CIRCABC Remote Audit Analysis

May 2021
Remote Audits Analysis

- Thanks to EUSurvey, the European Commission's tool
- Sent to all designated NBs (52) in the CIRCABC database
- Number of answers = 46 (i.e. 88%)
- Numbers of auditing days (> 33 000 days)

→ consider these results as revealing.
What is your experience with remote audits?

- Generally Successful: 30
- Very Successful: 9
- Moderately Successful: 4
- Generally Unsuccessful: 3
On average, did your NB raise more or less or equivalent number of non-conformities in remote audits compared to onsite audits?
How many audit days have been completed remotely for 'clinically necessary devices'?

- More than 100 days: 1
- Up to 100 days: 2
- Up to 50 days: 5
- Up to 10 days: 4
- None: 2

1/3 – 1 2/3 more days
5% - 33% more of the audit time
Number of Remote Audit Days by Type

<table>
<thead>
<tr>
<th>Type</th>
<th>AIMDD/MDD/IVDD - Legal Manufacturers</th>
<th>AIMDD/MDD/IVDD - Suppliers / Subcontractors</th>
<th>MDR/IVDR - Legal Manufacturers</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>2769,2</td>
<td>98</td>
<td></td>
</tr>
<tr>
<td>Initial - 'clinically necessary'</td>
<td></td>
<td></td>
<td>35</td>
</tr>
<tr>
<td>Initial - 'partially remote'</td>
<td></td>
<td></td>
<td>108</td>
</tr>
<tr>
<td>Surveillance</td>
<td>21511,1</td>
<td>818,1</td>
<td>112</td>
</tr>
<tr>
<td>Extension to Scope</td>
<td>896</td>
<td>50</td>
<td>22</td>
</tr>
<tr>
<td>Re-assessment</td>
<td>6244,7</td>
<td>343</td>
<td>60</td>
</tr>
</tbody>
</table>
Sharing Experiences

**Successful**
- Decreases travel time and cost
- Tight focus
- Easier to take notes
- Very effective for non physical processes (like software) and pure QMS aspects
- The verification of the quality of records is more accurate than in an onsite audit
- Remote audits are more successful with established customers

**Unsuccessful**
- Issues when there is a large time difference
- Issues with internet connections
- Video does not permit to see and look for as if we were onsite
- Generally, the spontaneousness of auditing, i.e. reacting immediately to an issue/sample picking
Are there particular clauses of MDR/IVDR related to audits that you think cannot be completed remotely?

- Infrastructure [ISO 13485 - §6.3]
- Work environment and contamination control [ISO 13485 - §6.4]
- Production and service provision [ISO 13485 - §7.5]
- Sampling for control of monitoring and measuring equipment [ISO 13485 - §7.6]
- Handling of nonconforming products [ISO 13485 - §8.3]
- MDR Clauses that must be audited on-site: 10.1, 10.9(g), 10.9(k), and 10.9(m)
- Cleanroom
- Physical devices (manufacturing process)
- For Surveillance a deeper look into production is needed, which is limited remotely
- Production
- MDR, Annex VII, 4.5.2 b)
- MDR Annex IX, Point 2.3, 3.3, however, Commission Notice C/2021/119 applies.
Have any of your remote audits been witnessed by an accreditation body, designating authority or other regulatory body?

- Auditors have been praised for good preparation and time keeping.
- Commented that there might be more time needed to be added to the usual calculated audit time.
- The remote nature of the audit did allow for multiple regulatory personnel to be present, which did feel a little like the witnessed auditor had 3 times the scrutiny, though.
- The observers' presence seems to be less noticeable and therefore less intimidating to the audit team and the auditee.
- The only noticed downside is the reduced opportunity for the observers to discuss the audit process with the audit team in a remote setting, resulting in a need to provide additional written explanations of the process after the witnessed audit, or a need of additional virtual meeting with the authority.

Yes; 19; 42%
No; 26; 58%