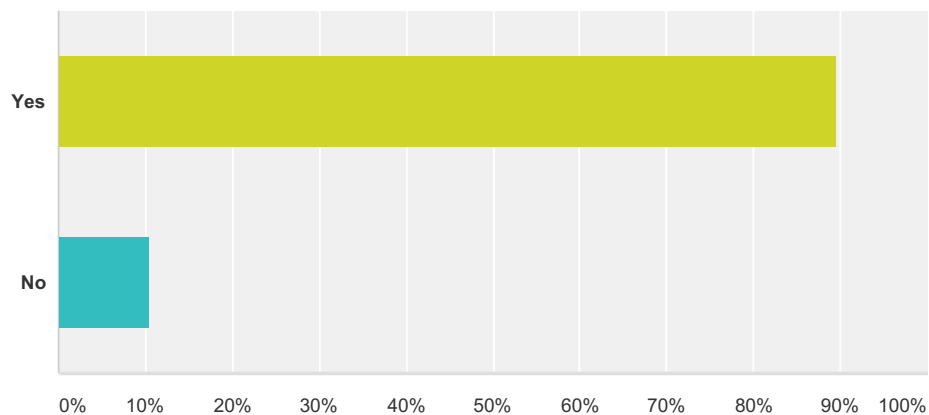


Q3 2. As defined in our most recent whitepaper, the supply chain for a pharmaceutical ingredient includes all facilities involved in the manufacture, storage, and ultimate use of the ingredient and the transportation of the ingredient (or its starting materials) between those facilities. As such, the upstream supply chain could include the facility that performs the initial harvest of a starting material for a pharmaceutical ingredient through to the company that uses the ingredient in the manufacture of a drug product. Accordingly, a supply chain map should account for all facilities within the supply chain (including contingency facilities) and provide transparency to how the ingredient moves throughout this supply chain. Is your company’s definition consistent with the description provided? (Note: the definition defined here or elaborated upon below should be the one that is kept in mind while filling out the remainder of this survey).

Answered: 19 Skipped: 0



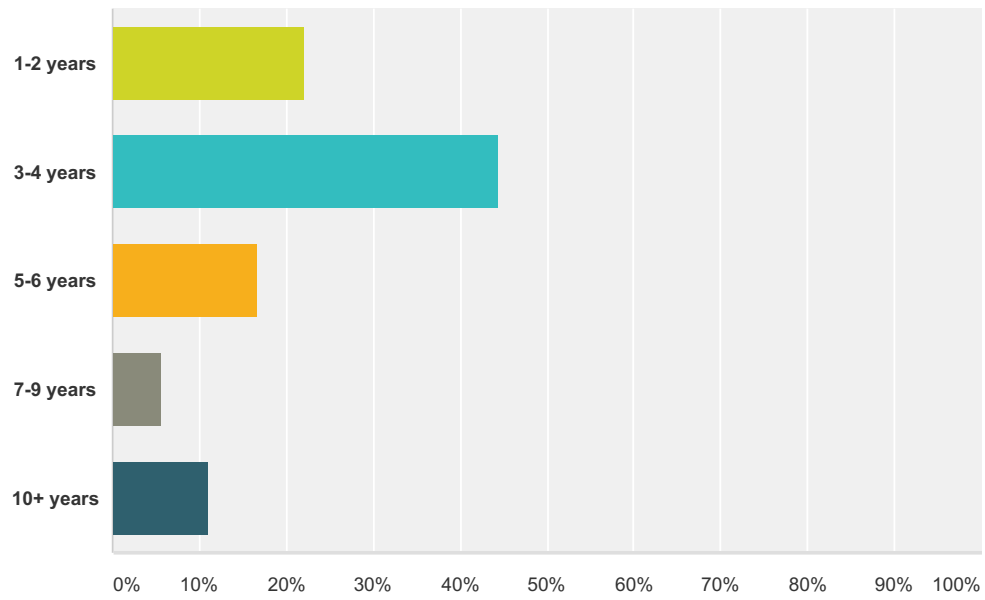
Answer Choices	Responses
Yes	89.47% 17
No	10.53% 2
Total	19

Upstream Supply Chain Security Working Group Survey

#	If no, please elaborate on any major differences:	Date
1	[Company]'s definition of the upstream supply chain includes initial raw material suppliers.	2/2/2016 2:34 PM
2	At this time, the Supplier Programs are not uniform across the various segments of our company, since we are a merger of multiple companies over the years. Therefore, we are unable to provide responses to this survey at this time.	1/19/2015 2:37 PM
3	Supply chain mapping include direct materials, such as, API, raw materials, excipients, and pkg. materials.	12/11/2014 3:24 PM

Q4 3. How long have you been formally mapping your supply chains?

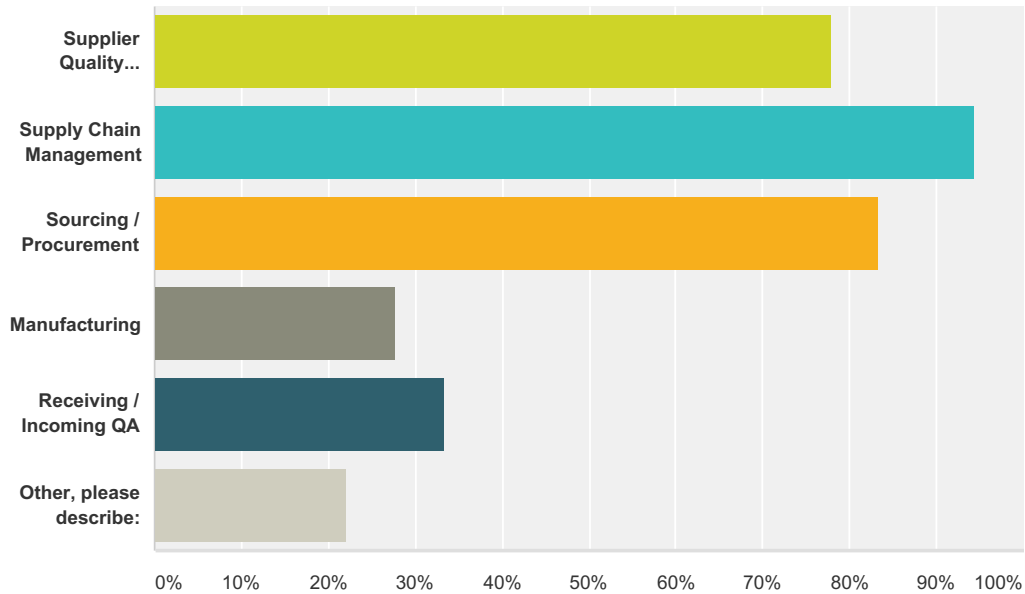
Answered: 18 Skipped: 1



Answer Choices	Responses
1-2 years	22.22% 4
3-4 years	44.44% 8
5-6 years	16.67% 3
7-9 years	5.56% 1
10+ years	11.11% 2
Total	18

Q5 4. Which functions/departments of your company are involved in the supply chain mapping process? Check all that apply. Leave blank those that do not apply:

Answered: 18 Skipped: 1

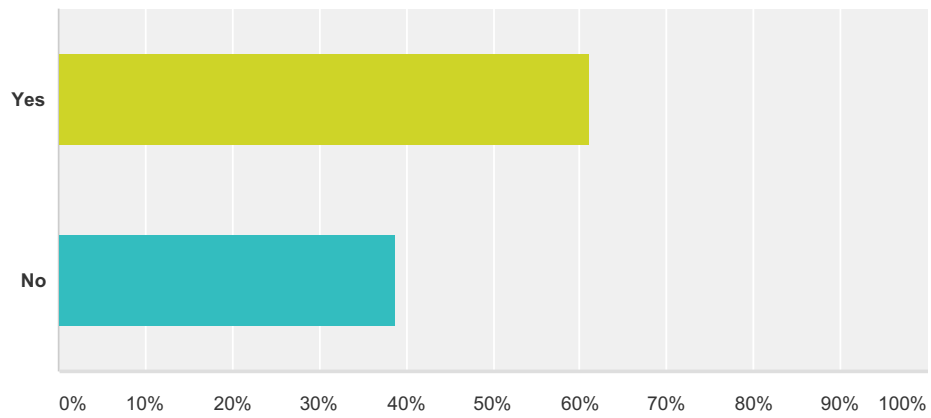


Answer Choices	Responses
Supplier Quality Management	77.78% 14
Supply Chain Management	94.44% 17
Sourcing / Procurement	83.33% 15
Manufacturing	27.78% 5
Receiving / Incoming QA	33.33% 6
Other, please describe:	22.22% 4
Total Respondents: 18	

#	Other, please describe:	Date
1	Process Development, CMC	2/4/2015 10:37 PM
2	Import/Export and the Audit Team	1/20/2015 9:23 AM
3	End to End Risk Management	1/19/2015 1:42 AM
4	QA compliance and Finance	1/14/2015 12:42 PM

Q6 5. Do you use any specific tools for supply chain mapping?

