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OUTSOURCE YOUR WAY TO OPERATIONAL EXCELLENCE

When it makes financial and strategic sense for medical device manufacturers to outsource specific preclinical, clinical, regulatory compliance, and market research activities

WHITE PAPER

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Optimizing Your Workflow

Managing teams in a medical device company can be a struggle. You're constantly trying to manage more than one workstream at a time. Priorities change. People leave. New projects pop up. Sometimes it's just not possible to keep all balls in the air and you need help to manage the workload or move a project forward. If applied smartly, outsourcing very specific workstreams can turbocharge the overall output of your company in a cost-effective manner.

7 Common Situations Driving Medical Device Companies to Consider Outsourcing

Managers are constantly trying to balance what gets done by internal teams, and what to outsource. At NAMSA we have worked with hundreds of medical device and in vitro diagnostic (IVD) companies and have found that the majority of senior managers choose to outsource certain tasks for one of the following seven reasons.

1. Big Project with a Hard Deadline

This is one of the most common reasons we see companies of all sizes outsourcing certain biological safety, clinical, and regulatory tasks. Typically, a company might have the skillset to handle a big project internally but they don't have the capacity due to ongoing obligations. In these cases, management will choose to outsource an important project with a firm target completion date to ensure that deadline is met. This is a smart approach because hiring someone full time is costly and time consuming, but the need is finite. This allows companies to scale up and down as needed, saving money overall.

Typical need	Common situations
3-12 months	A multinational medical device company needs to conduct annual independent Quality Management System (QMS) audits of their major suppliers prior to their next Notified Body audit to ensure compliance with ISO 13485:2016 and other regulatory requirements.
	Company recently had an FDA inspection or Notified Body audit and needs to quickly mitigate findings outlined in the inspection/audit report. The auditor found major deficiencies in clinical data and the company needs to get started on post-market clinical follow-up (PMCF) studies as soon as possible.
	An early-stage company has a study underway but enrollment is not happening fast enough or it is struggling to start up numerous sites. To maintain the product development timeline promised to investors, they need to accelerate enrollment and expand the number of sites.

2. Internal Departments Not Collaborating

Larger device companies often face a vexing problem. Their regulatory, clinical, lab, and marketing departments are siloed, making it difficult to move new product development projects forward in a timely manner. They need someone who can act as a liaison between departments and bring in specific resources to fill gaps and keep the project moving forward.

Typical need	Common situations
6-36 months	A large orthopedics manufacturer is developing a new high-profile device but their in-house lab and clinical teams are overloaded and have a history of not working together efficiently. The company decides to outsource preclinical and clinical research for the product in an effort to shorten the timeline to regulatory approval.
	The CEO of a multinational IVD manufacturer with offices in the US and Europe is frustrated by the lack of progress moving their new microfluidic assay from the development phase into preclinical and clinical phases. The teams are not communicating well and an outside testing and Contract Research Organization (CRO) is needed to get everyone in alignment and move the project forward.
	An established cardiovascular company recently merged with another company. The two companies have not yet fully integrated and are using different systems under different managers. Various departments are trying to work together to push a new product into the clinical phase but it's moving slowly and the teams disagree on strategy and next steps. The company needs someone to help with study startup activities and completion of a primary endpoint.

Functions Commonly Outsourced by Device Companies

- **Analytical Evaluations**
- **Biocompatibility Testing**
- **Biological/Toxicological Risk Assessments**
- **Clinical Studies**
- **Packaging and Sterility Testing**
- **Preclinical Development Testing**
- **User Experience Testing**
- **Regulatory Submissions/Compliance**
- **Medical Writing**
- **Database Development**
- **Data Management**
- **Clinical Evaluation Plans and Reports**
- **Biostatistics**
- **Market Research**
- **Post-Market Clinical Follow-up (PMCF)**
- **Reimbursement**

3. Recent Key Staff Departure Created a Gap

If you've been a manager for some time, you've certainly been in a situation where a key member of your team left for another job, internally or externally. If this person held a specialized position and their work is not easily spread out among other colleagues, this leaves a hole that can grind projects to a halt or stress your existing employees trying to fill the gap. At minimum, it will take at least three months to get a replacement employee on board and up to speed; therefore, a smart option involves bringing on a temporary resource who can hit the ground running and has "been there, done that."

