

# CAPA IN MEDICAL DEVICES

Results of a short survey  
2014/2015

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# Introduction

During the past years, CAPA was lifted to center stage during inspections as per 21CFR820 and audits as per EN ISO 13485 (see slides 3 and 4).

However, limited data on CAPA in medical device industries is available, besides the annual data published by FDA.

A non-representative and non-controlled survey was conducted by the author to gather some data from non-systematically selected medical device experts.

The survey does not claim any completeness or correctness of the results. It aims to show trends and opinion within the medical device industry only.



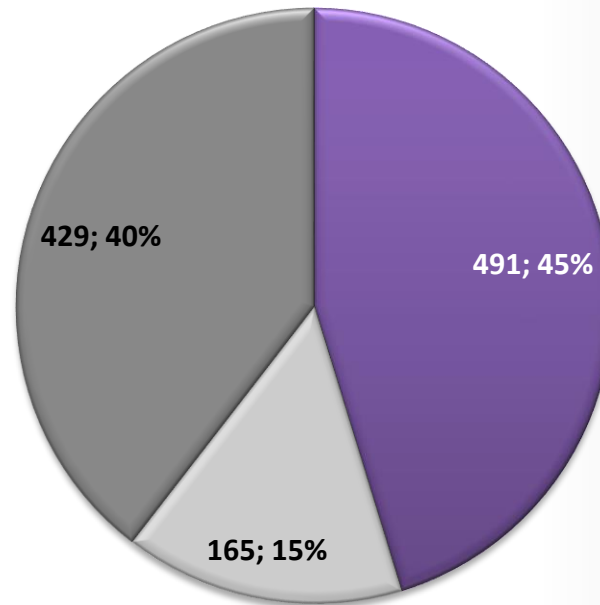
# Annual data published by FDA

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## FDA CY2013 CAPA Observations



■ CAPA (820.100)   ■ NC (820.90)   ■ Complaint Files (820.198)

Source:

[www.fda.gov](http://www.fda.gov), 2013 Annual FDA Medical Device Quality System Data

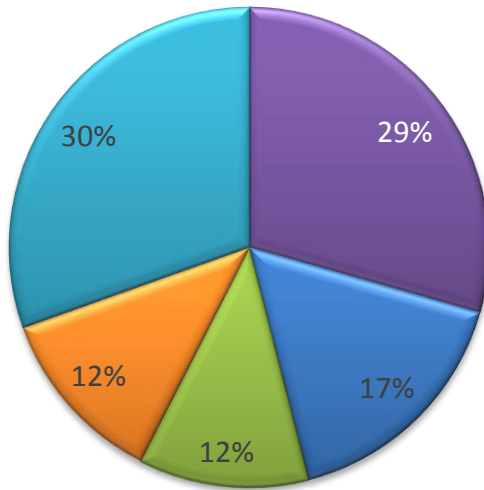
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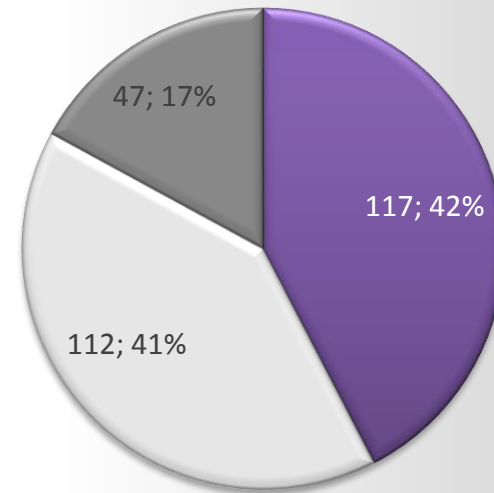
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### FDA CY 2013 Warning letters # of Citations



- CAPA
- Design Control
- Document Control
- Management
- Production&Process Controls

### FDA CY2013 CAPA Warning Letter Citations



- CAPA (820.100)
- NC (820.90)
- Complaint Files (820.198)

Source:

[www.fda.gov](http://www.fda.gov), 2013 Annual FDA Medical Device Quality System Data

# Results of the survey

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## Participants

- Survey was open from 14<sup>th</sup> Nov 2014 to 11<sup>th</sup> Jan 2015
- 28 medical device experts participated in the survey.
- Participants were located, as far as known, in Germany, Ireland, USA, Sweden, the Netherlands, and Switzerland.