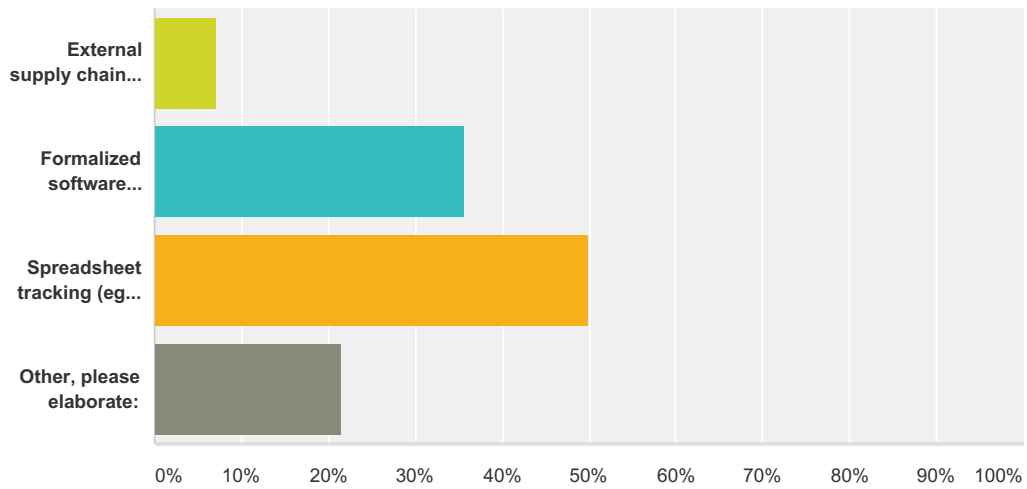
Answered: 18 Skipped: 1



Answer Choices	Responses	
Yes	61.11%	11
No	38.89%	7
Total		18

Q7 5a. If yes, please check which tools you use:

Answered: 14 Skipped: 5

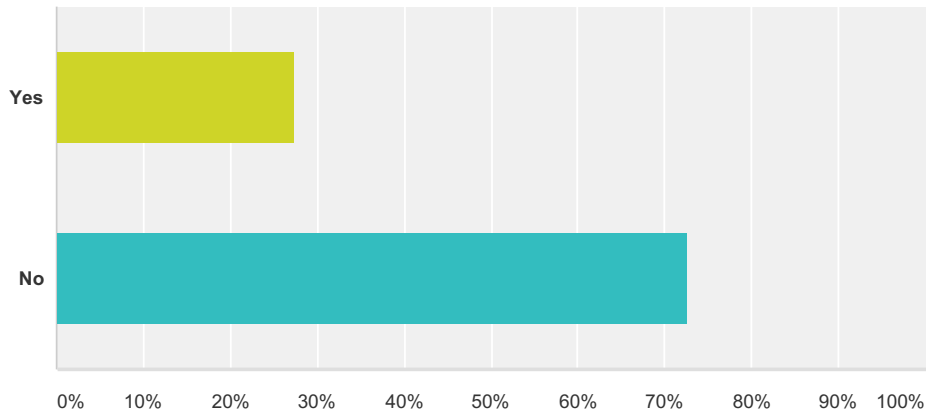


Answer Choices	Responses
External supply chain mapping service provider	7.14% 1
Formalized software specific to the goal of supply chain mapping	35.71% 5
Spreadsheet tracking (eg., Excel)	50.00% 7
Other, please elaborate:	21.43% 3
Total Respondents: 14	

#	Other, please elaborate:	Date
1	Visual diagrams in powerpoint slides	2/4/2015 10:37 PM
2	Spreadsheets tied to visio	1/14/2015 12:42 PM
3	Customized SAP module - Approved Supplier List	12/11/2014 3:24 PM

Q8 5b. If no, have you begun to consider new tools for supply chain mapping?

Answered: 11 Skipped: 8

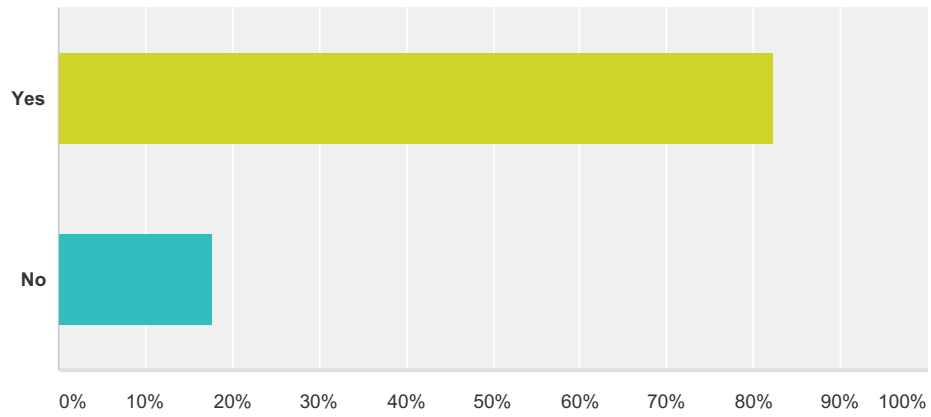


Answer Choices	Responses
Yes	27.27% 3
No	72.73% 8
Total	11

#	If yes, please describe the tool:	Date
1	Currently evaluating potential solutions to be adopted. Additionally, the implementation of MERPS system will aid in this task.	1/21/2015 2:48 PM
2	we are also looking for a more automated mapping tool - but so far have not found any	1/14/2015 12:42 PM
3	SAP or MasterControl (Quality Systems IT Package)	1/12/2015 9:03 AM

Q9 6a. To determine which product categories by which to map the supply chain?

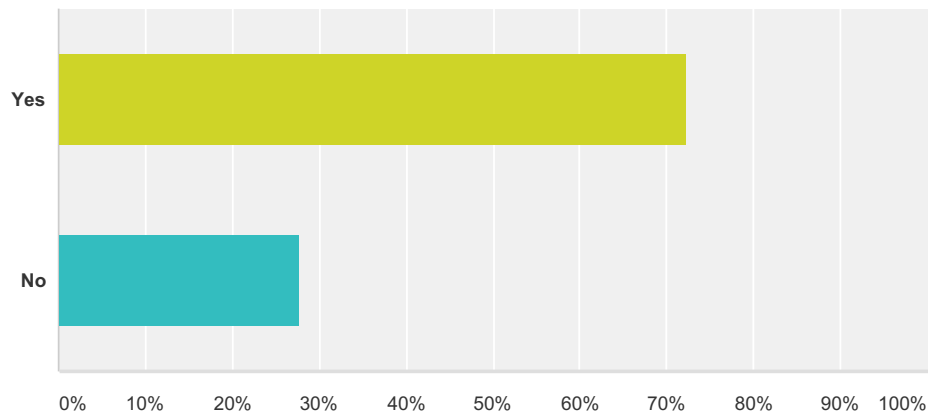
Answered: 17 Skipped: 2



Answer Choices	Responses
Yes	82.35% 14
No	17.65% 3
Total	17

Q10 6b. To determine how far back to go within the supply chain?

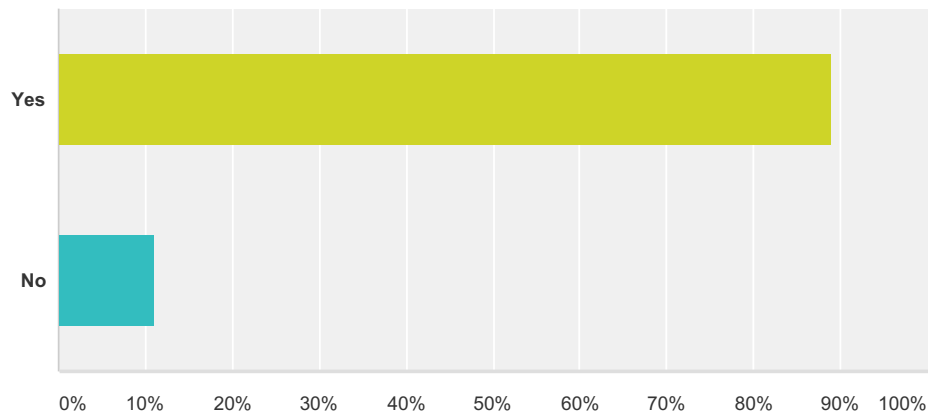
Answered: 18 Skipped: 1



Answer Choices	Responses	
Yes	72.22%	13
No	27.78%	5
Total		18

Q11 6c. To consider the criticality of the material being assessed?

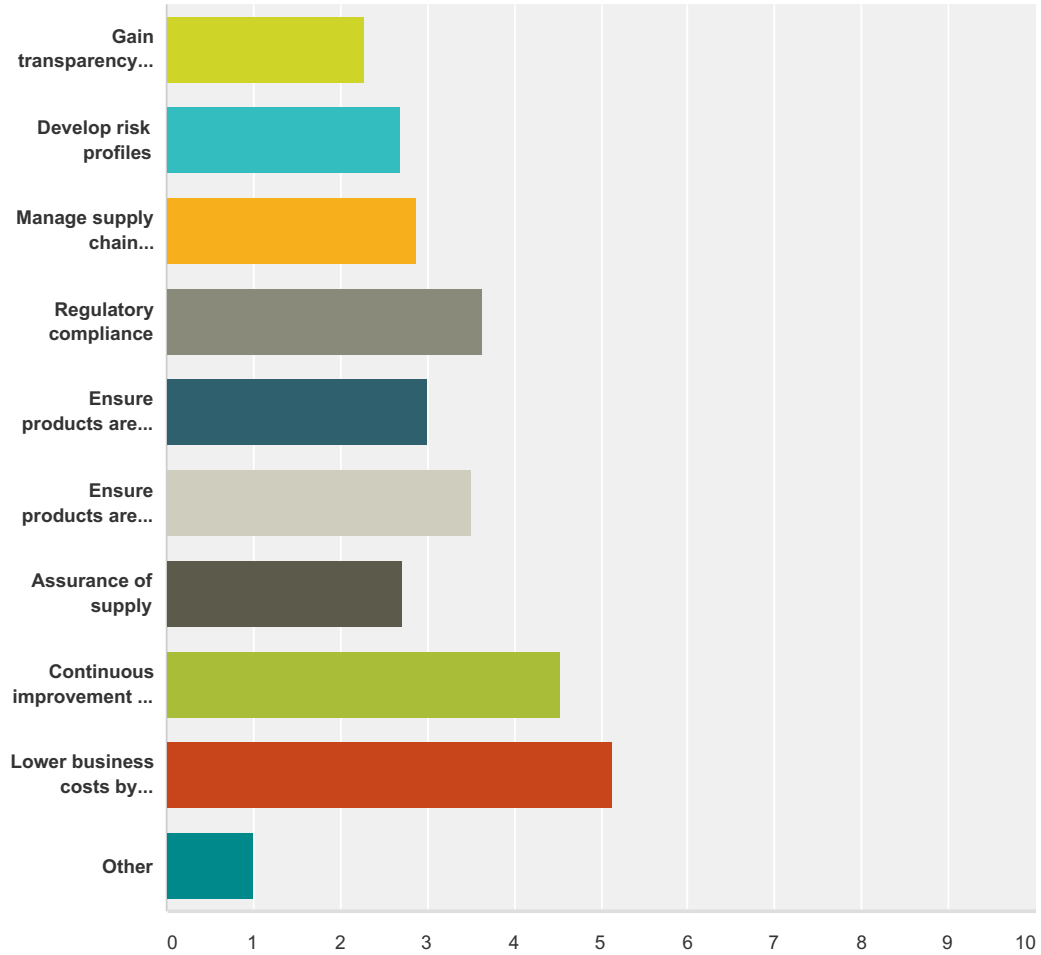
Answered: 18 Skipped: 1



Answer Choices	Responses	
Yes	88.89%	16
No	11.11%	2
Total		18

Q12 7. What are the main drivers for employing the practice of supply chain mapping? Please rank the following in order of strongest driver, with 1 being the strongest and 9 being the weakest:

Answered: 18 Skipped: 1



	1	2	3	4	5	6	7	8	9	N/A	Total	Weighted Average
Gain transparency and understanding of the supply chain	55.56% 10	11.11% 2	11.11% 2	11.11% 2	5.56% 1	0.00% 0	0.00% 0	5.56% 1	0.00% 0	0.00% 0	18	2.28
Develop risk profiles	27.78% 5	22.22% 4	16.67% 3	11.11% 2	5.56% 1	0.00% 0	0.00% 0	5.56% 1	0.00% 0	11.11% 2	18	2.69
Manage supply chain commensurate with risk profile already identified	27.78% 5	11.11% 2	44.44% 8	5.56% 1	0.00% 0	5.56% 1	0.00% 0	0.00% 0	5.56% 1	0.00% 0	18	2.89
Regulatory compliance	38.89% 7	5.56% 1	11.11% 2	5.56% 1	0.00% 0	0.00% 0	11.11% 2	11.11% 2	5.56% 1	11.11% 2	18	3.63

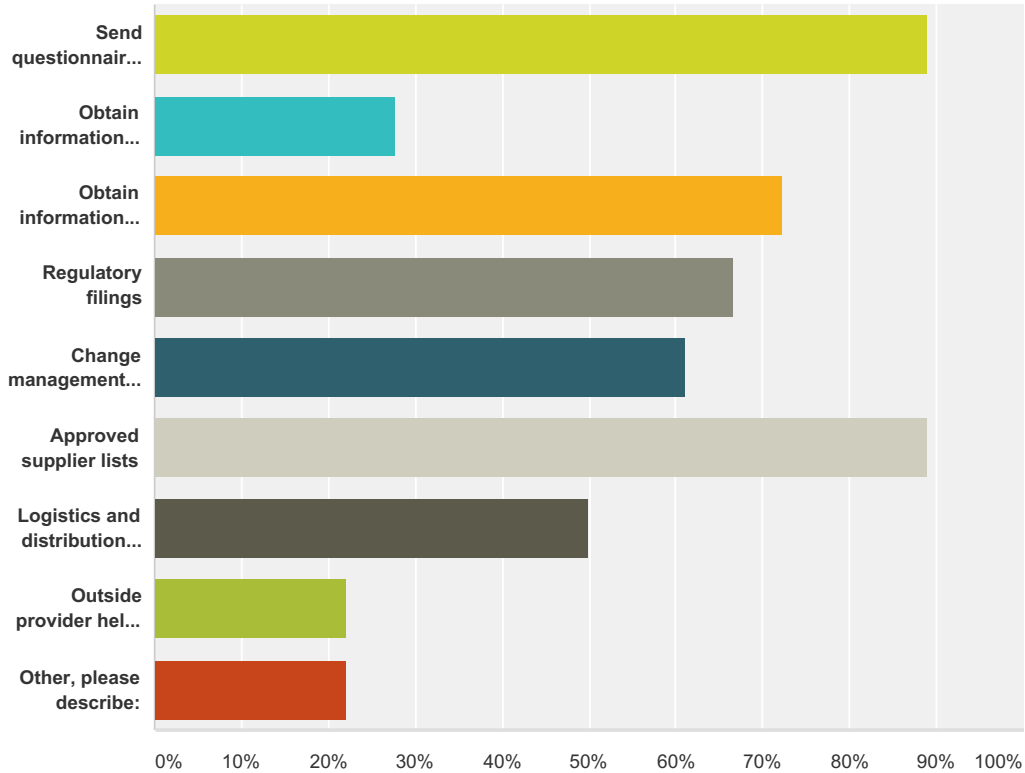
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Ensure products are not adulterated	22.22% 4	16.67% 3	16.67% 3	22.22% 4	0.00% 0	5.56% 1	5.56% 1	0.00% 0	0.00% 0	11.11% 2	18	3.00
Ensure products are not misbranded	22.22% 4	5.56% 1	16.67% 3	16.67% 3	16.67% 3	0.00% 0	11.11% 2	0.00% 0	0.00% 0	11.11% 2	18	3.50
Assurance of supply	16.67% 3	44.44% 8	11.11% 2	5.56% 1	5.56% 1	11.11% 2	0.00% 0	0.00% 0	0.00% 0	5.56% 1	18	2.71
Continuous improvement in supply chain processes	5.56% 1	11.11% 2	22.22% 4	11.11% 2	11.11% 2	11.11% 2	11.11% 2	11.11% 2	0.00% 0	5.56% 1	18	4.53
Lower business costs by understanding the supply chain better	5.56% 1	0.00% 0	27.78% 5	0.00% 0	16.67% 3	11.11% 2	5.56% 1	0.00% 0	16.67% 3	16.67% 3	18	5.13
Other	100.00% 1	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	0.00% 0	1	1.00

#	If you chose other, please specify:	Date
1	To identify risk in the supply chain (geographically, responsiveness to global events)	2/9/2015 5:16 PM
2	even though it started with Compliance activity to EU GDPs / EU FMD, the value has been seen	1/14/2015 12:42 PM

Q13 8. How do you obtain the information used to map the supply chain? Check all that apply.

Answered: 18 Skipped: 1



Answer Choices	Responses
Send questionnaire to supplier	88.89% 16
Obtain information from supplier's website	27.78% 5
Obtain information from standard documentation given by supplier	72.22% 13
Regulatory filings	66.67% 12
Change management documents	61.11% 11
Approved supplier lists	88.89% 16
Logistics and distribution practices, etc.	50.00% 9
Outside provider helps to obtain information	22.22% 4
Other, please describe:	22.22% 4
Total Respondents: 18	

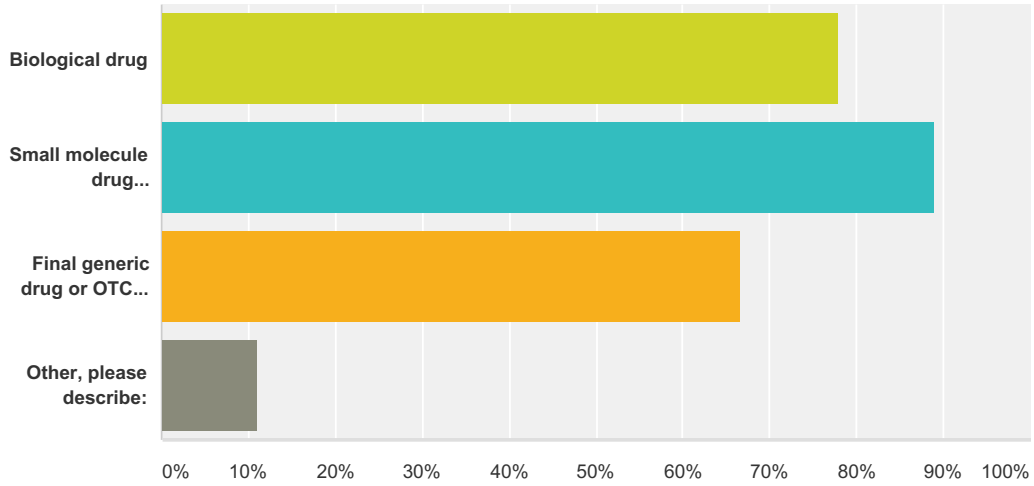
#	Other, please describe:	Date
1	Audits of Suppliers	2/9/2015 5:16 PM
2	On-site Assessments	1/20/2015 9:23 AM

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3	Direct communication with supplier	12/10/2014 12:14 PM
4	Audits	12/8/2014 11:02 AM

Q14 9. For which final pharmaceutical product(s) are you mapping your supply chain? Check all that apply.

Answered: 18 Skipped: 1

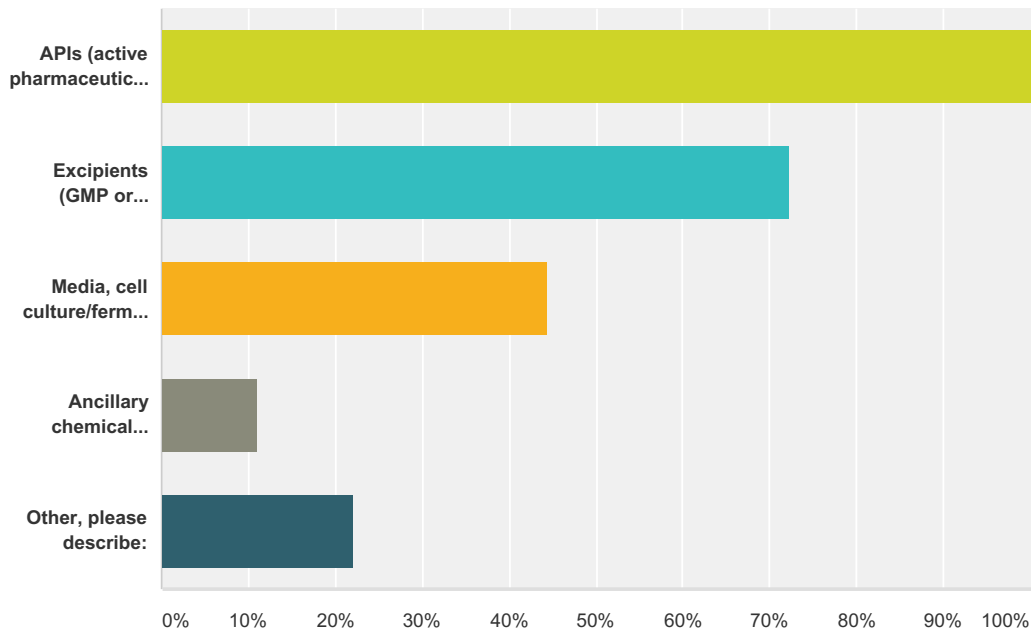


Answer Choices	Responses
Biological drug	77.78% 14
Small molecule drug (prescription)	88.89% 16
Final generic drug or OTC (over-the-counter) drug	66.67% 12
Other, please describe:	11.11% 2
Total Respondents: 18	

