

The State of the Medtech Industry

Market, margins, and outsourced manufacturing

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- Focus on precision manufacturing and specialty materials markets
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Two questions



PART I

State of the medtech industry?

- Size and growth rate?
- Are gross margins rising or falling?
- Is R&D spending rising or falling?
- Which product trends reach the supply chain?
- Five-year challenges for OEMs



PART II

What does it mean for the supply chain?

- How large is the supply chain?
- How fast is outsourcing growing and why?
- Where is growth concentrated?
- How the roles of CDMOs and CMs are changing
- Five-year playbooks for large and smaller suppliers

A ~\$600 billion industry with 2/3rds in 30 companies

~\$600B

global medtech revenue, 2025

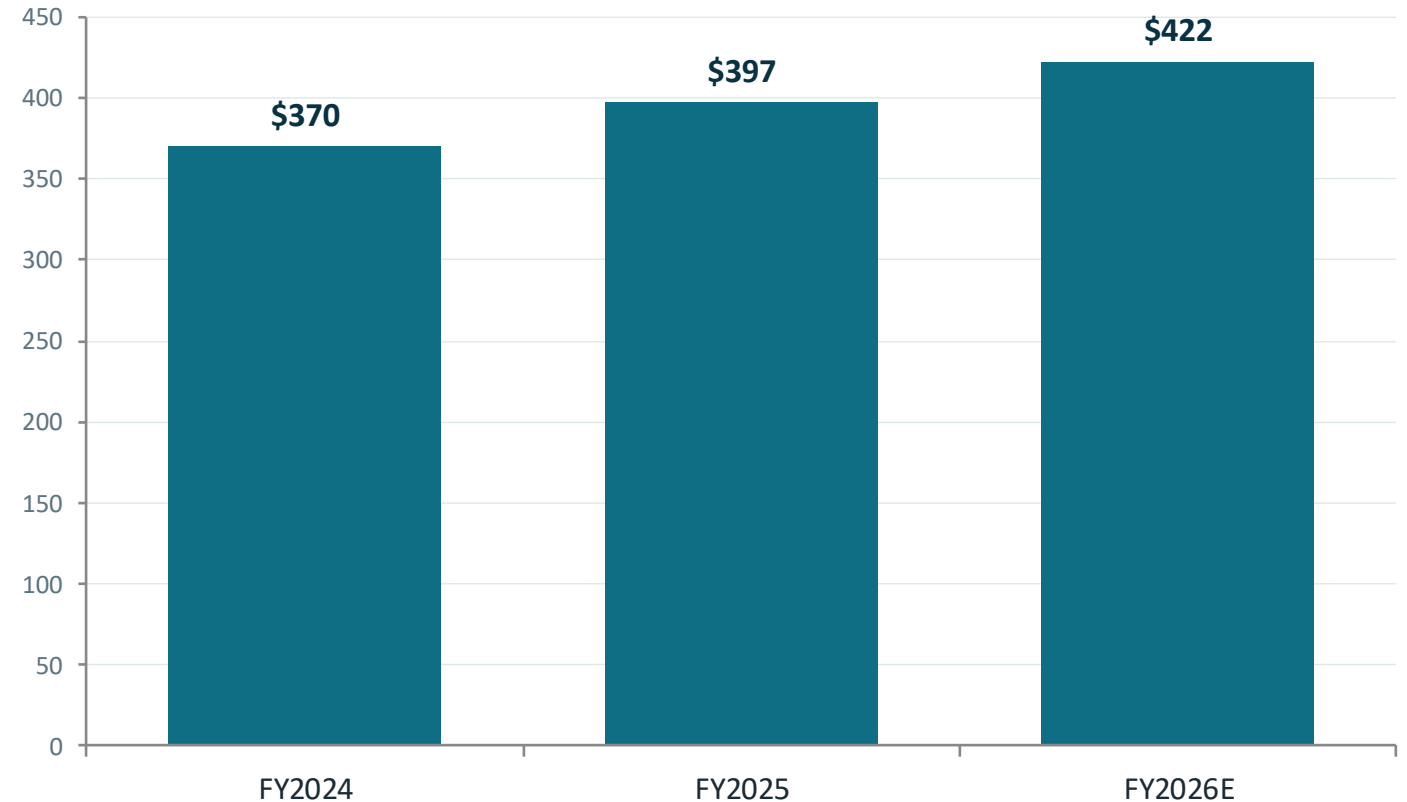
~\$620B+

projected 2026, at ~6% growth

~\$397B

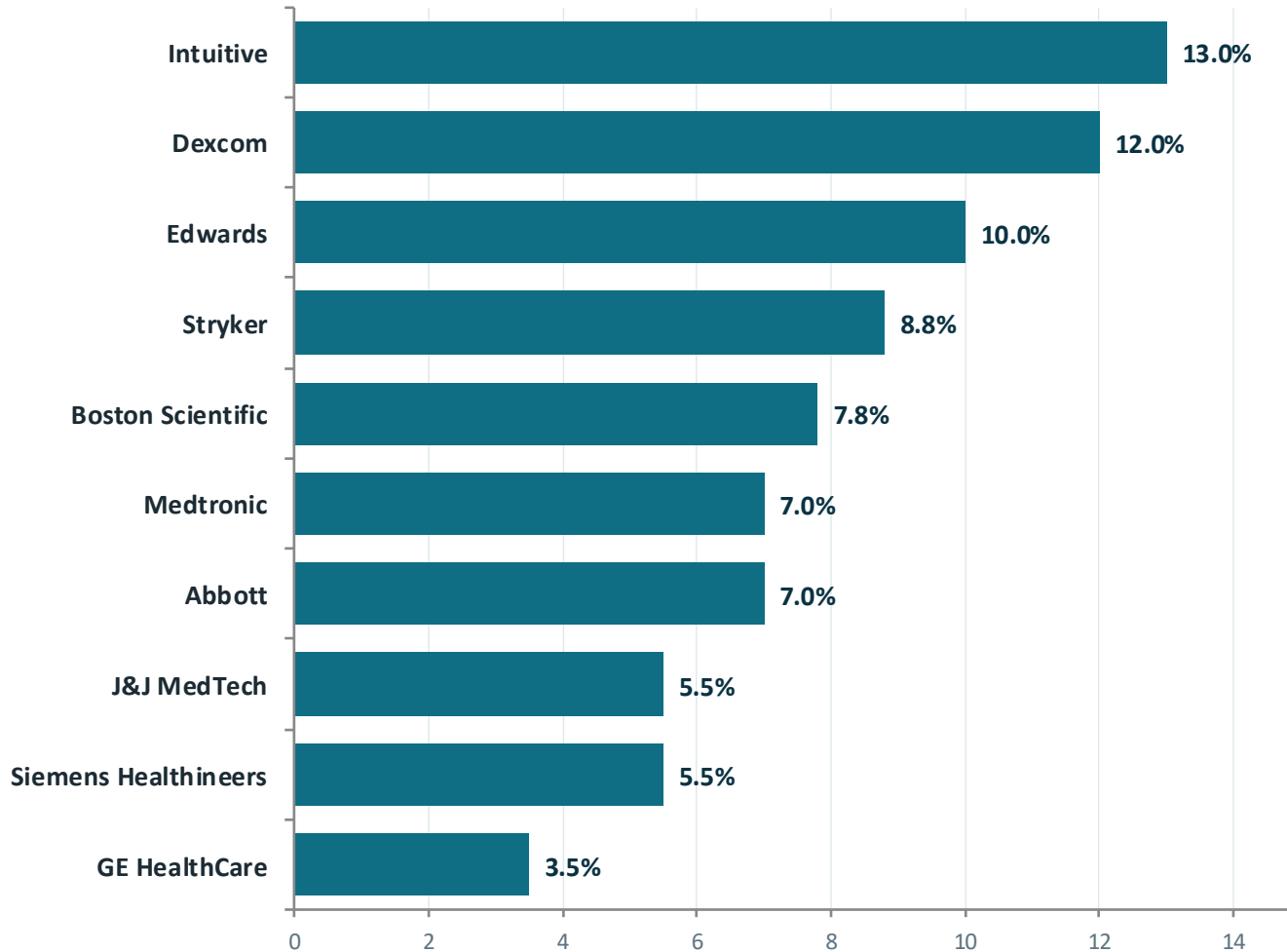
2025 revenue of the MPO Top 30
(medtech-only, est.)

MPO Top 30 combined medtech revenue (\$B)



2025 reported growth (+7.3%) included ~1.5 pts of currency tailwind for European and Japanese reporters.

