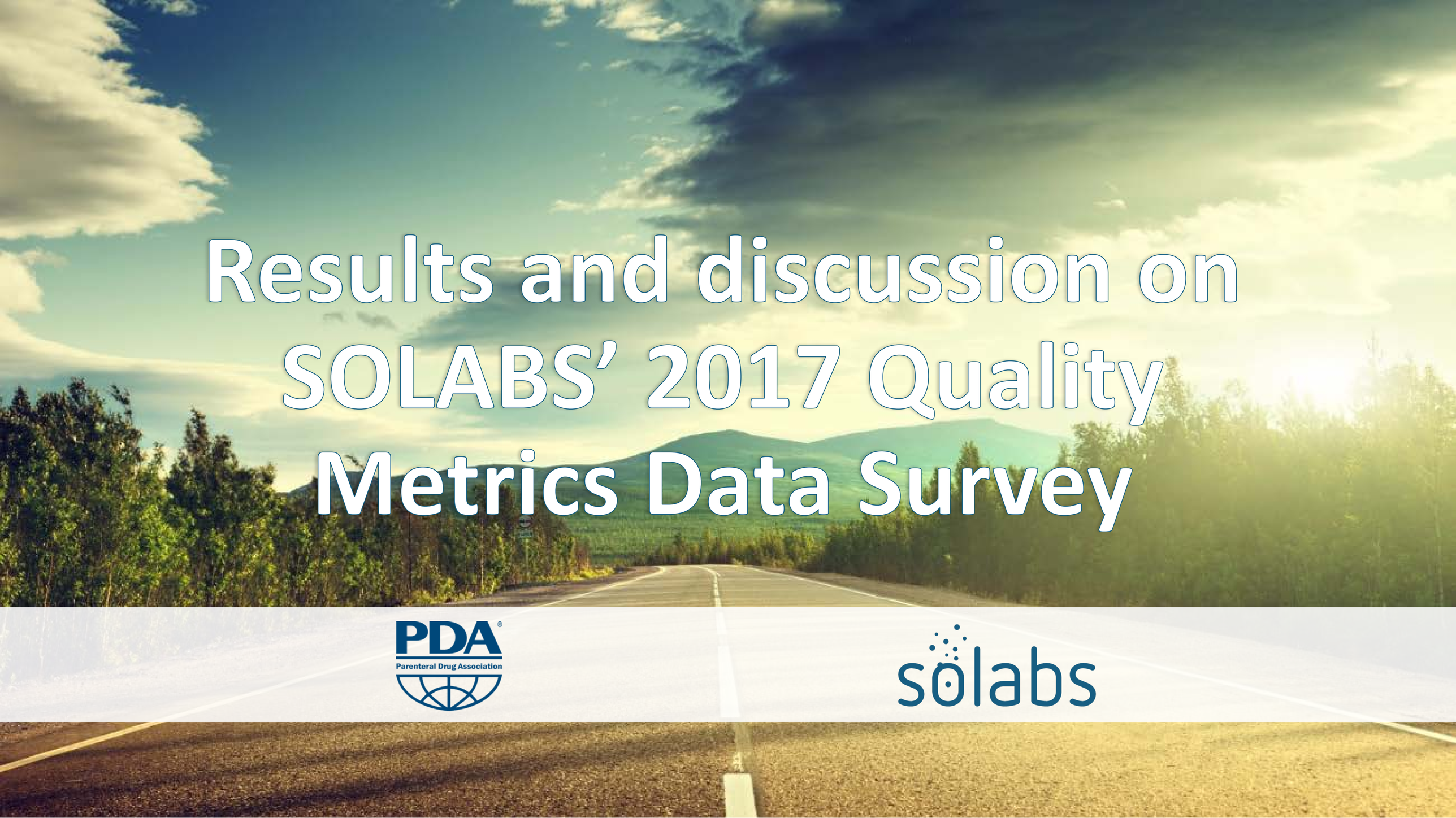

Results and discussion on SOLABS' 2017 Quality Metrics Data Survey

PDA Parenteral Drug Association

solabs

Introduction: Philippe Gaudreau

- President & CEO of SOLABS
- Co-founded SOLABS in 1999
- Chemical Engineer by Training
- Expertise as Business Analyst/Product Manager
- Passionate about quality automation, business process management and optimization, and an expertise in document life cycle management
- Email: philippe.gaudreau@solabs.com

Acknowledgement:

- This presentation includes publicly available information for the FDA. Reference:

https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm526869.htm

PDA Parenteral Drug Association

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Context of our Survey

- In November 2016, the FDA issued a Draft Guidance on the Submission of Quality Metrics Data. SOLABS' 2017 Quality Metrics Data Survey aims at understanding how Life Sciences companies have responded to these requirements.