#	Other, please describe:	Date
1	Combination products / device components / delivery devices	2/9/2015 5:16 PM
2	all products (Pharma and Biologics) are mapped	1/14/2015 12:42 PM

Q15 10a. Raw Materials and Chemicals:

Answered: 18 Skipped: 1

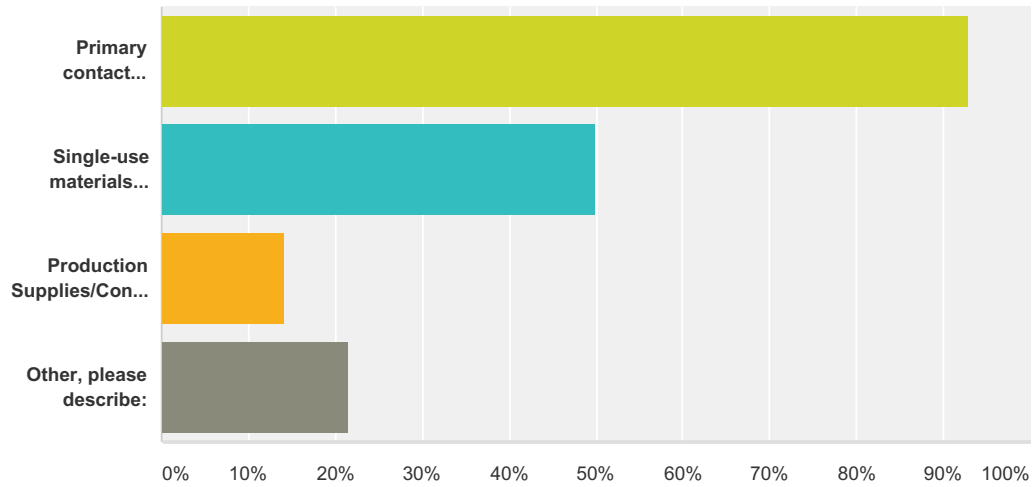


Answer Choices	Responses
APIs (active pharmaceutical ingredient)	100.00% 18
Excipients (GMP or compendial grade)	72.22% 13
Media, cell culture/fermentation media (not including agar plates)	44.44% 8
Ancillary chemical materials (QC solvents/standards, cleaning solutions, sanitizers, etc.)	11.11% 2
Other, please describe:	22.22% 4
Total Respondents: 18	

#	Other, please describe:	Date
1	GMP starting materials	2/4/2015 10:37 PM
2	Starting materials for API Manufacturing	1/19/2015 1:42 AM
3	In 2015 we will be adding intermediates (per new EU GMPs) and critical excipients	1/14/2015 12:42 PM
4	Devices & Cosmetics	1/12/2015 9:03 AM

Q16 10b. Other Production Materials:

Answered: 14 Skipped: 5

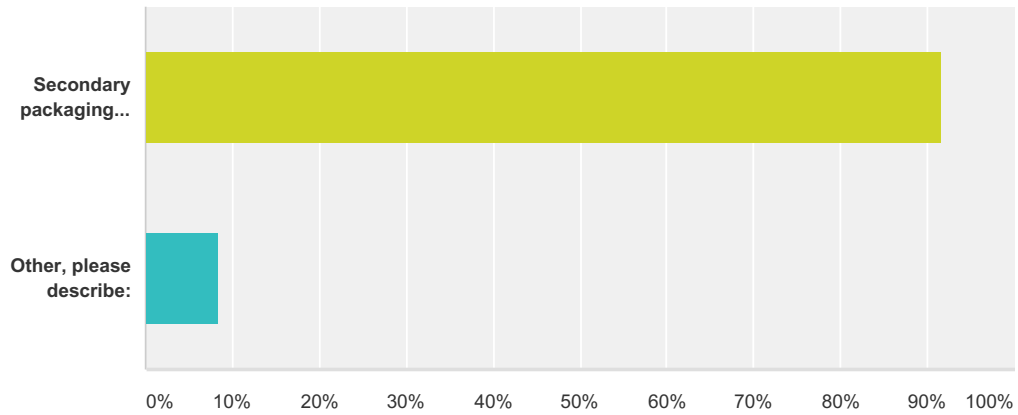


Answer Choices	Responses
Primary contact materials (example syringes, vials, etc.)	92.86% 13
Single-use materials (tubing, biotainers/bags, filters etc.)	50.00% 7
Production Supplies/Consumables (apparel, gloves, sticky mats, etc.)	14.29% 2
Other, please describe:	21.43% 3
Total Respondents: 14	

#	Other, please describe:	Date
1	Combination products / device components / delivery devices	2/9/2015 5:16 PM
2	Document information as available	1/12/2015 9:03 AM
3	gloves are included if there is a potential for product contact	12/11/2014 3:24 PM

Q17 10c. Packaging Materials:

Answered: 12 Skipped: 7

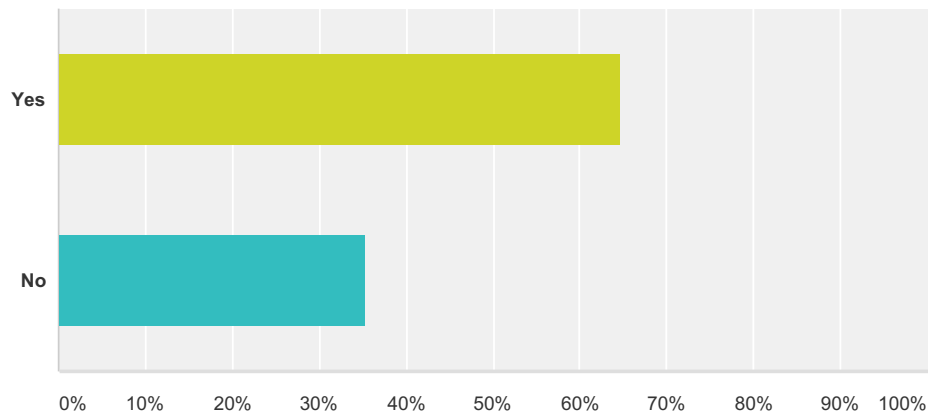


Answer Choices	Responses
Secondary packaging (packaging that does not contact the final product; outer product box, outer labels)	91.67% 11
Other, please describe:	8.33% 1
Total Respondents: 12	

#	Other, please describe:	Date
1	Document information as available	1/12/2015 9:03 AM

Q18 11. Will the list of materials mapped in question 10 change in the coming year(s)?

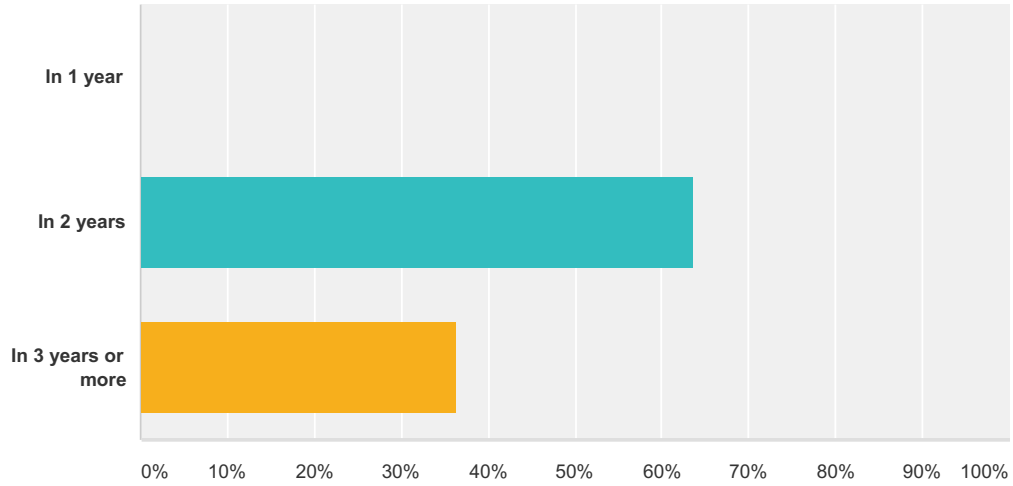
Answered: 17 Skipped: 2



Answer Choices	Responses	
Yes	64.71%	11
No	35.29%	6
Total		17

Q19 11a. If yes, please indicate how soon you plan to expand your mapping (choose which fits best):