Growing ~6% on but with spread driven by product category



Company guidance / consensus, organic or reported basis as disclosed

Sources: EY Pulse of the MedTech Industry (2025); MPO Top 30 (2025); Company FY2025/FY2026 filings and guidance. 2026 figures are estimates.



Leaders: procedure-driven devices

Robotics, electrophysiology, CGM, and structural heart are growing at 8–13%.



Middle: diversified giants at 5–9%

Medtronic posted its best growth in a decade; Abbott and J&J MedTech guide mid-to-high single digits.



Laggards: capital equipment & China

Imaging and diagnostics face China VBP, and hospital capex cycles.

Gross margins holding, under pressure in some markets



Pure-play therapeutic devices

Stryker, BSX, Edwards, Intuitive, ortho, endoscopy

- COGS 28–40% of sales → gross margins of 60–72%
- High margin protects heavy S&M (30–46%) and R&D
- The structural reason outsourcing keeps rising here



Capital equipment & imaging

Healthineers, GE HealthCare, Philips, BD, Baxter

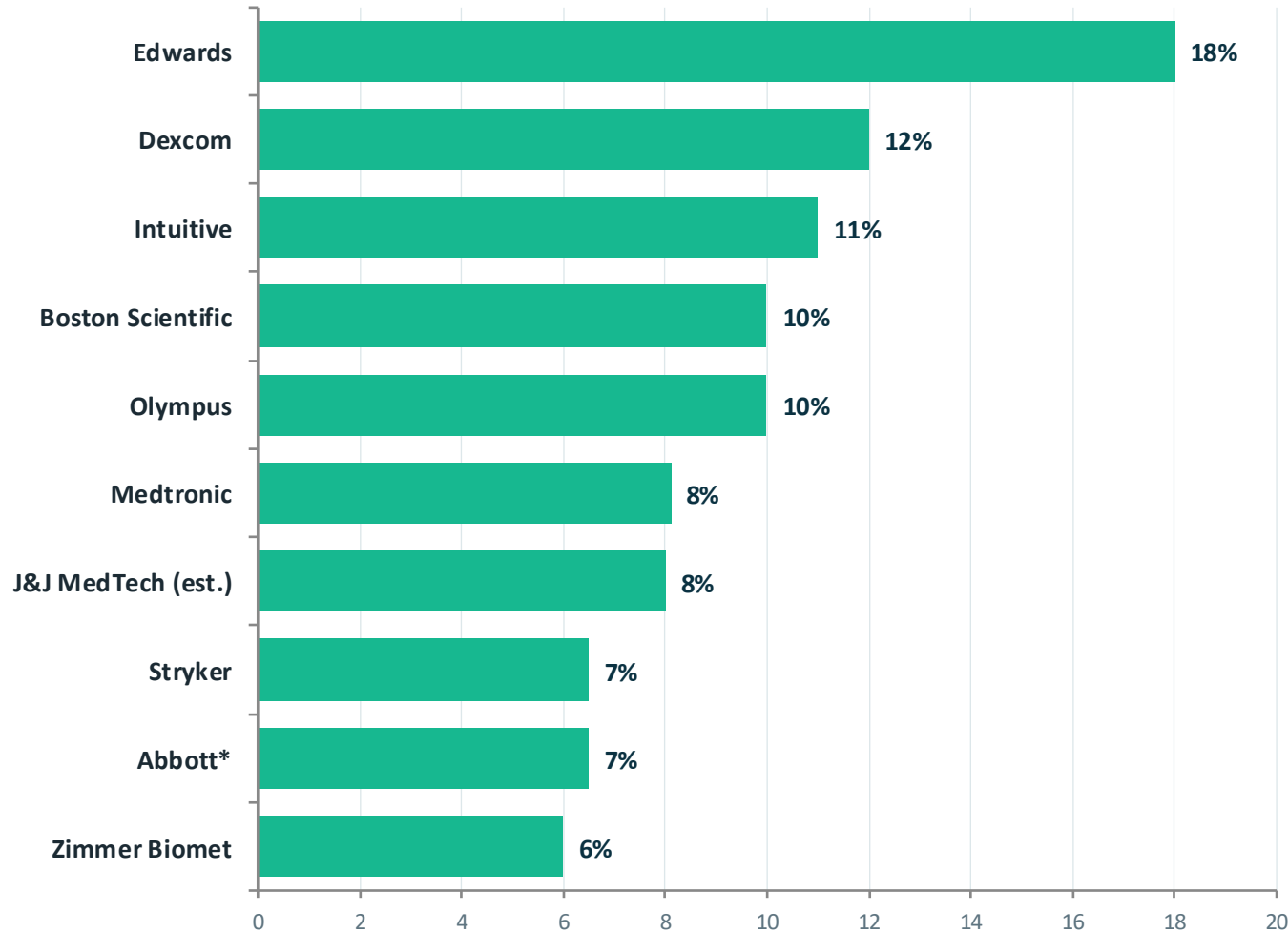
- COGS 54–63% of sales → gross margins of 37–46%
- Leaner commercial spend; service-heavy models
- Most exposed to tariffs, China pricing, capex cycles

