

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 user and after verification 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

Test	Date	Checked
Package for installation	____/____/____	<input type="checkbox"/>
Data system and calibration verification	____/____/____	<input type="checkbox"/>
System requirements	____/____/____	<input type="checkbox"/>
Software requirements	____/____/____	<input type="checkbox"/>
TSLog21 implementation	____/____/____	<input type="checkbox"/>
Logoff	____/____/____	<input type="checkbox"/>
System configuration	____/____/____	<input type="checkbox"/>
System security	____/____/____	<input type="checkbox"/>
Profile creation	____/____/____	<input type="checkbox"/>
Device creation	____/____/____	<input type="checkbox"/>
Device creation	____/____/____	<input type="checkbox"/>
Device creation	____/____/____	<input type="checkbox"/>
Device creation	____/____/____	<input type="checkbox"/>
Data backup	____/____/____	<input type="checkbox"/>
Data view	____/____/____	<input type="checkbox"/>
System	____/____/____	<input type="checkbox"/>
System	____/____/____	<input type="checkbox"/>
Audit trail	____/____/____	<input type="checkbox"/>

