

International Commercialization - *Sound or Risky Strategy?*

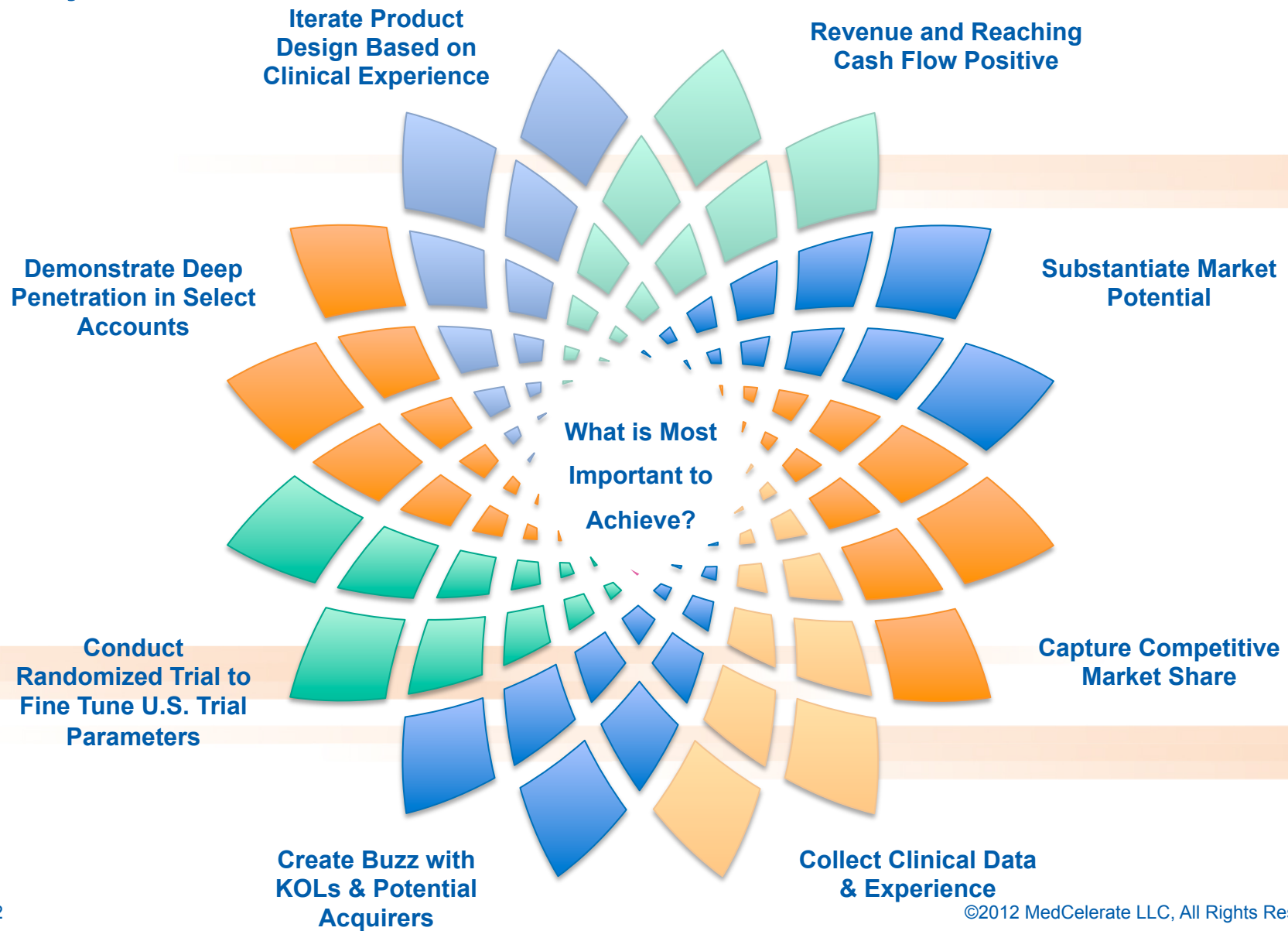
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Chasing Conflicting Commercialization Objectives

