify key publications and resources to utilize for product validation
- [ ] Work with marketing to determine conference presence and engage KOLs for speaking engagements to support launch
- [ ] Develop customer in-service procedures and identify support documentation needs

IT / ERP management

IT and Enterprise Resource Planning (ERP) management teams play a huge role in commercialized organizations, but in the pre-launch phase, these teams ensure that your organization is set up to accept orders.

There are a variety of ways customers can place orders. This includes EDI, phone calls with customer service representatives, setting up monthly deliveries, drop shipments through a distributor and even fax order placements. Your organization should make it as easy as possible to place orders and the IT/ERP team will be responsible for ensuring that the product and systems are set up appropriately.

- ◯ **Set up order management system with new product number, product description, EDI ordering, ERP management**
- ◯ **Conduct order placement testing**
- ◯ **Release controls for deployment, order placement and shipment after FDA approval and registration completion notification from marketing and regulatory**

R&D / program management

Without R&D and program management, you wouldn't have a medical device at all.

As you prepare to launch your medical device, these teams are finalizing all the digital paperwork involved in device design. The design history file and the device master record need to be transferred to your manufacturing teams or the third-party manufacturer so that production can begin.

While this one action item looks short and lack-luster, there are several steps and considerations within the design transfer that should be based on the FDA regulation.

- ◯ **Finalize design transfer per FDA 21 CFR Part 820**
- ◯ **Align closely with market access/HEOR and medical affairs to understand clinical evidence gathering requirements for reimbursement strategy**

Contracting / Contract marketing

The contracting function performs significant analysis initially to ensure that your agreements with HCOs, HCPS, IDNs and GPOs are enforceable and provide clarity in the event of dispute. Creating your contract strategy before launch ensures success once your device is on market.

There are multiple group purchasing organizations (GPOs) with different sets of terms, rebates and member compliance rates. IDN affiliations and physician group affiliations are often difficult to map and track for applicable contract memberships. All affiliation relationships can impact pricing strategy and execution, therefore pricing strategy amongst the complicated GPO, IDN and other affiliations require dedicated full-time employees. The contracting function should be tightly aligned with marketing, sales, finance and trading partner management.

- ◯ **Write detailed procurement specifications (according to customer requirements)**
- ◯ **Submit new device within GPO award cycle to ensure inclusion on GPO listing; if off-cycle understand with GPO's if new product can be added**
- ◯ **Research and develop reimbursement strategy to determine most common payers**
- ◯ **Work with identified payer organizations to understand how to include your device and what data is required to prove clinical and economic value**
- ◯ **Finalize and implement reimbursement strategy**
- ◯ **Set up distributor chargeback process (if applicable)**
- ◯ **Evaluate and select contract management and compliance tracking system**
- ◯ **Work in conjunction with marketing on pricing strategy**
  - → Including potential tier strategy for varying commitment/volume levels
  - → GPO or individual agreement pricing strategy
  - → WAC & list pricing
- ◯ **Develop internal processes for processing chargebacks, implementing pricing strategy, tracking contract memberships to GPO, IDN, and/or physician groups, monitoring contract compliance monitoring and executing rebate requirements.**

Marketing

A robust, comprehensive marketing plan can make or break the impact your launch has on the market. There are multiple roles within the marketing department that you should consider and evaluate as you develop your strategy:

- → Marketing leadership
- → Product marketing
- → Corporate marketing
- → Marketing communications
- → Marketing analytics
- → Marketing operations
- → Market research

Companies large and small will have different levels of departments, resources and budgets at their disposal. Regardless, it's critical to emphasize that marketing and sales collaboration is necessary. Alignment between marketing and sales ensures that the launch strategy is built together and that targets are shared.

Depending on the size of your company, the scope of each pre-launch activity in the checklist below will vary, but each is important to consider.

