

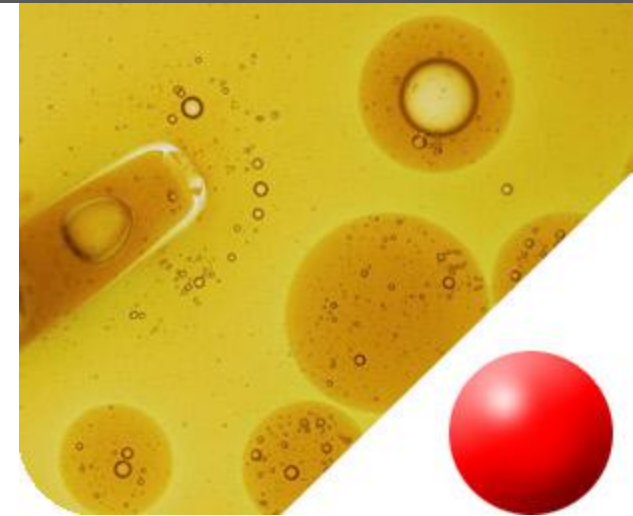


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Vendor Selection & Management

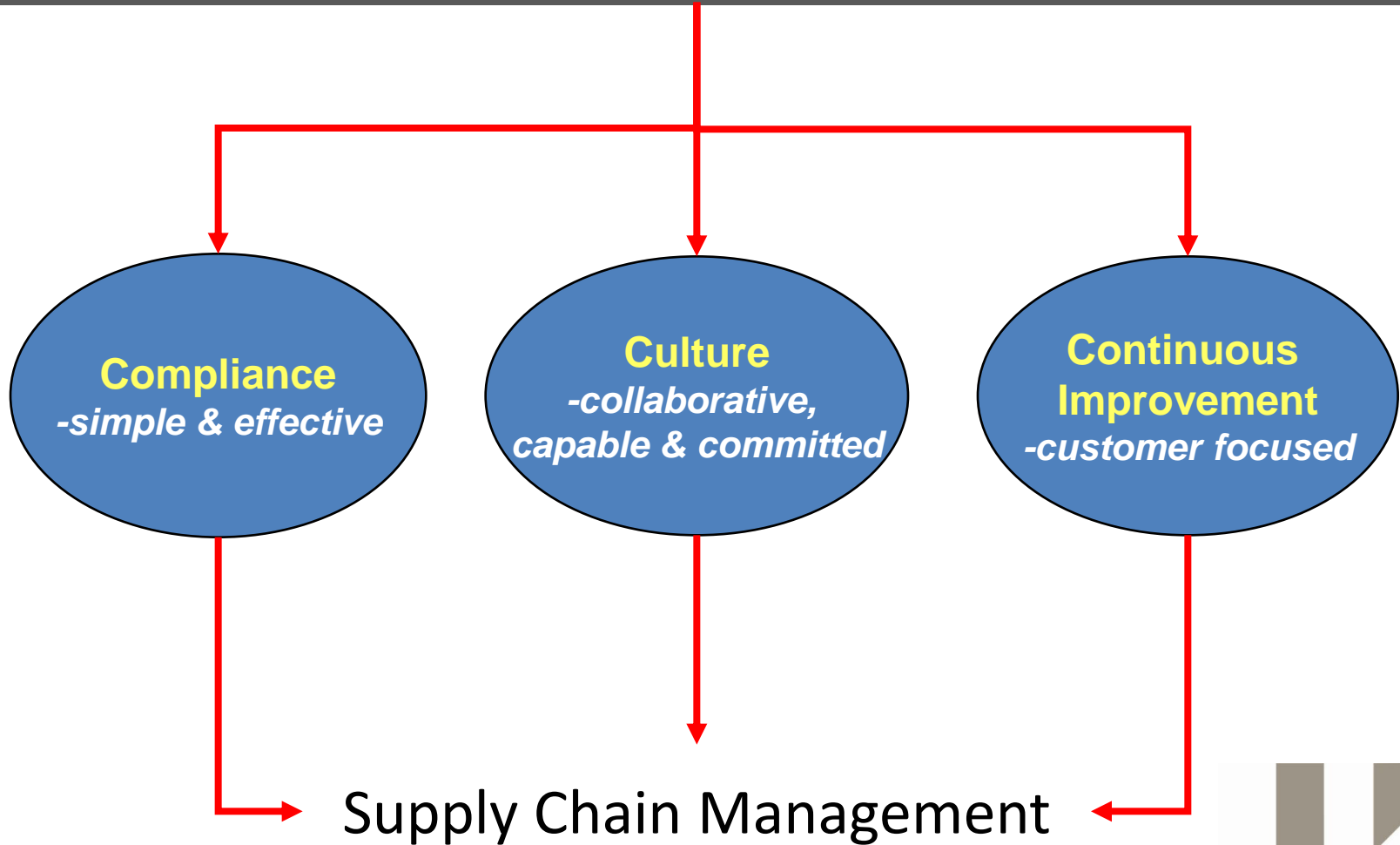
AIM:

- Present “3C’s” approach to establishing a quality foundation
- Describe LOPA risk methodology to identify key materials and suppliers
- Provide an overview of how vendors are selected and managed



