Key Supply Chain Integration Factors for success of Medical Device Startups

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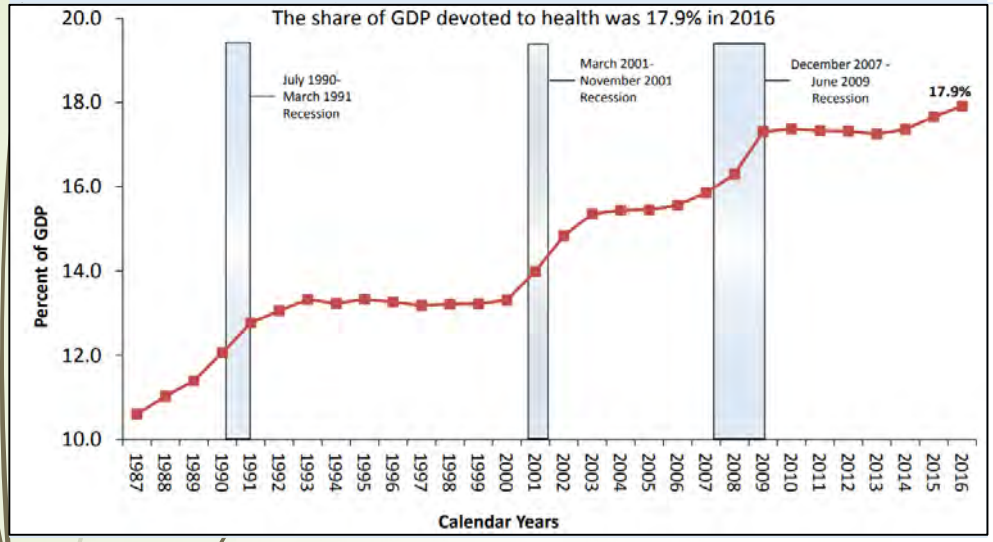
Agenda

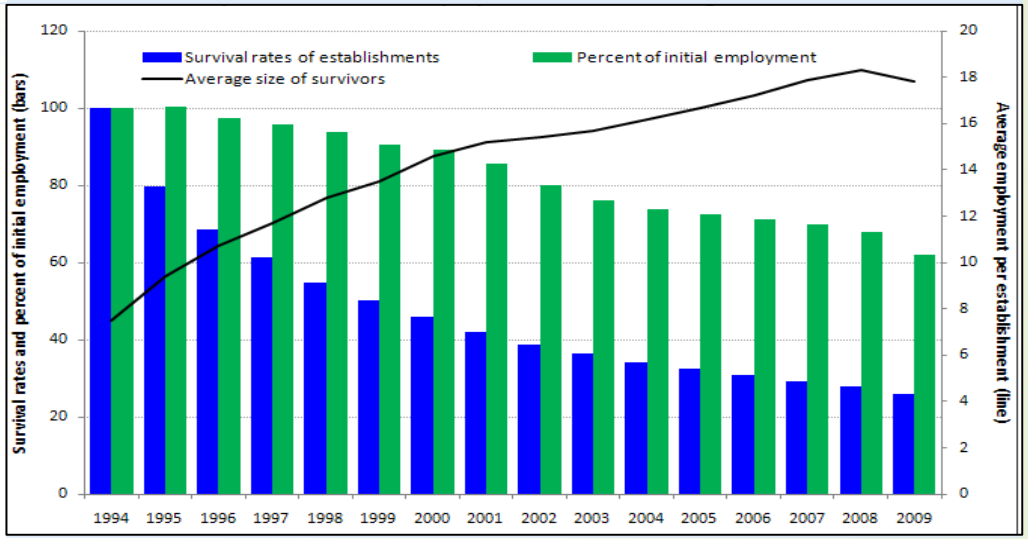
- Introduction
- Methodology
- Findings
- Recommendations

Failure of a Medical Device Startup present a big challenge in Healthcare industry