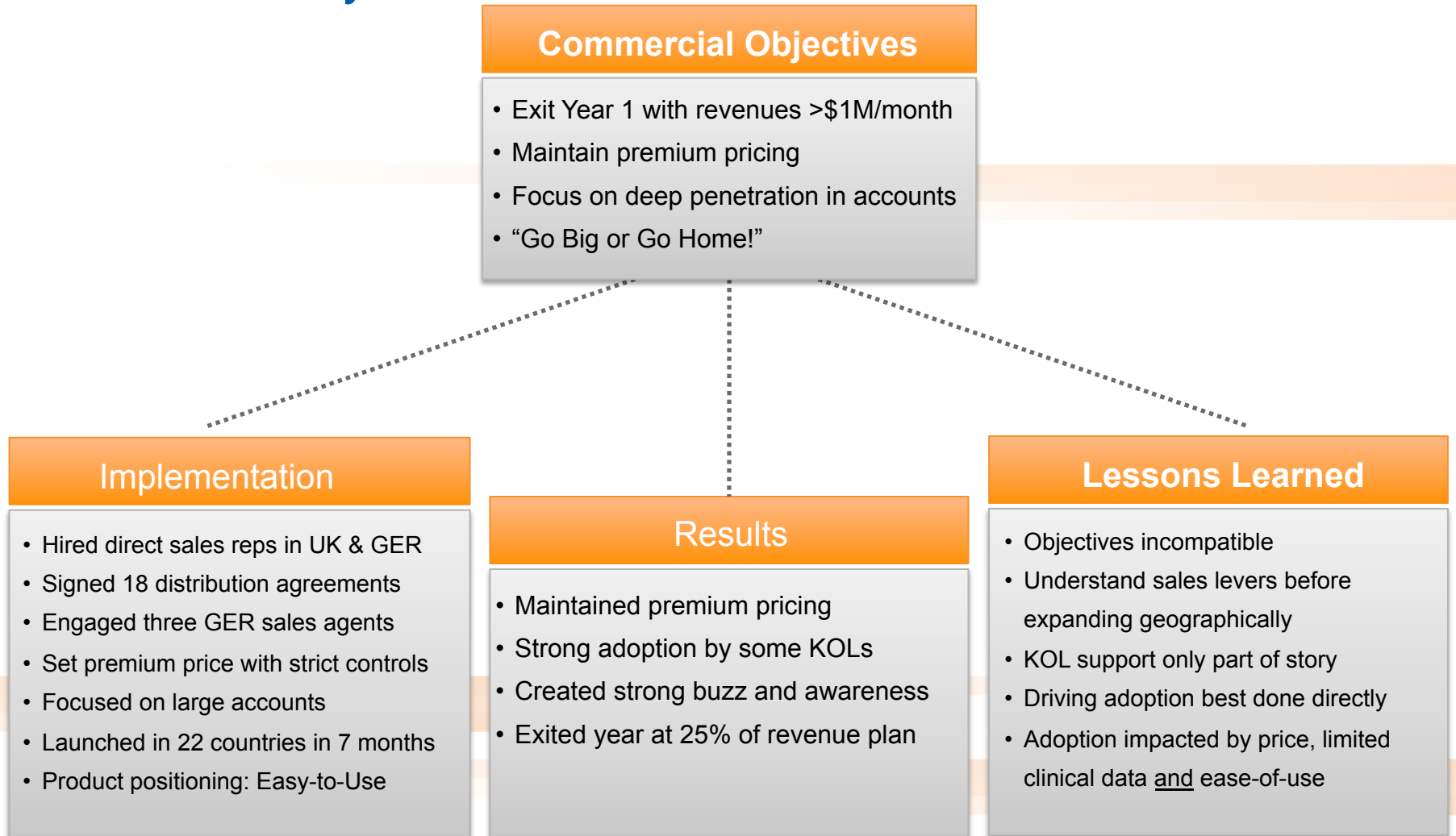
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Chasing Conflicting Objectives

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Blessing and Curse of CE Mark Approval