# Results of the survey

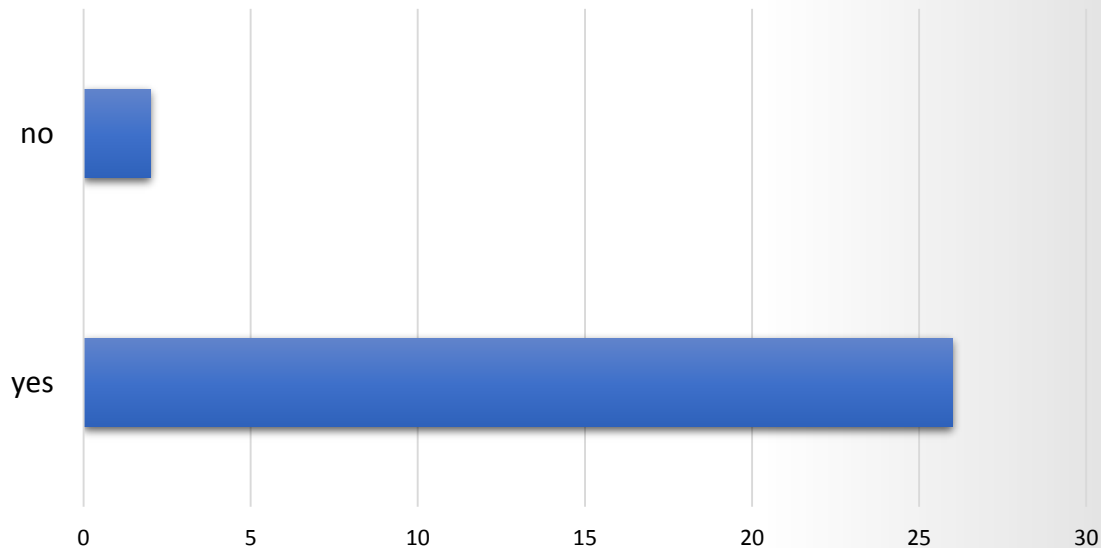
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## Question 1

Are you a manufacturer of Medical Devices?



All participants are involved in Medical devices (including one material supplier and one service provider for medical device companies).

# Results of the survey

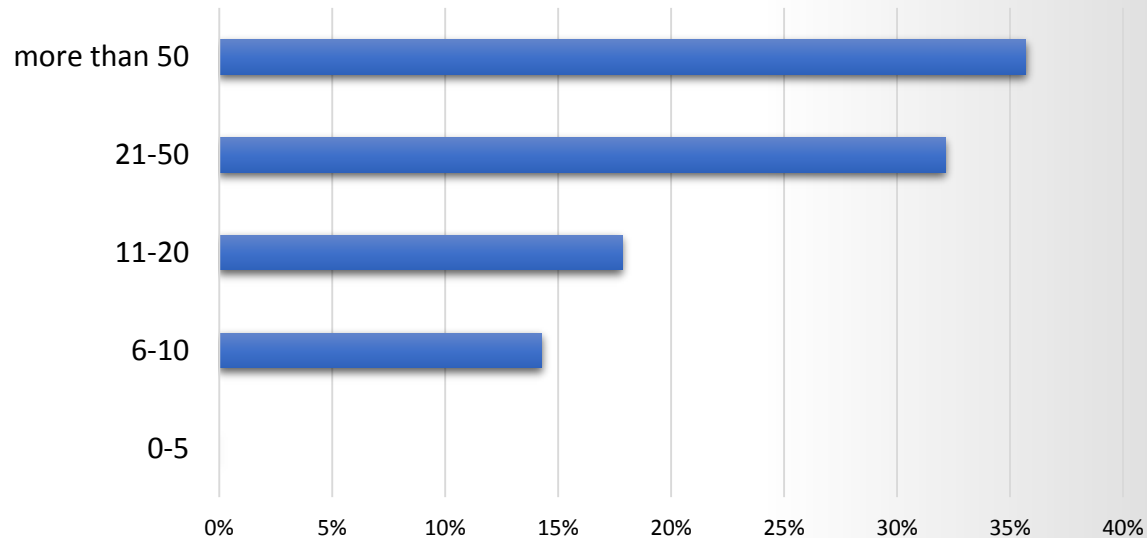
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## Question 2