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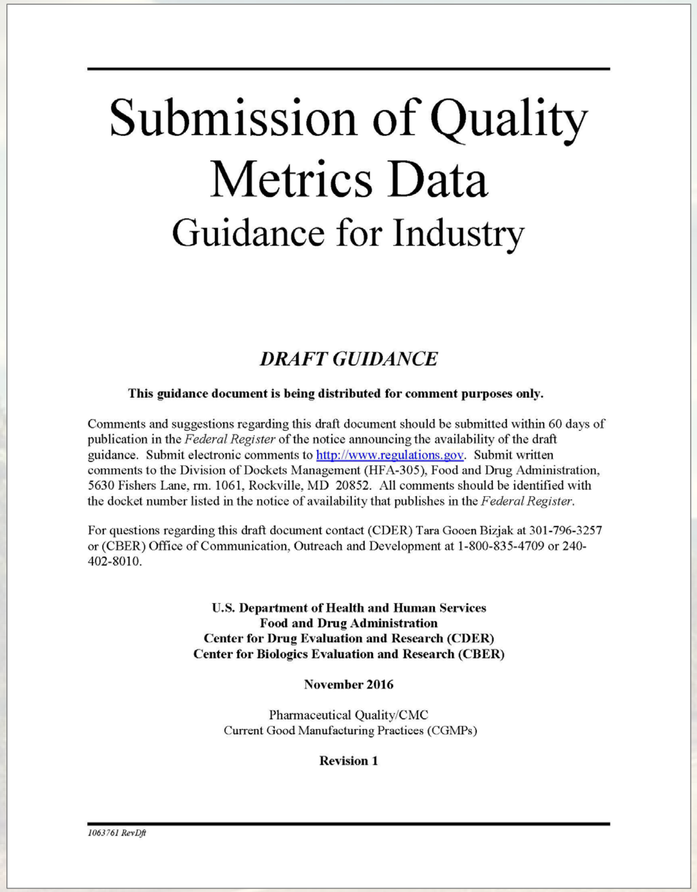
FDA Submission of Quality Metrics Data: Draft Guidance



Submission of Quality Metrics Data

Guidance for Industry

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Comments and suggestions regarding this draft document should be submitted within 60 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit electronic comments to http://www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number listed in the notice of availability that publishes in the *Federal Register*.

For questions regarding this draft document contact (CDER) Tara Gooen Bizjak at 301-796-3257 or (CBER) Office of Communication, Outreach and Development at 1-800-835-4709 or 240-402-8010.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)

November 2016

Pharmaceutical Quality/CMC
Current Good Manufacturing Practices (CGMPs)

Revision 1

1063761 RevDft

- The selected metrics are not intended to be an all inclusive set of the quality metrics that manufacturers may find useful to assess a product and manufacturer's state of quality.
- Submission of Information is Voluntary
- FDA does not intend to take enforcement action based on errors in a quality metrics data submission made to this voluntary phase of the reporting program, provided the submission is made in good faith
- Inclusion on the Quality Metrics Reporters List for participants
- Expected date for the electronic portal : early 2018

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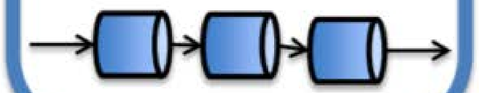
Metrics that FDA intends to Calculate

