# Internal Audit Report

ISO 13485:2016 Quality Management System Audit

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| **Audit Reference:** | AUD-2026-001 |
| **Audit Date:** | 2026-01-15 to 2026-01-17 |
| **Lead Auditor:** | Sarah Chen, ISO 13485 Lead Auditor |
| **Auditee:** | PactoSigna QMS - Document Control & Design |
| **Standard:** | ISO 13485:2016, Clauses 4.2, 7.3 |
| **Classification:** | Confidential |

## 1. Executive Summary

This internal audit was conducted to verify conformance of the PactoSigna Quality Management System with ISO 13485:2016 requirements. The audit scope covered document control procedures (Clause 4.2) and design and development processes (Clause 7.3).

Overall Assessment: The QMS demonstrates substantial conformance with the applicable clauses. Two minor nonconformities and three observations were identified.

## 2. Audit Findings

**NCR-001 (Minor Nonconformity)**

Document review records for SOP-002 revision 3 were not completed within the 30-day review cycle specified in SOP-001.

**NCR-002 (Minor Nonconformity)**

Design verification evidence for requirements SRS-003 and SRS-007 was not linked to the corresponding test protocols in the DHF.

**OBS-001 (Observation)**

The electronic signature workflow could benefit from additional guidance on the meaning of each signature type per 21 CFR Part 11 requirements.

## 3. Corrective Actions Required

NCR-001: Implement automated review cycle reminders in PactoSigna. Target completion: 2026-03-15. Responsible: Quality Manager.

NCR-002: Complete traceability linking between SRS-003/SRS-007 and test protocols TC-003/TC-007. Target completion: 2026-02-28.

OBS-001: Update WI-003 (Release Signing) with expanded signature meaning guidance. Recommended completion by next audit cycle.

## 4. Conclusion

The PactoSigna QMS demonstrates effective implementation of document control and design development processes. The identified nonconformities are minor in nature and corrective actions are expected to be completed within the specified timeframes. A follow-up verification will be scheduled for Q2 2026.

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**Sarah Chen**
Lead Auditor, ISO 13485
Date: 2026-01-20