Typical need	Common situations
3-9 months	The RA/QA manager in charge of implementing an ISO 13485 compliant quality system departed for a competitor, leaving the company with nobody to continue work on the implementation. Hiring a replacement will take 3+ months plus onboarding time and the manufacturer cannot afford the delay. An experienced QMS auditor/implementation expert is needed to maintain progress until the replacement is up to speed.
	The internal pathologist for a device manufacturer is about to go on maternity/parental leave but the company needs work to continue on a critical preclinical study. The company decides to outsource analysis of slides to ensure the project stays on track.
	The lead biostatistician for a large device manufacturer left to join a CRO. The company has a large trial underway and needs to outsource this aspect of the study while they hire a new biostatistician.

4. Internal Teams Overwhelmed

Medical device and IVD manufacturers often have situations where they need to expand capacity in their testing, clinical, or regulatory compliance departments but don't want to invest in in-house expansion for a variety of reasons. This can be due to budgetary constraints that limit hiring new full-time employees, a pending merger, or simply a desire to divest certain specialist activities.

Typical need	Common situations
6-24 months	A manufacturer of dental products has a need to evaluate dozens of Clinical Evaluation Reports (CERs) for compliance with the European Medical Device Regulation (MDR). However, current RA staff is completely booked with ongoing registration and compliance obligations.
	A large multinational IVD company purchased a niche competitor and is in the process of merging clinical and regulatory operations. Numerous people from the acquired company left soon after the acquisition but management does not want to replace them. Existing teams are overwhelmed. The parent company decides to outsource a portion of the work previously done internally.
	An orthopedics manufacturer decides to close one of their labs, which also had capabilities to conduct packaging, bioburden, and microbiological testing. Rather than shift those tests to other labs, the company has decided to outsource them to a third-party lab.

5. Managers Scramble to Handle Workload After Recent Layoffs

When companies experience a sustained or sharp dip in sales, a "reduction in force" usually follows. Unfortunately, when it comes to quality, regulatory, and clinical staff, the workload is only partially dependent on new product introductions or current sales. This means when departments are cut, many things simply don't get done, leaving the company at risk and adding to the stress levels of those who remain and need to be retained. Ironically, department heads will often tap discretionary budgets to plug the hole with outside resources.

Typical duration	Common situations
<12 months	A large device company saw a slump in sales during Q3/Q4 and the CEO mandated a "reduction in force" of 10% across the board, including RA/QA. The workload remains unchanged for RA/QA and the department VP redirects some funds to hire outside regulatory and clinical resources.
	A manufacturer with a large IVD portfolio needs to gather significant clinical evidence in support of IVDR submissions before a 2026 compliance deadline, but the team simply does not have the bandwidth to tackle it and there is no possibility to add staff this year to address it.
	One of the four labs within a large device manufacturer was closed and the work it was conducting was shifted to other facilities. However, the other three labs do not have enough capacity to handle the overflow. Some tests must be sent to an independent lab.

6. Company Needs Specific Expertise But Not on Staff

Some medical device and IVD companies need RA/QA or clinical expertise but there is not yet enough work to justify hiring someone full time. Thus, they outsource the work on a part-time basis to an expert who can hit the ground running and knows what needs to be done. Other companies consciously choose NOT to bring certain functions in-house because it's not core to their business and they know specialty companies can do it more efficiently and effectively.

Typical need	Common situations
12-24 months	A medical device startup is bringing their first implant device to market. They need an experienced consultant who can map out the biological evaluation plan and ensuing testing, clinical, and regulatory pathway for US Food and Drug Administration (FDA) premarket approval (PMA).
	A large medical device company has more than enough work to keep medical writers busy but the work comes in waves and the manufacturer has decided it would be more efficient to outsource this function.
	A device manufacturer is creating an inhaler product and needs very specific expertise on FDA pharma and biologics regulations to guide them through the preclinical and clinical phases.

