

# Best Practices in a Remote Environment

Regulatory and Industry Perspectives on Remote Auditing

 Veeva MedTech

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# Today's Speakers

## Panelists



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**Alexey Shiryaev**

President of Team-NB,  
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**Andreas Purde**

Director Active Medical  
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**Simon Richards**

VP, Divisional Regulatory Affairs,  
Abbott Rapid Diagnostics

## Moderator



**Annemien Pullen**

Director of Strategy,  
Veeva MedTech



The European Association Medical devices  
Notified Bodies

# MedTech Forum 2021

## Remote/Virtual audits

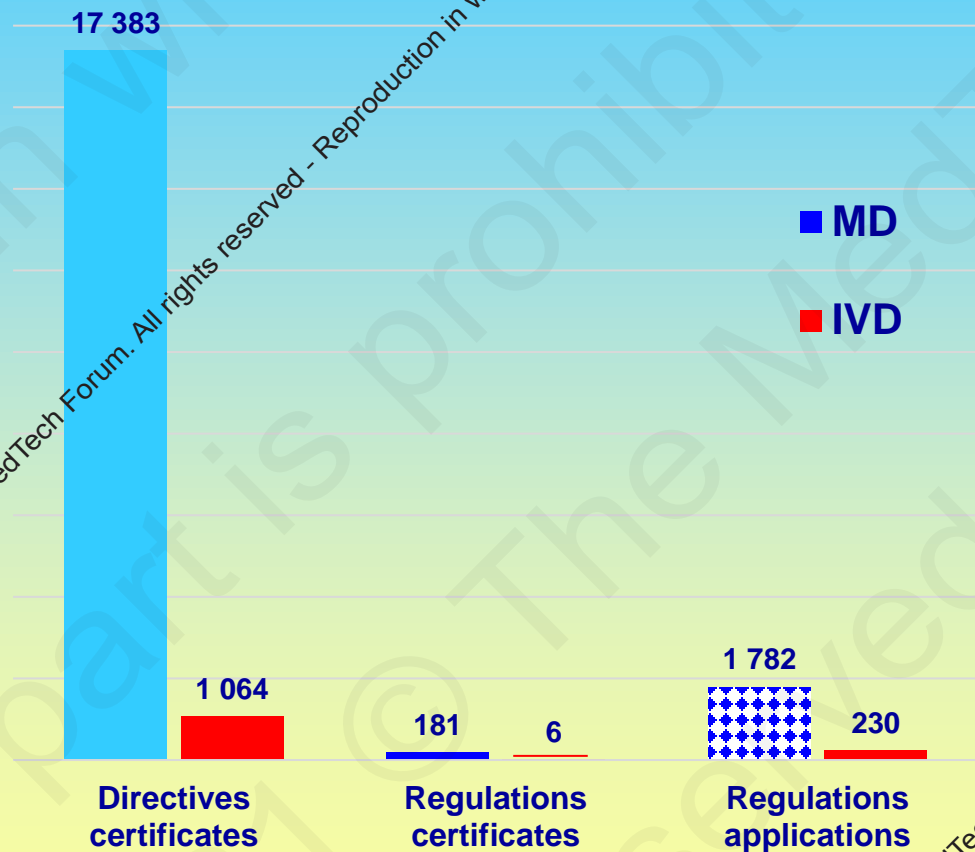
Françoise Schlemmer, Team NB Director

## ❖ Aims:

- **Communication with**
  - **European Commission**
  - **Competent Authorities**
  - **Industry**
- **Promote technical and ethical standards**
- **Participate in improving the legal framework**
- **Contribute to harmonization**
- **Represent Notified Bodies**