High cost pressure on Healthcare industry



High Failure rate of Startups



Challenges

- High Healthcare spending $3.3 trillion
- Highly concentrated industry
- High failure rate of a Startup
- Low innovation will increase healthcare cost

Research objectives:

- Develop an understanding of Healthcare Ecosystem
- Find key Supply Chain Integration factors for success of Medical Device Startups

4-Step approach

Processes

Findings

1 Data Collection

- Interviews Supply chain experts
- Literature Reviews
- Content Reviews Industry focus

Findings:
- Voice of Experts
- Academic papers

2 Data Analysis

- Industry Insights
- Previous Research
- Industry Report
- Consolidation

Findings:
- Facts from 3 sources
- Cross analysis
- Regulatory guidelines
- Consolidated list of factors

3 Result Validation

- Survey validation

Findings:
- Survey questionnaire
- Survey result analysis

4 Result Application

- Recommendations

Findings:
- Supply Chain Strategy

Data are collected through interviews, literature reviews and content reviews

1. **Data Collection**
2. Data Analysis
3. Result Validation
4. Result Application

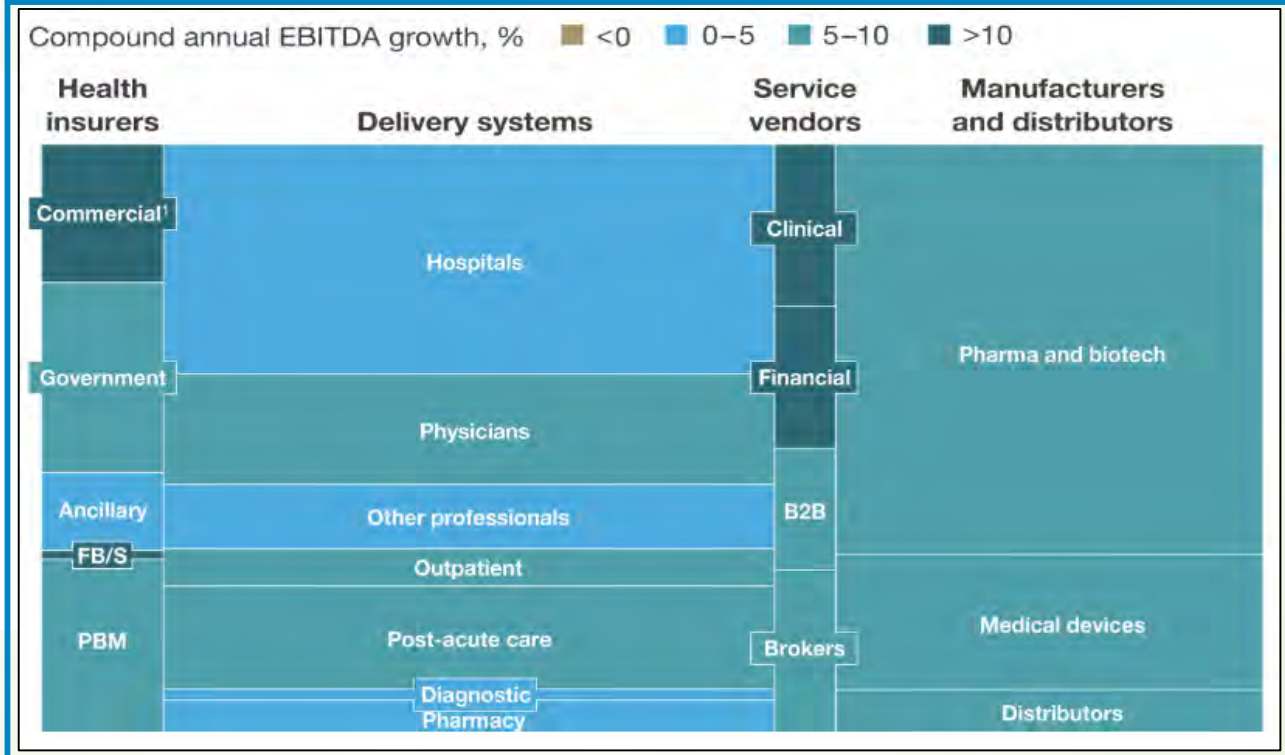
Data collected from 3 different sources

Interview	Literature Review	Content Review