Robustness of Commercial Manufacturing Process



Lot Acceptance Rate

Robustness of Laboratory Operation

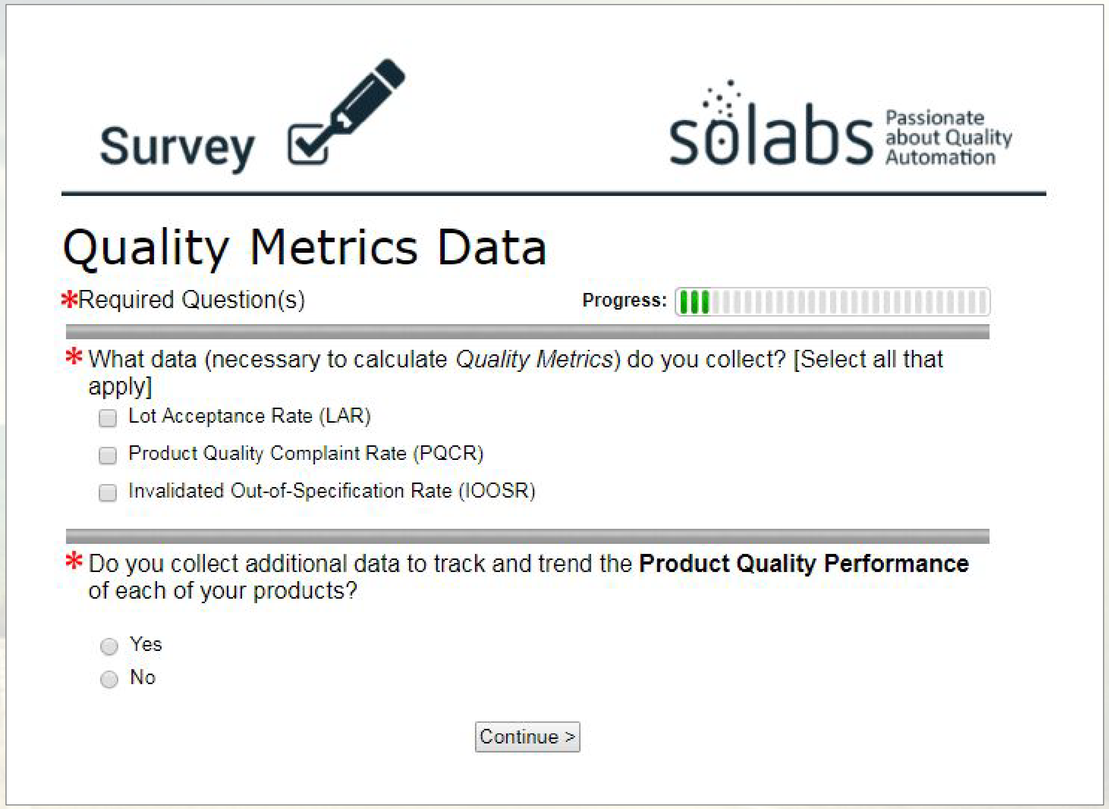
Invalidated Out-of-Specification Rate

Voice of the Patient/Customer

Product Quality Complaint Rate

SOLABS Quality Metrics Data Survey

Between June 18, 2017 and August 13, 2017, SOLABS requested survey responses from members of the North American Life Sciences community in regard to their practices collecting Quality Metrics Data, specifically pertaining to FDA's November 2016 Draft Guidance on the Submission of Quality Metrics Data.



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SOLABS Quality Metrics Data Report

- 56 surveys submitted in total
- We hope you will find the results interesting and very useful in comparing your current practices to other companies
- It is important to remember that regulatory agencies through their inspection obtain similar data
- The practices that most companies use are considered best practices and become the current good manufacturing practices or CGMP
- The concept is that the industry would evolve and higher standards would result without regulators constantly revising the regulations
- Compare and evaluate your practices to what are the best practices and don’t fall behind!

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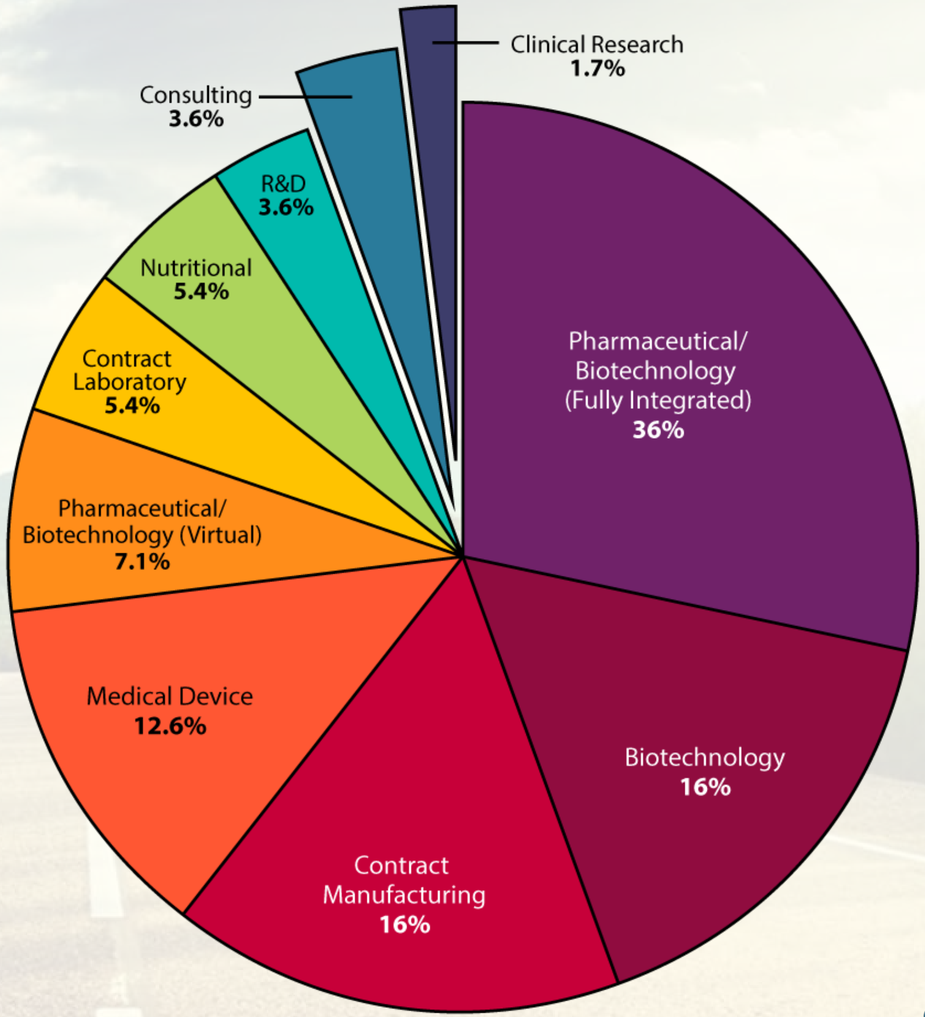
SOLABS Quality Metrics Data Report: Q1

Question #1: In what vertical of the Life Sciences does your company operate?



