

# IQ/OQ/PQ TSLog 21 Protocols



Installation, Operation and Performance Qualification Protocols documents are available for Tecnosoft systems compatible with the FDA 21 CFR Part 11, Annex 11 and GAMP regulation.

The documents are customised for each customer and can be filled directly by the user. Alternatively it is possible to ask Tecnosoft to perform the qualification.

## Operational qualification

The Operational Qualification is performed after the installation of the TSLog21 & Spine System and the Installation Qualification Protocol. Note to the customer order and order confirmation for system identification.

The OQ demonstrates that the TSLog21 & Spine System is functioning according to its specification. The Operational Qualification must be performed:

- when upon receipt of TSLog21 & Spine System
- when software and hardware are moved to a new platform
- when the OQ or TSLog21 program version are updated

## Checklist

Task	Date	Completed
Package for installation	2000/00/00	<input type="checkbox"/>
Data system and calibration	2000/00/00	<input type="checkbox"/>
System requirements	2000/00/00	<input type="checkbox"/>
Software requirements	2000/00/00	<input type="checkbox"/>
TSLog21 implementation	2000/00/00	<input type="checkbox"/>
Logoff	2000/00/00	<input type="checkbox"/>
System configuration	2000/00/00	<input type="checkbox"/>
System security	2000/00/00	<input type="checkbox"/>
Profile creation	2000/00/00	<input type="checkbox"/>
Device creation	2000/00/00	<input type="checkbox"/>
Device creation	2000/00/00	<input type="checkbox"/>
Device creation	2000/00/00	<input type="checkbox"/>
Device creation	2000/00/00	<input type="checkbox"/>
Data backup	2000/00/00	<input type="checkbox"/>
Data view	2000/00/00	<input type="checkbox"/>
System	2000/00/00	<input type="checkbox"/>
System	2000/00/00	<input type="checkbox"/>
Audit trail	2000/00/00	<input type="checkbox"/>