VALUE ADD

- ◯ Identify competitors to create objection handling and competitive counter-detailing
- ◯ Identify / target market(s) and key personas
- ◯ Market segmentation
- ◯ Identify buyer personas along with (use cases, customer journey, paint points, etc.)
- ◯ Define value proposition and differentiators
  - → Do differentiators vary based on market segment?
- ◯ Define messaging, features, and benefits
  - → Does messaging vary based on market segment?
- ◯ Work in conjunction with sales to understand target buying process
  - → Including where they buy (e.g. distribution channels)
  - → Is there a value analysis committee?
- ◯ Marketing material development (utilize clinical trial and other outcome data points in conjunction with medical affairs)
  - → As a reminder, products cannot be marketed until after FDA clearance/approval and registration

Marketing continued

- [ ] **Develop pricing strategy in conjunction with finance and contract marketing**
  - → Including potential tier strategy for varying commitment/volume levels
  - → GPO or individual agreement pricing strategy
  - → WAC & list pricing

VALUE ADD

- [ ] **Develop training content and collateral for commercial teams**
- [ ] **Budget planning**
- [ ] **Website strategy. Including content development, landing pages to convert traffic to leads, premium content, and implementation. Execute and strategize in conjunction with third-party web management agency or internal marketing communications department as applicable.**
- [ ] **Lead generation / marketing campaigns within budget restrictions. Execute on marketing plan. Considerations:**
  - → Advertising & promotion (including industry publications, societies, conferences)
  - → Social media
  - → Email marketing
  - → Thought leadership (identify KOLs, conference participation, abstracts / publications, webinars, advisory boards, etc.)
- [ ] **Submit marketing /promotional materials for medical/legal/regulatory review**

The pros and cons of using an agency vs. a dedicated staff

Marketing agencies

If your organization can't allocate the resources to build an internal marketing department, outsourcing to an external marketing agency is your best alternative. Agencies typically have access to broad, comprehensive networks and years of expertise which you can leverage to position your organization for success.

However, your organization may not be the only client the agency services. Agencies often have multiple clients and therefore are not solely focused on your product or organization. It is important to inquire about similar or like products the agency has as clients and understand their policies around this topic to avoid any potential conflicts.

The type of medical device you're bringing to market may also determine whether partnering with a marketing agency is valuable. Complex medical devices may require a significant amount of time spent learning about the product, its therapy area, the clinical outcomes and your target market. Any lack of clarity or understanding could result in the wrong message, unsubstantiated claims or inaccurate targeting. When budget is finite, any mistake could be costly.

You should take care to research multiple agencies and choose the one that is most affordable and has the most experience with your industry. Once your partnership begins, it's important to work closely with your agency to ensure their team has a complete understanding of your product, the market, and the message so that your budget is maximized and efforts are effective.

Dedicated staff

Hiring a full dedicated marketing team across the sub-functions can be daunting, resource intensive and expensive. However, there is no better way to manage your efforts than with your own staff. Dedicated marketing personnel ensures consistency in branding, subject matter expertise and most importantly, an ability to quickly pivot tactics if something is proven ineffective. All marketing materials should be reviewed by regulatory, legal and medical teams. Internal personnel may be better equipped to adjust and work more closely with these internal departments.

Sales

Figuring out the people who will be selling your medical device is just as important as identifying the right markets to target. You'll need to consider how your device will be sold, how competent and confident your salesforce is in clinical selling and identify the most viable markets.

There can be several layers to a medical device organization's salesforce. Below are some of the common roles:

- → Sales leadership
- → Field sales
- → National accounts
- → Major accounts / enterprise accounts
- → Corporate accounts
- → Sales operations
- → Inside sales

As you strategize on the multitude of sales activities, it's important to keep in mind that collaborating cross-functionally with marketing, sales ops, customer experience and more are extremely important. Tight alignment across teams ensures that everyone will know what to expect to post-launch, driving towards the same goals and singing the same tune to ensure success.

We'll explore the best options for your salesforce but before exploring how you're going to sell your device, the following important activities should be considered.

- ○ Identify target market(s)
- ○ Market segmentation
- ○ Territory alignment
- ○ Sales leadership to determine target accounts
- ○ Work in conjunction with marketing to understand targeting buying process
- ○ Determine sales process for new device

VALUE ADD

- ○ Determine staffing needs and onboard sales personnel
- ○ Create target account listing with potential dollar value broken out by sales territory & market segment

Sales continued

- [ ] Attend product and competitor training and ensure proficiency
- [ ] Research target accounts to determine pre-call planning and outreach strategy
- [ ] Identify GPO relationships with target accounts
- [ ] Develop customer onboarding and implementation plan:
  - → How will you ensure customers have success with your new device?
  - → In conjunction with medical affairs and marketing, determine in-servicing needs to be prepared for the first customer sale
  - → **As a reminder, products cannot be actively sold or discussed until after FDA clearance/approval and registration.**

VALUE ADD

If this is your organization's first device...