MY VIEW

OEM gross margins roughly flat near term, not expanding.

OEMs are expanding operating margins through SG&A leverage and by pushing COGS productivity to the supply chain.

R&D: Steady as a percentage of sales



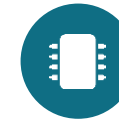
*Abbott shown at corporate level (nutrition/generics dilute the ratio). Approximate GAAP figures.

Sources: company 10-K / annual report filings (latest full FY, approximate); EY Pulse of the MedTech Industry (2025).



Device pure-plays hold at 6 to 12%

The ratio has been stable for a decade; dollars grow ~6%+ per year with revenue



The mix inside R&D is shifting

Software, AI/SaMD, and data integration are growing

Most life sciences CEOs say data quality, not new tools, is the AI bottleneck



What it means for suppliers

OEM R&D concentrates on clinical differentiation

DFM, verification, and process development increasingly land on suppliers

Six product waves



Pulsed-field ablation & EP

The fastest device rollout in years

Demand:

- Complex catheters
- Braided shafts
- Electrodes
- HV electronics



Surgical robotics

da Vinci 5, Hugo, Ottava

Demand:

- Precision machining
- Electromechanical subassemblies
- Single-use instruments.



CGM & wearables

Dexcom + Abbott Libre at huge volumes

Demand:

- High-volume automated assembly
- Sensors
- Adhesives
- Electronics.



Structural heart

TAVR reaccelerating; TMTT scaling.

Demand:

- Nitinol forming
- Valve assembly
- Delivery systems



Single-use endoscopy & disposables

Infection control economics, new therapies

Demand:

- Optics
- Micro-molding
- Volume disposables (~35% outsourced)



AI & software-defined devices

SaMD embeds compute everywhere.

Demand:

- PCBAs
- Connectivity
- Cybersecure electronics
- Software analysis systems

Four challenges facing OEMs through 2031



Pricing pressure at every door

Thin hospital margins, site-neutral payment, the move to ASCs, and China's volume-based procurement all cap price.

For suppliers: productivity roadmaps belong in every quote.



Regulatory capacity and complexity

FDA lost 21% of its workforce (Sept 2024–Jan 2026); QMSR took effect Feb 2026; EU MDR/IVDR deadlines run through 2027–2029.

For suppliers: audit-ready quality becomes a buying criterion.



Therapy disruption

GLP-1s are reshaping demand in diabetes tech, bariatrics, and sleep apnea; PFA is resetting EP share; new trial data can swing a franchise.

For suppliers: spread exposure; avoid single-program bets.



Turning AI and data into results

Interest is high, but most manufacturers remain in pilot mode; data quality, cybersecurity, and talent gate the payoff.

For suppliers: digital traceability becomes table stakes.

PART II

The Medtech Supply Chain

A ~\$90 billion outsourced manufacturing market growing nearly twice as fast as the industry it serves

~\$90B

outsourced mfg, 2025

7-12%

annual growth

~1/3

of production outsourced

From \$600B of revenue to the ~\$90B you compete for

~\$600B

Global medtech industry revenue

The full market served by device, diagnostics, and equipment OEMs

~\$270B

Total cost-of-goods pool

At a revenue-weighted ~45% COGS - materials, components, conversion, packaging, sterilization