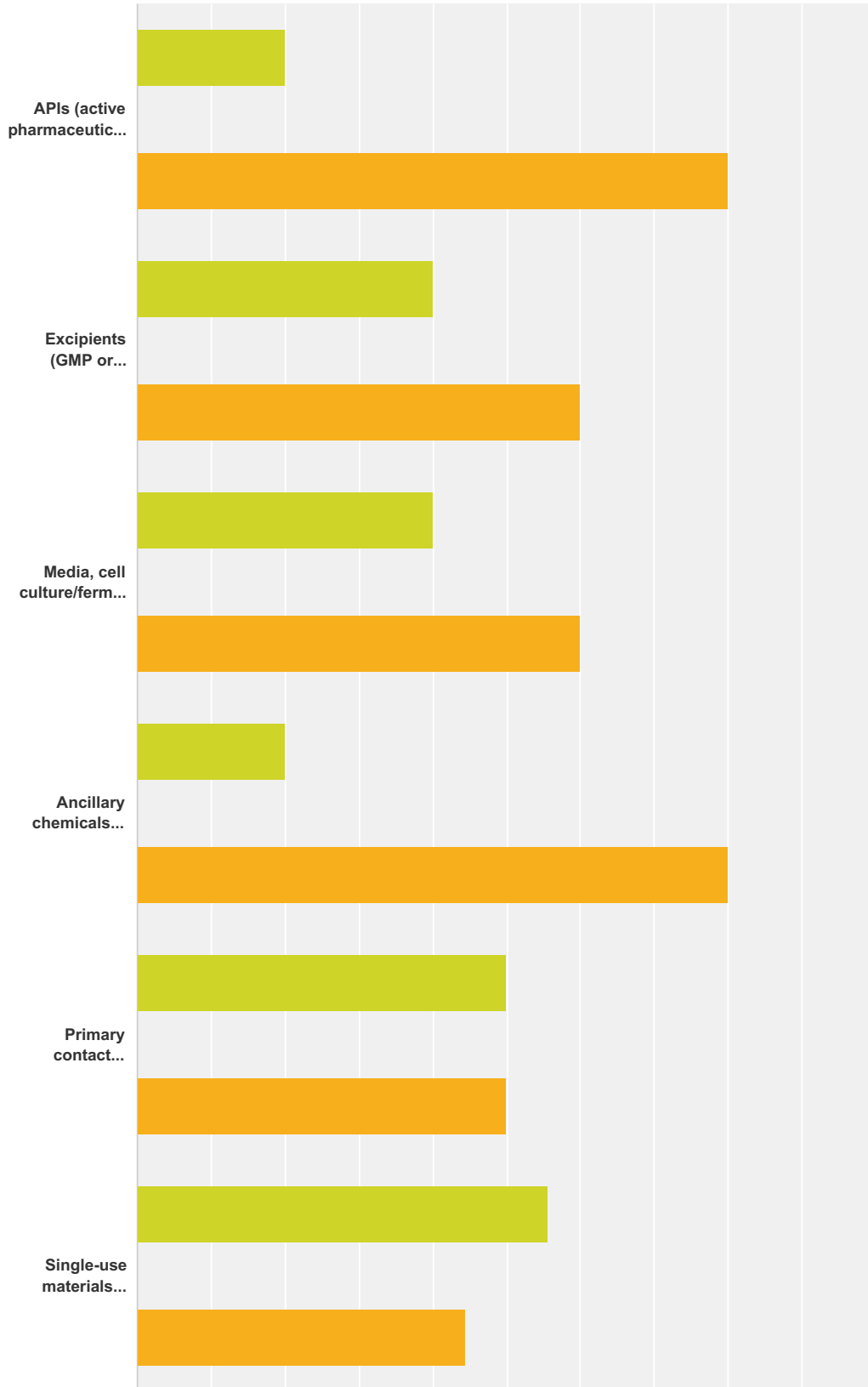
Answered: 11 Skipped: 8



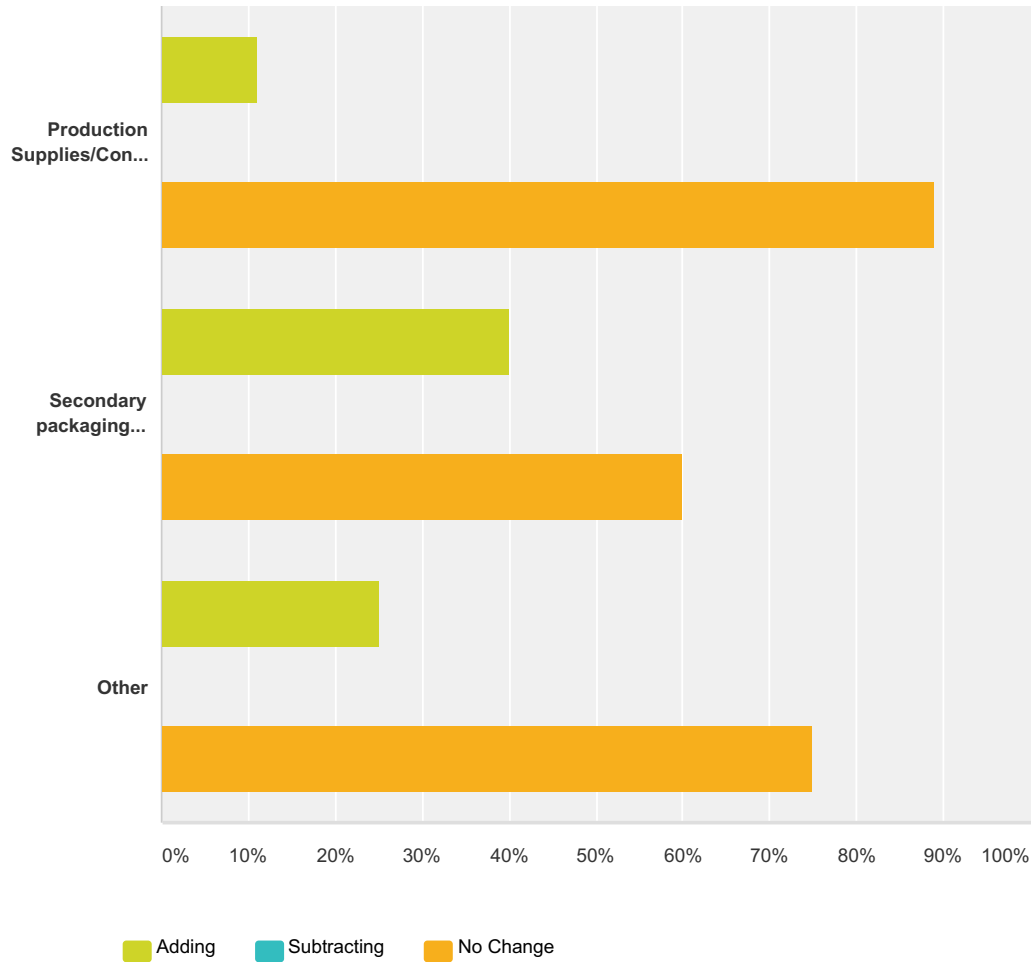
Answer Choices	Responses
In 1 year	0.00% 0
In 2 years	63.64% 7
In 3 years or more	36.36% 4
Total	11

Q20 11b. Additionally, if yes, which category would you likely be adding or subtracting?

Answered: 13 Skipped: 6



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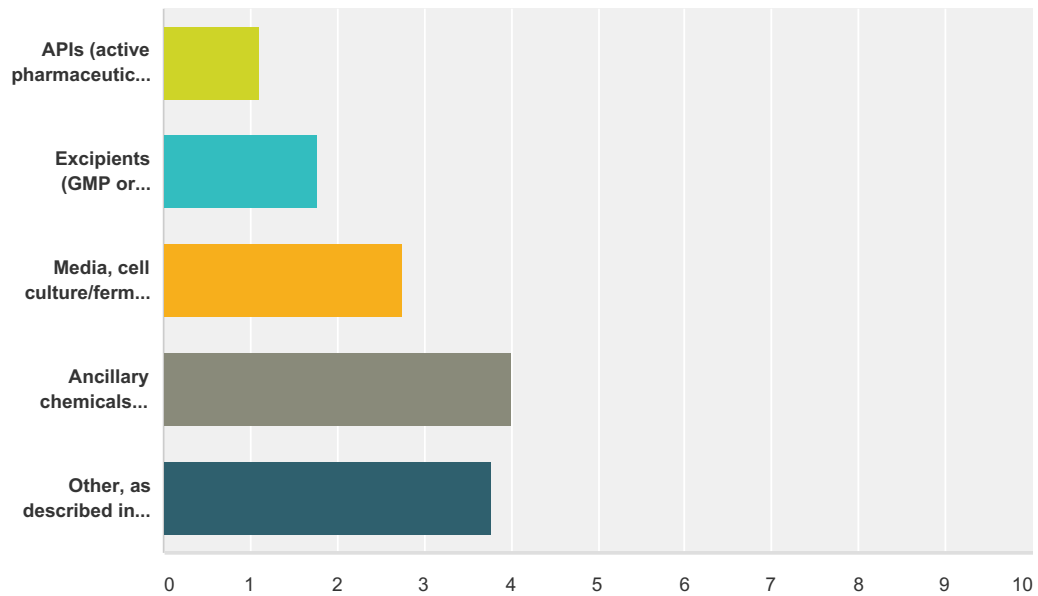


	Adding	Subtracting	No Change	Total
APIs (active pharmaceutical ingredient)	20.00% 2	0.00% 0	80.00% 8	10
Excipients (GMP or compendial grade)	40.00% 4	0.00% 0	60.00% 6	10
Media, cell culture/fermentation media (not including agar plates)	40.00% 4	0.00% 0	60.00% 6	10
Ancillary chemicals materials (QC solvents/standards, cleaning solutions, sanitizers, etc.)	20.00% 2	0.00% 0	80.00% 8	10
Primary contact materials (example syringes, vials, etc.)	50.00% 5	0.00% 0	50.00% 5	10
Single-use materials (tubing, biotainers/bags, filters etc.)	55.56% 5	0.00% 0	44.44% 4	9
Production Supplies/Consumables (apparel, gloves, sticky mats, etc.)	11.11% 1	0.00% 0	88.89% 8	9
Secondary packaging (packaging that does not contact the final product; outer product box, outer labels)	40.00% 4	0.00% 0	60.00% 6	10
Other	25.00% 1	0.00% 0	75.00% 3	4

#	If you chose other, please specify:	Date
1	product portfolio dependent	12/10/2014 11:37 AM

Q21 12a. Raw Materials and Chemicals:

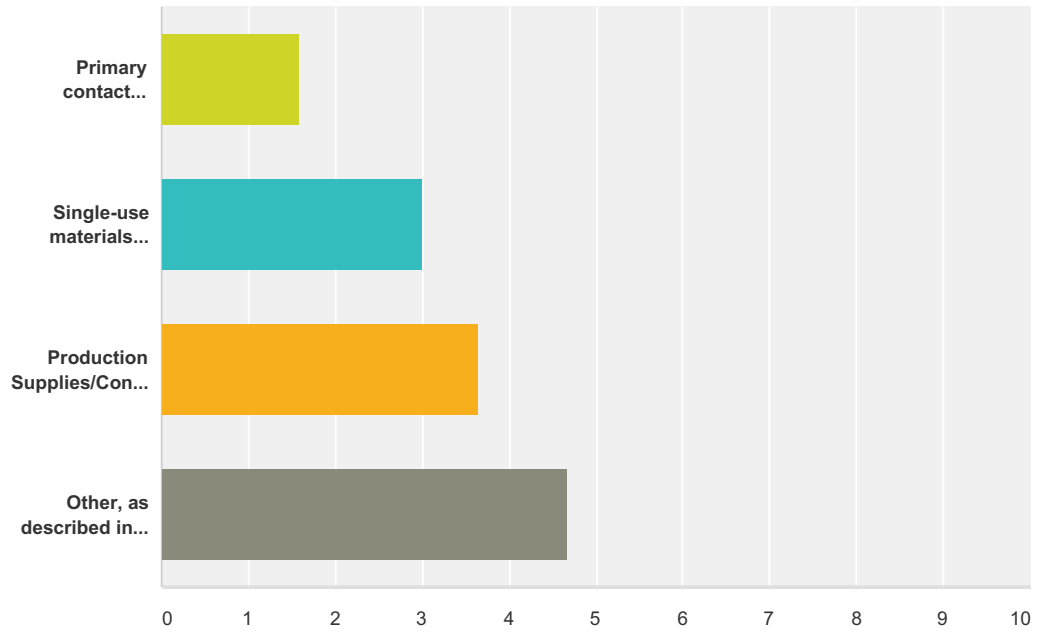
Answered: 18 Skipped: 1



	1	2	3	4	5	Total	Weighted Average
APIs (active pharmaceutical ingredient)	88.89% 16	11.11% 2	0.00% 0	0.00% 0	0.00% 0	18	1.11
Excipients (GMP or compendial grade)	38.89% 7	44.44% 8	16.67% 3	0.00% 0	0.00% 0	18	1.78
Media, cell culture/fermentation media (not including agar plates)	17.65% 3	47.06% 8	0.00% 0	11.76% 2	23.53% 4	17	2.76
Ancillary chemicals materials (QC solvents/standards, cleaning solutions, sanitizers, etc.)	0.00% 0	5.88% 1	23.53% 4	35.29% 6	35.29% 6	17	4.00
Other, as described in question 10, as applicable	11.11% 1	11.11% 1	22.22% 2	0.00% 0	55.56% 5	9	3.78

