Countdown to the MDR

1. MDR Implementation
2. MDR Audits

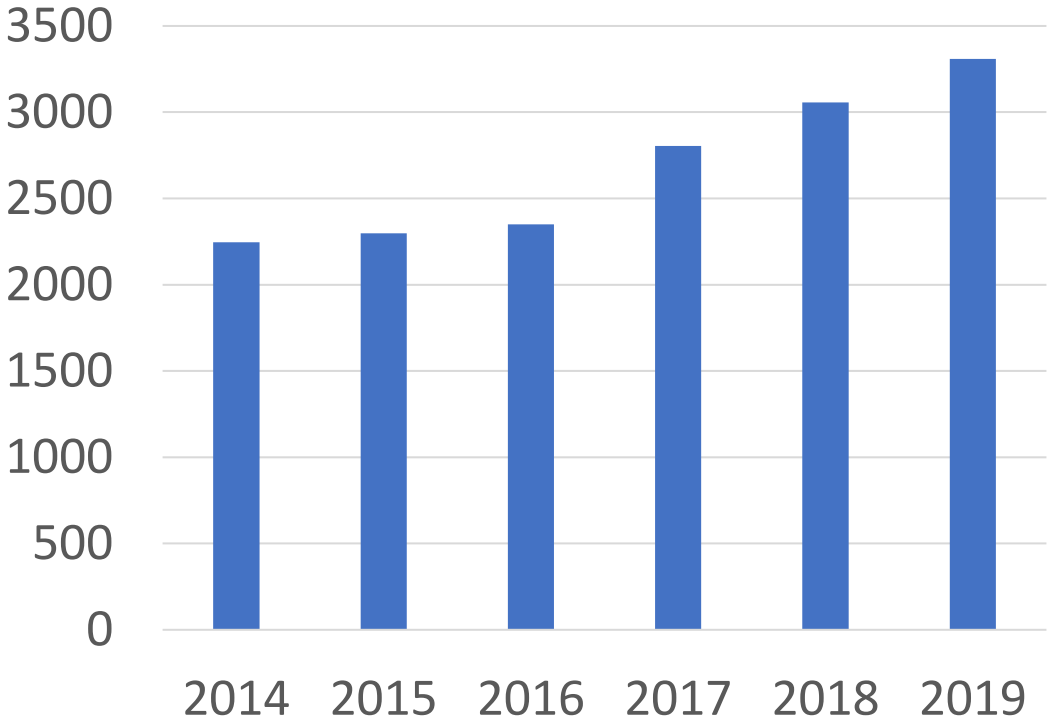
Wednesday 17 February 2021

MDR Implementation

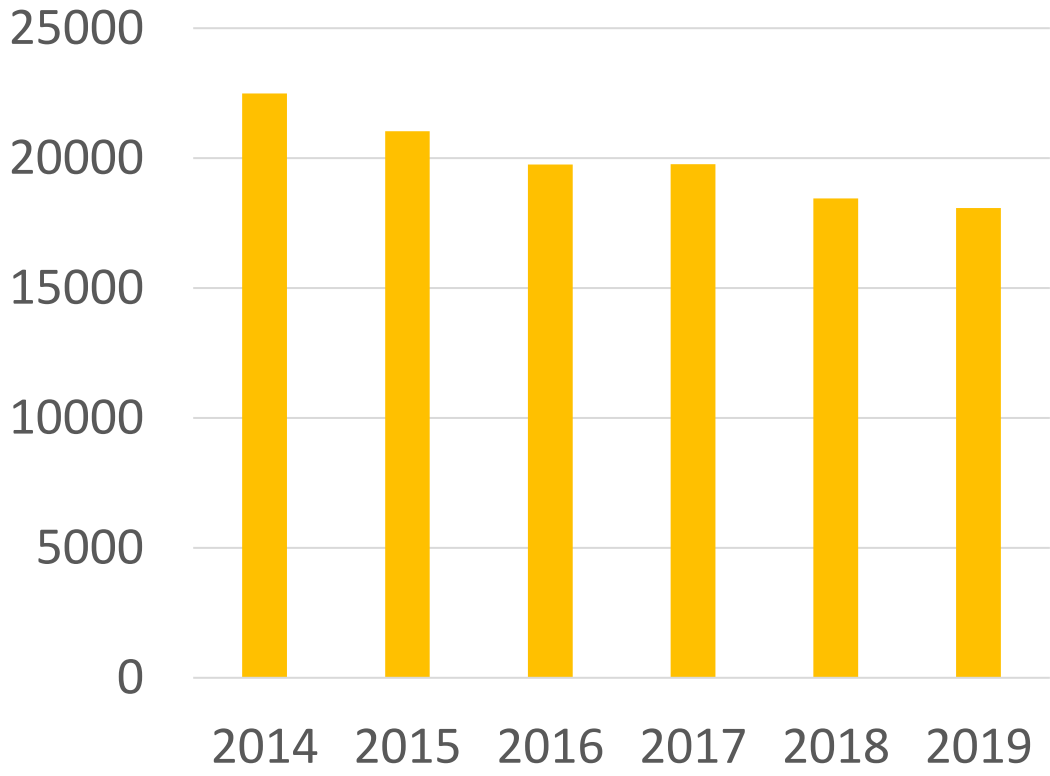
N=26 NBs

of Employees

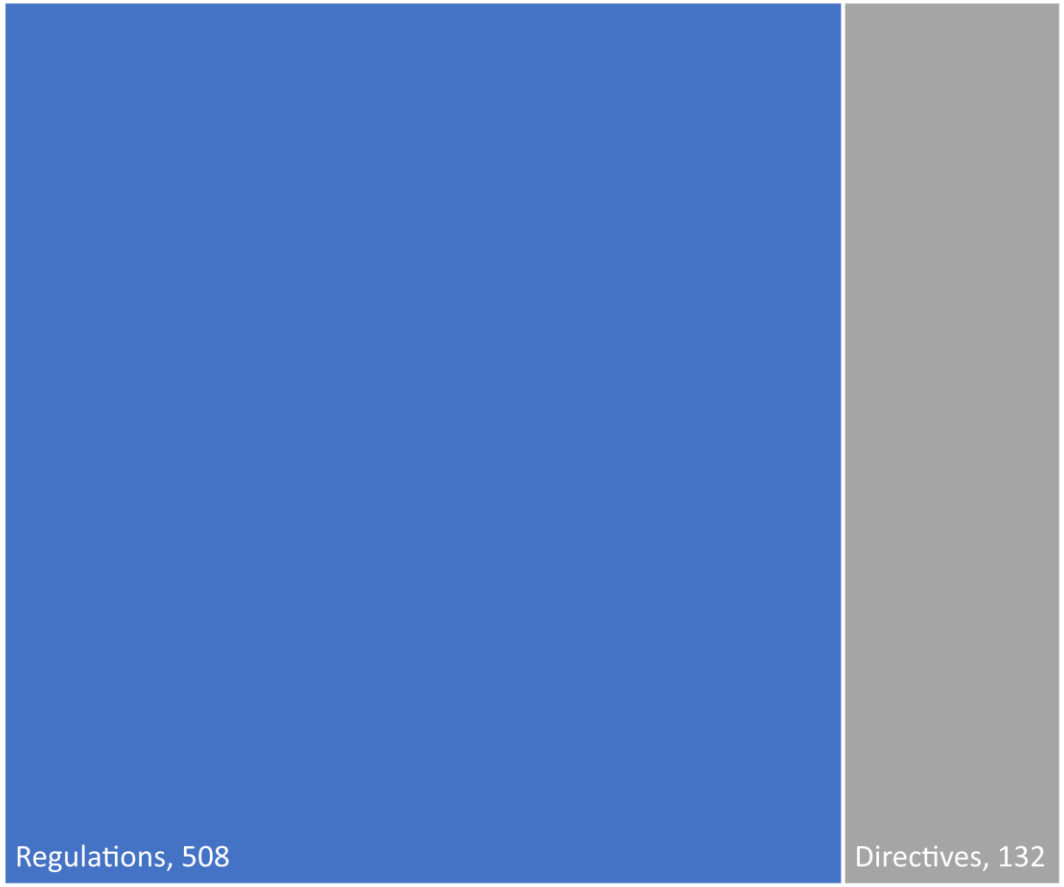
(not including subcontractors)