\$150–190B

External supply chain purchases

Third-party spend (typically 55–70% of COGS) vs. OEMs' own labor and overhead

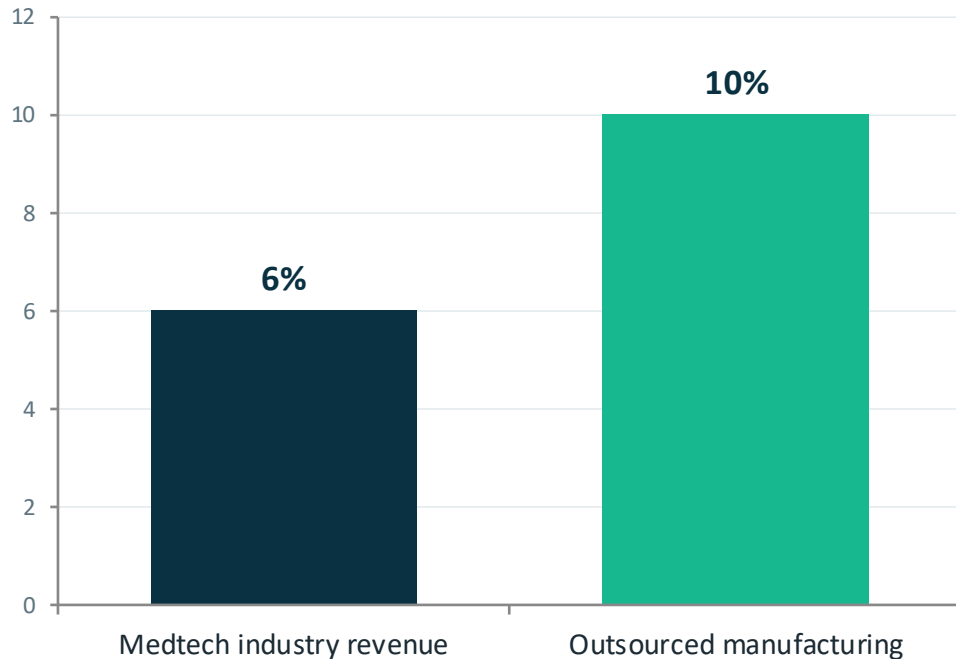
~\$90B

Outsourced device manufacturing

The CDMO/CM market: design support, components, assembly, packaging, sterilization, turnkey

Every point of outsourcing penetration $\approx$ \$2.5–3B of CDMO revenue.

Outsourcing grows ~2x the end market it serves



~1/3 of medtech manufacturing value is outsourced today - well below electronics, with years of headroom.



Capital efficiency

OEMs avoid cleanrooms, automation, and tooling capex; capital flows to clinical R&D and commercial instead. Working capital responsibilities shift.



Complexity & speed

Devices get more complex while launch windows shrink - specialists with validated processes win the transfer.



Line transfers

Portfolio reshaping strands manufacturing; CDMOs absorb transferred lines and orphaned volumes.



Turnkey manufacturing owns today. Components own growth



Turnkey / end-to-end manufacturing

~38% of the market (2025) - largest service segment

OEMs consolidate programs with partners who own the full build: - sourcing through sterile finished goods.



Precision components & subassemblies

Fastest-growing service segment

Machined implants, nitinol, micro-molding, catheters, electromechanical modules. **Complexity migrates outward first.**



Packaging & sterilization

Structurally short capacity

Sterile-barrier packaging and EtO/E-beam capacity remain bottlenecks.



Design, development & regulatory services

The on-ramp to manufacturing programs

D&D engagement converts to manufacturing at high rates - the 'D' in CDMO is a customer-acquisition engine.

Follow key OEM franchises



Interventional & catheter-based

EP/PFA and structural heart devices are the premier growth programs - catheter shafts, braids, balloons, handles, delivery systems.



Robotics & electromechanical

Robot subassemblies, instruments, and capital hardware - recurring single-use instrument volume is the prize.



High-volume sensors & wearables

CGM-class volumes (tens of millions of units) demand automated assembly at consumer-electronics scale with medical quality.



Drug-delivery & combination devices

Autoinjectors, on-body pumps, prefilled systems - the GLP-1 wave pulls device supply chains into pharma volumes.



Single-use & disposables

~35% of outsourced work: single-use scopes, procedure kits, consumables - infection-control economics keep converting reusables.



Class II–III complexity migration

Class II dominates volume (~80% share); Class III is the fastest-growing tier as OEMs outsource implantables they once guarded.