7. Management Mandates Cuts to the CapEx Budget

Sometimes buying the capital equipment and hiring the expertise in house is not feasible or desirable. Management may decide that a limited capital expenditures budget is better allocated to new product development rather than expanding in-house lab capabilities. In these cases, a natural solution is to outsource certain tests to an outside lab.

Typical need	Common situations
12+ months	A top 10 medical device manufacturer has several in-house testing facilities but the company has limitations in the types of tests it can complete and does not want to invest capex for new lab equipment or for people qualified to run and analyze those tests.
	An IVD manufacturer has minimal in-house lab capabilities but the equipment is older and not up to today's standards. Rather than investing in expensive equipment, it is considering closing the lab altogether and outsourcing all testing as a way to reduce capex and overall costs.

Outsourcing and Insourcing: Each Have Their Benefits

Outsourcing	Insourcing
Flexibility to quickly scale up/down to meet demand	More cost-effective once department is established and fully utilized
Manufacturer gains access to people with highly specialized expertise	Ability to pick and choose individual team members to suit needs of the company
Projects can get completed faster as more resources can be added quickly	Better visibility and ability to control activities of individual team members
Manufacturer benefits from partner insights gained from supporting hundreds of medical device companies	Company builds "institutional knowledge" and capabilities by hiring team internally
Outsource partner may have superior project management and systems because they work with so many clients	More ability to track, direct, and report on activities in a format that suits management preferences
Manufacturers are more likely to get an unvarnished opinion not influenced by internal politics and status	Managers are more in touch with people (employees) doing the work and can address questions and make decisions quickly
Manufacturer has less fixed cost overhead than they would keeping employees on staff	More predictable expenditures for budgeting purposes

Emphasize Skills Not Roles

For decades, manufacturers have traditionally hired people to perform a very specific set of tasks and given them titles that tend to limit their potential. For example, some engineers are gifted at breaking down complex topics and connecting with customers, and would serve the company well by being involved in big sales. But that's rarely the case. Job titles and roles are clearly defined so everyone stays in their lane.

Today some of the more progressive medical device manufacturers are looking for a more agile approach that shifts the mindset from roles to skills. Outsourcing is a way to get specific projects completed quickly rather than trying to build all specialized capabilities in house. According to a Deloitte survey of more than 1,200 professionals:

"Organizations are increasingly experimenting with decoupling some work from the job (and) atomizing it into projects or tasks, or broadening it so it's focused on problems to be solved, outcomes to be achieved, or value to be created. People can be freed from being defined by their jobs and instead be seen as whole individuals with skills and capabilities that can be fluidly deployed to work matching their interests, as well as to evolving business priorities. By basing people decisions on skills more than jobs, organizations can still have a scalable, manageable, and more equitable way of operating."

One Partner or Multiple Specialists?

Manufacturers are often tempted to work with different companies—one for device testing, another for clinical trials, and yet another for specialist activities like UX testing or regulatory submissions. Yet, while specialist companies excel in their respective areas, challenges occur during the handoff between entities who are siloed from one another. The "lost in translation" effect can have huge consequences on a manufacturers' ability to maintain progress, especially in new product development projects.

Think twice before outsourcing an entire project to one company just for the convenience of it—especially if there is a much stronger partner for one aspect of the process (example: biocompatibility). That being said, don't underestimate the value of continuity and its impact on project speed and efficiency. Downstream communication will be far superior and your project is much more likely to be done more quickly. Weigh your options carefully and make sure you consider the impact of working with one versus several firms.