*During the voluntary phase of the reporting program, FDA will accept voluntarily submissions of data from owners and **operators of human drug establishments**. FDA expects that the large majority of voluntary reports will be submitted by establishments engaged in the manufacture, preparation, propagation, compounding, or processing of finished dosage forms (FDF) of "covered drug products" or active pharmaceutical ingredients (API) used in the manufacture of "covered drug products."*

(https://www.fda.gov/Drugs/DevelopmentApprovalProcess/Manufacturing/ucm526869.htm)

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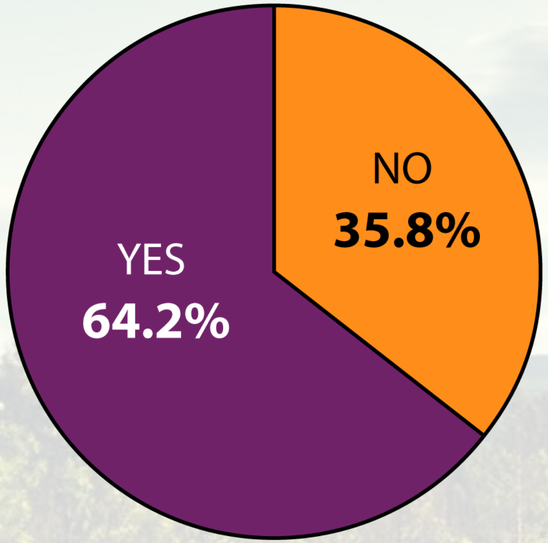
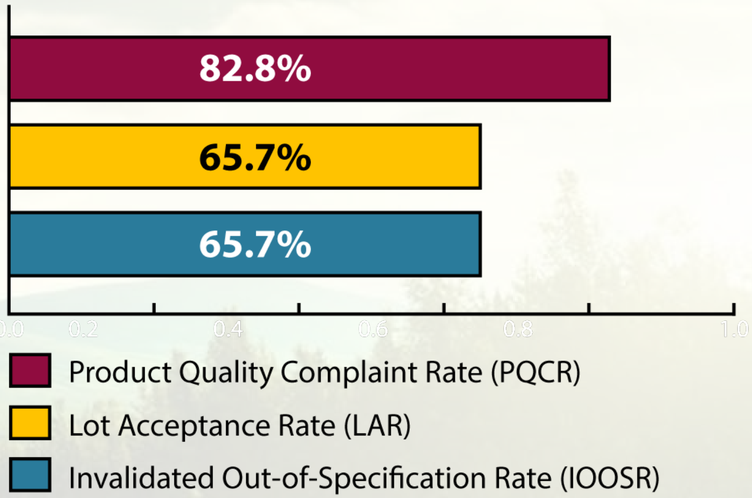
SOLABS Quality Metrics Data Report: Q2

Question #2: Are you currently collecting data necessary to calculate Quality Metrics as defined by FDA?



***COMMENT**: Appears that there is still some catch-up work to be done by the companies participating in our survey. The only effective way to collect the information required by FDA is to have an EQMS.*

Question #2A: IF YES to 2, what data (necessary to calculate Quality Metrics) do you collect?



***COMMENT**: These results pretty much reflect the different business models participating in the survey.*

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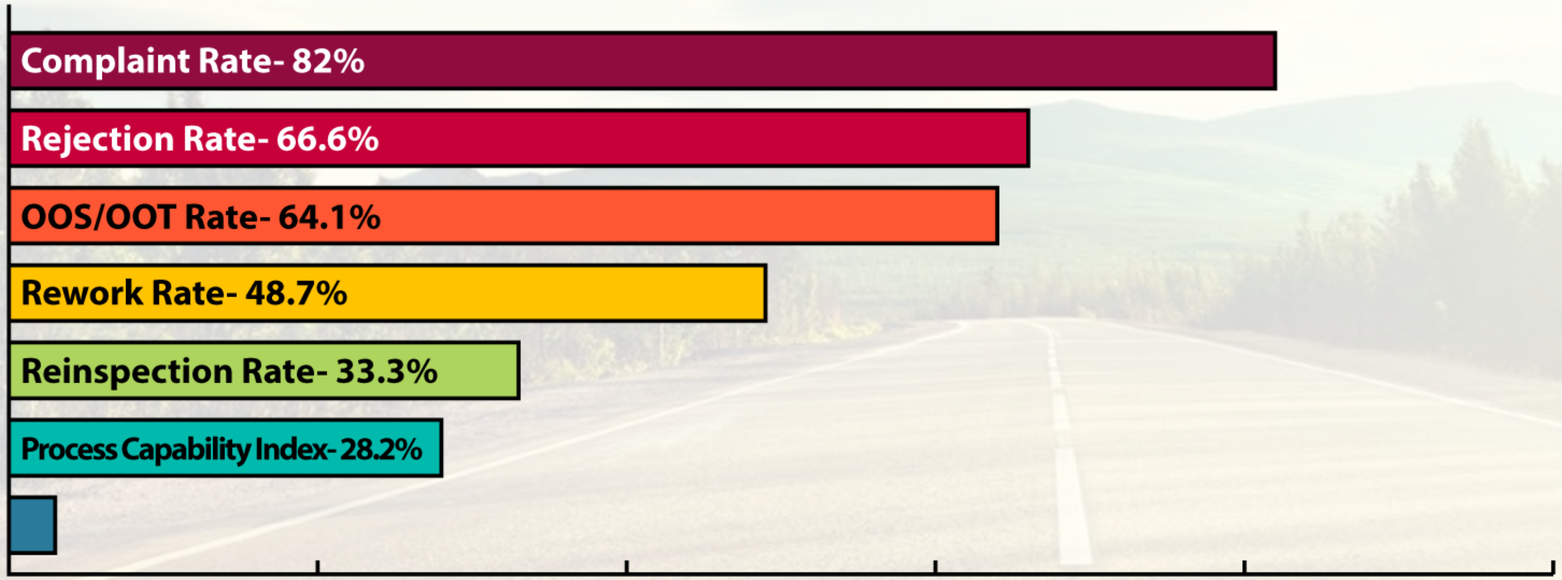
SOLABS Quality Metrics Data Report: Q3

