Electronic Regulatory Submissions Survey
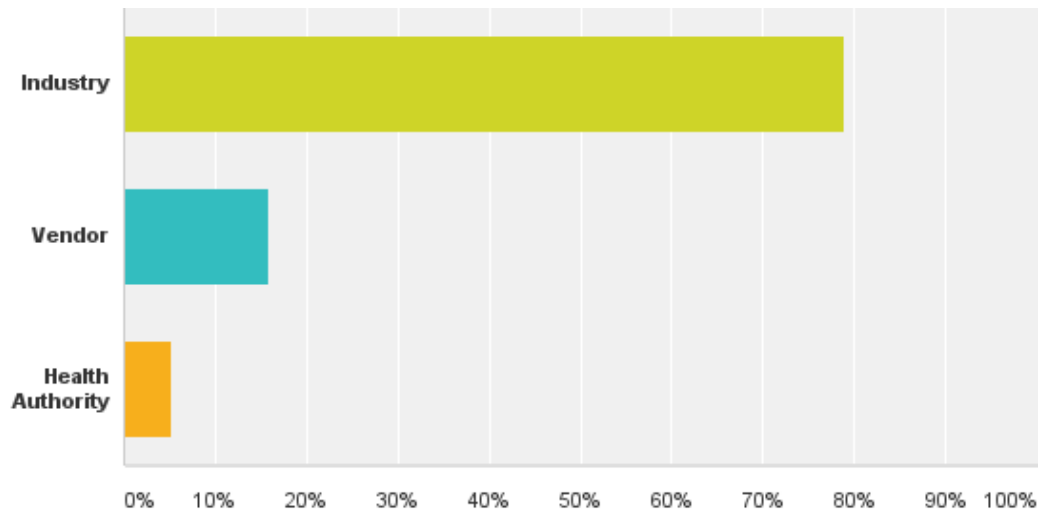
Monday, June 22, 2015

19

Total Responses

Date Created: Monday, June 15, 2015

Complete Responses: 19

Q1: Which best describes your work affiliation?
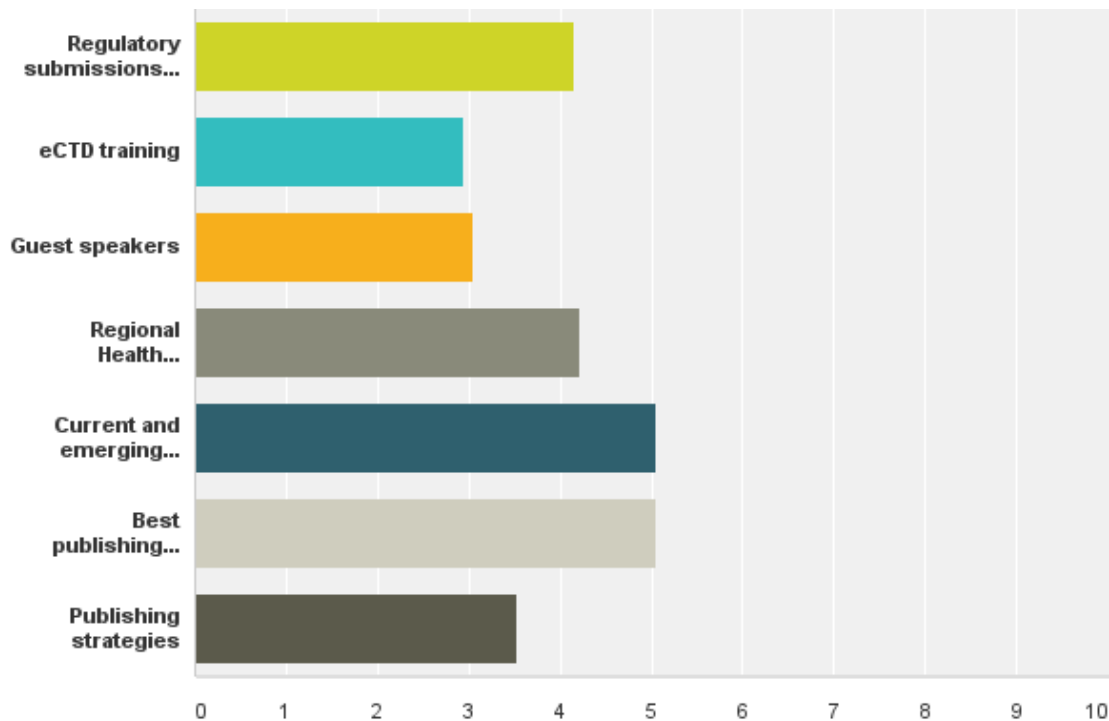
Answered: 19   Skipped: 0

Q1: Which best describes your work affiliation?