Q22 12b. Other Production Materials:

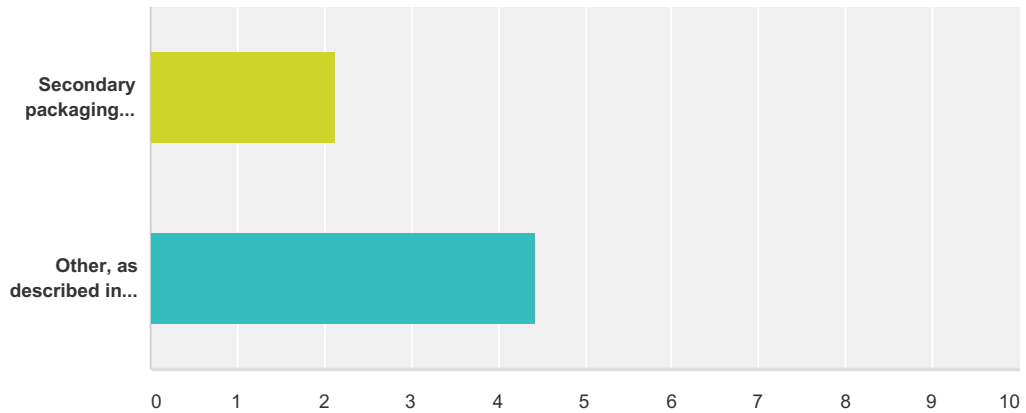
Answered: 17 Skipped: 2



	1	2	3	4	5	Total	Weighted Average
Primary contact materials (example syringes, vials, etc.)	47.06% 8	47.06% 8	5.88% 1	0.00% 0	0.00% 0	17	1.59
Single-use materials (tubing, biotainers/bags, filters etc.)	11.76% 2	23.53% 4	35.29% 6	11.76% 2	17.65% 3	17	3.00
Production Supplies/Consumables (apparel, gloves, sticky mats, etc.)	5.88% 1	5.88% 1	29.41% 5	35.29% 6	23.53% 4	17	3.65
Other, as described in question 10, as applicable	0.00% 0	0.00% 0	16.67% 1	0.00% 0	83.33% 5	6	4.67

Q23 12c. Packaging Materials:

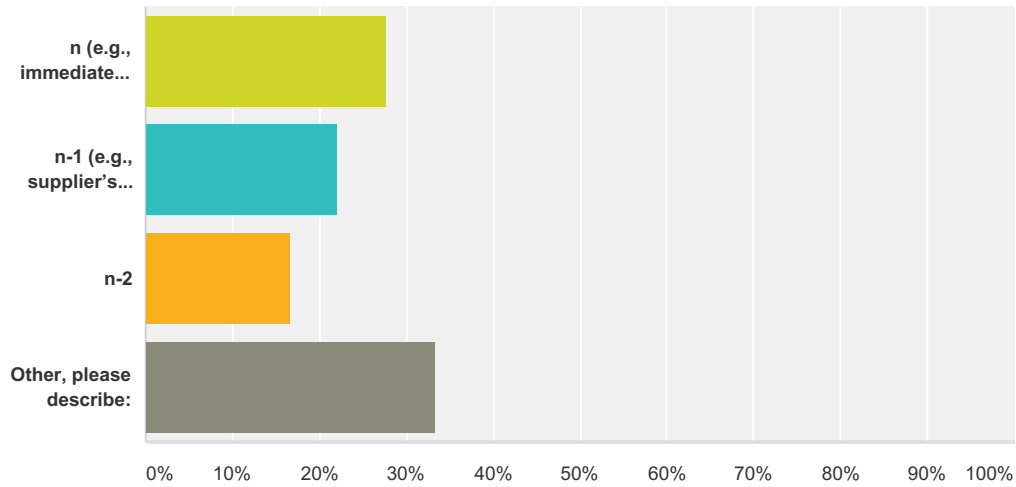
Answered: 17 Skipped: 2



	1	2	3	4	5	Total	Weighted Average
Secondary packaging (packaging that does not contact the final product; outer product box, outer labels)	23.53% 4	47.06% 8	23.53% 4	5.88% 1	0.00% 0	17	2.12
Other, as described in question 10, as applicable	14.29% 1	0.00% 0	0.00% 0	0.00% 0	85.71% 6	7	4.43

Q24 13a. High priority:

Answered: 18 Skipped: 1

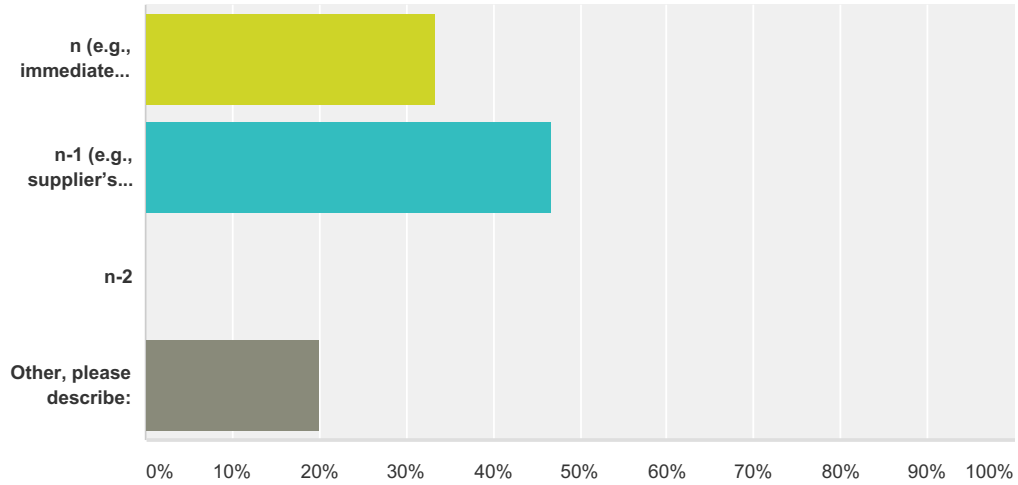


Answer Choices	Responses
n (e.g., immediate supplier to the pharmaceutical manufacturer)	27.78% 5
n-1 (e.g., supplier's supplier)	22.22% 4
n-2	16.67% 3
Other, please describe:	33.33% 6
Total	18

#	Other, please describe:	Date
1	API is source manufacturer -1. All others are n-source manufacturer	2/2/2016 2:34 PM
2	In some cases, as far back as n-4 or n-5	2/9/2015 5:16 PM
3	To the source manufacturer of the API	1/5/2015 2:32 PM
4	we will always try to identify the actual manufacturer and mfg. site of the material	12/11/2014 3:24 PM
5	To the manufacturer of the original chemical entity	12/10/2014 12:14 PM
6	from manufacturer to the point of use.	12/5/2014 9:01 AM

Q25 13b. Priority:

Answered: 15 Skipped: 4

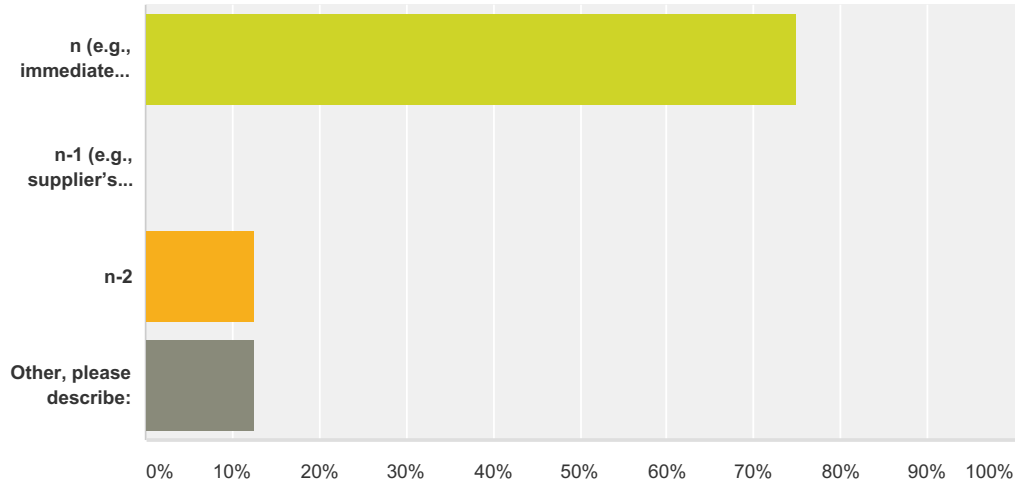


Answer Choices	Responses
n (e.g., immediate supplier to the pharmaceutical manufacturer)	33.33% 5
n-1 (e.g., supplier's supplier)	46.67% 7
n-2	0.00% 0
Other, please describe:	20.00% 3
Total	15

#	Other, please describe:	Date
1	n - source manufacturer	2/2/2016 2:34 PM
2	To the manufacturer of the original chemical entity	12/10/2014 12:14 PM
3	from manufacturer to the point of use.	12/5/2014 9:01 AM