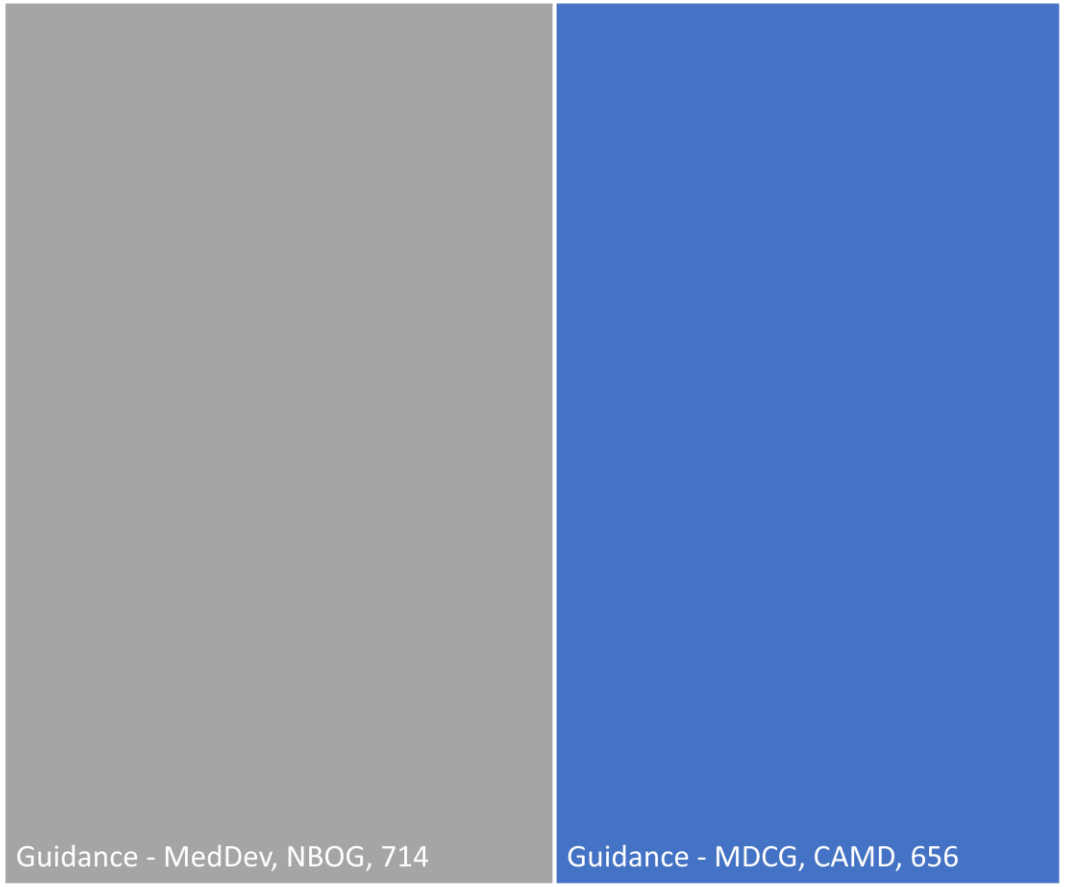


of Certificates



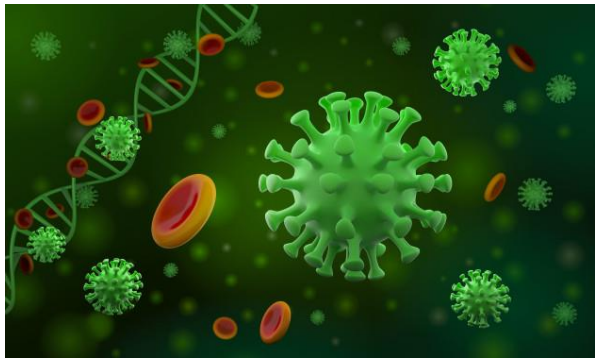
MDR Implementation





Remote Audits

IAF ID3 2011, ID4 2018, ID12 2015
UKAS TPS 62 2016



Audits postponed in North America
Mar 2020

Audits postponed in Europe
Feb 2020

Audits postponed in China
Jan 2020