Question #3: Do you collect additional data to track and trend the Product Quality Performance of each of your products?

Question #3A: IF YES to 3, what additional data to track & trend Product Quality Performance do you collect? [*Select all that apply*]



Other- 1 vote **EACH** for: APR, QMR, QMS, Root Cause on CAPA, Report/Project Turnaround Time

***COMMENT**: Data is not being collected regarding Deviations, NCRs and Change Controls for individual products.*

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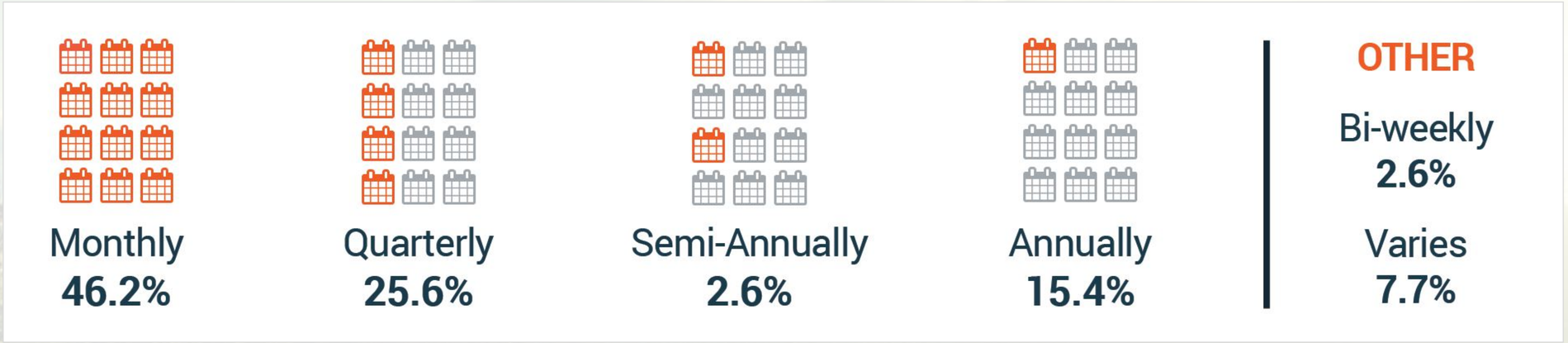
SOLABS Quality Metrics Data Report: Q3

Question #3B: IF YES to 3, what is the frequency of reporting Quality Metrics Data for Product Quality Performance?



***COMMENT**: From our experience regulators would be looking for at least quarterly but monthly is considered best practice.*

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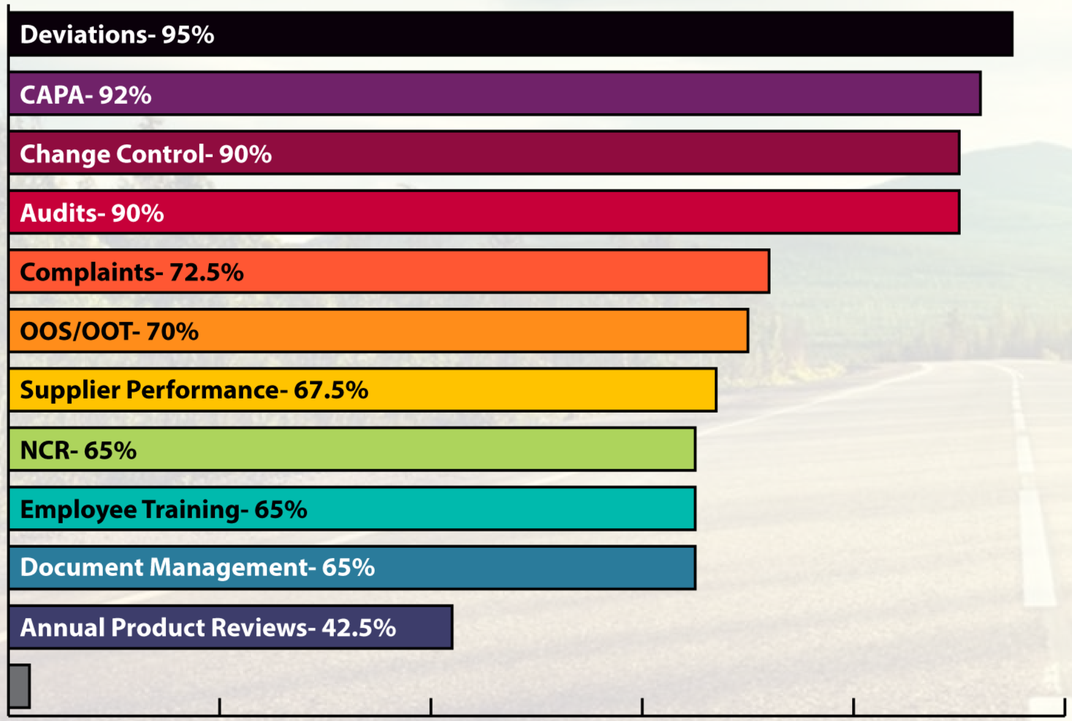
SOLABS Quality Metrics Data Report: Q4