# Certificates evolution



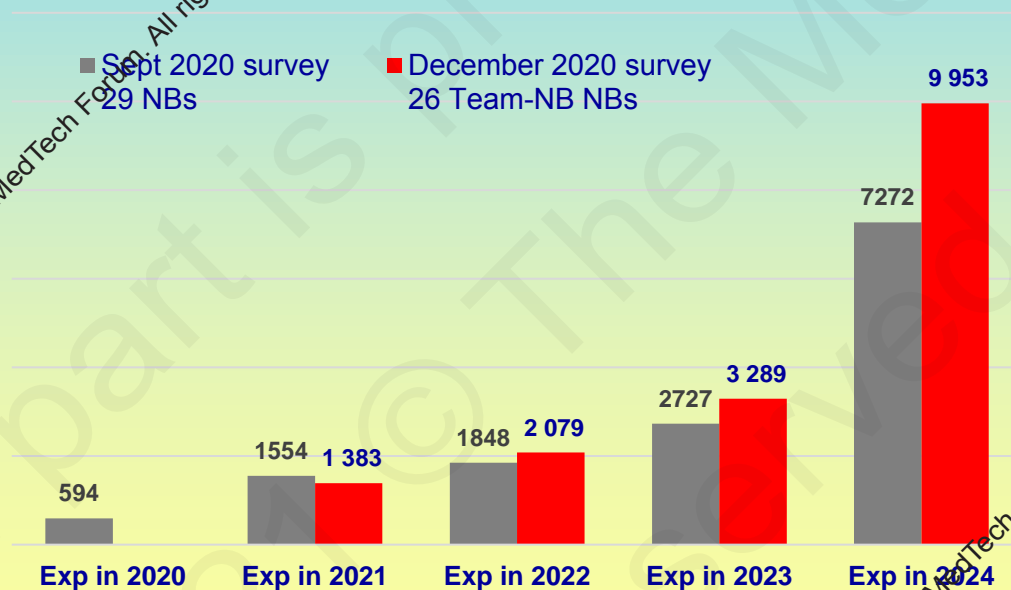
- 1% of MDR certificates has been issued.
- Applications represent 10% of MDD and AIMD certifications.

# Expiration of directives certificates

## ■ Sources:

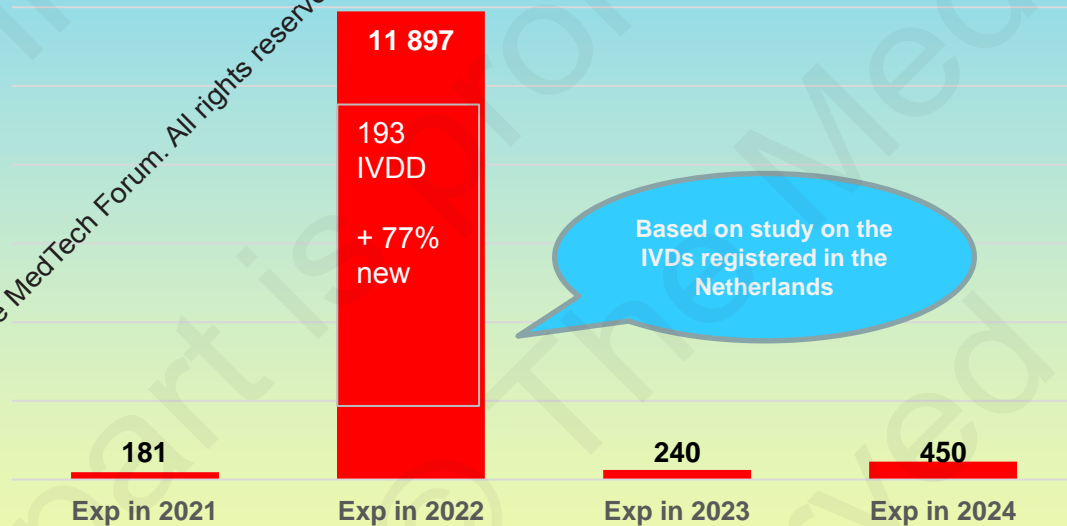
- September survey: CIRCABC with 29 responses – all NBs
- December survey: All Team-NB members – 26 responses

### Expiring AIMD + MDD certificates



- MDD / AIMD certificates against directives increased thanks to the remote audits authorised by the Commission

# IVD: expiration of directives certificates & new IVDR requests



- IVDD certificates = only small part
- Part of the devices requesting certificate against the IVDR more important (estimation thanks to study made in 2018 on the IVDs registered in the Netherlands)

# Remote Audit Survey : Analysis

## ❖ Source EUSurvey

- all Medical Devices Notified Bodies (n=54) received on September 28th, 2020, an invitation to the survey 'Notified Body Experience with Remote Auditing'
- The survey was closed on October 29<sup>th</sup> with 37 responses from Notified Bodies.

## ❖ Number of remote audit days

- 12 860 against the directives and
- 389 days against the regulations for Covid-19 clinically necessary products or partial audits.