Strategy: The 3 C's

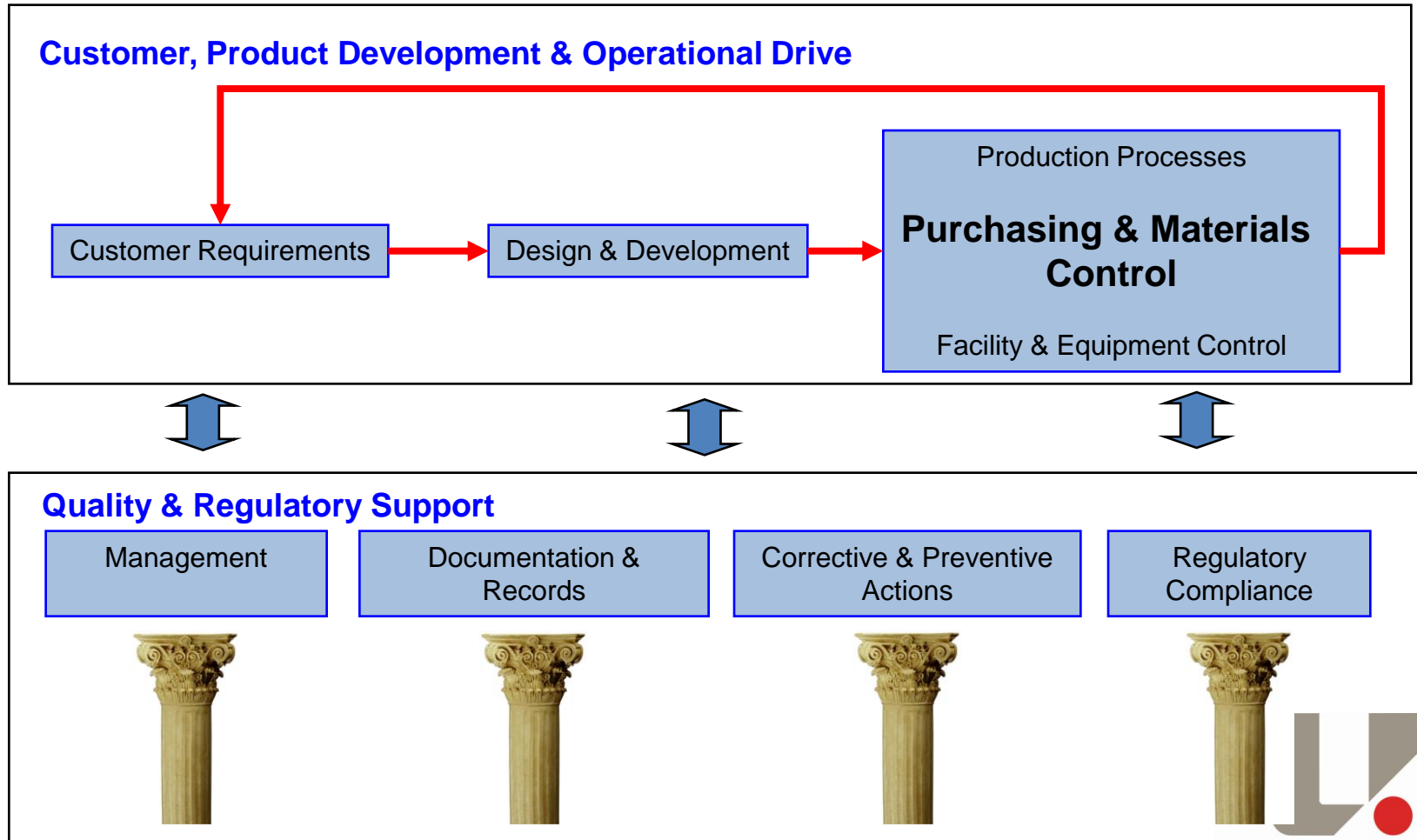
- establishing a quality foundation



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Compliance: *simple and effective*

QMS- 9 policies based on GHTF Guidelines for Regulatory Auditing
SG4/N30R20:2006 covering ISO13485 (and 21 CFR Part 820)



Culture: collaborative, capable and committed

SELF-ACTUALIZING

Shows strong commitment to organisation
 Receptive to change
 Creative problem-solver
 Non defensive
 Self respecting

ACHIEVEMENT

Achieves set goals
 Believes that individual effort is important
 Accepts and shares responsibility
 Takes on challenging tasks
 Insightful in diagnosing problems

HUMANISTIC-ENCOURAGING

Encourages growth and development in others
 Resolves conflict constructively
 Trustworthy
 Involves others in decision making
 Motivates by serving as a role model

PERFECTIONISTIC

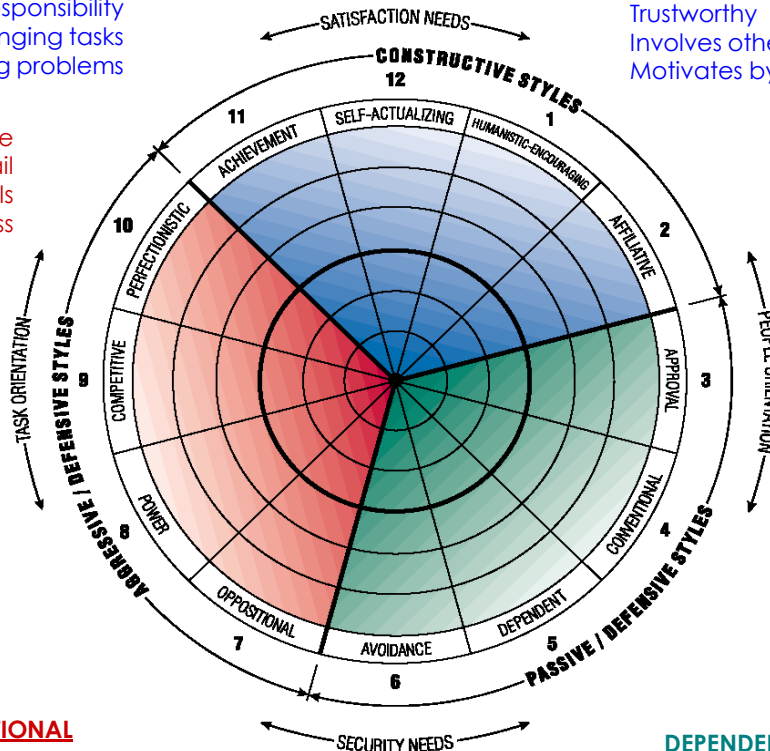
Never wants to make a mistake
 Personally takes care of every detail
 Sets unrealistic goals
 Creates self induced stress