Question #4: Do you collect data & calculate additional metrics to measure Quality System & Sub-Systems Performance?

Question #4A: IF YES to 4, please select the metrics you use for each of the Quality Sub-Systems. [*Select all that apply*]



***COMMENT**: There is good information here that can be used to benchmark against... Quality Control and Quality Assurance cycle times should be measured as well. Operational efficient and timely decision making is important. On-time testing percentage and on-time disposition percentage would be good additions to the list.*

***Other**- 1 vote EACH for: Validation Review Completion, Quality Improvement Initiatives*

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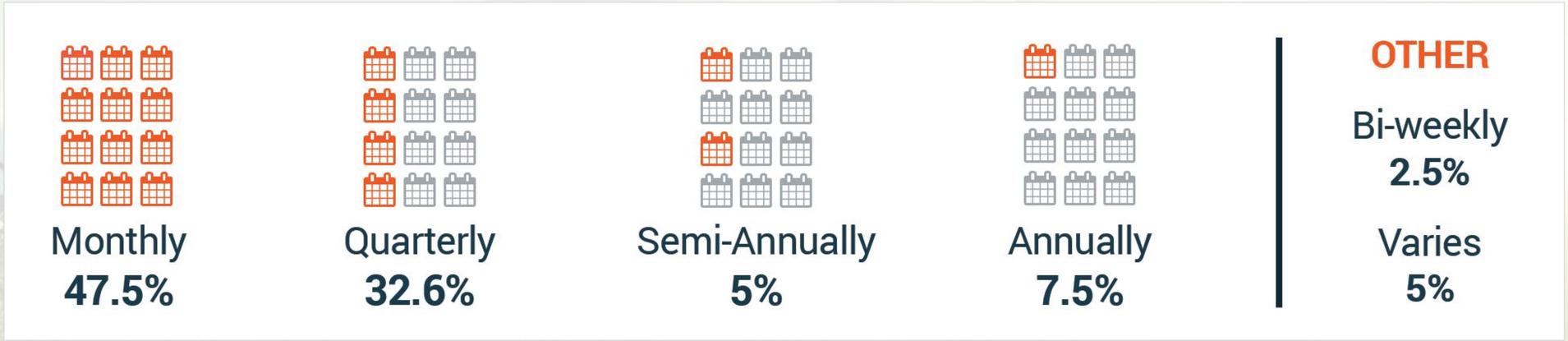
SOLABS Quality Metrics Data Report: Q4

Question #4B: IF YES to 4, what is the frequency of reporting Quality Metrics Data for the Quality System and Sub-System Performance?



***COMMENT**: From my experience regulators would be looking for at least quarterly but monthly is considered best practice.*

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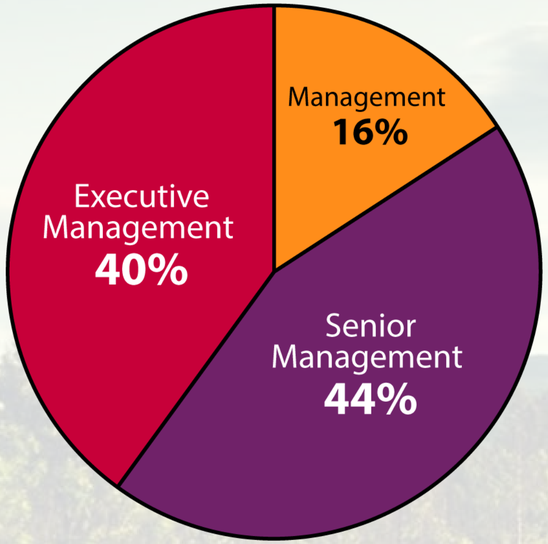
SOLABS Quality Metrics Data Report: Q5

Question #5: Do you collect any other data to evaluate the Quality culture at your company? If Yes, please describe briefly.