There are several salesforce options to consider when launching a new device.

1099 salesforce

Employing a 1099 salesforce is a good fit for organizations who don't have the resources to staff and train an internal team, or if you know it's a low lift to sell your medical device.

Like anything else, however, there are pros and cons. Data can help guide your thought process as you make these important strategic decisions.

A 1099 salesforce consists of independent sales representatives who earn their income through commission. They usually carry with them a built-in network of contacts and years of experience so you can execute your sales strategy with little delay. They also concentrate on specific geographic regions so there is an opportunity for more feet on the street without additional expenses incurred.

There is always a risk when handing the reins to an external team. These sales reps may rely on a stale network, or may not be familiar with the market segments or therapy areas you operate in. A 1099 sales team is also driven by commission, meaning they might have their attention split between multiple products.

If you select a 1099 salesforce, you can leverage Definitive Healthcare to verify their network and to help identify the right targets and ideal customers not on their radar.

Proprietary salesforce

Product differentiation matters. How best to communicate a clinically differentiated or complex device than with a salesforce that you have full control over? With a proprietary, in-house sales team, product training and decision-maker education is in your hands.

Healthcare commercial intelligence can set up your sales team for success right from the start. With the right insights, you can improve the effectiveness and efficiency of pre-call planning and streamline the sales cycles. This route does require budget, product training, time, and resources, but gives you full ownership of your device's success.

This option also provides the flexibility to build in layered sales members that manage different markets, account types or account sizes.

Distribution

Distribution may be a good option for your company if your device is simple or a commoditized type of product. It requires no internal sales personnel, but you are putting the profitability and success of your device in the hands of another organization. Distributors do charge a fee and typically do not spend significant budget on marketing. Distribution reps typically lead with the most profitable offering in their bag, so compensation via distribution channels is an important factor to consider.

Partner sales

Another option to consider is teaming up with an established sales force who call on your target persona. These reps will work for another life science company, and often times have credible relationships already built with customers to overcome the initial barrier to entry.

This option should be carefully considered. Both sides should agree to a quota so your product doesn't just sit in the bottom of the bag. Also, larger medical device companies typically partner with smaller startups to be able to throw in newer products to differentiate themselves from the competition during the buying process. You want to be careful to not diminish the selling price of your product while flooding the market.

Companies with multiple on-market devices

If your organization has already launched other medical devices, you should consider whether to use your existing salesforce or a new dedicated team for the new device.

Existing salesforce

If your new device is within the same therapy area, has similar functionality, or is complimentary to an existing device you sell, sticking with the existing sales team you have is a great option. A team with one or more devices under their belt can be trained on a new device quickly and rely on their current network to get a head start.

This option requires no new staffing but may need you to modify your incentive and compensation plans.

Time and attention are other important elements to consider. After your new device launches, you'll need to analyze where your salesforce is spending their time. What's the split between devices and are sales continuing to grow and thrive or is another device no longer receiving attention?

New dedicated salesforce

Building a new salesforce may be ideal if you're launching a complex device or entering a new therapy or treatment area. Devices competing in an extremely large market or have long and high-touch customer buying processes might also be better handled by a fresh, dedicated team.

Using healthcare commercial intelligence, you can analyze your total addressable market across multiple segments and treatment landscapes. Then, you can determine if your salesforce would be capable of effectively selling all devices (including the new one) in their book of business, or if the new device would result in a significant shift in focus that would negatively impact selling your other devices.

This option may also require a serious investment of time and manpower. A new sales team means new territory mapping based on market segments and high-value target account identification by sales operations. Fortunately, using the right data and executive contact info can help you determine market segments, map the new territories and identify high-value targets based on facility or physician claims, thus helping you to accelerate the sales cycle. With healthcare commercial intelligence, you'll be set up for success in staffing your new dedicated sales force.

Sales operations / business analytics

The overall goal of the sales operations and business analyst roles is to collect and interpret data from across your organization and then leverage those insights to improve business processes and solve problems. Effectively managing and analyzing data has become increasingly more important over the years. Generally, a medical device company who grounds their commercial strategies in data-driven decision-making reports greater success.

You can support your data analysis efforts by using the Definitive ID. This is a unique identifier that has helped many medical device companies align target accounts and affiliations with internal systems so that everyone across the organization is referencing a single source of truth. This drives synergies across teams, improves accuracy and overall data integrity.