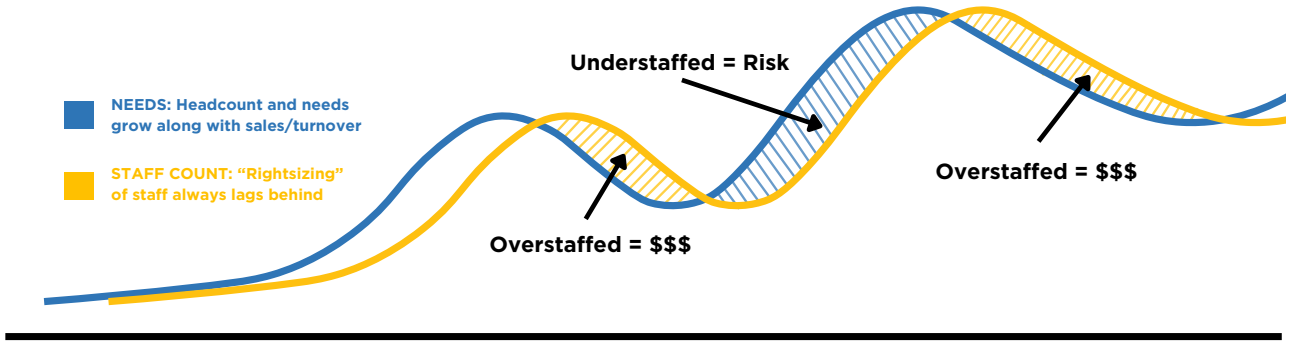
Sometimes It DOESN'T Make Sense to Outsource

Clearly there are many situations where it doesn't make sense to outsource for financial, control, and performance issues. For example, if you will be introducing a range of products over the next several years, you might be better off building clinical expertise in-house and only outsourcing certain specialist areas as needed. Also, there is the issue of talent availability. If your company supports remote work or the company is based in a geographic market with a robust ecosystem of talent, it may be better to build a team rather than find an outsource partner. Finally, if your company is more mature and has a track record of stable and growing sales from a broad product portfolio, building in-house capabilities may make financial sense.

The Hidden Cost of Full Time Employees

The desire to build an in-house team is strong, but you definitely need to be fully aware of the true costs of bringing on an employee. Generally, if you are going to add a mid-level employee to your preclinical, clinical, or regulatory teams, you should add 40-50% on top of their base salary to cover ALL costs including retirement benefits, vacation/holiday/sick pay, federal holiday pay, health insurance, unemployment insurance, IT support, HR support, laptop, office space, etc. Thus, if you hire a mid-level Regulatory Manager and pay them $100K, the total cost to the company is closer to $140-$150K when all benefits and ancillary costs are included. Consider this when pondering the next proposal you receive from an outsource vendor.

In a macro sense, companies also don't account for the costs of maintaining employees for too long after a clear downward trend has emerged. When so much work has been invested in building an internal team, managers understandably want to try to preserve the status quo as long as possible. However, not responding fast enough costs real money. Once a layoff occurs, senior management is reluctant to rehire until a clear upward trend has emerged. After that, it takes time to get approval to rehire and time to interview, hire, and onboard replacement team members. This creates stress on the existing team members who step in to fill the gap and creates more risk for the company as tasks fall through the cracks or get postponed.



Companies are often slow to reduce headcount, and slow to rehire in response to market dynamics.

Conclusion

Managers are always looking for the most efficient way to get the most done with limited resources. Outsourcing can be a very effective way to fill a gap in capacity, gain access to expertise that doesn't exist within the company, or drive a project forward faster than might have been possible internally. Whatever the situation, the team at NAMSA is ready to help.

About NAMSA

Helping medical device Sponsors improve healthcare since 1967, NAMSA is the world's leading MedTech Contract Research Organization (CRO) offering global end-to-end development services. Driven by its global regulatory expertise and in-depth therapeutic knowledge, NAMSA is dedicated to accelerating medical device product development, offering only the most proven solutions to move clients' products through the development life cycle efficiently and cost-effectively. From medical device testing; regulatory, reimbursement, and quality consulting; and clinical research services; NAMSA is the industry's premier, trusted partner for successful development and commercialization outcomes.
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About the Author

Chris Schorre has been working in the medical device and IVD industry since 2004. Prior to joining NAMSA, Chris spent 14 years as VP of Global Marketing for Emergo, a global medical device regulatory consultancy. He also spent several years as an independent Marketing Consultant assisting numerous medical device contract manufacturers and consultancies, including TE Connectivity, Freudenberg Medical, Oriel STAT A MATRIX, Luctor Medical, MedEnvoy, Celegence, and more. He has a deep understanding of how manufacturers can take advantage of outsourcing to solve short term problems, improve operational efficiency, and accelerate time to market.

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