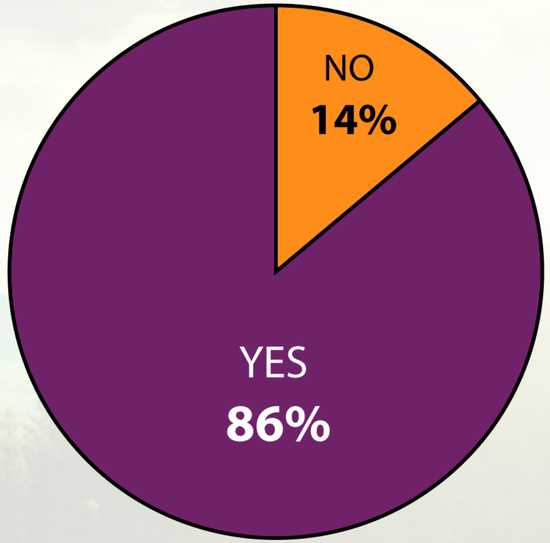
- Medwatch data
- Completed and communicated the results from a Quality Culture Survey
- Continuous Improvement protects, validation process and new product introduction
- We do employees engagement survey on a yearly basis.
- KPI for corporate reporting
- Right the first time batches
- Quality Improvement Initiatives including all the systems
- Deviation trending only

SOLABS Quality Metrics Data Report: Q6/7

Question #6: What level of your organization reviews Quality Metrics Data?



Question #7: Do you hold formal meetings to review the Quality Metrics Data and determine next steps?



***COMMENT**: There is good information here that can be used to benchmark against.*

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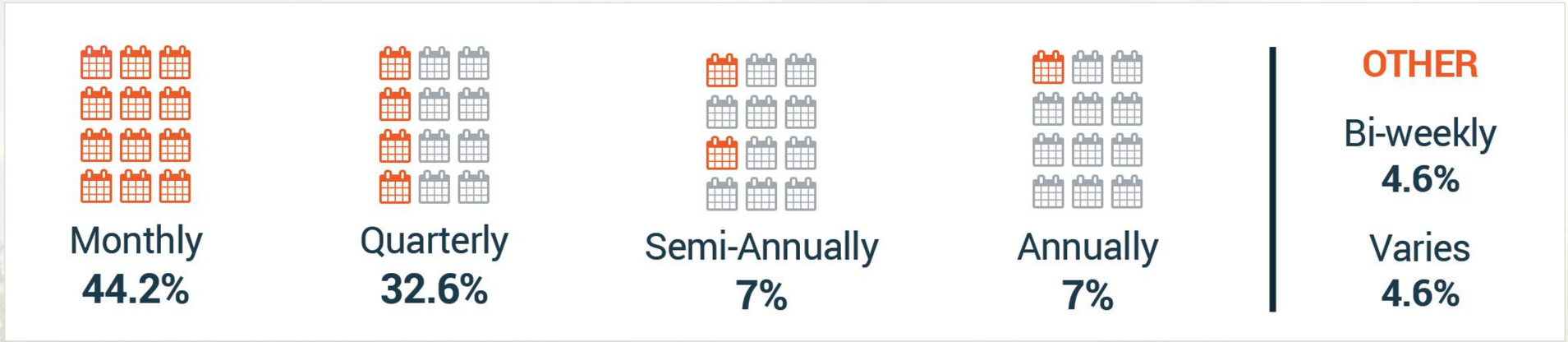
SOLABS Quality Metrics Data Report: Q7

Question #7A: IF YES to 7, at what frequency does that meeting occur?



***COMMENT**: From our experience regulators would be looking for at least annually.*

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Publishing quality metrics on a periodic basis

WORK SHOP

Understanding what is expected from the guidance.

Process to submit data and records.

Gather questions that can be submitted to the FDA
(responses would be shared)

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Submission of Quality Metrics Data

Benefits of Participation

- Work with establishments towards early resolution of potential quality problems
- Improved inspection effectiveness
- FDA is considering use of calculated metrics as an element of the post-approval manufacturing change reporting program
- Reduction in inspection frequency
- Inclusion on the Quality Metrics Reporters List

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Thoughts?

Submission of Quality Metrics Data

- 5 minutes to go through reference no. 1 for everyone.

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Submitting Data – Who is more likely to submit?

Quality Metrics Data Reports

- Product reports submitted by product reporting establishments
  - The subject of a product report is a covered drug product or an API used in a covered drug product

OR

- Site reports submitted by site reporting establishments
  - The subject of a site report is a single covered establishment, individually listing data associated with each covered drug product or API used in a covered drug product

11

References:

To add…

Submitting Data – Ownership within organizations

SITE REPORTING VS PRODUCT REPORTING		
Type of Organization	**Site Reporting**	**Product Reporting**
Medical Device	N/A	N/A
Biotechnology/Pharma (No Commercial Product)	Unlikely	Unlikely
Integrated Biotech/Pharma	Most likely	Most likely
Virtual Biotech/Pharma	Unlikely	Most likely
CRO	Unlikely	Unlikely
CMO	Most likely	Participant
Contract laboratory	Unlikely	Participant
Importer/Distributor of drug products	Unlikely	Most likely

Submitting Data – Ownership within organizations

FDA believes that the quality control unit (QCU) in each reporting establishment for a covered 188 drug product or API used in a covered drug product will generally be best positioned to compile 189 reports for submission to FDA, considering the QCU responsibilities and authorities for the oversight of drugs as described in 21 CFR 211.22.