AFFILIATIVE

Cooperative
 Friendly
 Genuine concern for others
 Accepts change

COMPETITIVE

Competes rather than co-operates
 Strong need to win
 Constantly compares self to others



APPROVAL

Sets goals that please others
 Supports those with the most authority
 Agrees with everyone
 Reluctantly deals with conflict

POWER

Wants to control everything
 Believes in force
 Has little confidence in people
 Seldom admits mistakes

CONVENTIONAL

Follows policies and practices
 Reliable and steady
 Sets predictable goals and objectives
 Treats rules as more important than ideas

OPPOSITIONAL

Opposes new ideas
 Looks for mistakes
 Resists change
 Critical of others

AVOIDANCE

"Lays low" when things get tough
 Avoids conflict
 Has difficulty making decisions
 Is non-committal
 Hopes that problems will take care of themselves

DEPENDENT

Relies on others for direction
 A good follower
 Doesn't challenge others
 Aims to please every one



Research and Development by
 Robert A. Cooke, Ph. D.
 J. Clayton Lafferty, Ph. D.
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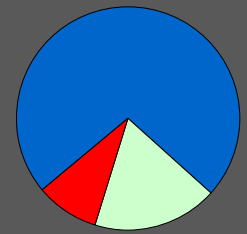



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Associated Outcomes



Individual	Department	Company
<ul style="list-style-type: none"> • Job satisfaction • Motivation 	<ul style="list-style-type: none"> • Intra-unit co-operation • Constructive customer service styles 	<ul style="list-style-type: none"> • High quality customer service • Inter-unit co-ordination • High quality products & services
<ul style="list-style-type: none"> • Role ambiguity • Person/role conflict 	<ul style="list-style-type: none"> • Turnover • Lack of motivation dissatisfaction • Work avoidance 	<ul style="list-style-type: none"> • Passive customer service styles • Inferior product/service quality
<ul style="list-style-type: none"> • Goal setting too hard • Job insecurity • Disempowerment (goals too high leading to blame) 	<ul style="list-style-type: none"> • Methods of reinforcement (reward/punishment) • Sources of power and influence (coercion, positional power) 	<ul style="list-style-type: none"> • Disrespect for members • Cultural values (competition over co-operation)  <p data-bbox="1595 1299 1903 1333">Universal Biosensors</p>

Continuous Improvement: *customer focused*

CAPA Management (root cause analysis):

- Cause & Effect Diagrams
- 5 Whys?

Specification Setting (Six Sigma):

- data trending (n= 30 development lots)
- alert, alarm and specification setting
- process capability (CpK, Ppk) to predict yield and defect rates

Operational Velocity (LEAN):

- value stream maps (current & future state) used to identify projects
- 5S

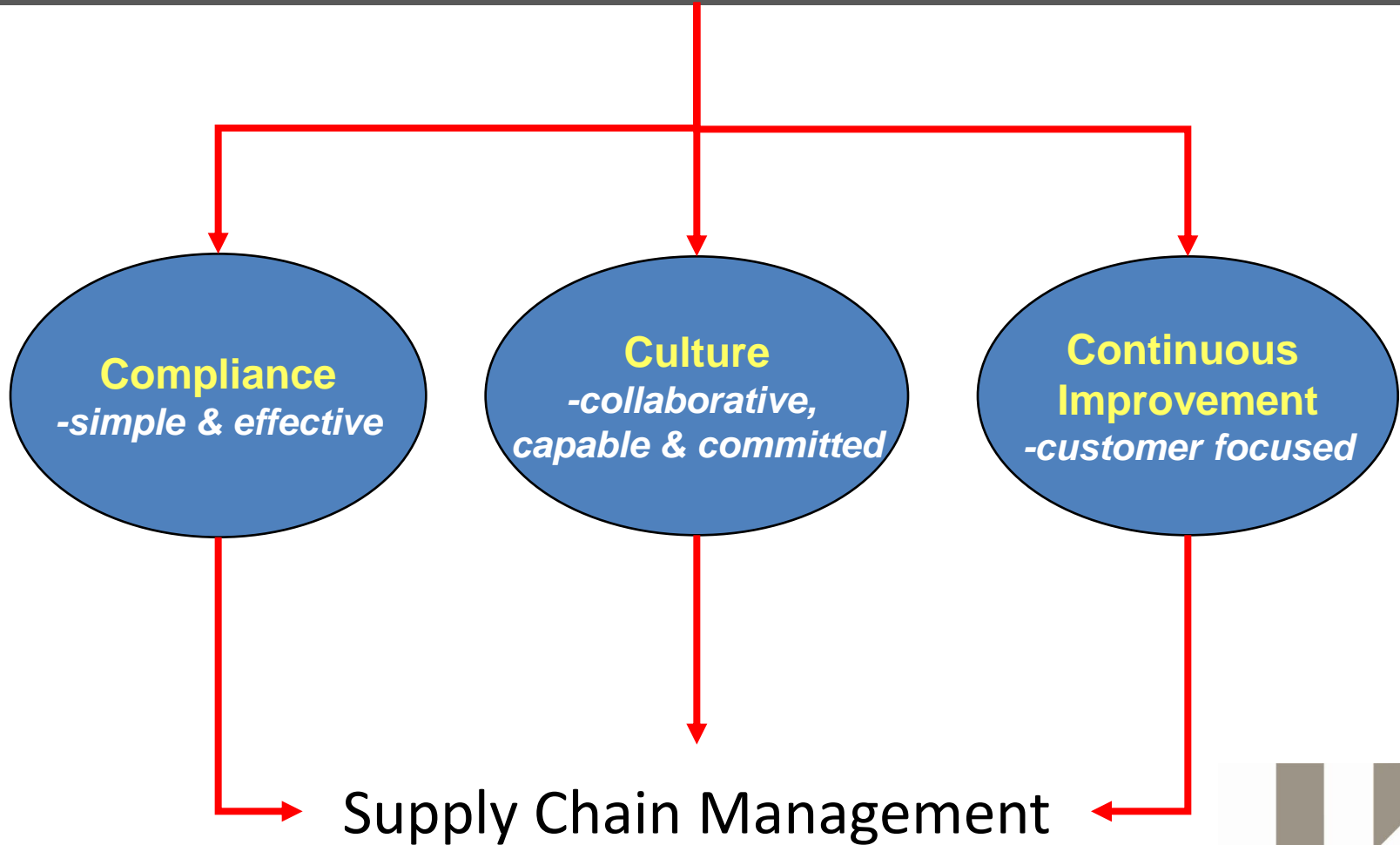
Implementation:

- Find a hands on practical consultant!
- Champions training for senior managers (R&D, operations, quality)
- Select a strategically important program of projects supported by CEO
- Program run by Black belt
- Projects run by Green black belts
- **Integrate Suppliers into the program (training/teaching)**



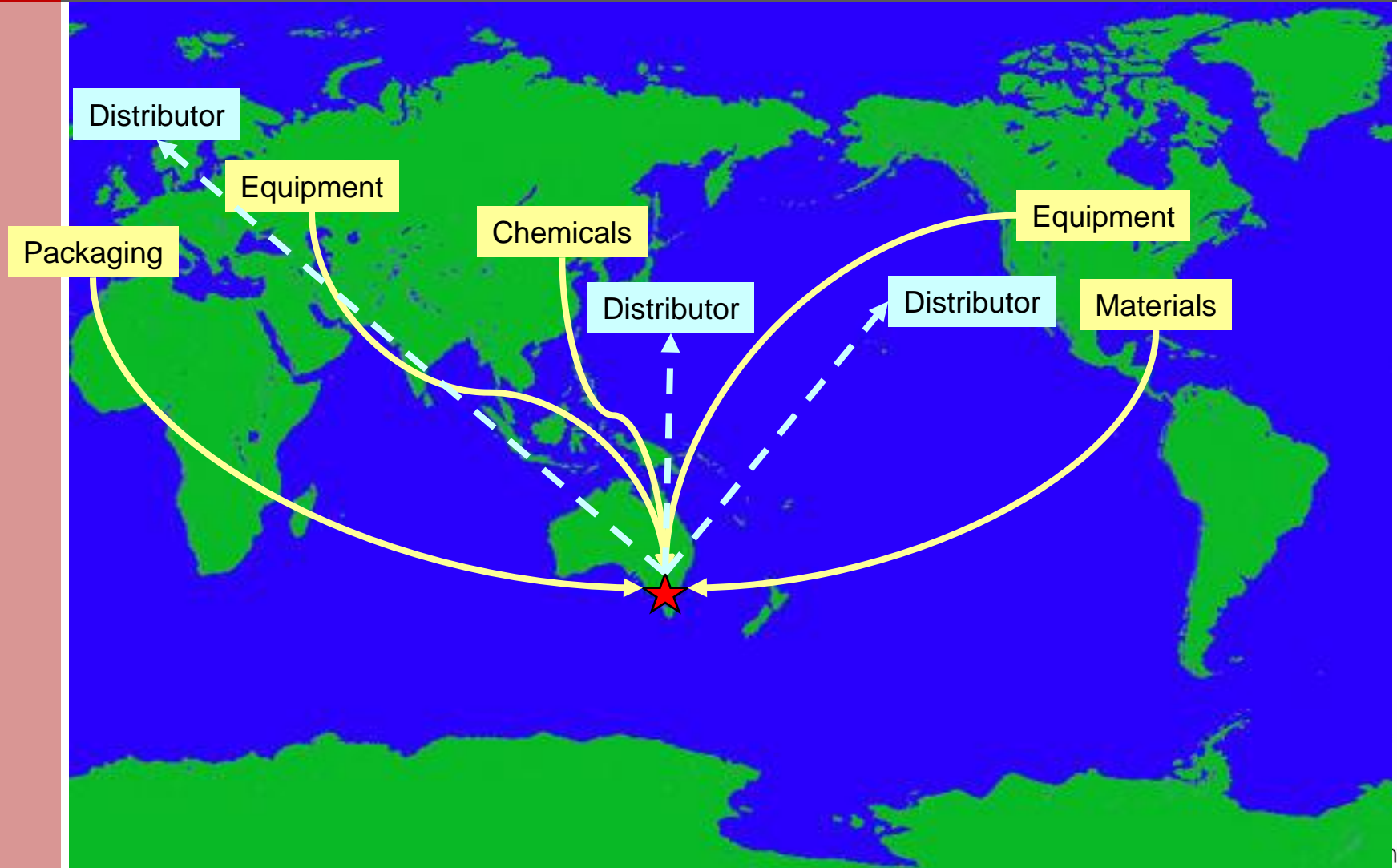
Strategy: The 3 C's

- establishing a quality foundation

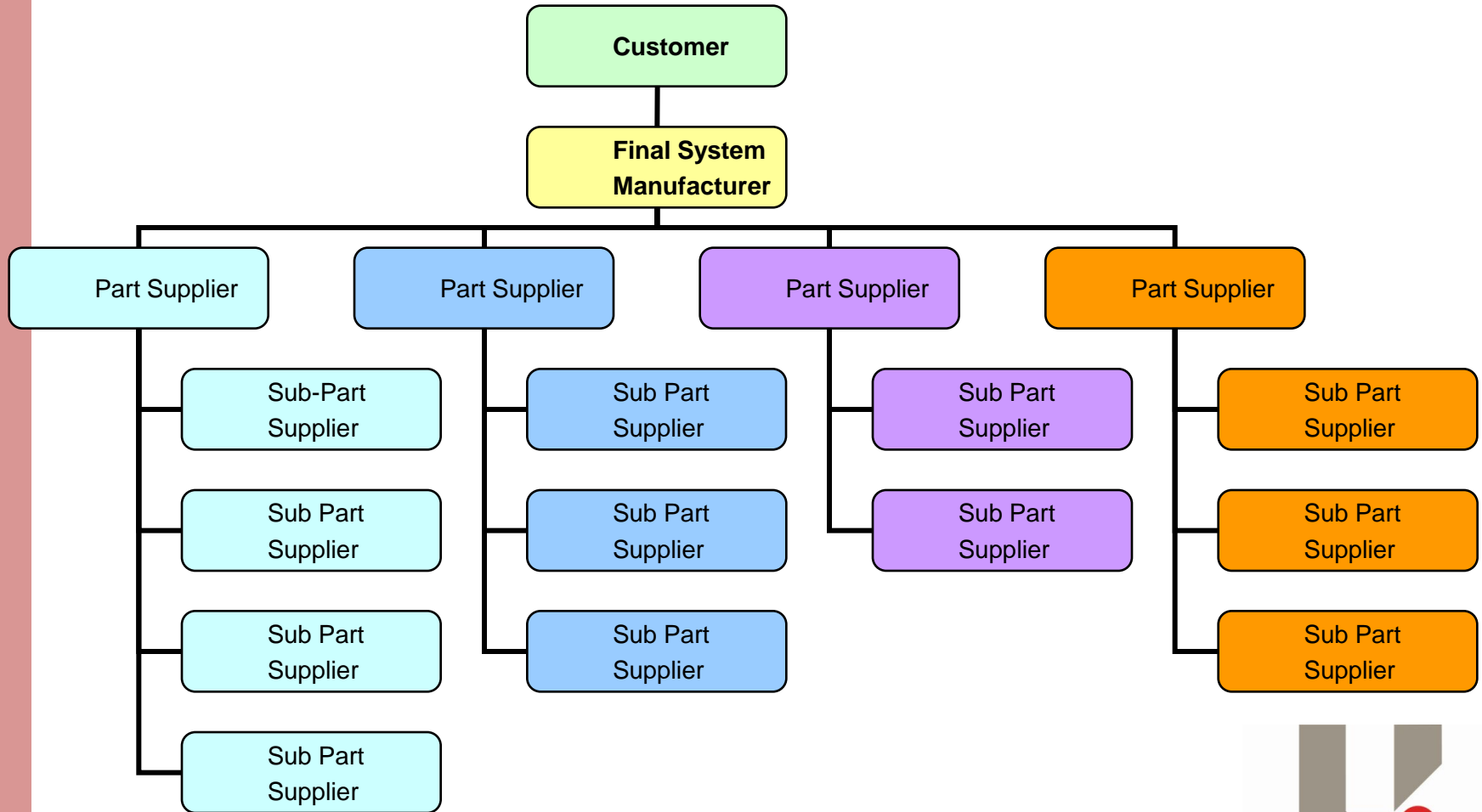


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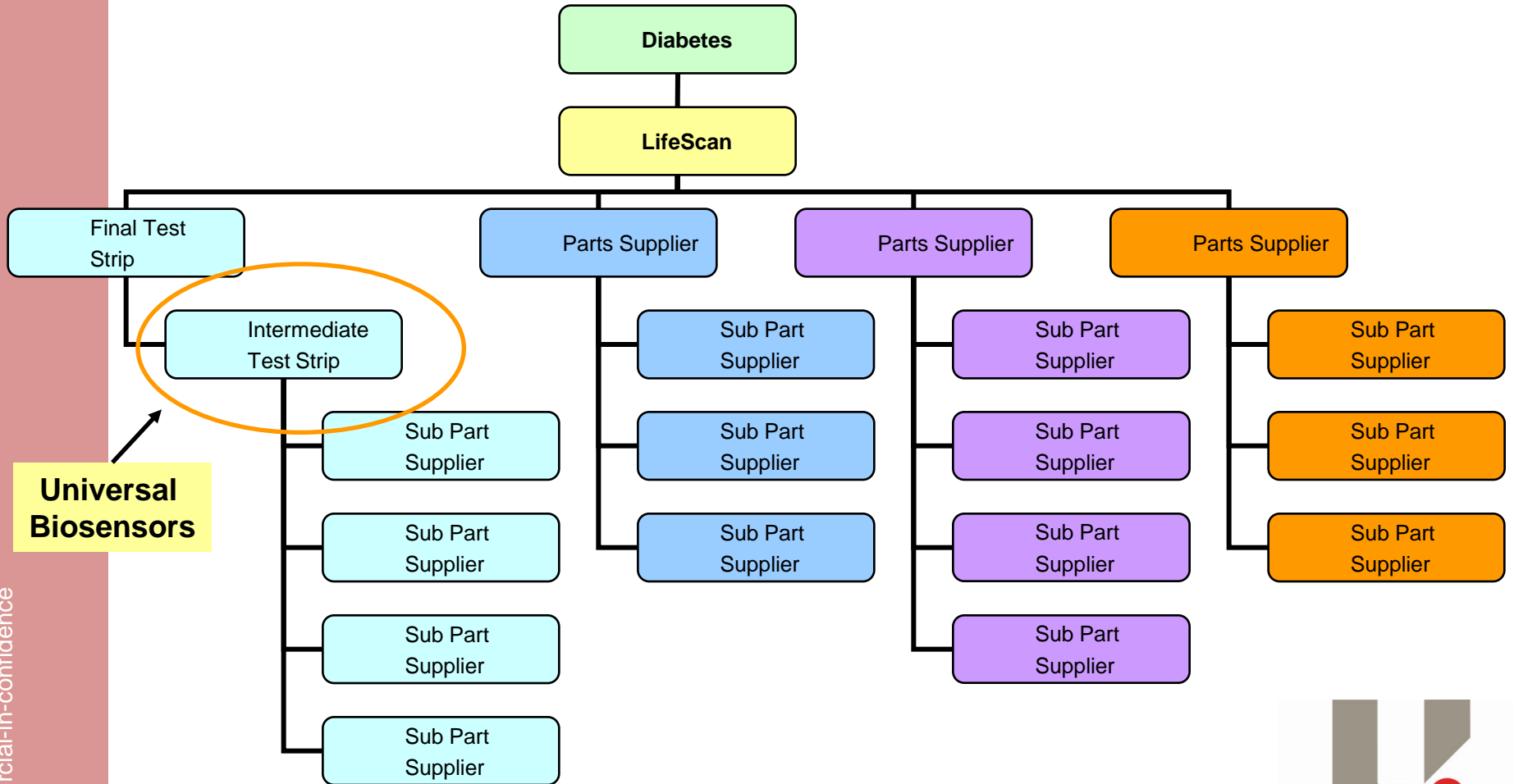
Supply Chain (example only)