→ **These significant numbers of auditing days can allow us to consider the results as revealing.**

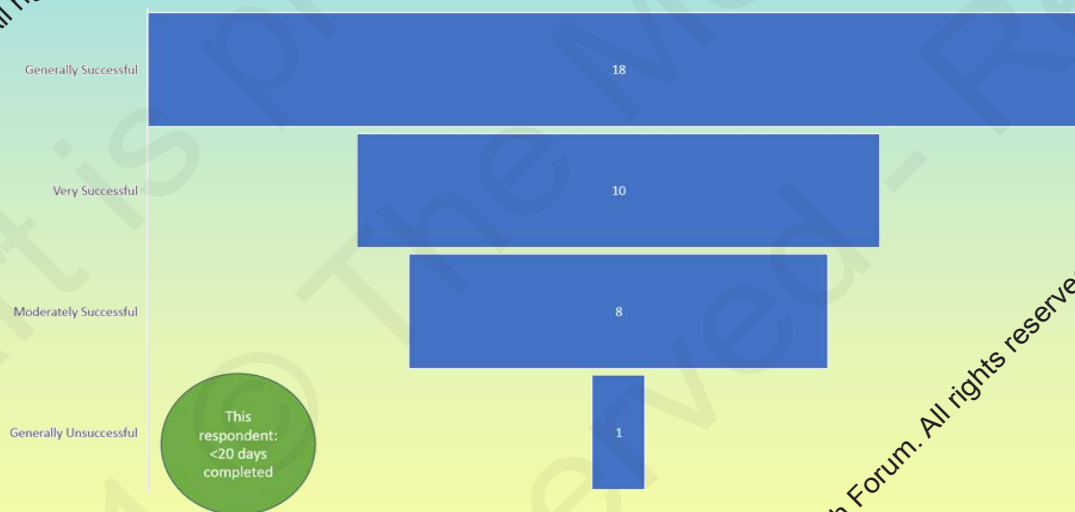


# Remote Audit Survey : Analysis

❖ **75% of these audits has been considered successful or very successful.**



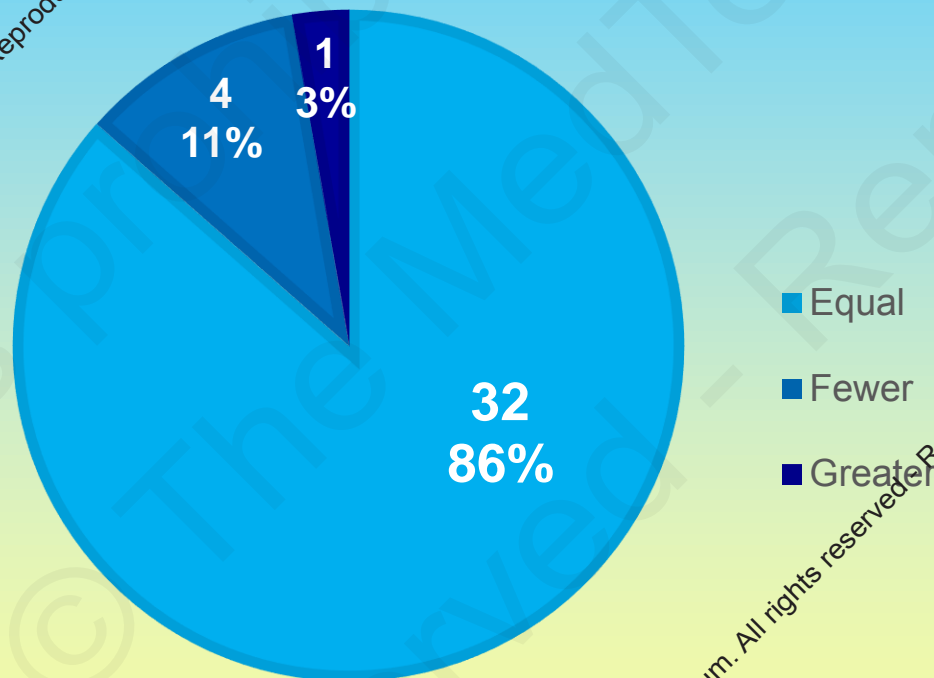
What is your experience with remote audits?



# Remote Audit Survey : Analysis



## Number of raised non-conformities



⇒ **86% of the notified bodies issued an equal number of non-conformities.**

# Remote Audit Survey : Analysis

- ❖ **These remote audits have allowed auditors to perform all necessary audit tasks:**
  - **interview operators of equipment**
  - **interview document and record owners**
  - **review documents**
  - **video camera view of records, equipment, manufacturing areas**
- ... not different from on-site tasks.
- ❖ **Ten different NBs witnessed by authorities.**
- ❖ **Remote audits allowed transparency**
- ❖ **Positive feedback is great majority.**

# Contacts



## Management:

- ◆ **Alexey Shiryaev** (Alexey.Shiryaev@dnvgl.com) – president
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# Members



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