Do we agree?

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Submitting Data – Information to submit

Data Element Name	Data Element Label	Data Element Type	Data Element Description
MONOGRPH	Applicable Monograph	Text	
PRODTYPE	Drug Product Type	Text	PRODTYPE = API, FDF
APPLICNT	Applicant Name	Text	
FINLBLER	Final Labeler Name	Text	
LABELER	Final Labeler Codes	Num	
APPLTYPE	Application Type	Text	APPTYPE = NDA, ANDA, BLA DMF, or NA
APPNUM	Application Number	Text	
NDCCODE	NDC Product Code	Num	
TIMEPRD	Time Period Start	Date	
TIMEPRD	Time Period End	Date	
LTSATT	Lots Attempted	Num	Number of lots attempted of the product
LTSREJ	Lots Rejected	Num	Number of specification-related rejected lots of the product
APRWIDD	Attempted Lots	Num	Number of attempted lots pending disposition (more than 30 days)
OOSRES	Out-of-Specification Results	Num	Number of OOS results - Finished product (including stability testing)
LTRELTST	Lot Release Tests	Num	Number of lot release tests conducted for commercial use

Submitting Data – Information to submit

OOSRESIN	Out-of-Specification Results Invalidated	Num	Number of OOS results for finished product and stability tests for the product that are invalidated due to lab error
PRODQCMP	Product Quality Complaints	Num	Number of product quality complaints received for the product distributed in the United States
LTSREL	Lots Attempted and Released	Num	Number of lots attempted that are released for distribution or for the next stage of manufacturing the product
APRWIDD	APR/PQR Completed	Text	Have associated APRs or PQRs been completed within 30 days of annual due date for the product? APRWIDD = Y or N
APRPQRS	APR or PQR Required	Num	Number of APRs or PQRs required for the product
DUNSNUM	DUNS Number	Num	A unique nine-digit identification number for each physical facility

Submitting Data – Information to submit

Data Element Name	Data Element Label	Data Element Type	Data Element Description
			location
DOSAGE FORMS	Dosage Form	Text	Associated finished dosage form
FEINUM	Facility Establishment Inventory Number	Num	Facility Establishment Inventory Number
ACTIVITY	Establishment Activity	Text	Subset of Business Operations: Analytical testing, Pack, Manufacture, Other
QUARTER	Reporting Quarter	Text	QUARTER= 1, 2, 3, or 4

Submitting Data – Format


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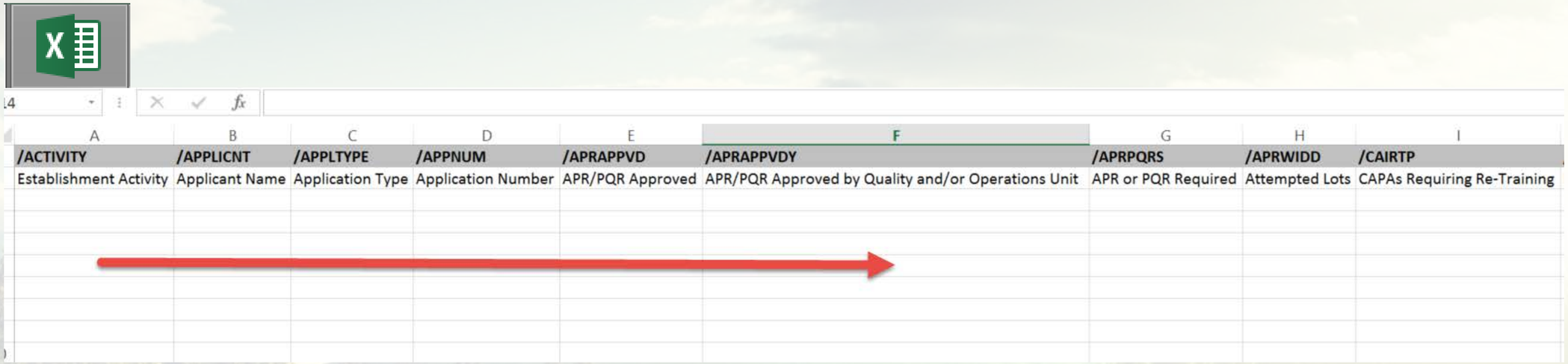
Submitting Data – Format



	A	B	C	D	E	F	G	H	I
	/ACTIVITY	/APPLICNT	/APPLTYPE	/APPNUM	/APRAPPVD	/APRAPPVDY	/APRPQRS	/APRWIDD	/CAIRTP
	Establishment Activity	Applicant Name	Application Type	Application Number	APR/PQR Approved	APR/PQR Approved by Quality and/or Operations Unit	APR or PQR Required	Attempted Lots	CAPAs Requiring Re-Training

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Typical Flow

- Create repository for this program
- Decide which appendices is relevant for your organization
- Create template
- Collect data and generate calculations for year 2017
- Exchange with FDA (Email: OPQ-OS-QualityMetrics@fda.hhs.gov)
- Prepare report (Optional 300 word field for reporters)
- Format data and report
- Archive and store data reported
- Upload on FDA’s portal


ENGAGE!
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