MedTech Outsourcing: Is the Past Any Indication of the Future?

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Strategic Perspective
As outsourcing in the medical device space becomes more prevalent, there are many variables to consider when making the decision to involve a third party. This paper will explore why companies should consider outsourcing, the keys to successful implementation, the potential problems associated with outsourcing, and when it may not be the best model for your company. It is important to not only understand when you should or should not outsource, but also to understand the different effects outsourcing will have on a startup medical device maker vs a large industry manufacturer, as this paper will discuss.

Outsourcing: Working Definition
Outsourcing is the contracting out of a business process, product, or service to a third party. It may involve transferring employees and/or assets from one firm to another, but not always. Outsourcing includes both foreign and domestic contracting, and sometimes includes offshoring or relocating a business function or service to another country.

Trends, Past and Present
Outsourcing in the medical device space is on the rise as the amount of global “dollars” that Sponsors (also known as the medical device manufacturers) spend on Contract Research Organization (CRO) services is expected to increase from $3.5 billion to more than $7.2 billion by 2018 (GlobalData). Globalization of medical device manufacturers large and small, combined with the growing complexity of devices, continues to fuel the need for not only more proof data, but also better and faster proof data. These trends in MedTech and BioTech are adding to an already complex landscape that will challenge current medical device development processes and methodologies. The growth predictions for CRO services are not all that shocking to anyone working in the medical device arena. Looking through the lens of pharma history and comparing it with current MedTech trends may give us insight on what the medical device future will look like.

Current trends in medical devices:
- Hospital utilization for devices are trending down, meaning companies struggle to sell the same volumes while healthcare providers are incentivized to consider the cost of treatment.
- Device margins are under pressure as affordable healthcare laws will squeeze reimbursements while global regulatory bodies are requiring substantially more data to clear technologies. Forecast: Longer, more costly development timelines with lower margins upon market adoption.
- Implementation of US medical device taxes is having a significant impact in the marketplace.
- Ongoing debt crisis in Europe is impacting innovation for many EU-based manufacturers.
- MedTech space is maturing – Big MedTech has seen annual revenue growth “plummet from 15%-20% between 1994 and 2004 to just 5%-6% today” (Moore, Minneapolis Star Tribune).
- MedTech dollars spent in regulatory, quality & compliance, and clinical affairs are growing more than three times the rate of market growth.
- MedTech R&D spending will grow 3.9% per year to reach $26.7 billion by 2018 – but slowing relative to compound annual growth rate (CAGR).
- Mergers & acquisitions (M&A) activity predicting more mega deals and consolidation across the medical device space.
Growth that satisfies Wall Street and MedTech investors is becoming harder to achieve and it is probable that what worked 10 years ago won’t work tomorrow. Device utilization, margin pressures, and regulatory pressures will remain in the foreseeable future, which in a maturing market will accelerate the need for industry consolidation and new R&D models. Consolidation by definition leads to operational changes (downsizing), more shared services, new ways to use the balance sheets (investment strategies), and a need for more efficient methods to bring devices through the development process.

**Big Pharma History**

Before the millennium, big pharmaceutical companies began utilizing outsourcing models that today are quite normal in the pharmaceutical world. But how did they get there? The shift was a result of pain—specifically, Wall Street-imposed pain. Pharmaceutical companies were making money developing 1 or 2 drugs a year, but during the late 1980s into the 1990s shareholders expected companies to have 3, then 4, blockbuster drugs per year while avoiding the patent cliffs that loomed over current marketed products. The challenges in designing and developing were obvious and regulatory burdens were not improving the game. Big Pharma companies began maturing, which led to massive industry consolidation.

The consolidation morphed the industry into sales and marketing giants, which helped to offset the utilization challenges and provided the growth Wall Street expected. Even this was not enough though. In order to bring more blockbuster drugs to market faster, Big Pharma developed outsourcing methods and “partners” as a way to better utilize operational resources, work in parallel, penetrate new global markets, and satisfy compliance needs. As relationships with these partners grew, we saw the emergence of strategic alliances that took over more control of the process in areas where Big Pharma found themselves deficient compared to their strategic partners. What was a core competency in the 1980s was no longer a core competency in the 1990s; outsourcing partners who could do it faster and cheaper, and with more variability, became a necessity as the challenges mounted. Pain forced this fundamental shift—and comparisons to the Medical device space today is eerily similar.

Perhaps there is something we can learn from the past:

- What are the benefits of having strategic development partners? How do these benefits differ for startup medical device makers vs large industry manufacturers?
- What are the keys to making good outsourcing decisions?
- When did/does outsourcing not make sense?
- What should one expect from a strategic partner?

There is a trend in the MedTech space to become more variable as it relates to the development process. Companies big and small are moving from less committed costs (Fixed) to more discretionary (Variable) models, which aligns well with an iterative, variable development process. Companies need to preserve cash for R&D investments and move toward more efficient and flexible development models.
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Benefits of Outsourcing
As we explore the MedTech and Pharma history next to data points from CROs, Sponsors, and analysts, there are common themes that are fundamental to outsourcing success. Strategic partnerships will be quite different because device makers are uniquely challenged with tactical, strategic—and in some cases transformational—structures that address their unique corporate objectives, specific tasks, or individual deficiency. The benefits of the outsourcing partnerships as reported by Sponsors generally speak to:

- Reduced costs and improved operational margins
- Improved quality or judgment proofing by using a third party—less biased lens
- Access to expertise beyond current staff, equipment, or therapeutic/facility capabilities
- Access to geographical, cultural, global capabilities
- Geographical penetration and/or cost advantages
- Ability to focus on core competencies
- Improved revenue per employee
- Flexibility to address capacity constraints
- Access to leading edge technology, expertise, or insights
- Reducing risks—eg, extending/paralleling regulatory pathways to market

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Startup vs Large Manufacturer

The benefits of outsourcing for a startup medical device maker are fundamentally the same as they are for a large industry manufacturer, although the financial situation, equipment needs, and human capital are quite different in scale, creating a unique set of partnership criteria to address the unique pains.

