



DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY: FINDINGS

Presented at *MDSAP: Current Status and Future Plans*
Seminar hosted by DITTA in conjunction with IMDRF
Monday, March 13 2017

Patrick Hope
MITA Executive Director; DITTA Chair





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

A few words about our friend Klaus Stitz:





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY INTRODUCTION

Objective:

Improve industry participation in MDSAP

Goal:

Widespread adoption and use of MDSAP

Survey methodology:

Conducted online January 15-February 24
53 participants

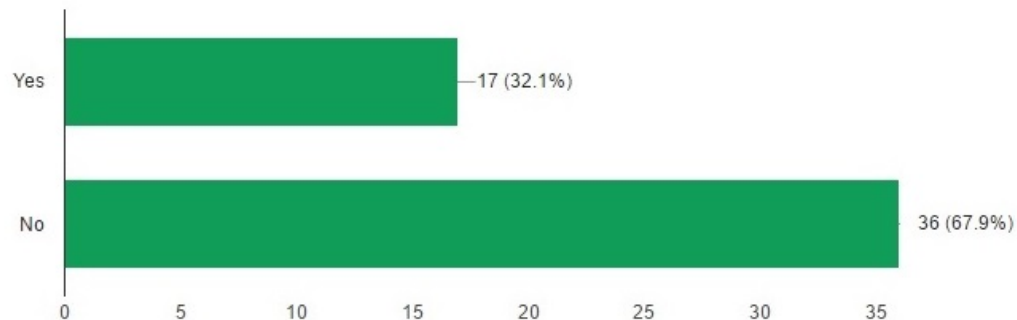




MDSAP INDUSTRY PARTICIPATION SURVEY MAJOR THEMES

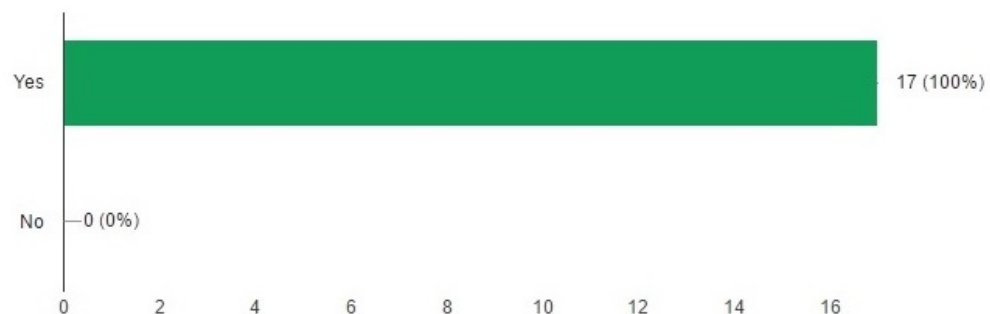
- Most respondents did NOT participate in MDSAP pilot

Has your company participated in the MDSAP pilot? (53 responses)



- Those that DID participate found value in the program

Was the participation of value? (17 responses)



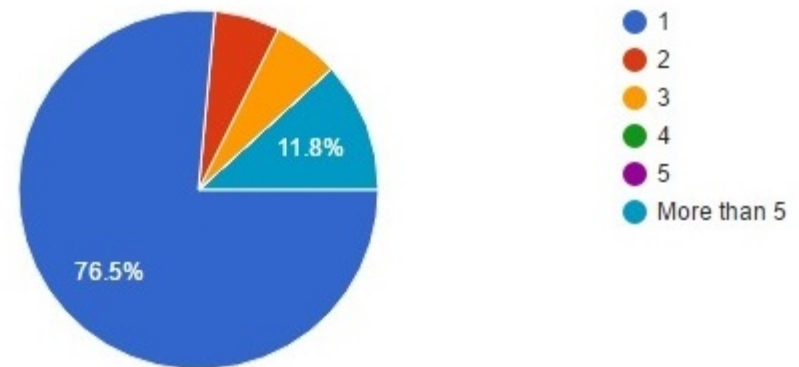


DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY MAJOR THEMES

- Most participants only signed up 1 facility/manufacturing site

How many sites/facilities participated? (17 responses)