Four types of suppliers – 2026-2031

WHERE THEY WIN TODAY

CRITICAL SUCCESS FACTORS, 2026–2031

Global EMS-scale players

Jabil Healthcare, Flex, Sanmina, Plexus

Electronics DNA and global footprint. They take connected devices, capital equipment, and mega-programs where scale and automation decide.

Medical-grade discipline at electronics volumes dedicated device capacity and quality depth.

Scaled medtech CDMO platforms

Integer, Phillips-Medsize, West, Viant, Tecomet

\$500M–\$2B+ pure-plays with deep device categories - cardio, drug delivery, ortho - design-to-volume capability and multi-site networks.

Integrating what they bought - one quality system, one front door, real design engagement.

Mid-market specialists

Cretex, Cirtec, Confluent, SteriPack & peers

\$50–500M. They win on category depth - catheters, implants, micro-components - speed, and engineering intimacy.

Deciding the role early - buyer, seller, or independent and proving it with depth and margin.

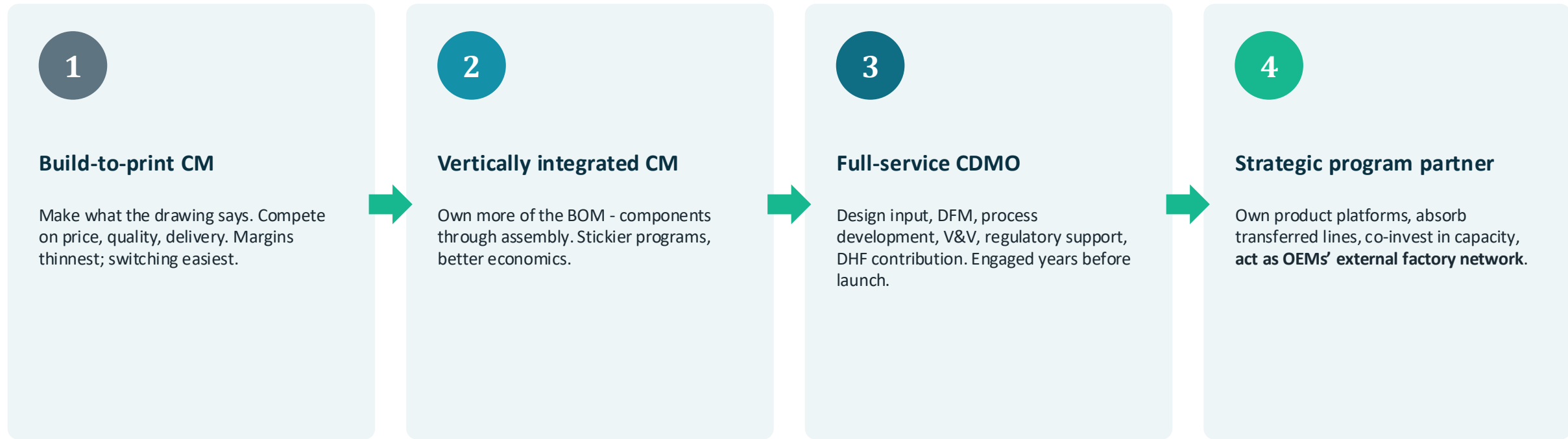
Component & process houses

Machining, molding, extrusion, coatings, sterilization

The foundation layer. Validated niche processes are the differentiation; most exposed to pricing pressure, and the most acquirable.

Absorbing line transfers and escaping commodity pricing with validated, automated niche processes.

Value and valuation migrates up the curve



Value - and valuation - migrate up this curve. OEMs are consolidating supplier counts and rewarding partners who take on scope. Suppliers stuck at Step 1 face the pricing pressure OEMs can't pass to hospitals.

Five OEM trends and their demands on suppliers

WHAT THEY'RE DOING

HOW IT SHOWS UP

WHAT IT DEMANDS OF YOU



Consolidating supplier bases

Fewer, deeper partnerships; preferred-supplier programs with volume commitments

Scale, multi-capability scope, and flawless quality history decide who makes the list.



Transferring lines & carving out plants

Divesting internal factories; moving orphaned volumes after portfolio deals

Capacity, transfer expertise, and willingness to absorb workforces become differentiators.



Dual-sourcing & regionalizing

Qualifying second sources by region to cut risk of disruption and tariffs (?)