Supply Chain Complexity



Supply Chain Complexity



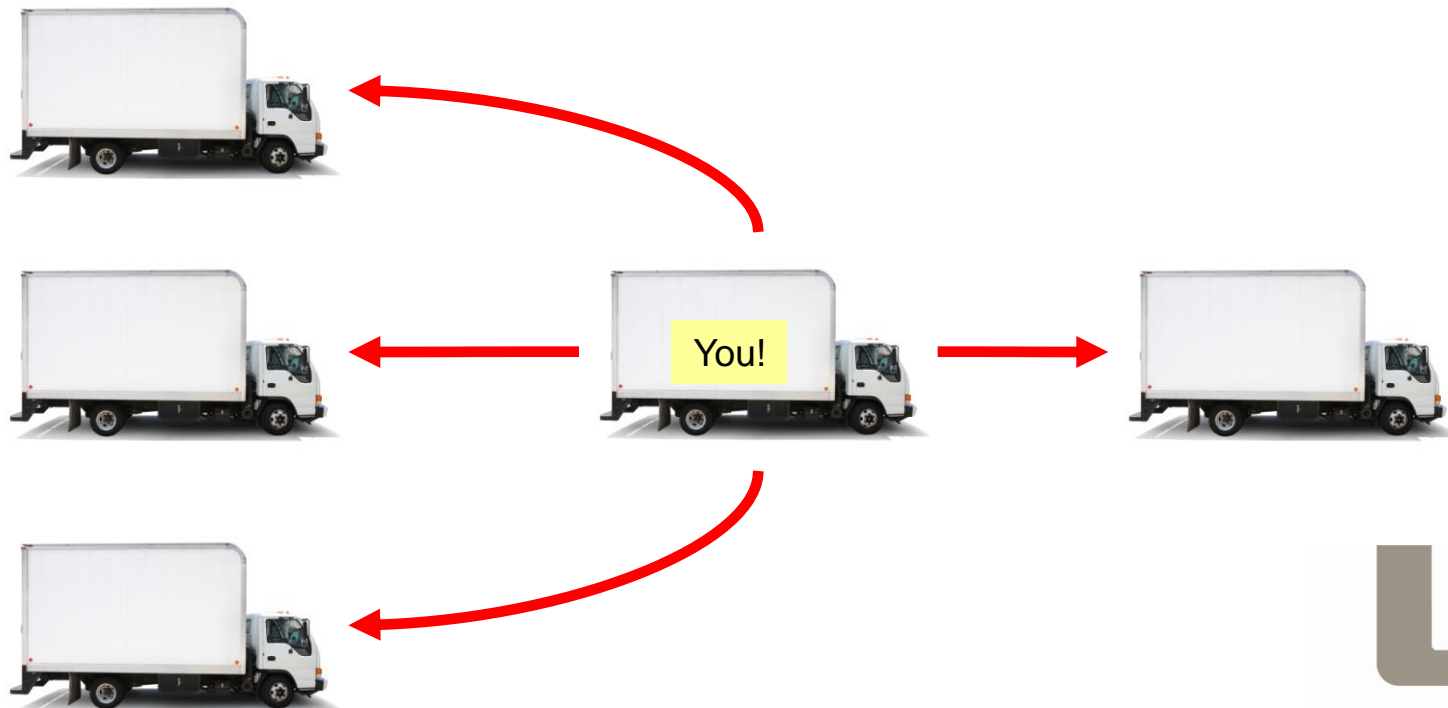
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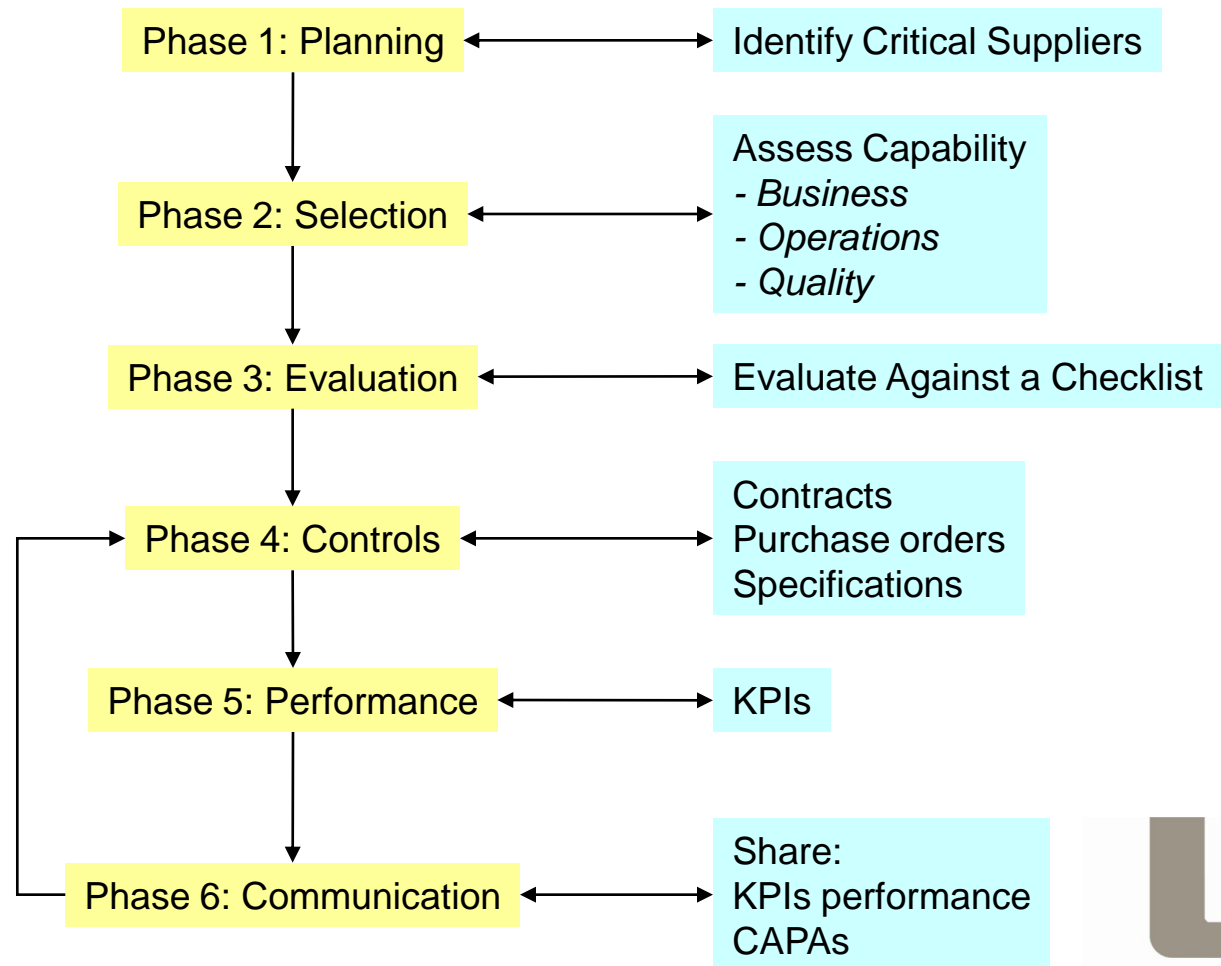
Supply Chain Complexity