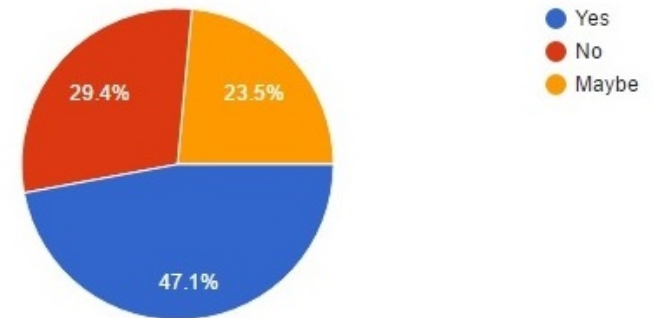


DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

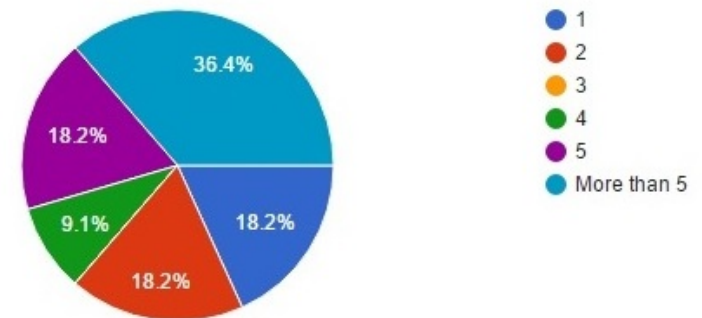
MDSAP INDUSTRY PARTICIPATION SURVEY MAJOR THEMES

...although they are
planning to add more

Do you plan to enroll more sites in the pilot? (17 responses)



If yes, how many? (11 responses)



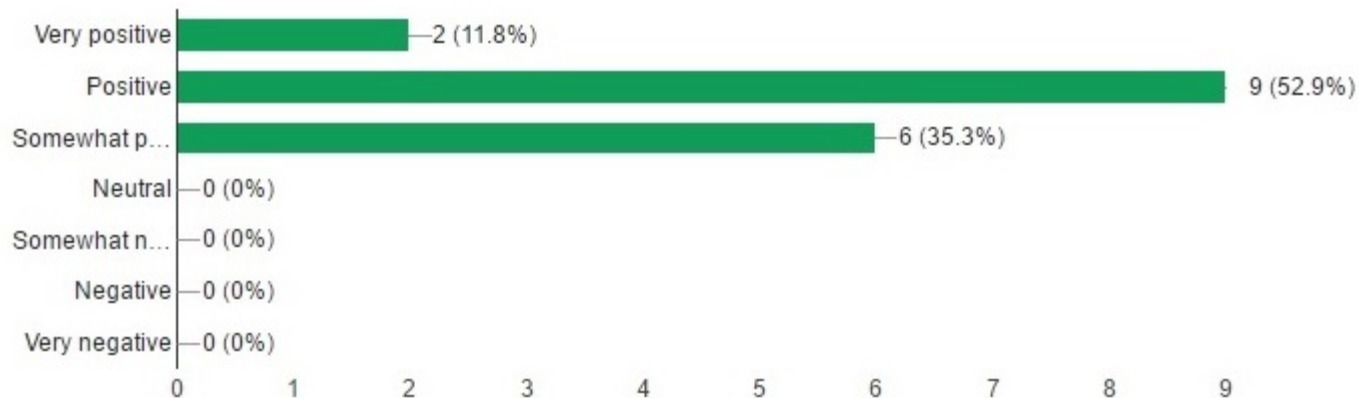


DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY MAJOR THEMES

Overall experience of participants: POSITIVE!

Please share an overall opinion of your experience: (17 responses)



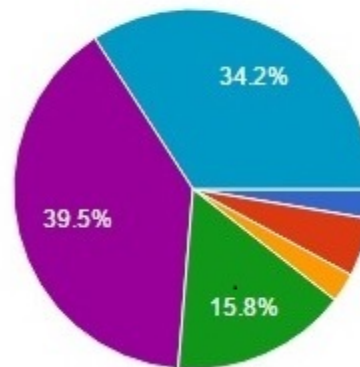


DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY NON-PARTICIPANTS, EXPLAINED

- 55% did not attempt, deterred by cost or lack of interest
- 10.5% attempted, but deterred by issues with cost or AO

What are the main reasons why you have not participated? (38 responses)



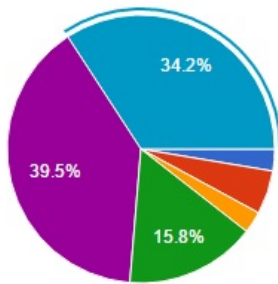
- Attempted, but was deterred by cost
- Attempted, but accrediting organization unable to accommodate your request due to resources
- Attempted, but my registrar is not an approved AO
- Did not attempt, was deterred by cost
- Did not attempt, was not interested in participating
- Other



MDSAP INDUSTRY PARTICIPATION SURVEY NON-PARTICIPANTS, EXPLAINED

- 34% report their decision not to participate was based on other, often complex factors

What are the main reasons why you have not participated? (38 responses)



- Attempted, but was deterred by cost
- Attempted, but accrediting organization unable to accommodate your request due to resources
- Attempted, but my registrar is not an approved AO
- Did not attempt, was deterred by cost
- Did not attempt, was not interested in participating
- Other

- However: none so complex that they can't be fixed!