MDSAP Transmittal
2020 03, 04 & 05

MDCG 2020-4

UKAS TPS 73

SCC 2020 12

RvA T051

MDSAP Transmittal
2020 10

MDCG 2020-17

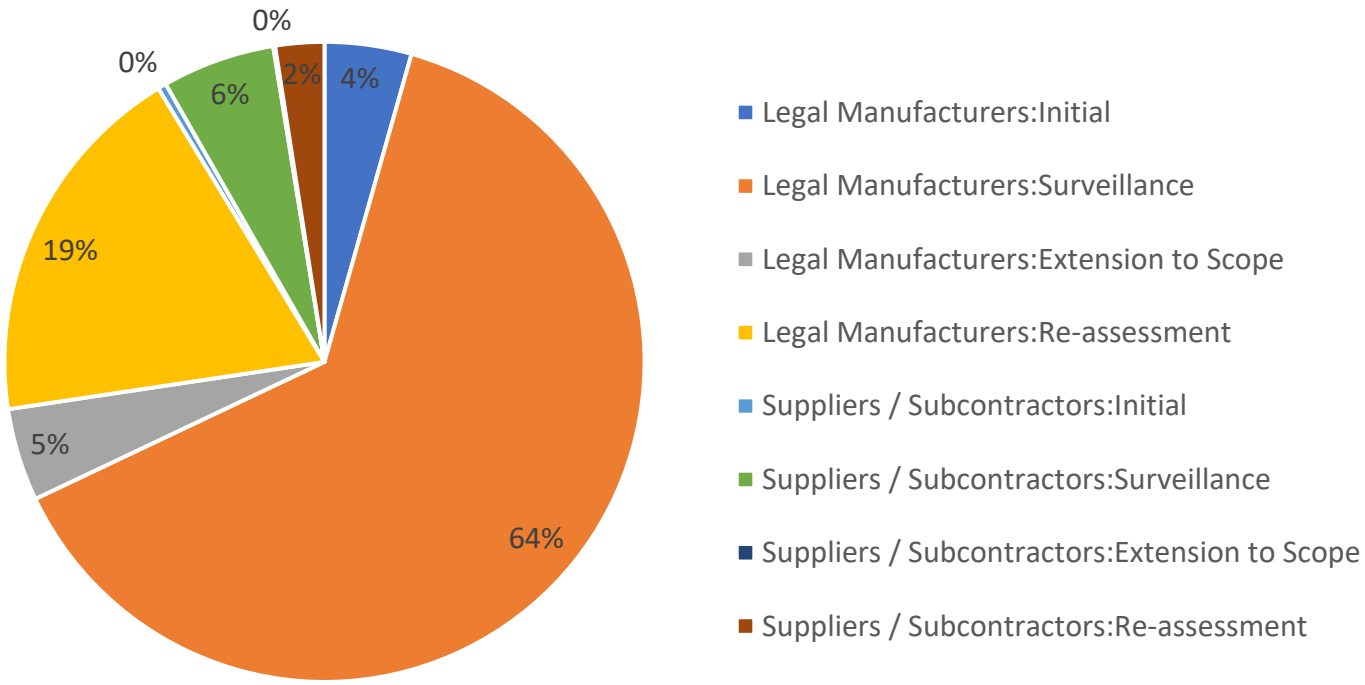
Commission Notice
2021/C 8/01

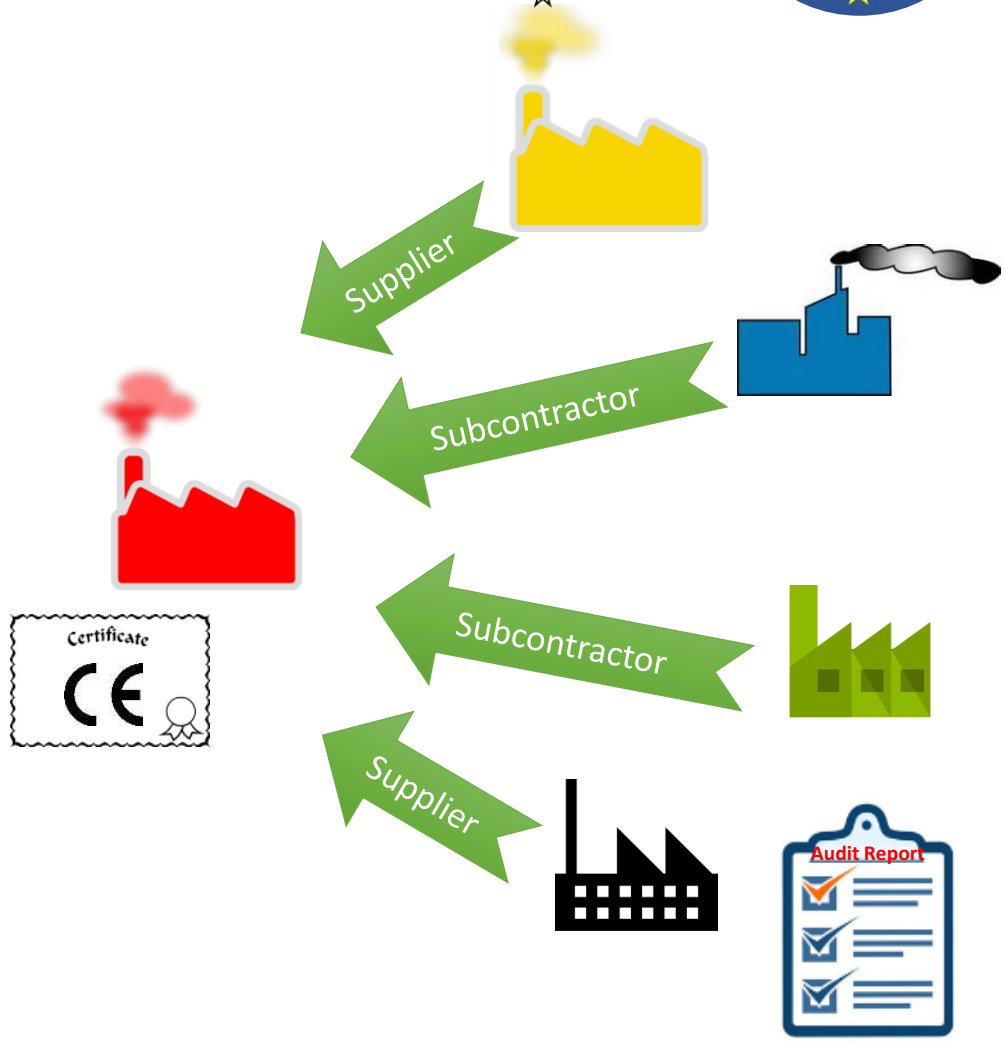
Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4 Q1 Q2 Q3 Q4