How many CAPA's did your Company initiate over the last THREE years?



Company sizes vary, therefore a comparison may not be possible. 67% reported more than 20 CAPA's annually.

# Results of the survey

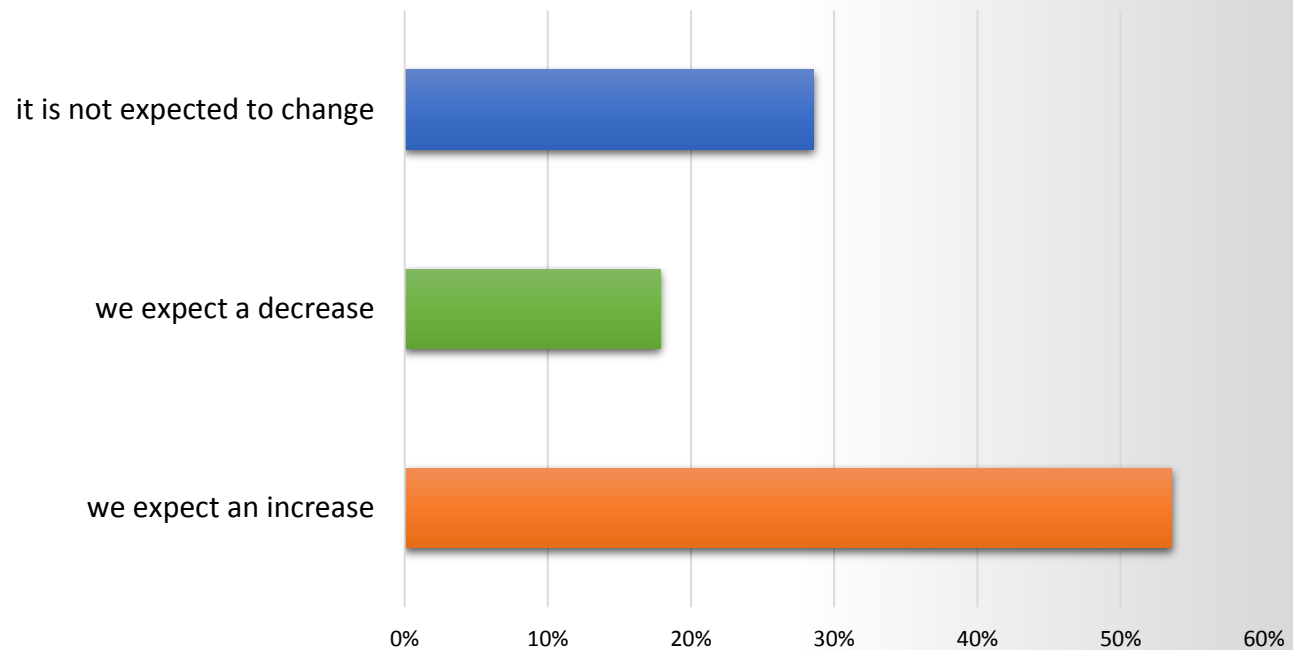
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## Question 3

Is the number of CAPA's per year increasing or do you expect a decrease in the numbers of CAPA's?



