

Remote GLP Study Inspections:

From An Integration Tool For People with Physical Disability Towards An Opportunity For COVID-19 Pandemic Disruption

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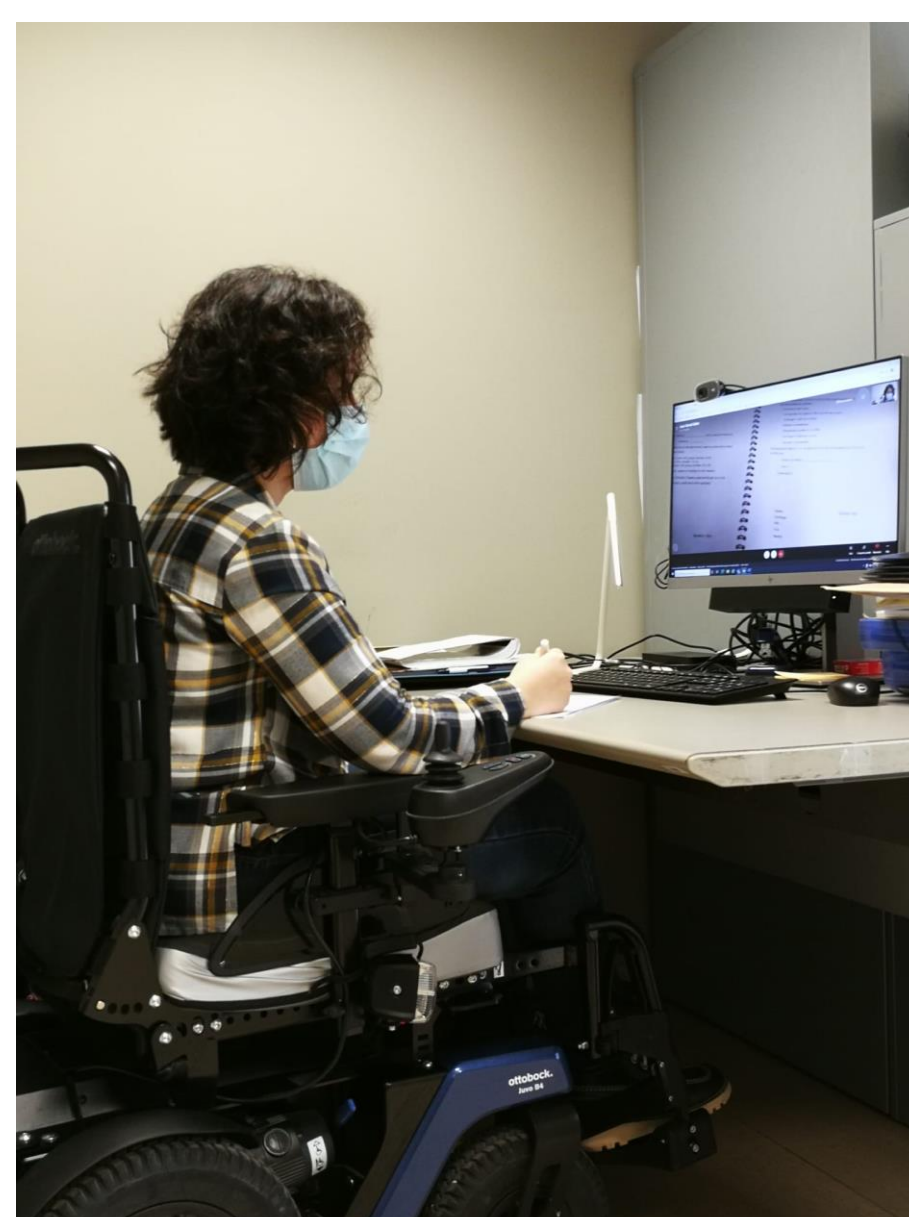
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A remote study-base inspection practice was developed in 2019 by both UTOX-PCB and QRS-UB to allow the integration of physical disabled people. Experimental phases of toxicological studies are performed in animal houses and some of them in Specific Pathogen Free (SPF) facilities. The specific contention measures of this kind of animal facilities hinder to the access of people who has physical handicaps.

The project was developed as the result of the recruiting of a new Quality Assurance Unit responsible person at UTOX-PCB, after 10 years of the quality assurance program being performed by the QRS-UB. The new QAU responsible person had a physical disability.



30 % of studies in 2020
15% of studies prevision in 2021



Validation test inside-outside:

- 1.First study inspection of OCDE guideline TG 429*: one senior inspector of QRS-UB inside the room of the SPF animal house and the new inspector of UTOX-BSP connected remotely.
- 2.Comparison of the evidences documented in the inspection checklists of both when finished
- 3.The procedure is repeated for another study inspection and with a different senior inspector of QRS-UB.
- 4.It is concluded that the observations made in person and remotely are equivalent.