2019 2020 2021

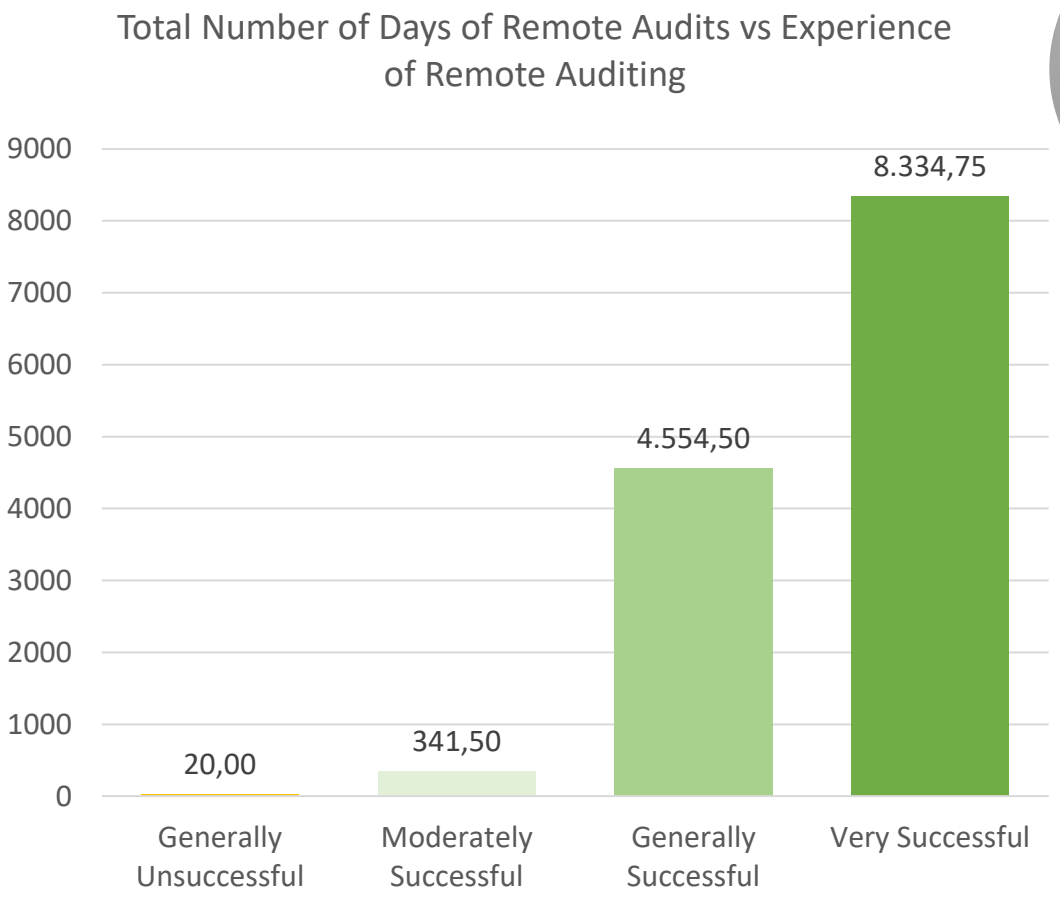
Remote Audits – n=37 – Nov 2020

How many audit days has your Notified Body completed remotely (AIMDD/MDD/IVDD)?