Q26 13c. Low Priority:

Answered: 16 Skipped: 3

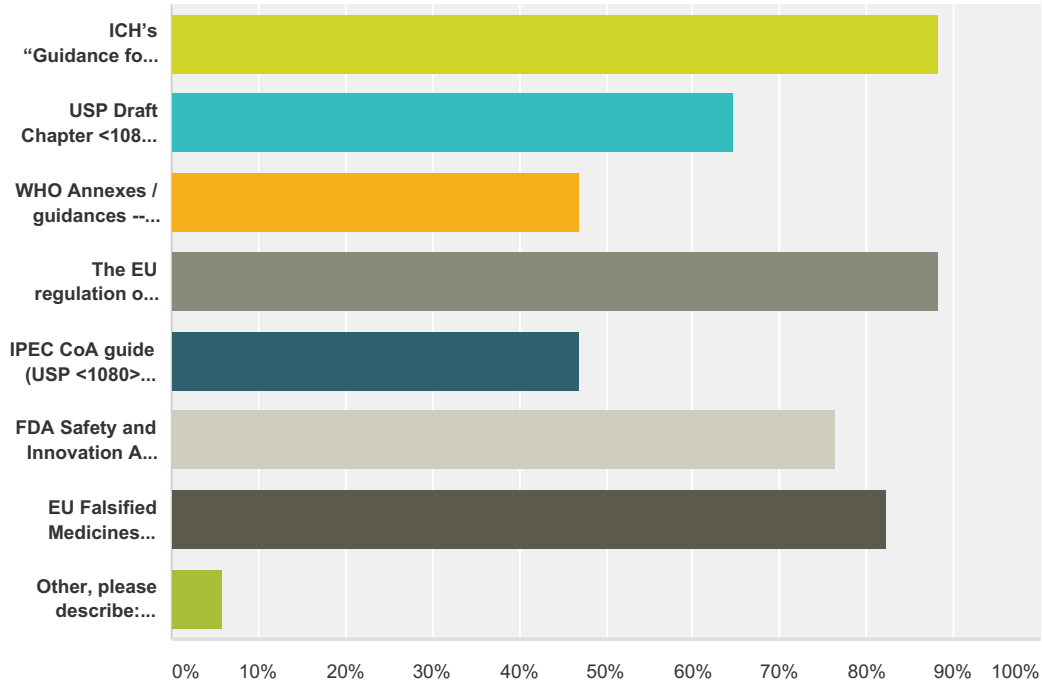


Answer Choices	Responses
n (e.g., immediate supplier to the pharmaceutical manufacturer)	75.00% 12
n-1 (e.g., supplier's supplier)	0.00% 0
n-2	12.50% 2
Other, please describe:	12.50% 2
Total	16

#	Other, please describe:	Date
1	n - source manufacturer	2/2/2016 2:34 PM
2	from manufacturer to the point of use.	12/5/2014 9:01 AM

Q27 14. Which of these regulations, guidelines or standards significantly influence your efforts in the area of supply chain mapping? Choose all that apply:

Answered: 17 Skipped: 2



Answer Choices	Responses
ICH's "Guidance for Industry Q10: Pharmaceutical Quality Systems" (April, 2009) -- States that management of outsourced activities and purchased materials is a key management responsibility	88.24% 15
USP Draft Chapter <1083> on Good Distribution Practices -- Pharmaceutical components and products, medical devices, and dietary supplements beginning with material flow at initial procurement and continuing throughout the supply chain through delivery to the end user	64.71% 11
WHO Annexes / guidances -- Covering GDPs for drug products, actives, and excipients - adhering to guidance that states "to every step in the distribution and supply chain" from when a material is designated to be used in a pharmaceutical process to the person dispensing or providing pharmaceutical products directly to a patient, and that "there should be collaboration between all parties."	47.06% 8
The EU regulation on Good Distribution Practice of Medicinal Products for Human Use -- Includes sections on qualification of suppliers, including transporters, and requires written contracts between supply chain partners that expressly identifies the duties of each party	88.24% 15
IPEC CoA guide (USP <1080> Bulk Pharmaceutical Excipients — Certificate of Analysis -- References the need to provide original manufacture information for pharma excipients	47.06% 8
FDA Safety and Innovation Act (FDASIA) Title VII – drug supply chain -- Language from Title VII along with associated guidances (i.e., DUNS number unique facility identifier for drugs)	76.47% 13
EU Falsified Medicines Directive (Directive 2011/62/EU)	82.35% 14
Other, please describe: (Please copy full regulation or guidance name if applicable)	5.88% 1

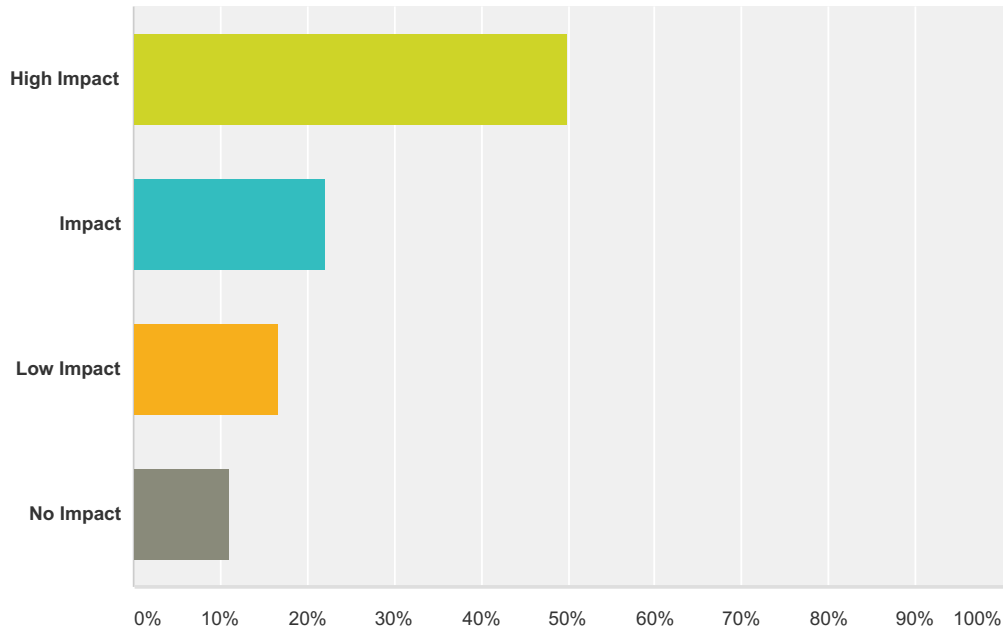
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Total Respondents: 17

#	Other, please describe: (Please copy full regulation or guidance name if applicable)	Date
1	Guarantee authenticity or product, patient safety, and supply to patients	2/9/2015 5:16 PM

Q28 15. What level of influence does the location of the source material impact your focus to prioritize mapping of the supply chain?

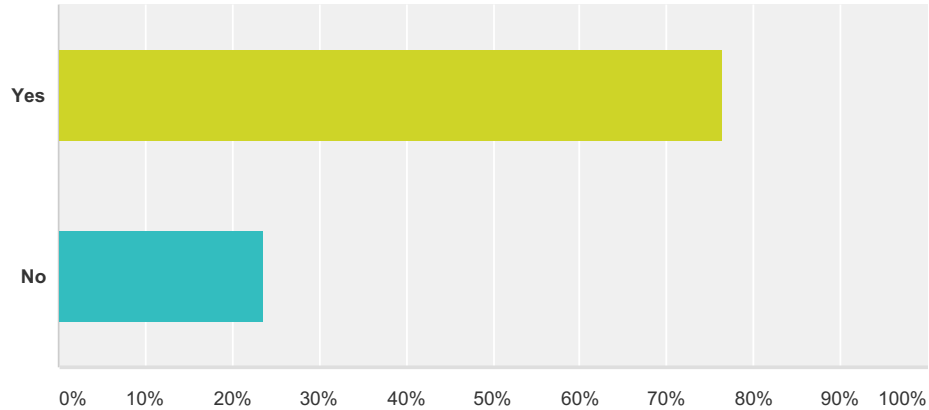
Answered: 18 Skipped: 1



Answer Choices	Responses
High Impact	50.00% 9
Impact	22.22% 4
Low Impact	16.67% 3
No Impact	11.11% 2
Total	18

Q29 16. Are there any specific practices or policies your company uses to take into account location of the source material?

Answered: 17 Skipped: 2

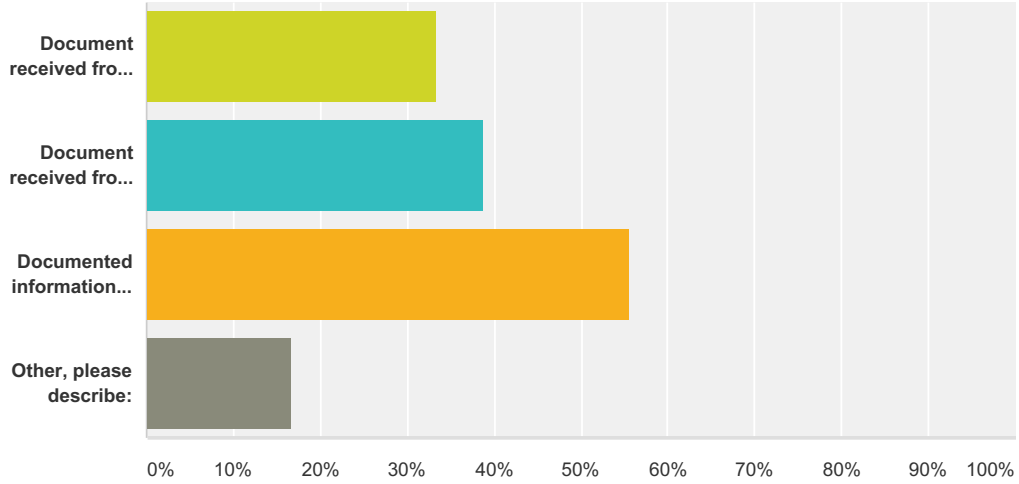


Answer Choices	Responses	
Yes	76.47%	13
No	23.53%	4
Total		17

#	If yes, please elaborate:	Date
1	impacts audit frequency and dual sourcing decisions	2/2/2016 2:34 PM
2	SOP that guides selection of suppliers by source / geography / maturity of country (emerging countries)	2/9/2015 5:16 PM
3	We continuously evaluate the regulatory requirements for the markets we supply and any macroeconomic or geopolitical factors in the locations where we manufacture our products.	2/4/2015 10:37 PM
4	Location / Market Security Risk profiles.	1/21/2015 2:48 PM
5	We gather regulatory intelligence based on location and use that data to design specific on-site reviews.	1/20/2015 9:23 AM
6	Alternative supply chain for critical materials (e.g. API) must be implemented when sourcing of emerging countries is done	1/19/2015 1:42 AM
7	GS1 location and QTA (quality technical agreement) with supplier	1/14/2015 12:42 PM
8	higher risk starting point for China and India	1/9/2015 1:06 PM
9	We use location as a risk factor for assessments and qualifications but not in prioritization of supply chain mapping	1/5/2015 2:32 PM
10	Annual supplier risk assessment process takes into account supplier geographical region of the mfg. location. Using RX360 communication to assess trends/current topics/areas of concern.	12/11/2014 3:24 PM
11	Risk Classification is increased, so oversight increases.	12/10/2014 12:14 PM
12	global decisions and practices govern this process, not our local business unit	12/10/2014 11:37 AM
13	It is taken into account how regulated is the location of the source material.	12/5/2014 9:01 AM