- How far backwards and forwards do you look?



Supplier Selection & Management

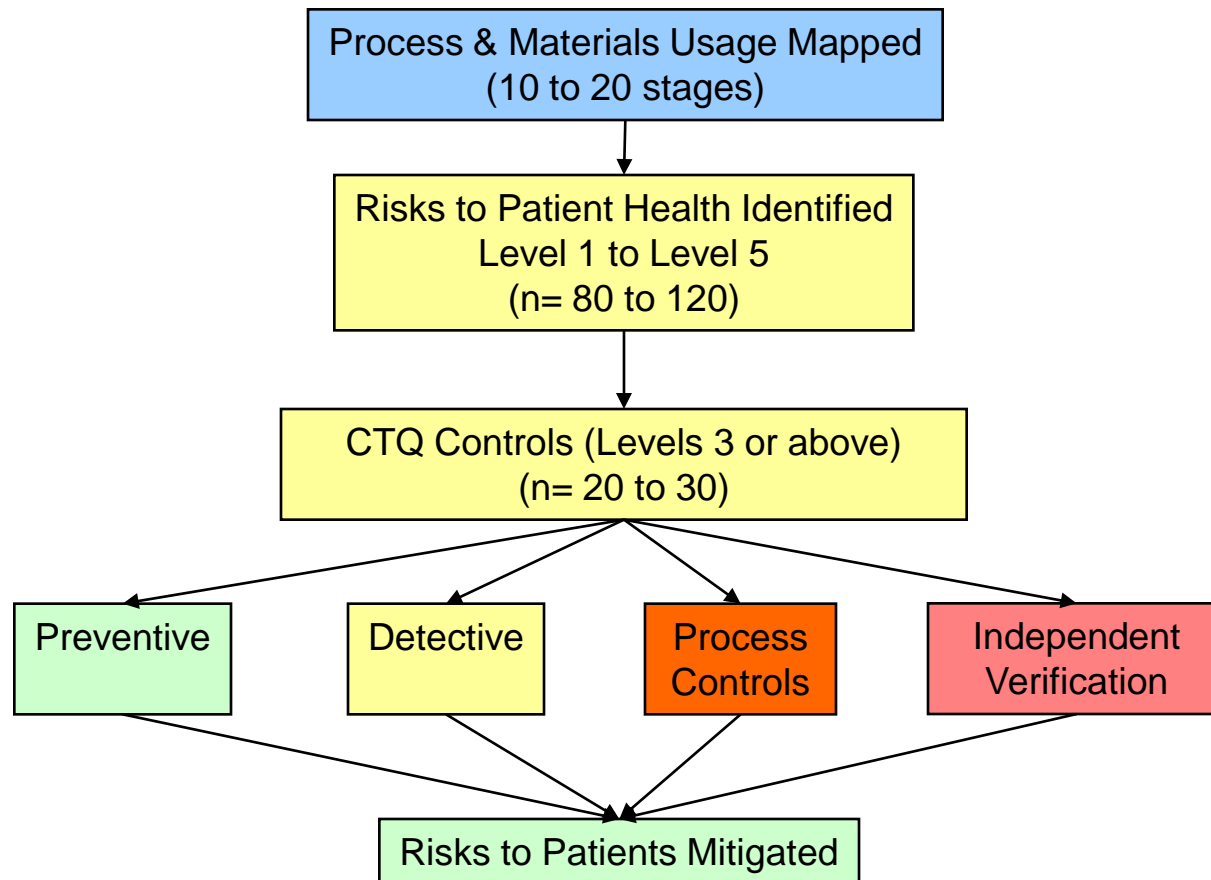
- GHTF Guidance on the Control of Products and Services
Obtained from Suppliers (SG3/N17R9:2008) and Risk Based Approach