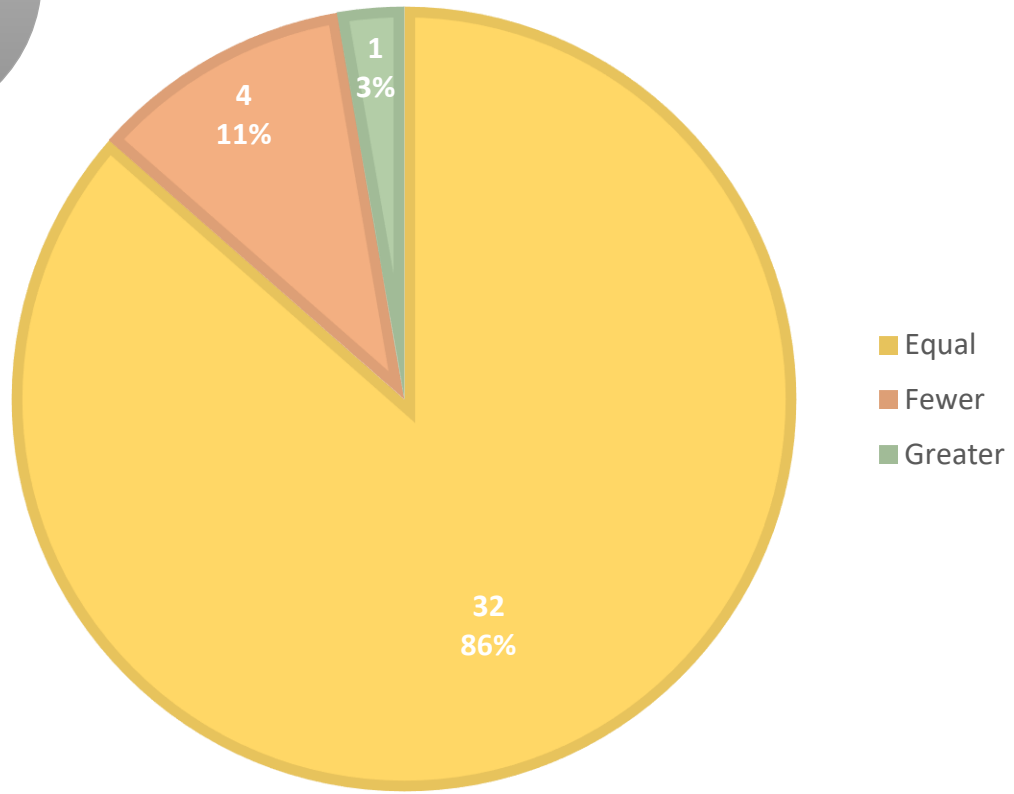




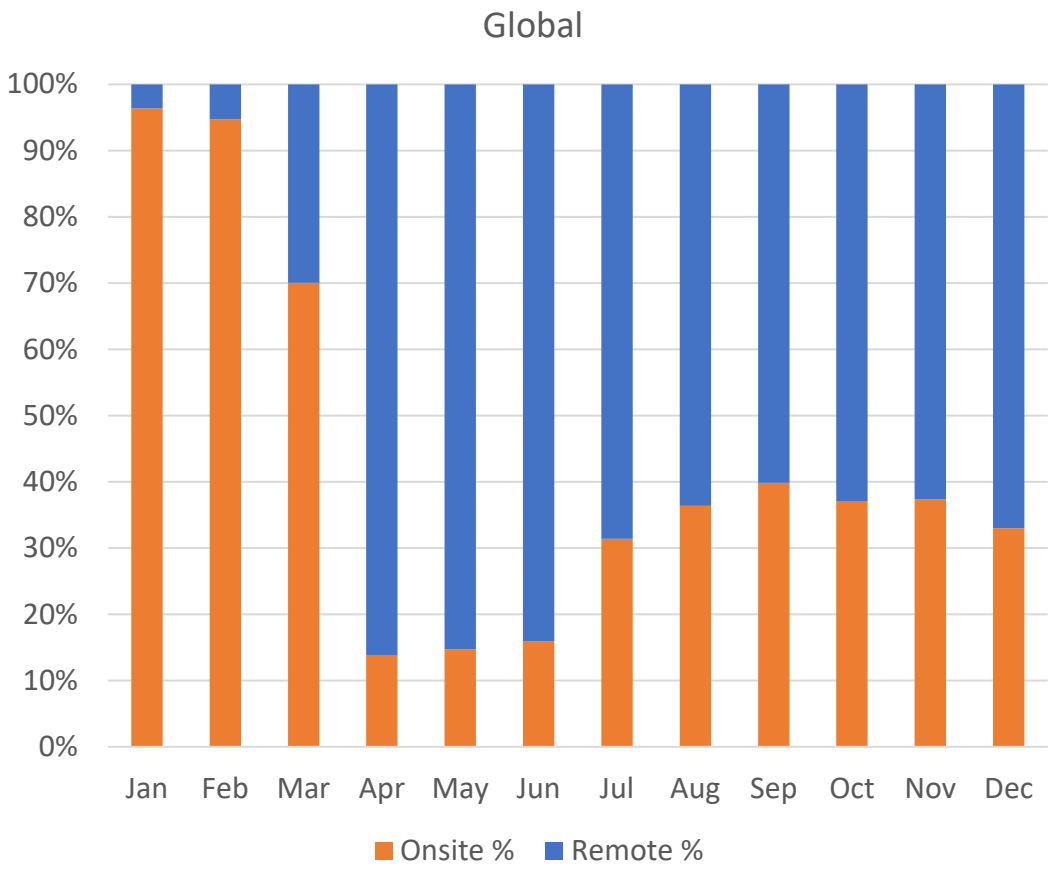
Remote Audits – n=37 – Nov 2020



>13,000 days



Remote Audits