The majority of participants expect an increase in CAPA



# Results of the survey

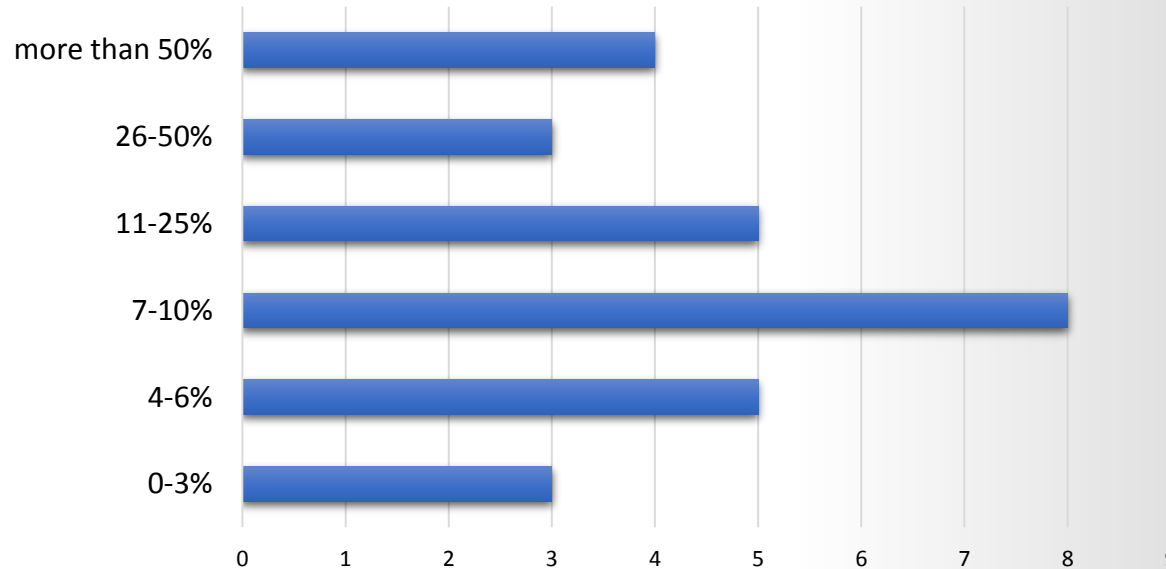
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## Question 4

Please estimate the percentage of early warnings (like Non-conformities, Audit findings, serious trends) which resulted in CAPA.



The ratio of escalating early warnings up to CAPA varies widely. The median is about 1:10.

# Results of the survey

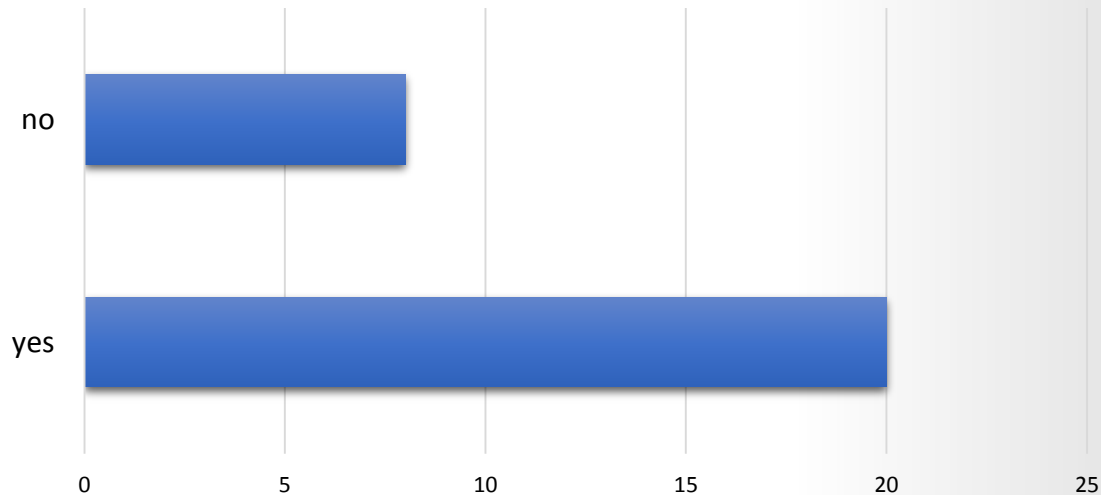
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## Question 5

Does your CAPA System include risk-based CAPA Triggers?