Q30 17. How is the supply chain mapping information maintained? Choose all that apply:

Answered: 18 Skipped: 1

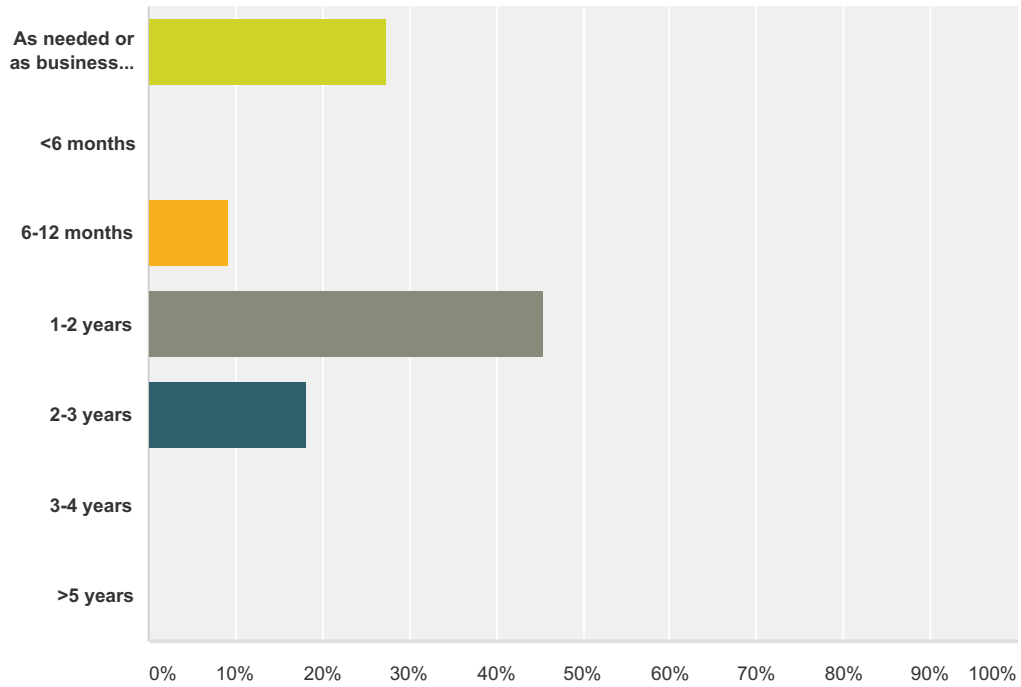


Answer Choices	Responses
Document received from supplier is electronically filed for future retrieval upon business need	33.33% 6
Document received from supplier is electronically filed and periodically reviewed	38.89% 7
Documented information received from supplier is transcribed into software/ program/ document	55.56% 10
Other, please describe:	16.67% 3
Total Respondents: 18	

#	Other, please describe:	Date
1	It is contained in our regulatory filings.	2/4/2015 10:37 PM
2	On a change driven basis	1/15/2015 7:40 AM
3	Internally owned process, periodically reviewed	12/10/2014 11:37 AM

Q31 17a. If you said that the "Document received from the supplier is electronically filed and periodically reviewed", is it reviewed every:

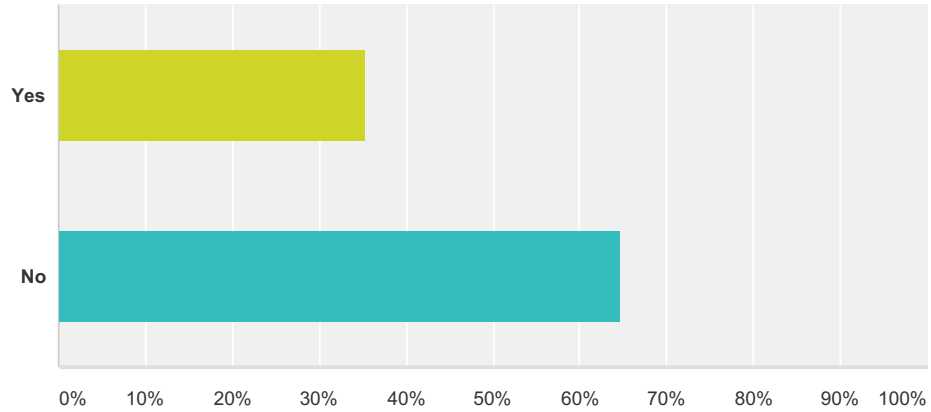
Answered: 11 Skipped: 8



Answer Choices	Responses
As needed or as business demands require	27.27% 3
<6 months	0.00% 0
6-12 months	9.09% 1
1-2 years	45.45% 5
2-3 years	18.18% 2
3-4 years	0.00% 0
>5 years	0.00% 0
Total	11

Q32 18. Does your company plan to expand company resources towards supply chain mapping processes in the future?

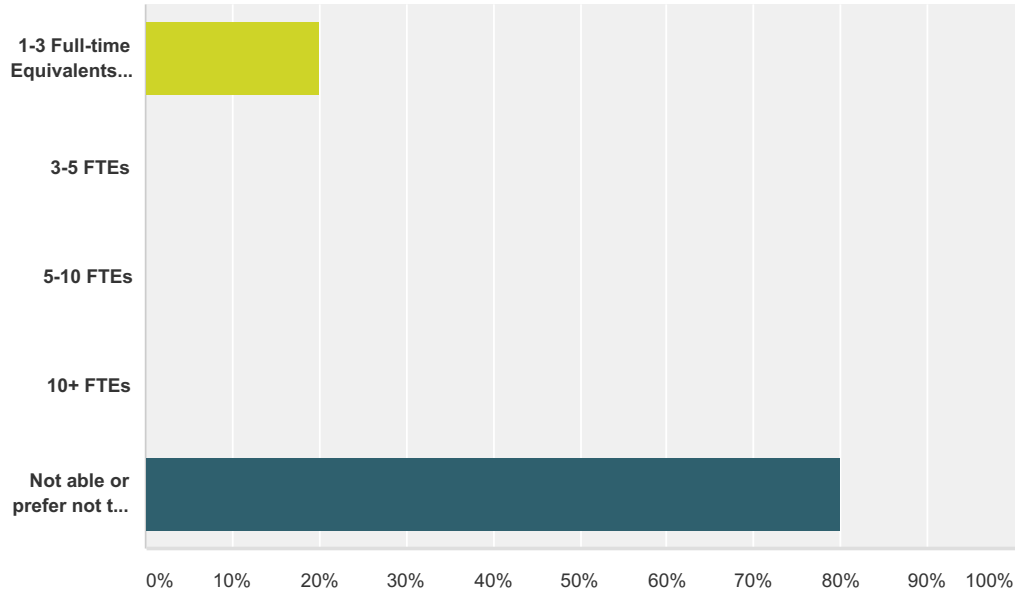
Answered: 17 Skipped: 2



Answer Choices	Responses	
Yes	35.29%	6
No	64.71%	11
Total		17

Q33 18a. If yes, please attempt to quantify the resources, whether it be a combination of a full time responsibility, shared responsibility, or outside resources (i.e., contractor)?

Answered: 10 Skipped: 9



Answer Choices	Responses
1-3 Full-time Equivalents (FTE)s	20.00% 2
3-5 FTEs	0.00% 0
5-10 FTEs	0.00% 0
10+ FTEs	0.00% 0
Not able or prefer not to disclose an estimate	80.00% 8
Total	10

Q34 18b. Please estimated your total organizational expense directly related to supply chain mapping efforts. Please estimate expenses in USD if you are located elsewhere. (all information received will be kept completely confidential):

Answered: 12 Skipped: 7

Answer Choices	Responses
Start-up costs (USD)	100.00% 12
Maintenance costs (per budget year) (USD)	91.67% 11

#	Start-up costs (USD)	Date
1	\$75K (internal) + third party costs	2/9/2015 5:16 PM
2	\$300,000	2/4/2015 10:37 PM
3	Not able to estimate	1/21/2015 2:48 PM
4	2,000,000	1/20/2015 9:23 AM
5	no information disclose	1/19/2015 1:42 AM
6	\$240,000	1/14/2015 12:42 PM
7	300,000	1/12/2015 9:03 AM
8	unknown	1/9/2015 1:06 PM
9	200000	1/5/2015 2:32 PM
10	unknown	12/11/2014 3:24 PM
11	No idea	12/10/2014 12:14 PM
12	n/a	12/10/2014 11:37 AM
#	Maintenance costs (per budget year) (USD)	Date
1	\$20K (internal+ + third party costs	2/9/2015 5:16 PM
2	\$50,000	2/4/2015 10:37 PM
3	Not able to estimate	1/21/2015 2:48 PM
4	100,000	1/20/2015 9:23 AM
5	no information disclose	1/19/2015 1:42 AM
6	75,000	1/14/2015 12:42 PM
7	75,000	1/12/2015 9:03 AM
8	100000	1/5/2015 2:32 PM
9	unknown	12/11/2014 3:24 PM
10	No idea	12/10/2014 12:14 PM
11	n/a	12/10/2014 11:37 AM