Interviews with supply chain executives from the medical device industry.	Systematic literature review of various academic publications in field of supply chain, entrepreneurship, innovation and medical devices .	Review of various reports issued by trade associations, consulting firms and government bodies related to healthcare industry.

Healthcare Industry Dynamics

1. Data Collection
2. **Data Analysis**
3. Result Validation
4. Result Application

Healthcare Ecosystem



Source: McKinsey & Company

Healthcare Industry Dynamics

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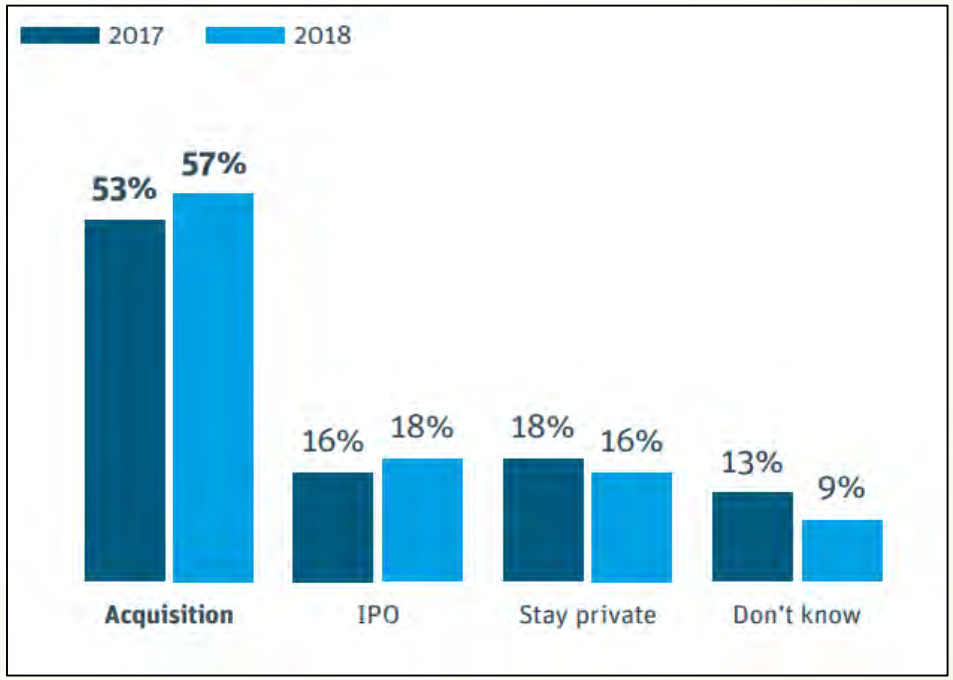
Success - Exit strategy of Healthcare startups



Source: Silicon Valley Bank

Gained Industry insights through interviews with Medical Device Supply chain experts

1. Data Collection
2. **Data Analysis**
3. Result Validation
4. Result Application

Highlights of interview

"If medical device companies want to continue to make money as prices face continued pressure, their only option is to take cost out." Purchasing Manager at a major medical device manufacturer.

"Generally, equipment downtime is associated with revenue loss in an industry, but in Medical Device Industry it can mean human lives at stake" Customer support Manager at major medical device manufacturer.

