



The Three Cs Of Med Device Outsourcing

How Creativity, Collaboration & Consensus Spell Success In Getting Diagnostic Devices To Market

Among medical device and diagnostics companies, there is no shortage of breakthrough ideas ready to take the market by storm, to redefine what's possible and profitable in category after category.

But not so fast.

Invariably, as if they were villains in some superhero movie, challenges arrayed against such breakthroughs can appear distressingly on cue. Broadly speaking, they rear their ugly heads during the transformation from concept to manufacture.

Most typically, they appear this way:

- What works in test doesn't ultimately work in production.
- What initially seemed like the ideal component, material, or process suddenly suffers from performance issues.
- Early and perhaps optimistic production estimates run headlong into the budgetary realities of making a breakthrough tangible.

Addressing these challenges and others (or defeating these minions, if you prefer) increasingly requires the recruitment of a powerful ally. For a start-up, a partner with a commercialization process that also offers access to facilities like a biochem lab or dedicated QC team might answer the need. For a more established manufacturer, access to high-volume automation is arguably more critical.

On a deeper level, a trend is becoming clear. Although ideation – coming up with the initial concept – is for all intents and purposes an insular process, and should remain so, achieving commercial success requires an outside perspective. Exemplifying this trend is the burgeoning number of “super teams.” More device manufacturers than ever before are engaging with contract manufacturers from the earliest possible developmental stages to gain access to a continuum of support.

Call It “Mindful Outsourcing”

Far beyond what is typically considered outsourcing – the off-loading of discrete manufacturing activities – mindful outsourcing taps into the spirit of adaptive engineering to offer device manufacturers end-to-end risk mitigation and decision support. The right contract manufacturer runs the problem-solving gamut and embodies an engine that can accelerate speed-to-market by giving device manufacturers the resources they need to compress time – for faster, more efficient product commercialization. With confidence.

Technically, such a relationship can be mapped to well-understood phases:

- Project definition
- Technical transfer
- Commercialization

However, as medical devices and markets become increasingly integrated, sophisticated, and regulated, a more nuanced path to commercialization comes into focus. There can and, in most cases, should be overlap among these phases. In response, mindful outsourcing takes a more expansive view of the means to success, supported by the 3 Cs:

Creativity, Collaboration & Consensus

1. Creativity: There's More To It Than Just Being Creative

There's nothing less satisfying than creating a winning idea for a diagnostic device that can't be built. Fortunately, creativity isn't finite. The exercise of holistic creativity – in this case thinking about a new device from concept through production – maximizes possibilities and minimizes risks.

Consider the wall between concepting and manufacturing for what it is – an illusion. By extending ideation into the realm of manufacturability – by vaulting that imaginary wall – device manufacturers are experiencing an increase in the conversion rate of “Eureka! moments” into successfully commercialized devices.

They’re making this happen by enlarging their frame of creative reference to harness the power of collective thinking. Early on, they are sharing ideas with all key stakeholders and influencers, including supply chain partners, pertinent consultants and regulators. The result: A device-development roadmap informed both at the outset and throughout by applied creativity, as open to opportunity as it is mindful of risks.

2. Collaboration: Getting It Together

Device manufacturers and Contract Manufacturing Organizations (CMO) thrive when they’re on the same wavelength, which invariably occurs when a CMO is engaged early in the development process. Such an arrangement makes possible a continuum of communication, which tends to keep design options open, identify optimal manufacturing opportunities, and avoid rash decisions.

Case in point: Specifying a material because it’s in stock rather than optimal for the final product can lead to a material that just...stops...performing.

Whether it’s ensuring that a material’s physical properties are well suited for high-speed manufacturing or identifying the optimal intersection between mass production and usability, tight and creative collaboration between a device manufacturer and CMO enables the team to think first and design-freeze later.

The right process typically involves these four important steps:

- Evaluation and Planning – Meeting face-to-face to discuss project scope, assess risk, and define goals and requirements.
- Technical Transfer – An outside technical team transfers every aspect of the product to the production environment – which might include a biochemistry lab, an automated manufacturing platform, quality systems and preparation for regulatory approval.



- Process Verification – Once technical transfer and initial trials are complete, the manufacturing process is validated for successful repetition during commercial-scale production.
- Continuous Improvement – After successful commercialization, the process is constantly examined, including suppliers, processes, and systems, to drive out waste and ensure high efficiency.

3. Consensus: 1+2 = Trust

It is an arithmetic certainty. The combination of collective creativity (1) and close collaboration (2) yields consensus born of trust. It is an inescapable result that represents incalculable value, in which mindfulness can become a kind of mind reading, risks of all kinds are minimized, and the road to successful product commercialization is made less expensive and far more certain.

In a world in which perils and pitfalls lurk at every stage of device development, recruiting a trusted CMO partner – at the right time, and for the right product – makes solid strategic sense.

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