The majority of participants are using risk-based CAPA triggers.

# Results of the survey

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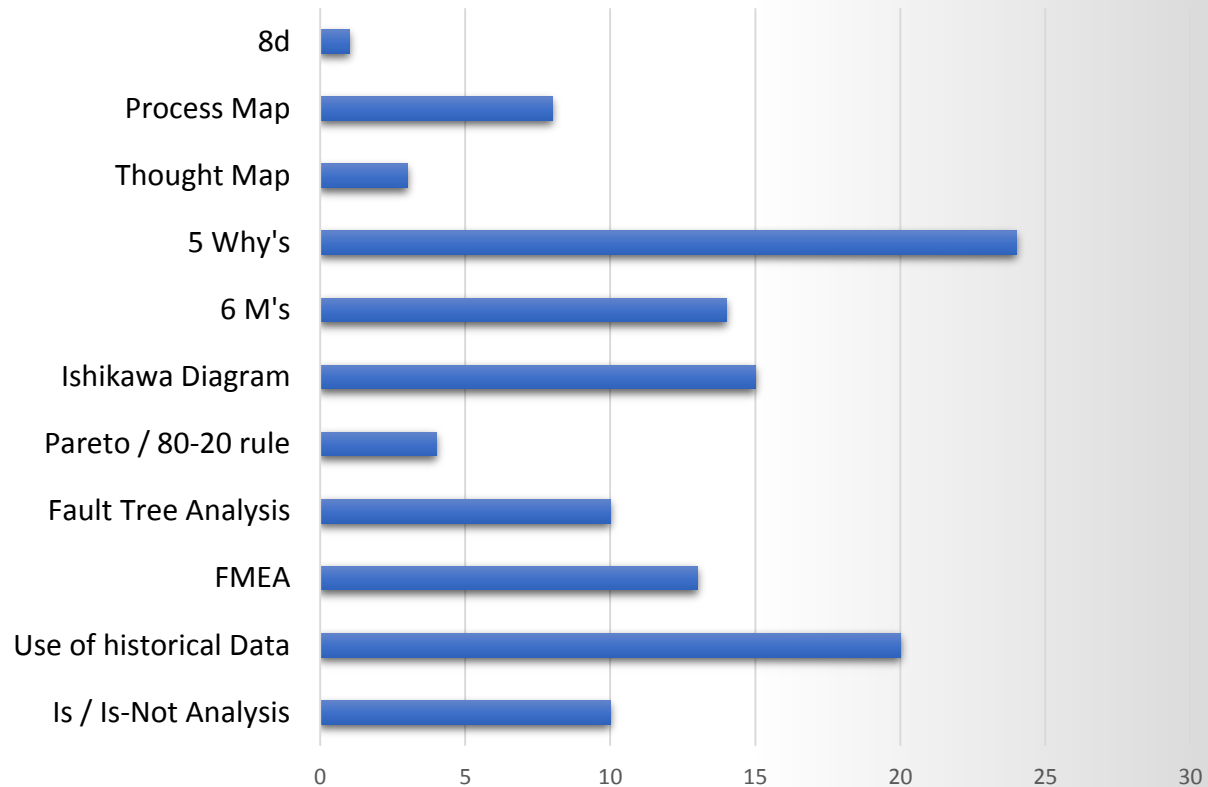
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## Question 6

Which methods and tools are you using within Root Cause Analysis?