Literature reviews provided insights from various academic research

1. Data Collection
2. **Data Analysis**
3. Result Validation
4. Result Application

Example of findings from systematic literature reviews

Literature Review					
Document Reference				**Supply Chain Integration Factors**	
Partnering pitfalls and success factors.	Ellram, L. M. (1995).	Feasibility of Sourcing Study in a startup	Gunawan 2016	**Factor 1**	**Large firm over a medium or small firm as Supplier**
Business Eco-Systems: Relationships between large and S	Fine (2006)	Feasibility of Sourcing Study in a startup	Gunawan 2017	**Factor 2**	**Large firm over a medium or small firm as Distributor**
Early Supplier Involvement in Customer New Product Development: A Contingency Model of Component Supplier Intentions	Douglas and Robert (2000)	Early Supplier Involvement: Implications for New Product Development Outsourcing and Supplier-Buyer Interdependence	Juliana & Tage 2003	**Factor 7**	**Early Supplier Involvement (ESI)**
Centrality of customer and supplier interaction in innovation	Thomas Johnsen, Wendy Phillips, Nigel Caldwell, Michael Lewis (2005)	Stakeholder Engagement in Early Stage Product-Service System Development for Healthcare Informatics	Man Hang Yip, Robert Phaal & David R. Probert (2015)		
			Montzer		

Content reviews provided insights from industry

1 Data Collection

2 Data Analysis

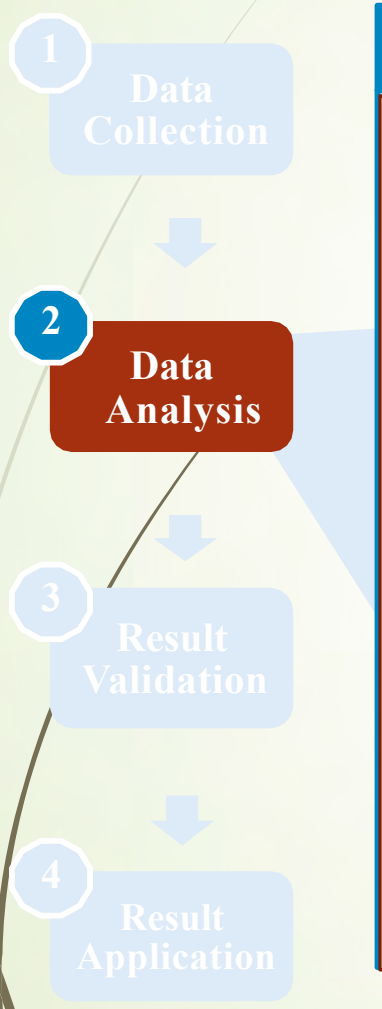
3 Result Validation

4 Result Application

Example of findings from content reviews

Content Review			
	Supply Chain Integration Factors	**Reference Documents**	
Factor 3	**Quality Management System (QMS)**	FDA Small Business Regulatory Education for Industry (REdI)	FDA 2014
Factor 4	**Good Manufacturing Practice(GMP)**	FDA Small Business Regulatory Education for Industry (REdI)	FDA 2014
Factor 8	**Co-development with supplier**	Out of the valley of death:How can entrepreneurs,corporations,and investors reinvigorate early-stage medtech innovation?	Deloitte 2017
Factor 10	**Design Transfer to Supplier**	Design Control guidance for Medical Device Manufacturers	FDA 1997
Factor 11	**Supplier qualification process**	CFR - Code of Federal Regulations Title 21 Subpart E--Purchasing Controls	FDA 2013
Factor 12	**Product Traceability strategy**	CFR - Code of Federal Regulations Title 21 Subpart F--Identification and Traceability	FDA 2013
Factor 13	**Service parts strategy**	CFR - Code of Federal Regulations Title 21 Subpart N--Servicing	FDA 2014
Factor 14	**Manufacturing validation**	CFR - Code of Federal Regulations Title 21 Subpart G--Production and Process Controls	FDA 2015
Factor 15	**Critical to Quality (CTQ)**	CtQs in Design Controls	AdvaMed 2014
Factor 16	**Contracts with suppliers and distributors**	CFR - Code of Federal Regulations Title 21 Subpart E--Purchasing Controls	FDA 2013