What would convince your company to participate? (26 responses)

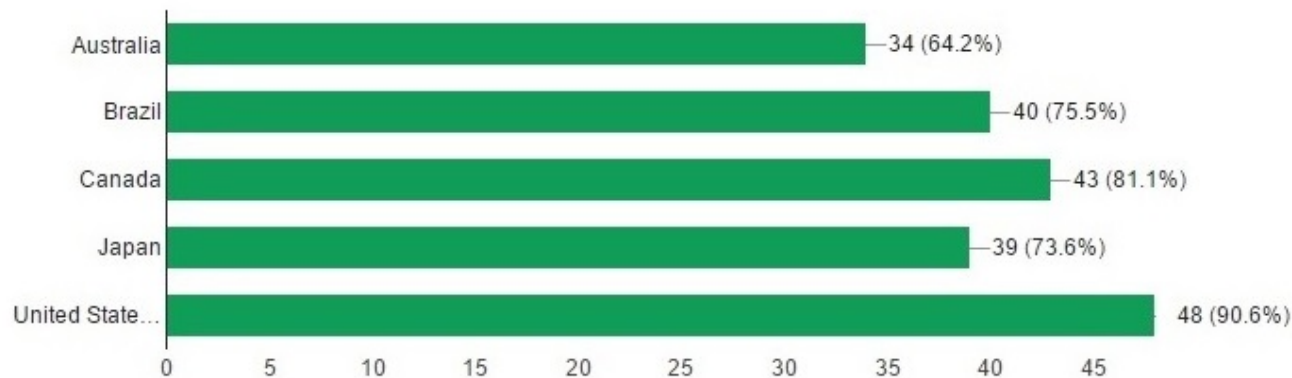
- Longer timeline as cost are related to the change will participate in the next year
- Organization very concerned about the increased workload, now and upon release of the mandatory process.
- Include the EU ISO 13485 and Directive requirements into the MDSAP process make the overall audit time more manageable
- It was explained that there is no merit which introduces this surveillance from the third party.
- Assurance of consistency, coordination and use of information.
- CMDCAS certification will be replaced with MDSAP certification, which we will be required to obtain MDSAP for selling medical device product into Canada
- Be consistent on audit criteria
- Just not interested as there is additional cost and time required for no real benefit.
- We are already convinced, but have limited resources
- Nothing to mention
- Reduce time and cost to have product registration in ANVISA
- Decrease in the costs. The company needs to pay ANVISA's fee and also MDSAP audit.
- N/A
- Costs indeed are higher than the current GMP certification pipeline. If there was a way of demonstrating/assuring that the extra investment of monetary values and also time could be returned as swifter and quicker timelines for getting sites GMP certified, I'm sure that my company would see it as a good opportunity.
- n/a
- Another opportunity
- We could not find any information on the advantage for manufacturers to join MDSAP Pilot Program in advance. It may had been released or announced in public, but we could not see that.
- Lower cost
- Now we are interested and we depend on manufacture approval



- Most survey respondents sell into all MDSAP countries

Which participating regulatory jurisdictions are target markets for your company? (check all that apply)

(53 responses)

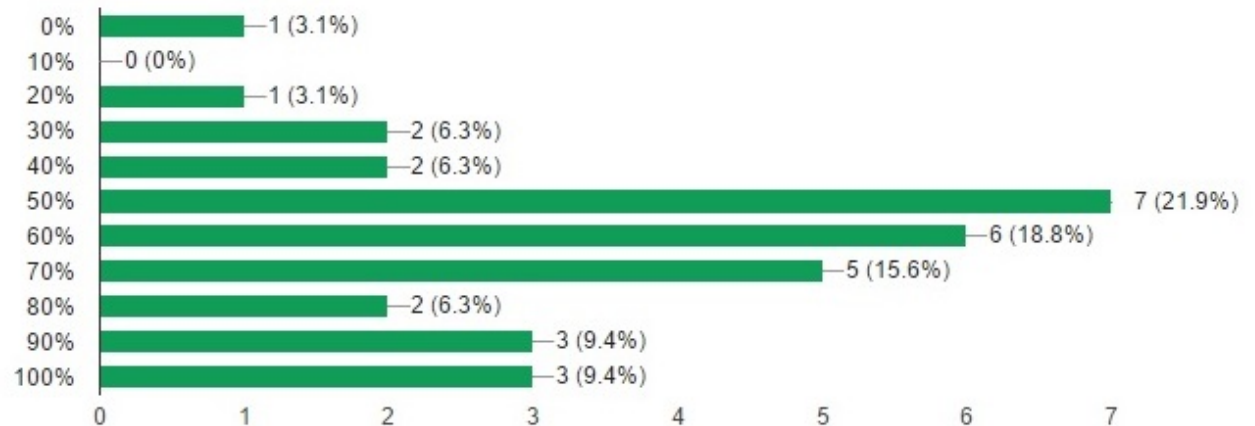




- More of respondents' business is covered by MDSAP than is not

What volume (percentage) of your company's business is in regulatory jurisdictions supported by MDSAP?