Effective sales operations and business analytics teams will work closely with sales, marketing, finance and contracting to get a full view of the market, targets and internal performance.

The following tasks are specific to the role of sales operations or business analytics in the go-to-market process. You may notice that some of the activities overlap with sales. This is intentional, due to the tight alignment and need for sales operations to provide the data analysis that goes into strategic decision-making:

- ◯ Identify target market(s)
- ◯ Market segmentation
- ◯ Build territory alignment based on market and account research with sales leadership direction
- ◯ Develop target account criteria with sales leadership and perform analysis for account identification
- ◯ Determine sales process for new device and develop tracking/monitoring mechanism
- ◯ Create target account listing with potential dollar value broken out by sales territory & market segment
- ◯ Research target accounts to assist sales with pre-call planning and outreach strategy
- ◯ Evaluate and select CRM vendor > set up maintain CRM
- ◯ Work with marketing to build lead generation and lead communication mechanism
- ◯ Develop mechanism for win/loss analysis tracking

Sales training

Whether your organization staffs an internal salesforce or uses independent 1099 workers, a comprehensive sales training program helps create a team of confident, competent salespeople who have the information and guidance they need to be effective in the field.

This role should work very closely with product marketing, and in smaller organizations the role of sales training may even be filled by product marketing.

- [ ] **Determine sales training deployment mechanism:**
  - → In-person / on-site sales training
  - → Live virtual sales training
  - → Use of eLearning platform

- [ ] **Identify training topics in conjunction with marketing:**
  - → Market segments
  - → Messaging
  - → Available tools and collateral
  - → Buyer personas
  - → Buying process
  - → Selling practices

Trading partner management

Even if your organization is establishing its own proprietary sales team, it's still important to evaluate distributor channels to determine device availability.

Many hospitals and physicians consolidate their buying through a preferred distributor. To maximize your sales efforts, it's wise to make it as easy as possible for customers to buy your product. Keep in mind that many distributors won't pre-stock your soon-to-launch product without some hefty fees. It is common for distributors to hold off on order placement until after they begin to see customer demand.

If you're considering using a distributor, you should ensure the following is completed before your product is commercially available. Once complete, customers will have the option to order through their normal purchasing channel.

- [ ] **Work in conjunction with marketing to determine distribution strategy – where / how do targets typically buy?**
- [ ] **HDA form completion for med-surg distributor or wholesaler set up**
- [ ] **Work in conjunction with contract marketing on setting up the distributor chargeback* contract and process**

*Chargebacks give your organization visibility into which end accounts are buying your product through a distributor. Without a chargeback agreement in place you will not have visibility into end customer purchasing.

Supply chain / logistics

Developing a solid supply chain and logistics strategy is important for two reasons:

- → Your strategy can guide decision-making around the cost and price of your device
- → Your customers will expect their products to be delivered on-time and in perfect condition

Generally speaking, you should choose the most efficient and cost-effective option. It's wise to research warehouse and logistics companies thoroughly, as they often give discounts based on volume and exclusivity.