Consolidated list of Supply Chain Integration Factors (SCIFs)



Example of findings from content reviews

	Supply Chain Integration Factors(SCIFs)	Interview	Literature Review	Content Review
Factor 1	Large firm over a medium or small firm as Supplier	X		
Factor 2	Large firm over a medium or small firm as Distributor	X		
Factor 3	Quality Management System (QMS)	X		X
Factor 4	Good Manufacturing Practice(GMP)	X	X	X
Factor 5	Target Costing			X
Factor 6	Concept Scoping	X		
Factor 7	Earlier Supplier Involvement (ESI)		X	
Factor 8	Co-development with supplier	X		X
Factor 9	Souring Strategy		X	X
Factor 10	Design Transfer to Supplier		X	X
Factor 11	Supplier qualification process			X
Factor 12	Product Traceability strategy	X		
Factor 13	Service parts strategy	X		X
Factor 14	Manufacturing validation			X
Factor 15	Critical to Quality (CTQ)			X
Factor 16	"Contracts" with suppliers and distributors	X	X	X

Survey - Validate the relevance of Supply Chain Integration factors

1. Data Collection
2. Data Analysis
3. **Result Validation**
4. Result Application

Example of survey

Q3

How would you rate THE importance of selecting large firm over a medium or small firm as supplier of various components during design development and commercial release of a product by Medical Device Startup?

- Extremely important
- Very important
- Moderately important
- Slightly important
- Not at all important

Q19

Which supply chain factor you feel is most important in success of Medical Device Startup?

Large firm as Supplier

Most of the factors are rated around very important in survey

1. Data Collection
2. Data Analysis
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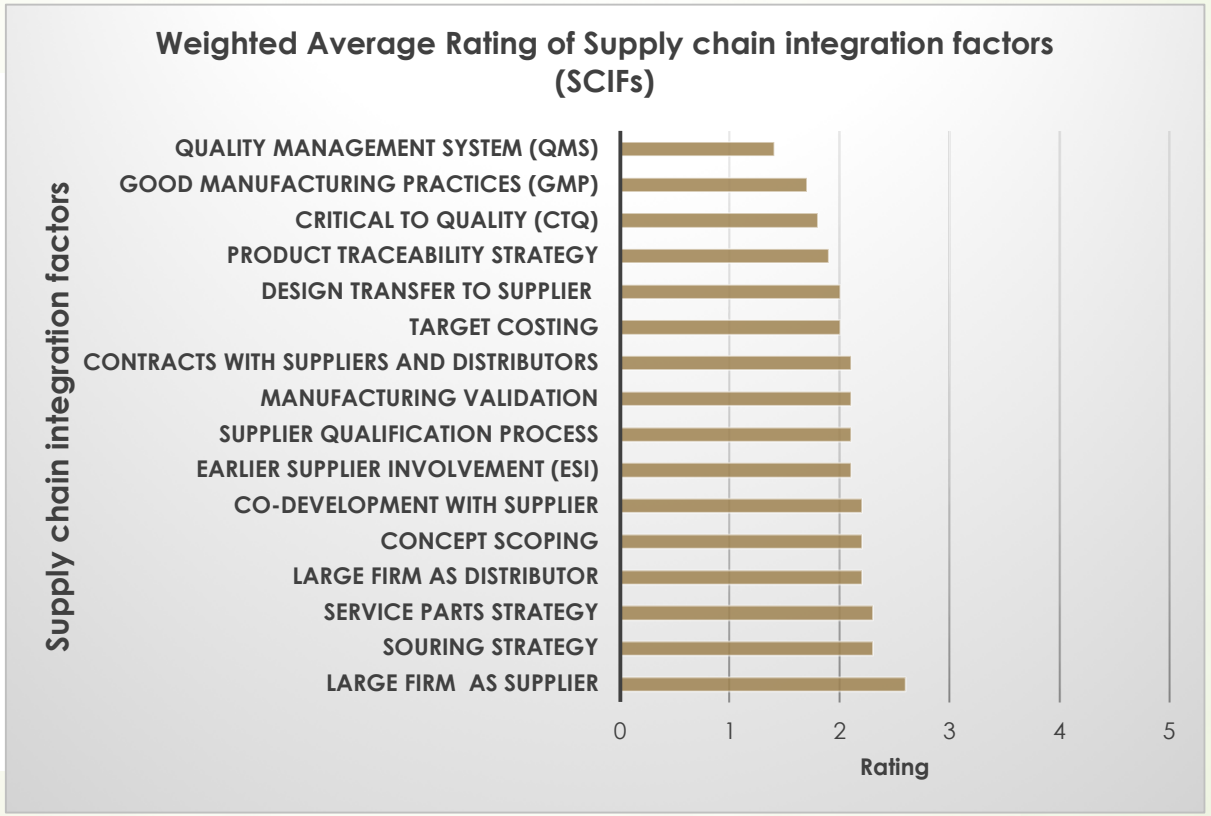
Survey result