Answered: 19   Skipped: 0

Answer Choices	Responses	
Industry	78.95%	15
Vendor	15.79%	3
Health Authority	5.26%	1
Total		19

Q2: What would you like the ERS Group to focus on?

Answered: 19   Skipped: 0

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Answered: 19   Skipped: 0

	1	2	3	4	5	6	7	Total	Score
Regulatory submissions technology	15.79% 3	5.26% 1	15.79% 3	21.05% 4	26.32% 5	15.79% 3	0.00% 0	19	4.16
eCTD training	0.00% 0	15.79% 3	10.53% 2	15.79% 3	0.00% 0	26.32% 5	31.58% 6	19	2.95
Guest speakers	5.26% 1	5.26% 1	5.26% 1	15.79% 3	31.58% 6	15.79% 3	21.05% 4	19	3.05
Regional Health Authority requirements	31.58% 6	5.26% 1	0.00% 0	15.79% 3	21.05% 4	15.79% 3	10.53% 2	19	4.21
Current and emerging standards impacting electronic submissions	26.32% 5	36.84% 7	5.26% 1	5.26% 1	10.53% 2	5.26% 1	10.53% 2	19	5.05
Best publishing practices	21.05% 4	21.05% 4	31.58% 6	10.53% 2	0.00% 0	15.79% 3	0.00% 0	19	5.05
Publishing strategies	0.00% 0	10.53% 2	31.58% 6	15.79% 3	10.53% 2	5.26% 1	26.32% 5	19	3.53

Q3: What size is your organization?

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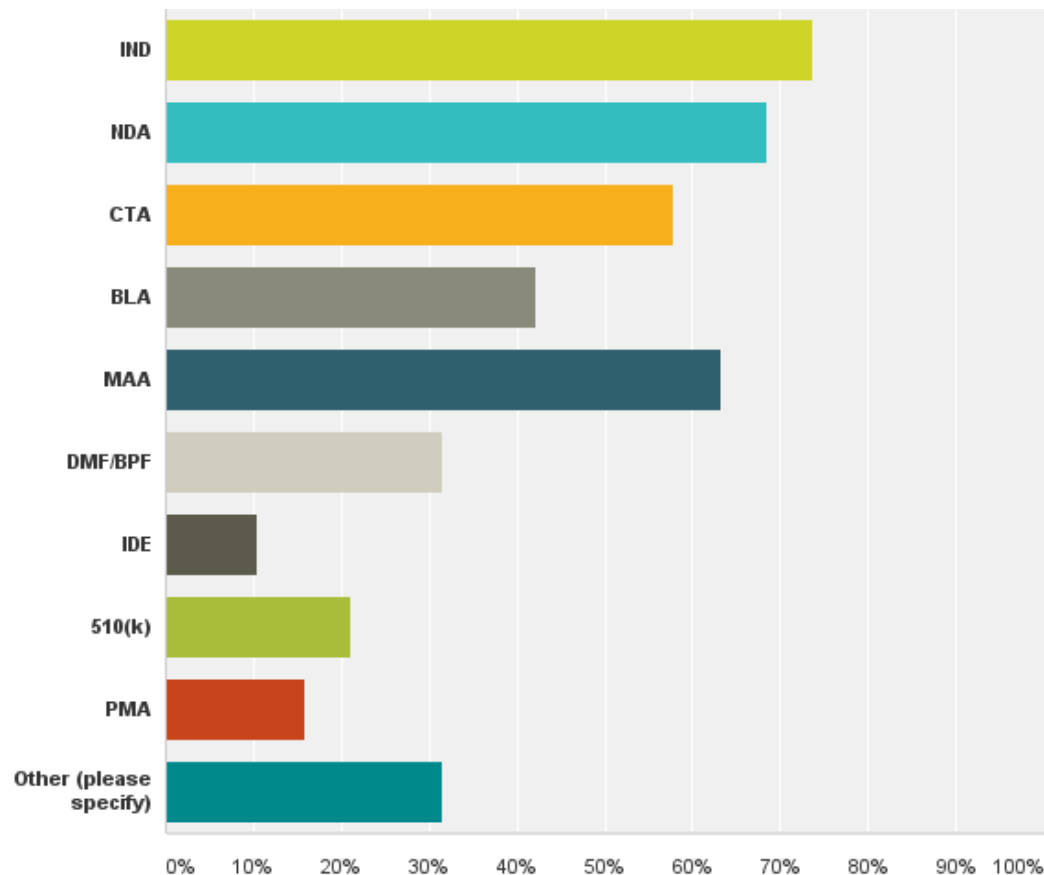
Answered: 19   Skipped: 0