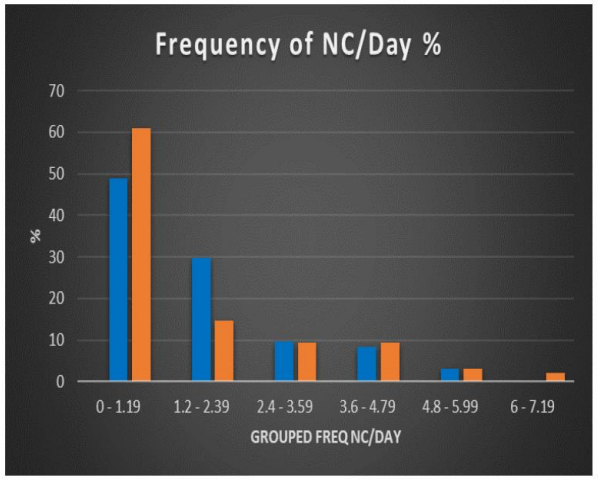
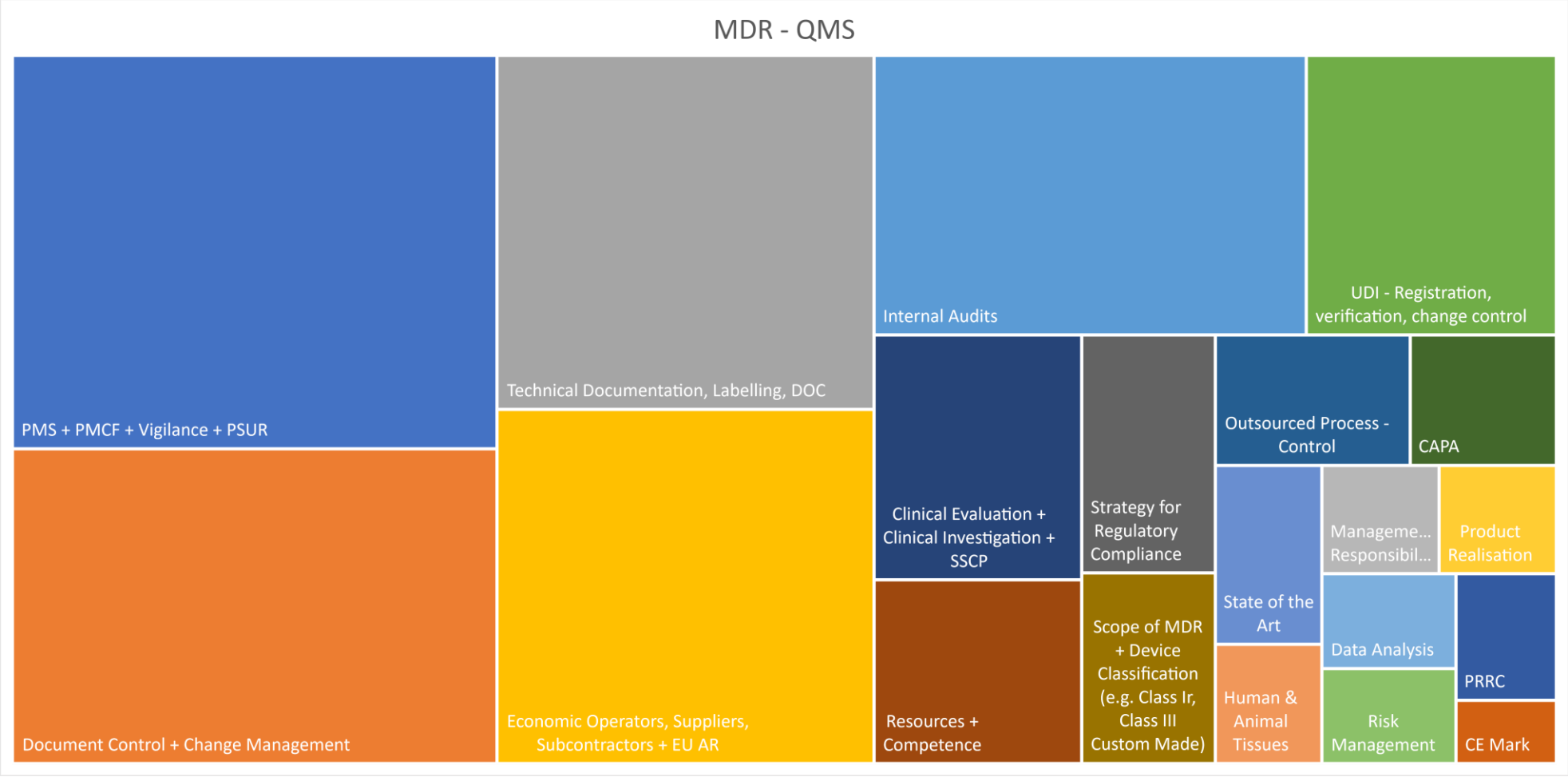


Figure 2 Grouped frequency data Remote (Blue) and Onsite (Orange)