(32 responses)





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY GENERAL INFORMATION

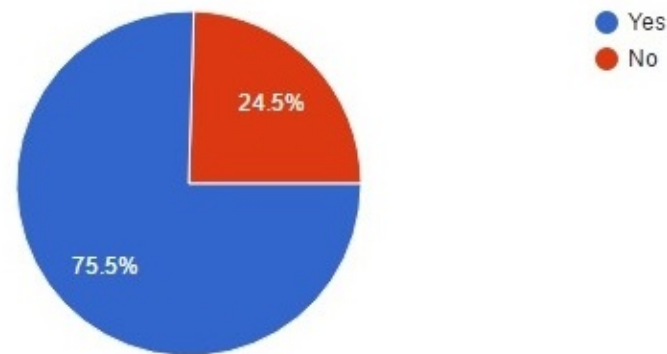
- Most respondents used US FDA's online resources

Have you explored the information on the MDSAP webpage, including the Q&A?

<http://www.fda.gov/MedicalDevices/InternationalPrograms/MDSAPPilot/default.htm>

<http://www.fda.gov/downloads/MedicalDevices/InternationalPrograms/MDSAPPilot/UCM430563.pdf>

(53 responses)

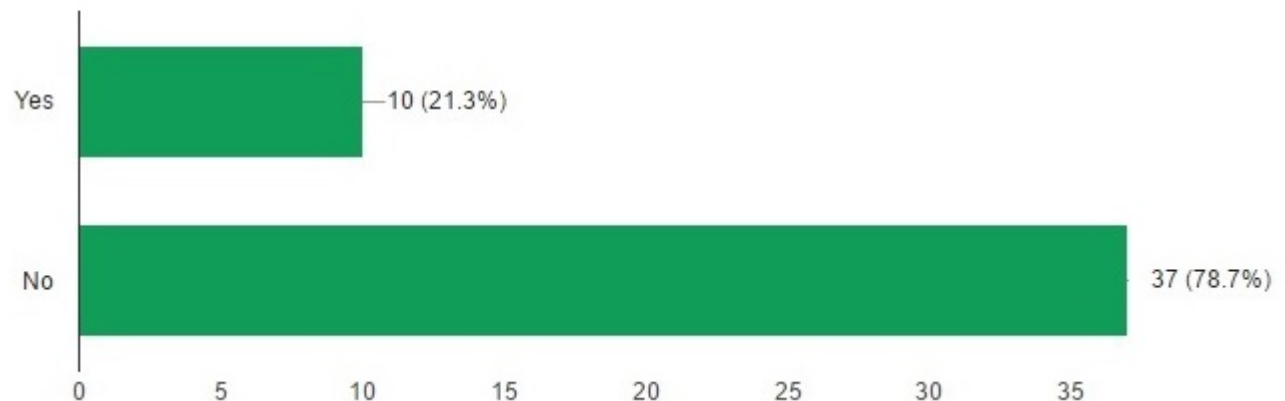




- Most respondents reported that the survey touched all aspects of concern with MDSAP

Does your company have concerns about an aspect of MDSAP that are not addressed in this survey?

(47 responses)





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY TAKEAWAYS & NEXT STEPS

- Survey respondents that participated in MDSAP liked it
- Those that did not participate were open or planning to participate in MDSAP in the future





DITTA GLOBAL DIAGNOSTIC IMAGING,
HEALTHCARE IT & RADIATION THERAPY
TRADE ASSOCIATION

MDSAP INDUSTRY PARTICIPATION SURVEY TAKEAWAYS & NEXT STEPS

MDSAP success depends on:

- Regulators wide use MDSAP as total replacement for current QMS audits
- Auditors have sufficient capacity to carry out all MDSAP audits by deadline
- Industry has sufficient time for all facilities to undergo MDSAP audit





DITTA GLOBAL DIAGNOSTIC IMAGING, HEALTHCARE IT & RADIATION THERAPY TRADE ASSOCIATION

THANK YOU!

www.globalditta.org