Answer Choices	Responses	
1-10	**5.26%**	1
11-50	**10.53%**	2
51-200	**15.79%**	3
201-500	**5.26%**	1
501-1,000	**26.32%**	5
1,001-5,000	**5.26%**	1
5,001-10,000	**10.53%**	2
10,000+	**21.05%**	4
Total		**19**

Q4: What type(s) of health authority applications does your company submit? (select all that apply)
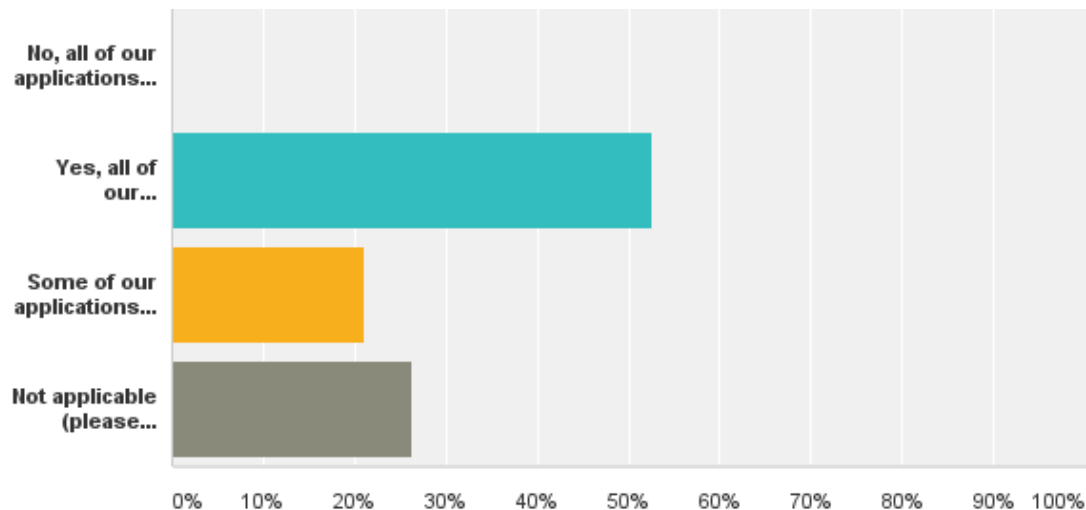
Answered: 19   Skipped: 0

Q4: What type(s) of health authority applications does your company submit? (select all that apply)

Answered: 19   Skipped: 0

Answer Choices	Responses	
IND	**73.68%**	14
NDA	**68.42%**	13
CTA	**57.89%**	11
BLA	**42.11%**	8
MAA	**63.16%**	12
DMF/BPF	**31.58%**	6
IDE	**10.53%**	2
510(k)	**21.05%**	4
PMA	**15.79%**	3
Other (please specify)	**31.58%**	6
Total Respondents: 19		

Q5: Does your company already submit health authority applications in eCTD format?