n=100 remote & on site – Stage 2, CAV, re-assessment

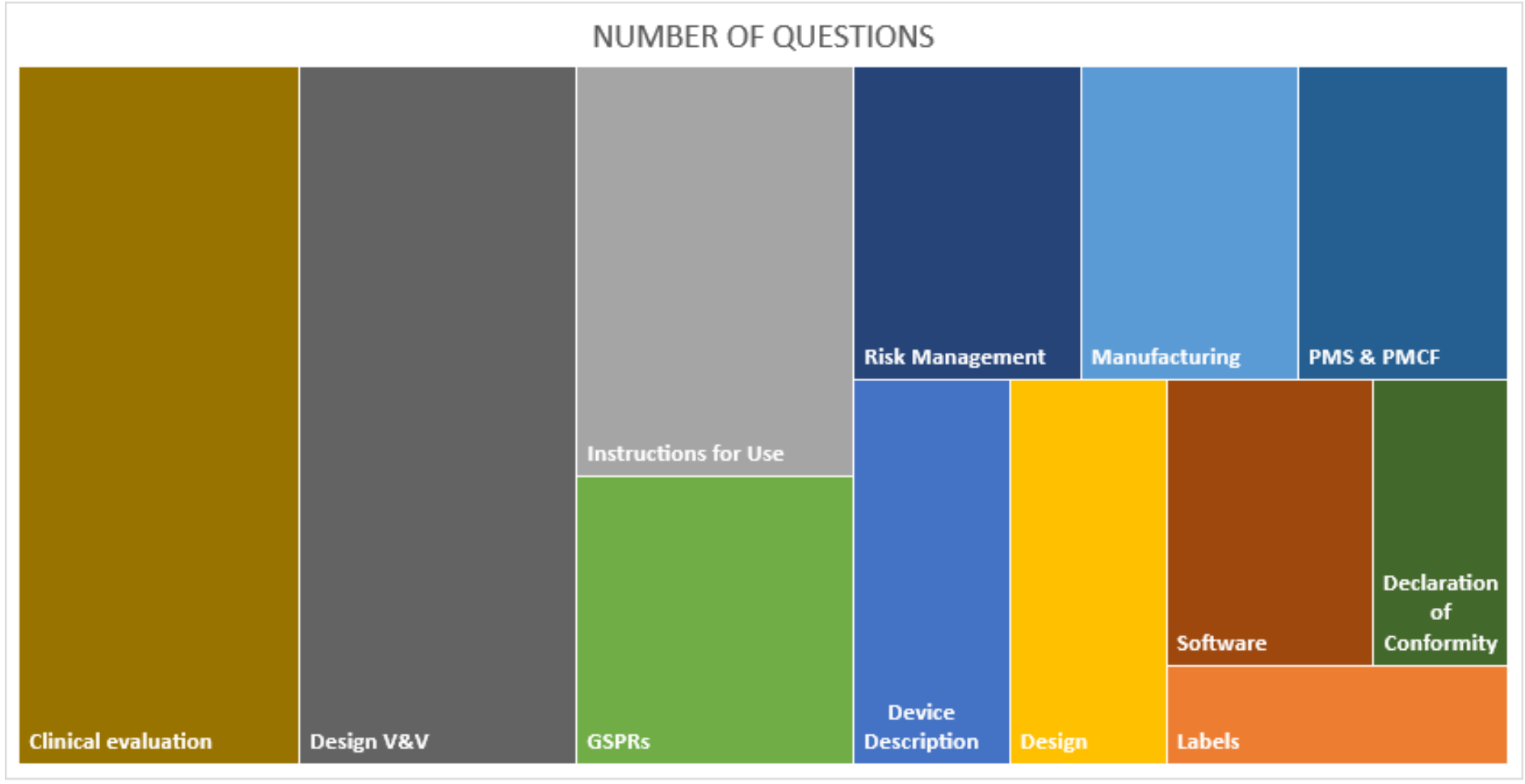
Figure 6 Average NC/Day per clause for remote cohort (Blue) and onsite (Orange)