Low Variation in survey response

1. Data Collection
2. Data Analysis
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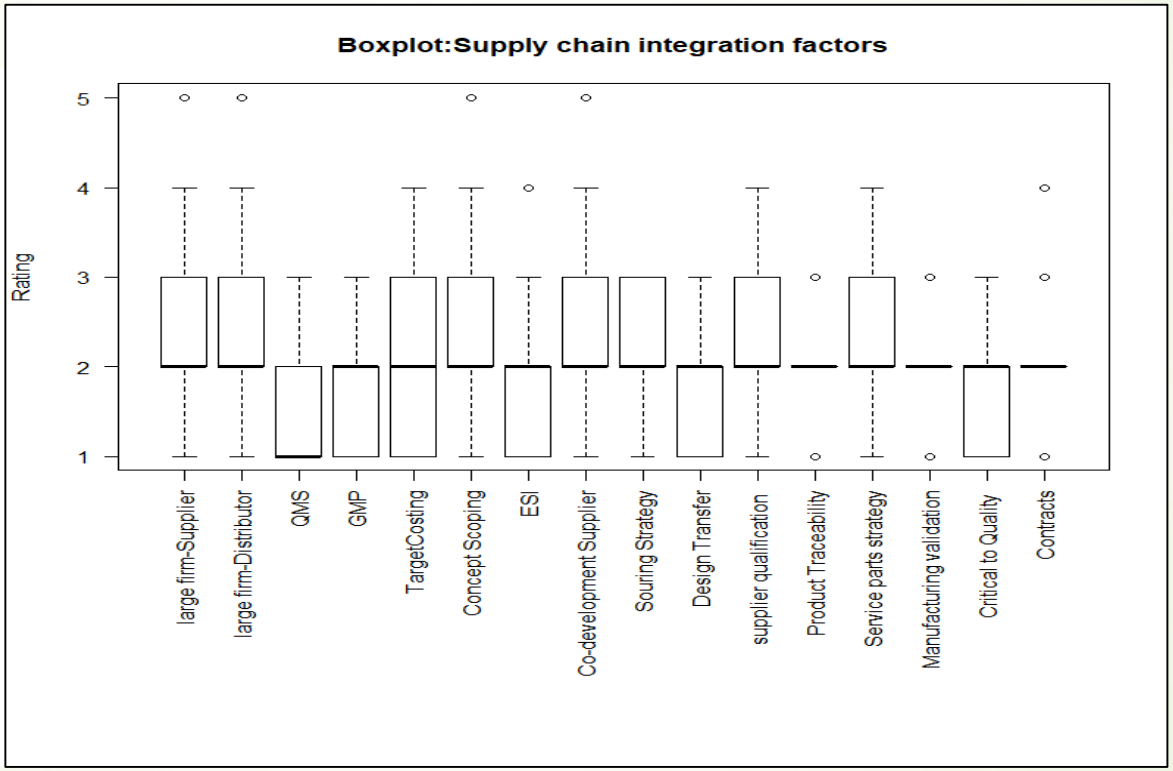
Box plot of survey responses