5 Why's and historical data are most often used in root cause analysis.



# Results of the survey

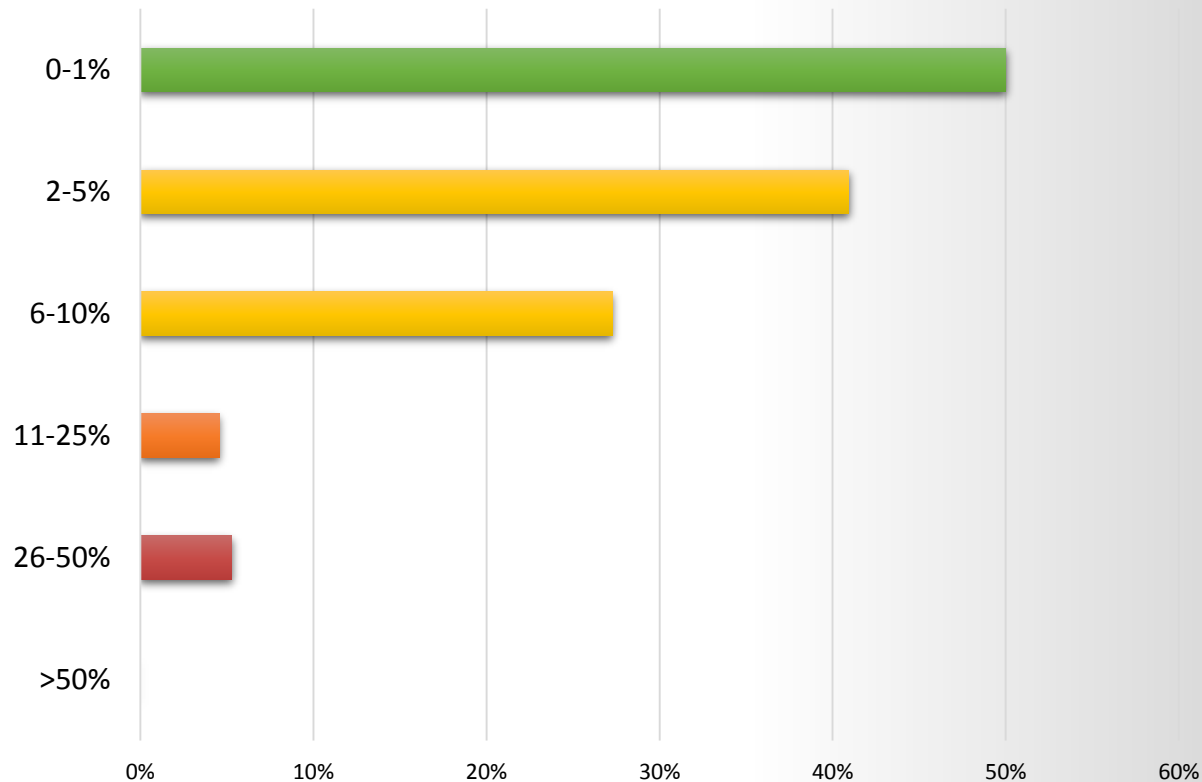
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## Question 7

How many of the failures which were removed by CAPA did reoccur within 6 MONTHS after the closure of CAPA?



About 60% of participants are reporting significant recurrences of failures.