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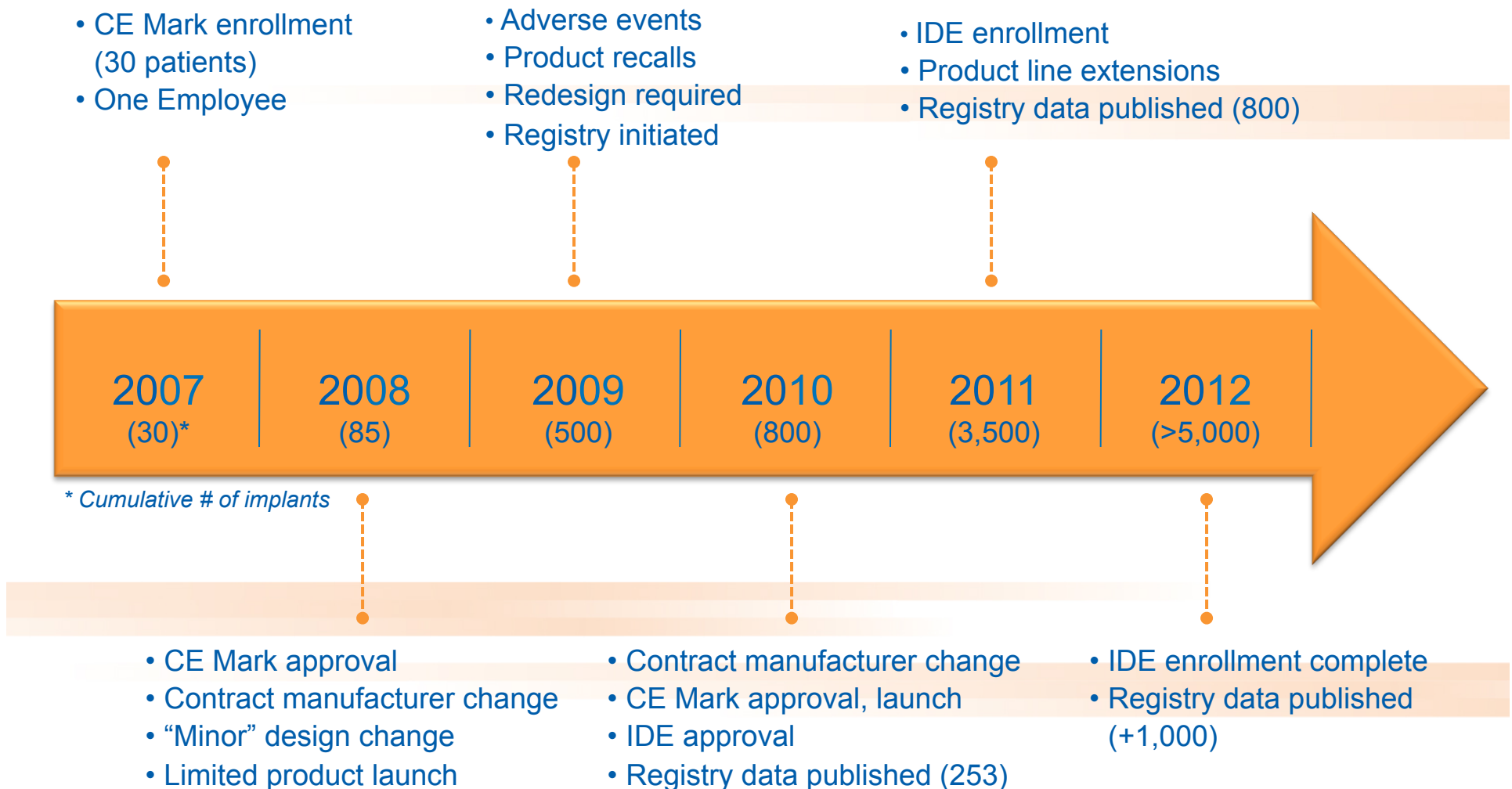
	EU Regulatory Class	# of Patients	Trial Region
Cardiovascular	III	30	Europe
Peripheral Artery	IIb	11	South America
GERD	III	24	South America
Venous Disease	IIb	11	Caribbean
Cardiovascular	III	25	Europe

- Limited clinical experience, with small number of KOLs, does not guarantee product viability

Building Clinical Data Set Post-CE Mark

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Deciding Approach to Customer: Distributors versus Direct Employees?

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Product Profile

- Changing clinical practice?
- Physician learning curve?
- Market development?
- Gross margin?
- Niche product?

Commercial Objectives

- Alignment with objectives?
- Revenue ramp?
- Investor patience/dry powder?
- U.S. market strategy?

Market Dynamics

- Reimbursement?
- Local tenders?
- Hospital payment terms?
- Number of accounts?
- Geographical spread?

Distributor Capabilities

- Customer relationships?
- Technical expertise?
- Financial stability?
- Product portfolio?
- Interest/desire?

Distributor as Commercial Partner

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Strategy

- Involved early in commercial planning
- Open and frequent communication to build trust
- Collaboration on programs aimed at our commercial objectives
- Open about company's progress towards major milestones
- Offered equity investment opportunity
- Joint visibility with KOLs