Most Important factor – Quality Management System

1. Data Collection
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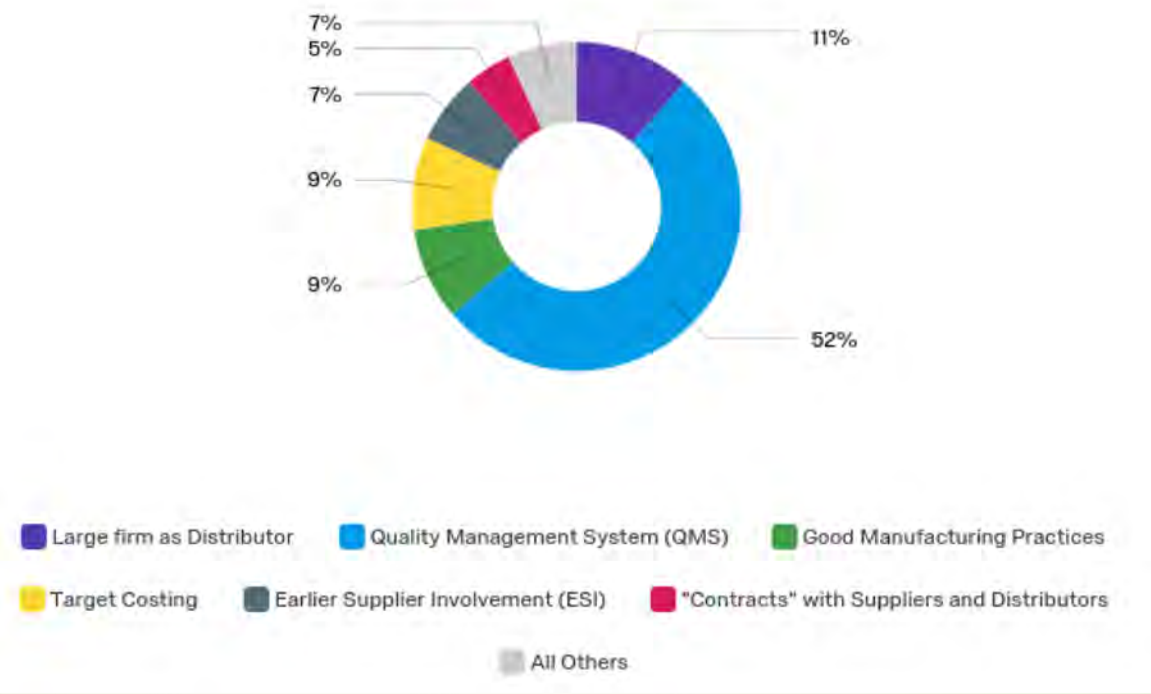
Survey response



Regulatory compliance

1. Data Collection
2. Data Analysis
3. **Result Validation**
4. Result Application

FDA- Quality Management System

Supply chain integration factors (SCIFs) framework

1. Data Collection
2. Data Analysis
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Supply chain integration factors in product life cycle