**Startup Medical Device Maker (project-focused, milestone-driven)**

- Cost and time reductions:
  - End-to-end translational services to reduce cost and time—what is learned early can be translated efficiently into later development efforts
  - Ability to parallel path tasks that reduce time with fewer full-time employees
- Reduce investor risks by running parallel “get to market” strategies
- Access to expertise in any discipline at your fingertips
- Global exposure and insights
- Preserve cash flow by outsourcing departments and staying variable
- Avoid excessive bricks and mortar

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**Tactical Outsourcing**

- Achieves some operational efficiencies
- Derived from simple cost/benefit analyses between existing internal operations and external service provider

**Strategic Outsourcing**

- Redirects the Sponsor’s resources toward core competencies and highest value-creation activities

**Transformational Outsourcing**

- Takes advantage of innovation and new business models
- Redefines the way the business operates and achieves rapid, sustainable improvement
- Aligns Cultural and Operational processes
- Asset transfers that benefit the strategic relationship
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Large Industry Manufacturer (task focused – remediation, flexible, address deficiencies)

- Operational improvement and cost reductions compared to current operational models
- Address specific deficiencies where expertise or internal capabilities are lacking
  - Tackle projects that never get off the back burner due to resource deficiency
  - Bring in specific expertise for a specific task, short or long term
- Manage the overflow of internal capabilities
- Manage less critical tasks
- Ability to focus on core competencies

Outsourcing Fears?
Outsourcing can come with risks, and deciding when to outsource is likely a decision unique to the individual Sponsor because tasks, capabilities, and resources will vary from company to company. Good strategic partnering begins and is centered on trust, which is likely built over time and has mutual benefit. This trust grows as the solutions to innovation, cost, performance, and speed prove to be worthy. There are times and situations where the risks are perceived too great and in our experience Sponsors typically point to certain risks as unacceptable:

- Loss of control
- Increased cost
- Sponsor reputation on the line
- Lack of urgency, “CRO can’t share our vision”
- Continuity of projects
- Complexity in managing CROs
- Confidentiality/IP exposed
- Business strategy exposed
- Too much uncertainty
- Forecasting in question
- Process changes and business re-engineering
- Cultural fit, values, and alignment in question

Outsourcing Do’s and Don’ts

- Do outsource
  - To create variable and fixed cost flexibility
  - To gain expertise you do not have
  - To increase core competencies on work you cannot outsource
- Do set expectations appropriately
  - Plan start-up time realistically
  - Expect significant cultural and communication issues—know what they are and train accordingly
  - Address the internal resistance
  - Execute transfers between Sponsor and service provider staff—flip badges and other assets in an upfront and structured manner
• Do partner with experience, longevity, and reputation
• Do set up key performance indexes that speak to the shared vision and shared risk
  ▫ Trust – Surveys, project reviews
  ▫ Time – On time performance, on time delivery
  ▫ Quality – Error free metrics, aligned quality indexes
  ▫ Cost – Volume discounting, shared performance incentives
• Do adjust early and often
• Do use a common-sense approach that works for your situation
• DON’T
  ▫ Outsource for short-term cost savings
  ▫ Select your partner on price alone
  ▫ Outsource if it would compromise your core competencies
  ▫ Expect immediate gains
  ▫ Expect outsourcing to solve your workflow or business process problems
  ▫ Expect ROI calculations to tell the entire truth

“The challenge for CROs is to shape the relationships to suit their strengths. The ability of these companies to provide new, higher-value services will not be self-evident to the client. Instead, while continuing to provide ever-improving, high-quality, lower-cost services that led to the relationship in the first place, CROs should identify new areas where they can do work and convince clients of the benefits. Alliances and partnerships provide the ideal forum for such an expansion of sales, but it is up to CROs to seize the opportunity.”—Economist Intelligence Unit
Conclusion
As trust and alignment develop, today’s concerns may translate into new opportunities that benefit the device maker, service provider, and employees on both sides while addressing the core needs of innovating faster, better, and cheaper. The key is long-term trust that mutually benefits and speaks to the “must haves” of good strategic outsourcing. The path to true “transformational outsourcing” starts at the transactional levels where performance and quality are witnessed and simple cost/benefit analyses can be identified. The real efficiencies develop when there is cultural and operational alignment in processes that take advantage of best practices. Industry pains are complex and growing, which presents industry with new challenges or new opportunities, depending on whether your glass is half empty or half full. Today’s economic and regulatory burdens on industry have pushed us (MedTech space) to the point where industry consolidation and better strategic partnering are moving from essential needs to mandatory. The pains are real, they are here, and it is likely that “outsourcing partnerships” and “strategic partnerships” are the logical evolution that will help industry bring bigger and brighter innovations to the marketplace in a more efficient model.

Resources
  
  