Phase 1: Planning

Risk Management- ISO14971

- **Quality Control Plan:** *Describes how the manufacturer will mitigate and control risks associated with production process and materials*



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QC Plan Controls-

4 layers of protection for CTQs (LOPA)

Prevention

- ⇒ Supply contracts & POs in place
- ⇒ On site audit to qualify vendor
- ⇒ Specifications in place

Detection

- ⇒ C of A Specifications checked at goods inwards

Process Control

- ⇒ C of A tests trended for shifts in data

Independent Secondary Verification

- ⇒ Incoming goods QC test
- ⇒ Final product QC test



Materials Risk Management (example only)

CTQs

Risk Profile

Risk Rating Table		SEVERITY				
		Insignificant Level 1	Minor Level 2	Moderate Level 3	Major Level 4	Catastrophic Level 5
LIKELIHOOD	Almost Certain	7	6	1 5	2 3	4
	Likely					
	Possible					
	Unlikely					
	Highly Unlikely					

Very Low
 Low
 Moderate
 Significant
 High
 Very High

Significant, High & Very High: Executive Reporting

High & Very High: Board Reporting



Phase 2: Selection (example only)

- Suppliers to be qualified against a predetermined checklist (GHTF Guidance), SG3/N17:2008
- Score suppliers as 0, 1, 3, 9 for each criteria and multiply by agreed weightings

Material/Criteria	Weighting (1-5)	Current Supplier	Alternative Supplier	Alternative Supplier
XXXX				
Vendor		AAA	BBB	CCC
Business Capability				
- Business Conduct	4			
- Business Reputation	5			
- Financial Viability	4			
- COGS	5			
Operational Capability				
- Lead times	3			
- On time delivery	5			
- Response time	4			
- Ability to meet specifications	5			
Quality Capability				
- Quality System Audit	5			
Total Score				

Phase 3: Evaluation (example only)

- Suppliers to be qualified against a predetermined checklist (GHTF Guidance), SG3/N17:2008
- Score suppliers as 0, 1, 3, 9 for each criteria and multiply by agreed weightings

Material/Criteria	Weighting (1-5)	Current Supplier	Alternative Supplier	Alternative Supplier
XXXX				
Vendor		AAA	BBB	CCC
Business Capability				
- Business Conduct	4	9 (36)	3 (12)	9 (36)
- Business Reputation	5	3 (15)	3 (15)	9 (45)
- Financial Viability	4	3 (12)	1 (4)	9 (36)
-COGS	5	9 (45)	3 (15)	9 (45)
Operational Capability				
- Lead times	3	9 (27)	9 (27)	9 (27)
- On time delivery	5	9 (45)	3 (15)	9 (45)
- Response time	4	9 (36)	9 (36)	9 (36)
- Ability to meet specifications	5	3 (15)	9 (45)	9 (45)
Quality Capability				
- Quality System Audit	5	3 (15)	9 (45)	9 (45)
Total Score		236	214	360

Phase 4: Controls

QC Plan documents 4 layers of protection for CTQs (LOPA)

Prevention

- ⇒ Supply contracts & POs in place
- ⇒ On site audit to qualify vendor
- ⇒ Specifications in place

Detection

- ⇒ C of A Specifications checked at goods inwards

Process Control

- ⇒ C of A tests trended for shifts in data

Independent Secondary Verification

- ⇒ Incoming goods QC test
- ⇒ Final product QC test



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Phase 5: Performance

KPIs (example only)

	J	F	M	A	M	J	Comment
# Vendor Audits Performed	1	0	2	0	0	1	
% Vendor Audits Performed to Schedule (>95%)	100	100	100	0	0	100	Back on track
On time delivery % (>95%)	100	95	100	89	75	70	Late deliveries
Total Number Parts/materials inspected	20	25	23	26	31	12	
Total Number of failures or non-conformances (< 3)	0	0	2	0	5	4	Quality problems

Vendor is having quality issues causing late deliveries

⇒ Call to gather facts- offer assistance



Phase 6: Communication

Management Review Meetings (example only)

Material	Vendor	1.Business Capability?	2.Operational Capability?	3.Quality Capability?	Comment
A	AAA				Operating
	BBB				Assist with QMS
	CCC				Review status- on site audit required
B	DDD				Operating
C	EEE				Operating
D	FFF				Assist with QMS
E	GGG				Operating
	HHH				DISCONTINUE
F	III				Operating
G	JJJ				Operating
H	KKK				Operating



Summary

- implement a global quality system
- identify critical vendors
- evaluate capabilities
 - 1) *business*
 - 2) *operations*
 - 3) *quality*
- foster a “constructive” environment



- END SLIDE