A domestic or nearshore footprint is now a commercial weapon, not overhead.



Raising the quality & data bar

FDA QMSR alignment, cybersecurity, full traceability, ESG reporting

Compliance capability has become a moat - and a cost of entry.



Passing margin pressure downstream

Provider pricing squeeze flow into supplier negotiations

Productivity roadmaps and cost-down engineering must be part of the offer.

Five moves for the next five years



Climb the complexity curve

Catheters, electromechanical assembly, implantables, drug handling - complexity is where pricing power lives.



Sell the 'D' to win the 'M'

Design, DFM, and regulatory services lock in programs years before production volumes arrive.



Build a two-region answer

Domestic/nearshore capacity plus cost-competitive offshore - the footprint OEM sourcing teams are told to find.



Treat quality as strategy

QMSR, cybersecurity, traceability - audit-readiness now wins deals, not just keeps them.



Ride the franchise winners yet to come

Index your pipeline to EP/PFA, robotics, CGM, structural heart, and drug delivery - growth compounds where OEMs' growth compounds.

Where smaller CDMOs and component suppliers win



Capabilities the platforms need to buy

Specialists are the consolidators' shopping list

Platforms are building one-stop offerings bolt-on by bolt-on: micro-molding (Cordica–RapidWerks), design services (Currier–Sage), laser processing, nitinol. A validated niche process is worth more than general capacity.



Customers the giants underserve

Speed and engineering intimacy beat scale

Sub-\$2 billion OEMs in specialized niches.



Second-source and regional capacity

Geopolitics make U.S. capacity a sales asset

OEMs are qualifying second sources by region. A U.S.-based, FDA-registered precision shop can win share of a program without winning the whole program.



Components for the growth franchises

Precision components are the fastest-growing service

PFA catheters, robotic instruments, structural-heart nitinol, and CGM subassemblies all need tight-tolerance parts, often before the OEM has chosen a turnkey partner.

How smaller suppliers should rewrite the five-year plan

PLANNING AREA	FROM	TO
 Positioning: pick the niche	A broad job-shop menu; winning on price and availability.	<i>One or two defensible, validated processes tied to growth franchises, plus the adjacent step up (DFM, subassembly).</i>
 Customers and pipeline	Two or three anchor accounts; reactive quoting.	<i>Tiered account plans across OEM sizes and franchises; design-stage work that feeds future production.</i>
 Quality as a sales asset	An ISO 13485 certificate on the wall.	<i>QMSR-ready (in effect Feb 2026), MDSAP where it opens markets, and digital traceability shared with customers.</i>
 Operations and cost	Labor-heavy processes; price-downs absorbed in margin.	<i>Automation and back-office AI that fund annual productivity commitments written into quotes.</i>
 Ownership and capital	Exit considered only when an offer arrives.	<i>Choose early: platform, add-on, or independent. Clean financials, peer-level margins, and low customer concentration drive value as PE exits pick up from 2026.</i>

FIVE THINGS TO REMEMBER

The supply chain is growing faster than the industry it serves

- 1 Medtech is a ~\$600B industry compounding at ~6% - durable, demographic-driven demand.
- 2 Gross margins are holding but pressured by tariffs and pricing - OEMs will buy COGS productivity from partners.
- 3 R&D dollars keep rising and concentrate on clinical differentiation - manufacturing scope shifts outward.
- 4 The ~\$90B outsourced market grows 7–12% - penetration, carve-outs, and regionalization are the engines.
- 5 Value migrates from build-to-print toward full-service CDMO partnership - position on that curve deliberately.

The hot zone: regulated capacity close to home



North America

~\$30B (US, 2025) • ~12% CAGR

- Largest regulated finished-device market; premium for FDA-registered, QMSR-ready facilities
- Reshoring and Section 232 exposure drive net-new domestic qualification
- PE-backed consolidation is building scaled platforms



Asia-Pacific

~40% share of global CM revenue

- Dominates cost-driven component fabrication and high-volume disposables
- China: rising local champions + geopolitical requalification risk
- “China + 1” strategies benefit Malaysia, Vietnam, India



Europe & nearshore

Steady, specialist-led

- Ireland and CEE anchor European OEM supply; Costa Rica & Mexico serve US nearshoring
- EU MDR compliance burden pushes small OEMs toward certified partners
- Tariff math favors dual-region footprints over single-site scale, sort of