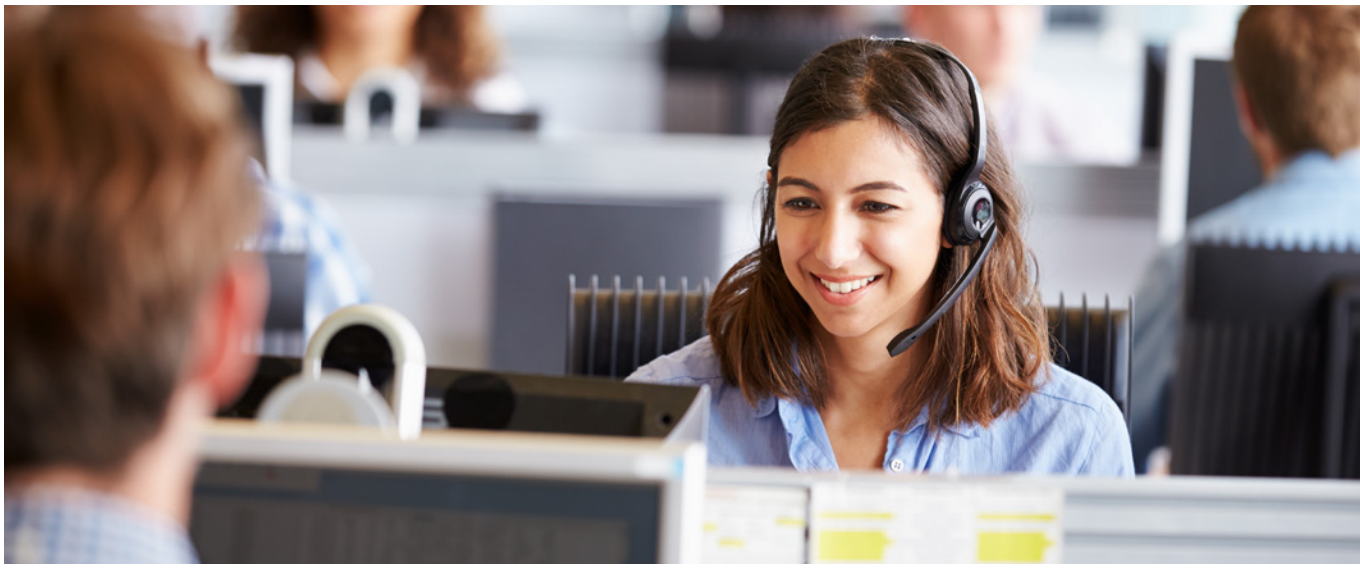
- ◯ **Develop supply chain and logistics strategy?**
  - → Third-party logistics (3PL)
  - → Distributors?
  - → Owned distribution / warehousing?
  - → Proprietary fleet
- ◯ **If owned warehousing, how will product be shipped?**
  - → Owned fleet?
  - → Popular shipping service
  - → Use of freight company?
- ◯ **Deployment planning**
  - → Determine timing, quantity and where product will be shipped for distribution
- ◯ **Demand planning / forecasting**
- ◯ **Before your first sale, you need to make forecasting assumptions to determine production schedule and the volume of your first lot to stock.**
- ◯ **This can be done using market data and company-determined growth targets and should be done in conjunction with marketing.**
  - → Develop future forecasting cycle with accuracy tracking, to have in place after the new device is launched

Customer experience

Customer experience isn't going to have a lot to do before the device is launched because your new device isn't available to customers yet. However, processes need to be established for when the product is marketable, and teams need to be trained on those processes and systems. If this is a device being added to an existing portfolio, you'll need to determine what, if anything, needs to change from the current process to support the new device.

The checklist below is more aligned with process considerations rather than a tactical preparation checklist:

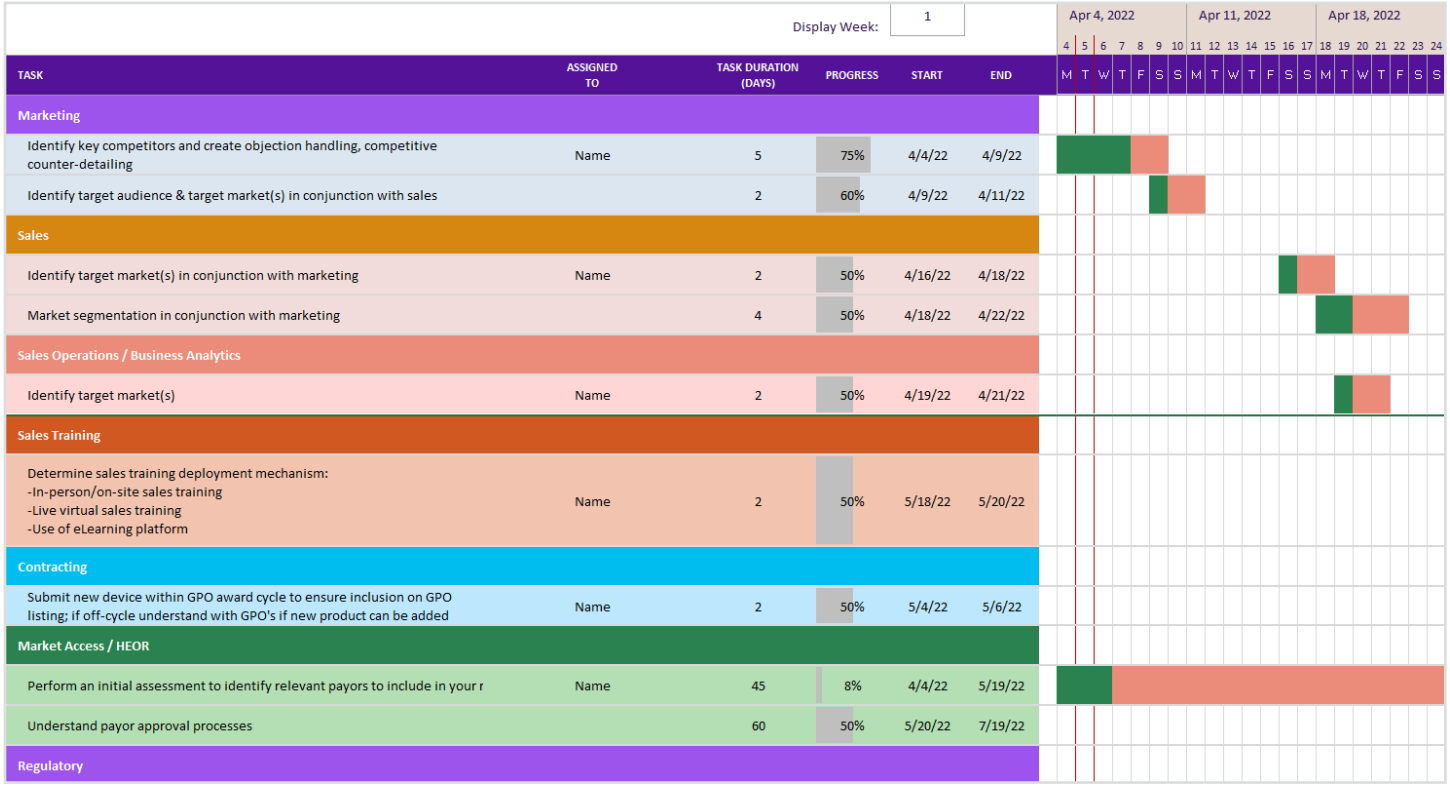
- ◯ **New customer onboarding**
- ◯ **Customer service support:**
  - → Will there be a dedicated team for your new device?
  - → Will there be a direct point of contact for each customer?
  - → Will there be customer support by geographical region?
  - → Will customer support be aligned to sales territory?
- ◯ **What kind of customer communications will the team handle? (Ensure there is a documented process that the team is trained).**
  - → Product enhancements
  - → Supply disruptions
  - → New releases
  - → Updates



Connecting the functions and leading a successful launch

Successfully launching your medical device requires a comprehensive, customizable strategy with support from teams across the organization. To help prepare you for success, we built a GANTT chart pre-populated with all the go-to-market tasks in this guide. This tool coupled with Definitive Healthcare intelligence can give you a leg up on bringing the cross-functional teams together to develop and execute on your launch strategy.

Download the GANTT tool **here** to start optimizing your launch strategy!



Display Week: 1

TASK	ASSIGNED TO	TASK DURATION (DAYS)	PROGRESS	START	END
Marketing					
Identify key competitors and create objection handling, competitive counter-detailing	Name	5	75%	4/4/22	4/9/22
Identify target audience & target market(s) in conjunction with sales		2	60%	4/9/22	4/11/22
Sales					
Identify target market(s) in conjunction with marketing	Name	2	50%	4/16/22	4/18/22
Market segmentation in conjunction with marketing		4	50%	4/18/22	4/22/22
Sales Operations / Business Analytics					
Identify target market(s)	Name	2	50%	4/19/22	4/21/22
Sales Training					
Determine sales training deployment mechanism: -In-person/on-site sales training -Live virtual sales training -Use of eLearning platform	Name	2	50%	5/18/22	5/20/22
Contracting					
Submit new device within GPO award cycle to ensure inclusion on GPO listing; if off-cycle understand with GPO's if new product can be added	Name	2	50%	5/4/22	5/6/22
Market Access / HEOR					
Perform an initial assessment to identify relevant payors to include in your r	Name	45	8%	4/4/22	5/19/22
Understand payor approval processes		60	50%	5/20/22	7/19/22
Regulatory					

Improve your chance of success

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Definitive Healthcare provides the most comprehensive healthcare commercial intelligence you need to prepare for every step of the commercialization process and accelerate your go-to-market journey. Our data products, tools and services can assist you with all aspects of planning, strategy and execution. With insights across multiple market perspectives all unified in one single source of truth, you can improve your chances of success.

Our solutions for medical device organizations are aligned with the FDA device development process to ensure that you have the greatest chance of success in bringing your device to market and making a positive impact on patient care.

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