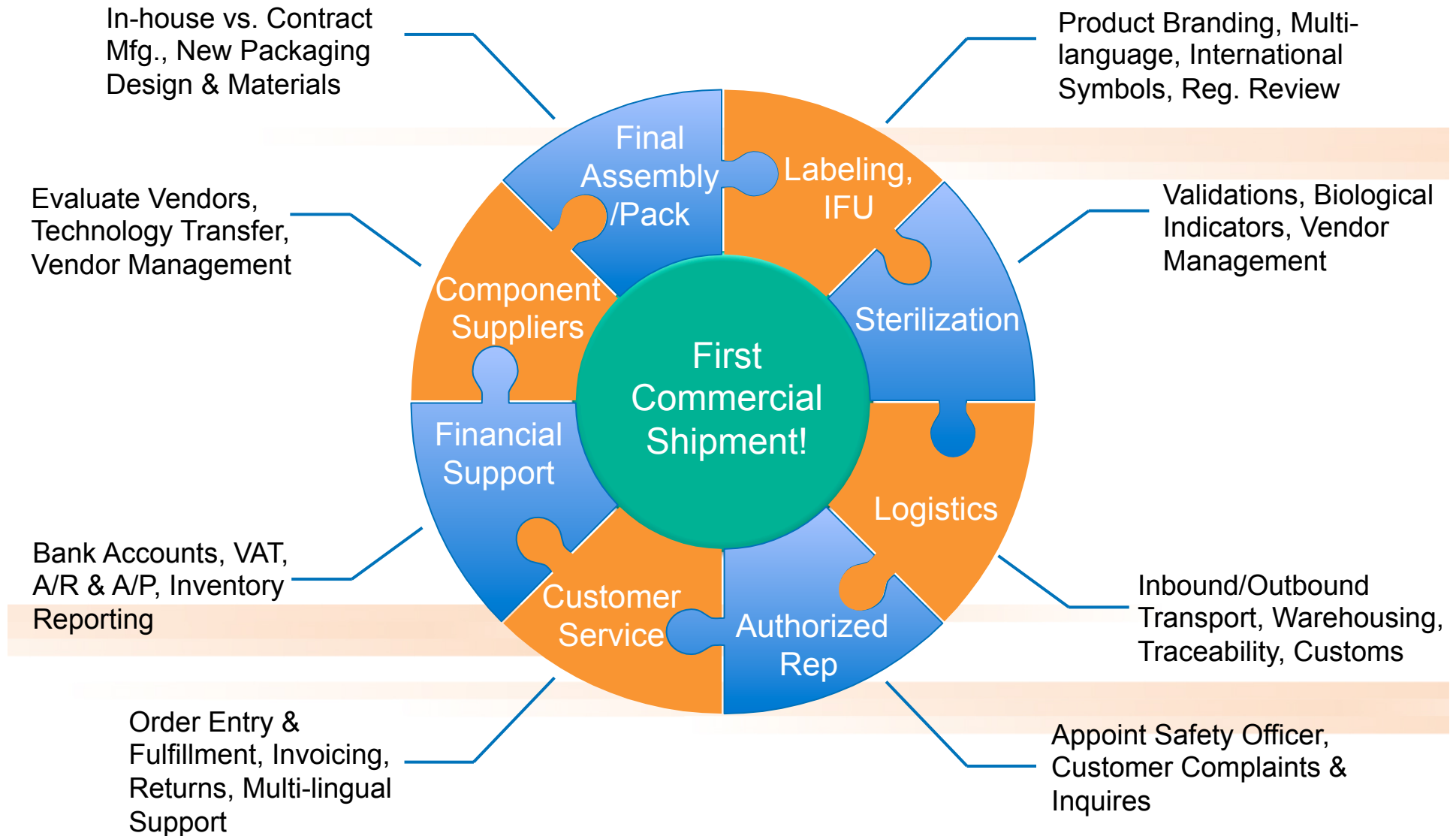


Results

- Remained with us during 10-month redesign effort
- Consistently achieved/exceeded quarterly sales targets
- Produced strong product adoption in key accounts
- Award for outstanding sales & clinical support performance, 2011

Delivering Robust Product Supply Requires Time & Teamwork

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Building Capable Supply Chain

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	Pre-CE Mark (Q1 2011)	Post-CE Mark (Today)
Manufacturing	<ul style="list-style-type: none"> • U.S. component mfgs • Adhesive, kitting & pack in CA • Sterilization in CA 	<ul style="list-style-type: none"> • Product made in Ireland • Adhesive production in NC • Sterilization in Belgium • EU Operations Director (Irish)
Labeling/IFU	<ul style="list-style-type: none"> • English only • Generic labeling 	<ul style="list-style-type: none"> • 8 languages • New branding, Venaseal®
Logistics	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • NL distribution center (outsourced)
Authorized Rep	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • Emergo - NL
Customer Service	<ul style="list-style-type: none"> • Non-existent 	<ul style="list-style-type: none"> • Multi-language call center - NL
Financial Support	<ul style="list-style-type: none"> • U.S. bank account 	<ul style="list-style-type: none"> • 3 EU bank accounts • In-depth VAT analysis

Product Transformation

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Key Takeaways

- Align commercial objectives, focus on few
- CE Mark does not mean you have product
- Validate sales levers before expanding
 - “It’s all about what happens at the account level”*
- Product profile important for determining approach
- Don’t underestimate supply chain complexities
- How does technology save HC system money?

Good Luck!