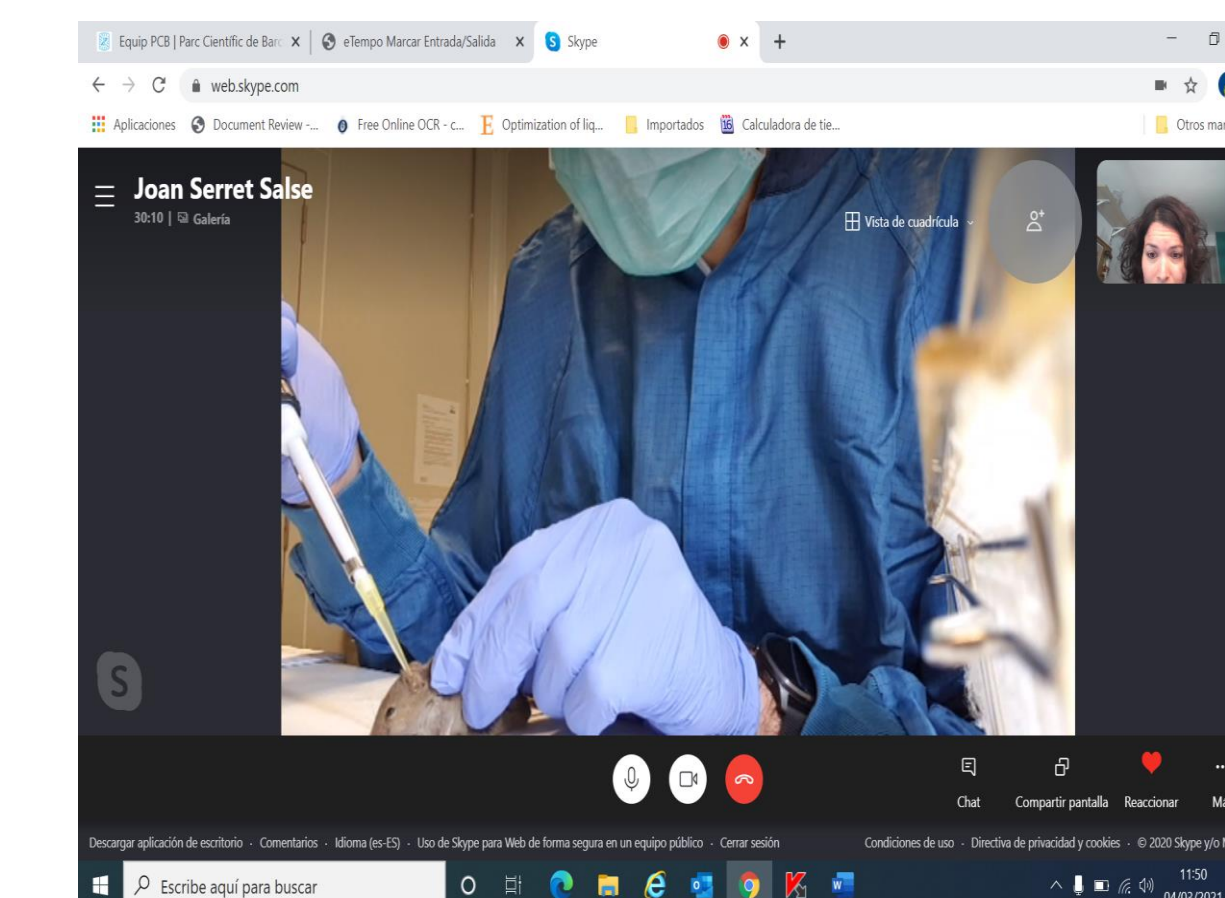


- Integration of a person with a physical disability in this type of job position.
- Experimental phase or facilities inspections can be made, regardless of the distance or impossibility of traveling to the place.
- Possibility to include images in the inspector notes



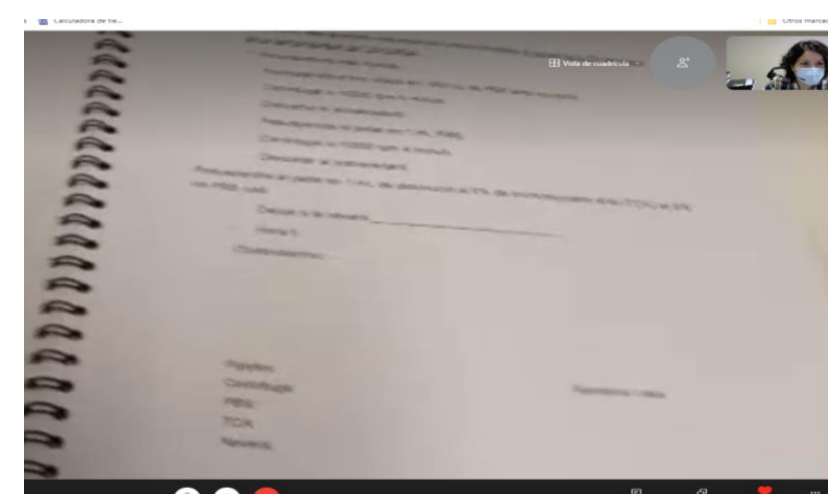
- Dependence on Internet connection and coverage.
- One more person may be required just to focus the images if the person doing the experimentation has to be moving in different areas during the experimental phase.
- It takes more time to do the same activities

The GLP inspection authorities in Catalonia (Spain) evaluate and accept this practice in July 2020.



During the COVID pandemic, both OCDE TG 429 and other study inspections are being carried out remotely, depending on the degree of lockdown

Elaboration of a SOP for remote inspections, becoming part of the quality assurance program.



- ✓ The experimentation area must be properly illuminated.
- ✓ It is more comfortable to use the camera of a mobile phone than that of a laptop. It is less heavy to move and can be placed in more places.
- ✓ To display the letters of container labels, it is advisable to put a flat white surface behind.
- ✓ If the experimentation is carried out in only one area, the study staff should place the camera device in a place where the viewing angle allows the inspector to see what he is doing, so no other person would be required.
- ✓ It would be convenient to carry out a contingency plan taking into account possible internet coverage problems and others.

The project allowed to validate that the result of the study inspections are equivalent when the inspector is in the same room where the study is being conducted or is observing the activities remotely. This has allowed the complete integration of a person with physical disabilities and to be the new responsible person of the GLP quality assurance program of UTOX-BSP. The new practice was found very useful to carry on with the study and facility inspections with the unexpected scenario of COVID-19.

*OECD TG 429 "Skin Sensitization: Local Lymph Node Assay"