MDR Audits – QMS



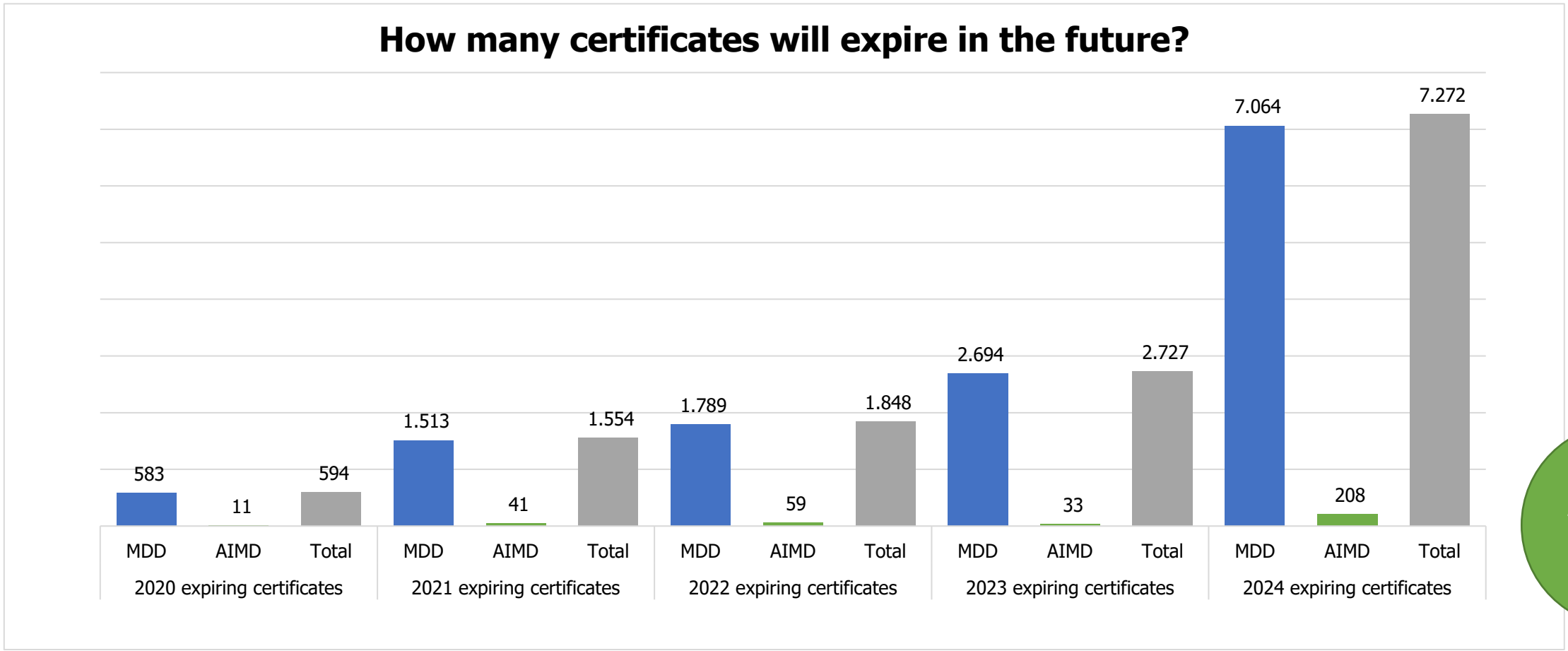
2019 & 2020

MDR Audits – Technical Documentation



2019 & 2020

Expiring Certificates – n=34 – Sept 2020



MDR Audits – Don't wait …

Countdown to the MDR

Questions & Answers