# Results of the survey

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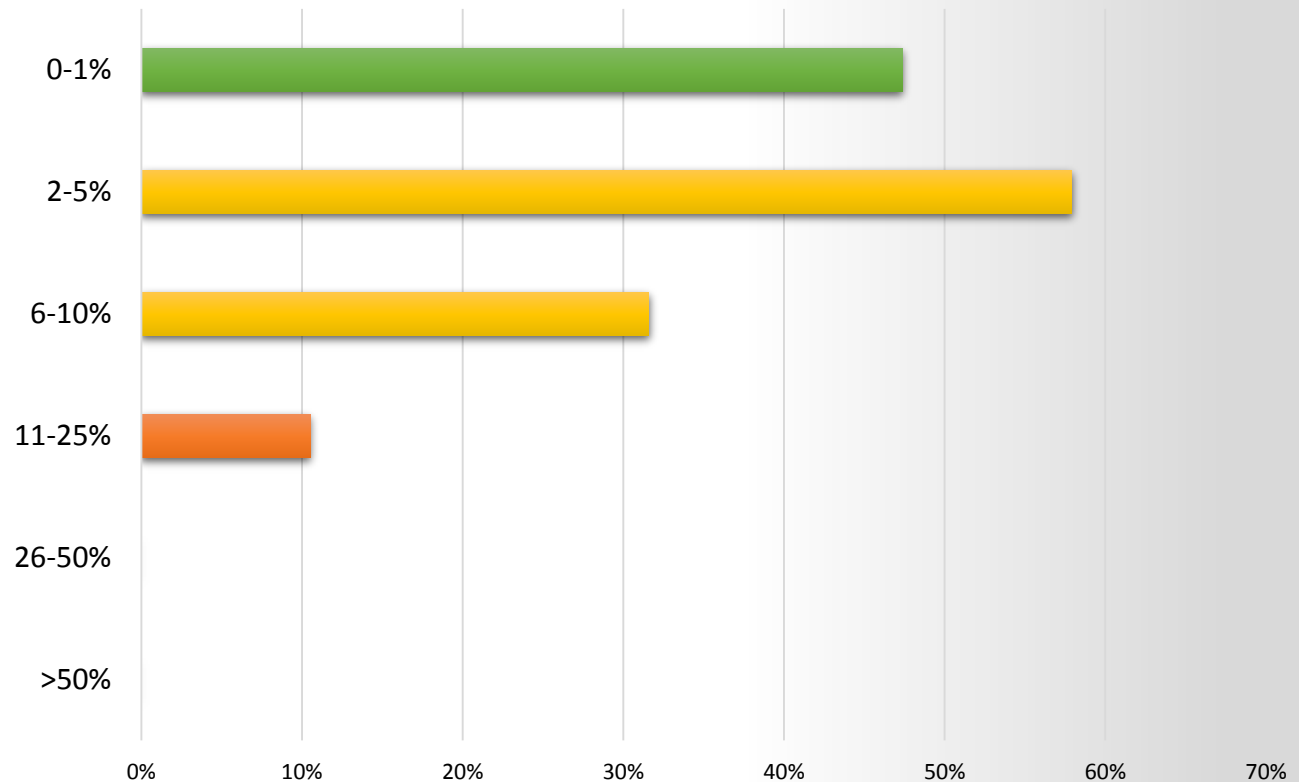
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## Question 8

How many of the failures which were removed by CAPA did reoccur within 2 YEARS after the closure of CAPA?

Recurrence rate of failures seem to be higher after 2 years compared versus 6 months after CAPA closure.



# Results of the survey

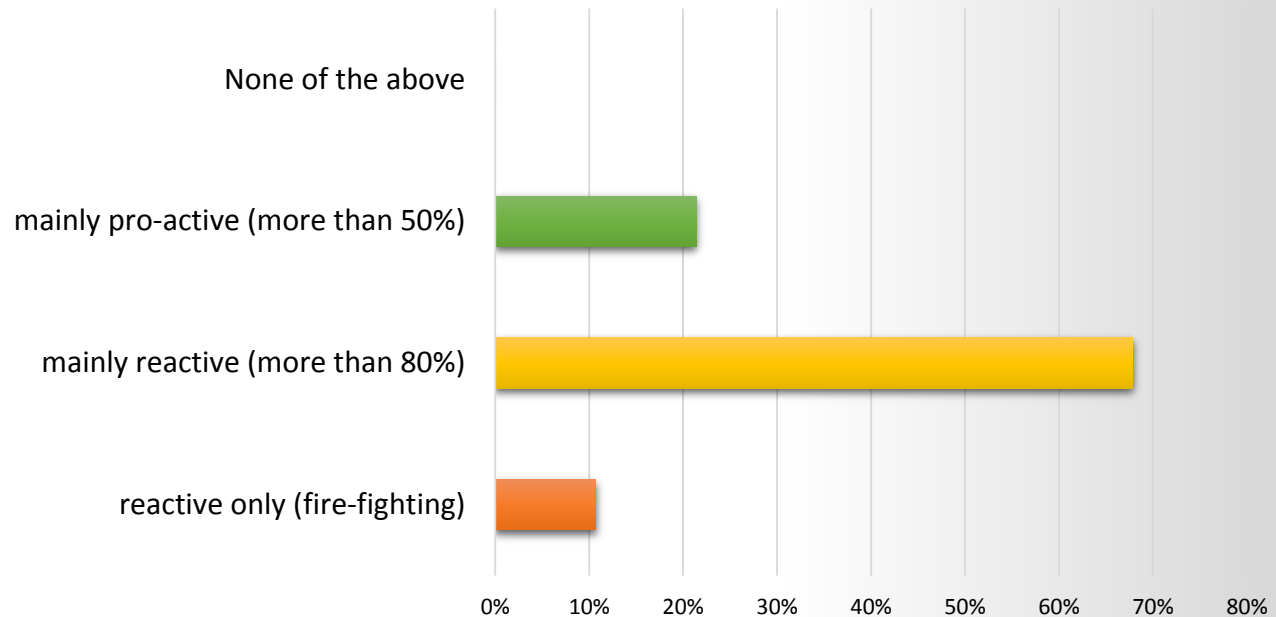
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## Question 9