Product lifecycle : Development to Commercialization

Supply chain integration factors	Phase I Product Proposal	Phase II Product Planning	Phase III Design & Development	Phase IV Design Verification	Phase V Validation & Launch	Phase VI Manufacturing & Monitoring	Phase VII Maintenance	Phase VIII End of Production
	Develop Product proposal Develop Business case Capture customer requirements	Define detailed product, system requirements. Prepare detailed project plan including interface with internal and external partners	Design and implement the product. Build prototype. Test on module level	Verify technical specifications	Validate product according to intended user requirement. Validate production process Transfer to production, sales and support.	Product commercial production. Feedback from customer service to development team	Maintain design of the product throughout product lifecycle while retaining form , fit and function	Stop product form production Manage spare parts as per applicable regulations
	Concept scoping	Earlier Supplier Involvement (ESI) Sourcing strategy Service parts strategy Product Traceability strategy Target costing	Co-development with supplier Critical to Quality (CTQ)	Supplier qualification process	Manufacturing validation Contracts with suppliers and distributors Design Transfer to supplier	Large firm as supplier Large firm as distributor Good Manufacturing Practices (GMP)	Service parts	Product Traceability
	Quality Management System (QMS)							

Supply chain integration factors (SCIFs) framework

1. Data Collection
2. Data Analysis
3. Result Validation
4. Result Application

Internal and External to Medical device startups

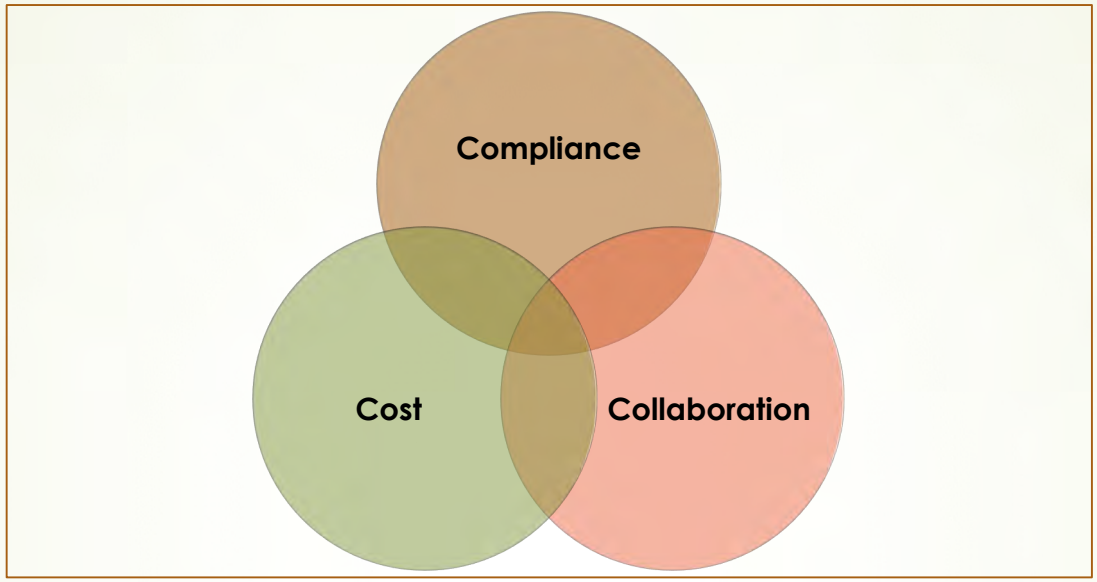
SCIF-Internal and External

Supply chain integration factors

Internal Factors	External Factors
Concept scoping	Earlier Supplier Involvement (ESI)
Sourcing strategy	Co-development with supplier
Supplier qualification process	Manufacturing validation
Service parts Strategy	Contracts with suppliers and distributors
Product Traceability	Design Transfer to supplier
Target costing	Large firm as supplier
Earlier Supplier Involvement (ESI)	Large firm as distributor
Product Traceability strategy	Good Manufacturing Practices (GMP)
Design Transfer to supplier	
Good Manufacturing Practices (GMP)	

Quality Management System

Recommendations



"Three C" of supply chain integration factors for medical device startups

- Ensure **compliance** of supply chain with regulatory requirements as mandated by the FDA
- Bring **cost** effective solution to market to reduce overall healthcare cost
- Embrace **collaboration** with large players to take leverage of established distribution channels and reduce supply risk

Q&A