Answered: 19   Skipped: 0

Q5: Does your company already submit health authority applications in eCTD format?
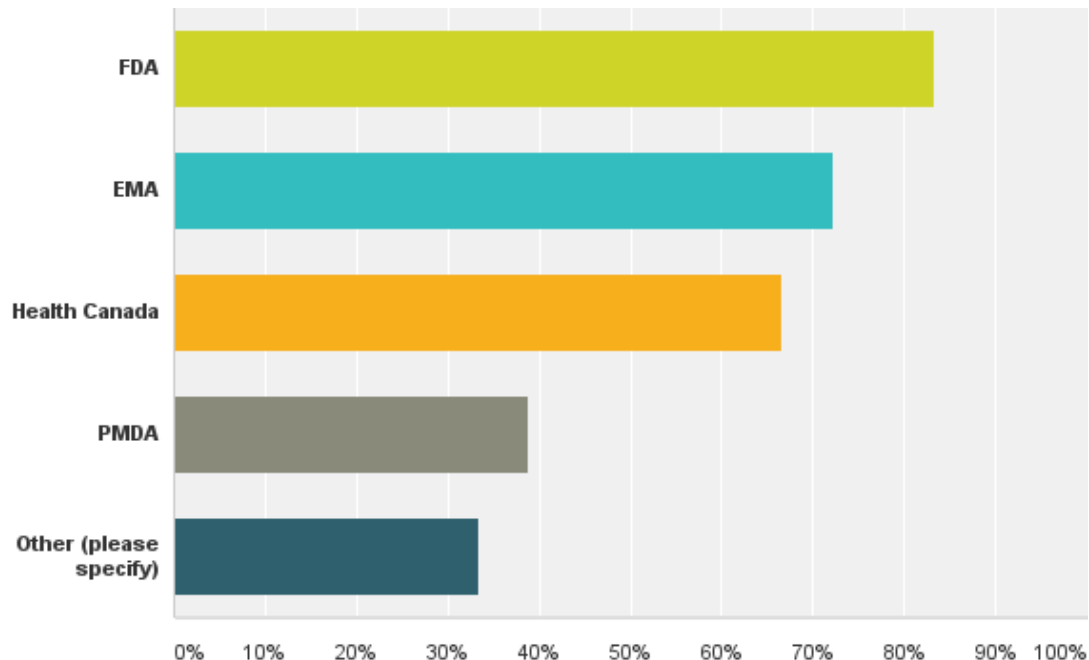
Answered: 19   Skipped: 0

Answer Choices	Responses	
No, all of our applications are in paper format.	0.00%	0
Yes, all of our applications are in eCTD format.	52.63%	10
Some of our applications are in eCTD format and some are still in paper format.	21.05%	4
Not applicable (please specify)	26.32%	5
Total		19

Q6: To which health authorities does your company submit applications in eCTD format?

Answered: 18   Skipped: 1

Q6: To which health authorities does your company submit applications in eCTD format?

Answer Choices	Responses	
FDA	83.33%	15
EMA	72.22%	13
Health Canada	66.67%	12
PMDA	38.89%	7
Other (please specify)	33.33%	6
Total Respondents: 18		

Other (please specify)

- Saudi, Swissmedic
- Swiss AU
- We are the health authority
- Saudi Arabia
- Many international including Australia, South Africa, Saudi Arabia
- Don't actually do submissions, interested in all

Q7: What are your biggest hurdles to submitting applications in eCTD format?

13 out of 19

Response Text

- Harmonizing standards throughout the company. IT problems affecting performance.
- Awareness in HA requirements
- Poor submission-readiness
- No support for technology e.g. Toolbox, eCTD builder
- Resources; additional staff would be nice. Budget for tools is adequate... just not enough hands at the required times.
- Vigilance
- Document lifecycle management standards, proper and consistent metadata tagging, evolving submission standards compliance (IDMP, RPS, SPL), systems integration, validation compliance and implementation
- Late document receipt.
- Knowing where to place out of the ordinary documents.
- We do not have writing or publishing services in-house but use contractors
- Nil
- We've got it covered
- Don't have an eCTD tool

Q8: Any additional thoughts and/or ideas for the community?

Response Text

- Working globally in a global company raises many issues. Keeping up to date with a fast-changing environment. Overcoming problems when working to tight timelines when submissions are being prepared in several different locations and time zones.
- Should have set agenda for discussion.
- Excited to have a new venue. Many thanks.
- Troubleshooting issues and questions that arise
- Not at this time
- Nil
- No reason to not submit electronically!