If you would need to categorize the way you handle failure Investigation, what would fit your daily practice?



Most of the participants handle failure investigations reactively.

# Results of the survey

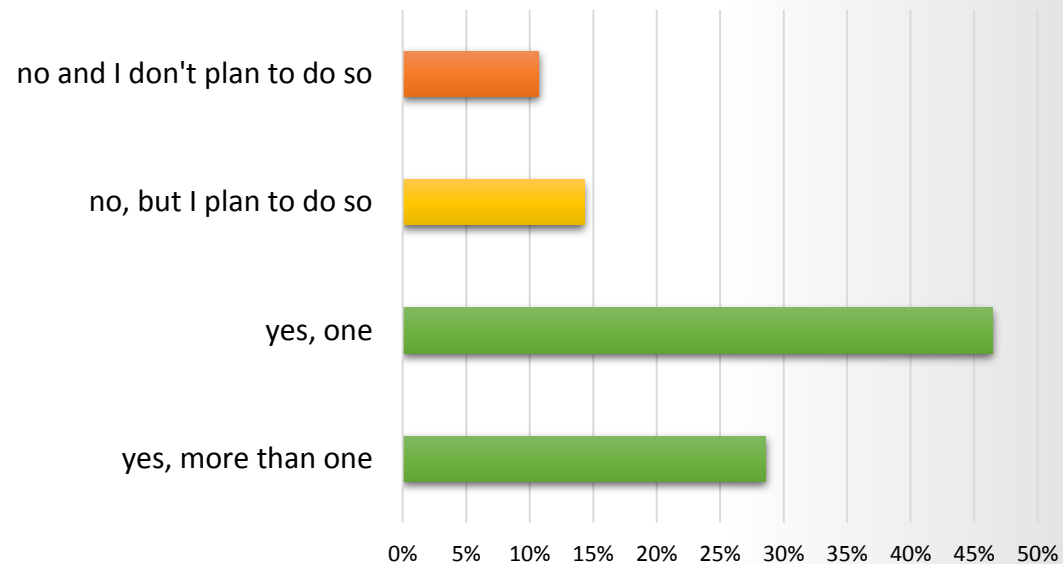
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## Question 10

Have you ever visited an external CAPA Training?



Degree of training is 75% and can be considered high.

# Results of the survey

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## Summary

- 67% reported more than 20 CAPA's annually.
- The ratio of escalating early warnings up to CAPA varies widely. The median is about 1:10.
- The majority of participants expect an increase in CAPA.
- Most participants are using risk-based CAPA triggers.
- 5 Why's and historical data are most often used in root cause analysis.
- About 60% of participants are reporting significant recurrences of failures. Recurrence rate of failures seem to be higher after 2 years compared versus 6 months after CAPA closure.
- Most of the participants handle failure investigations reactively.
- Degree of training is 75% and can be considered high.



# BEST PRACTICES IN CAPA

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