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Compliance Advisory: U.S. Food & Drug Administration Electronic Records; Electronic Signatures Rule: 21 CFR 11 and General GxP Applicability for Oracle Fusion Cloud Supply Chain and Manufacturing

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DISCLAIMER

This document is for informational purposes only and is intended solely to assist you in planning for the implementation and upgrade of the product features described. It is not a commitment to deliver any material, code, or functionality, and should not be relied upon in making purchasing decisions. The development, release, and timing of any features or functionality described in this document remains at the sole discretion of Oracle.
Due to the nature of the product architecture, it may not be possible to safely include all features described in this document without risking significant destabilization of the code.

The information contained in this paper does not constitute legal advice. Customers are advised to seek their own legal counsel to develop and implement their compliance program and to assess the features and functionality provided by Oracle in regard to their specific legal and regulatory requirements.

DOCUMENT PURPOSE

Oracle commissioned USDM Life Sciences (https://www.usdm.com/Home), an experienced life sciences consulting firm, to review Oracle's practices in the context of FDA Electronic Records; Electronic Signatures (ERES) Rule: 21 CFR 11 and general GxP applicability. As a result of this engagement, USDM Life Sciences drafted a formal report: the *Vendor Assurance Report.* This report was published in August 2020.

Oracle commissioned this report for the purpose of helping Oracle life sciences customers assess the suitability of using certain Oracle services in the context of "*FDA Electronic Records; Electronic Signatures (ERES) Rule: 21 CFR 11 and general GxP applicability."*

APPLICABILITY

The assessment was carried out for the following GxP-impacted Oracle cloud services (per section "7 Intended Use" of the report):

- Product Lifecycle Management
- E-Signatures and E-Records
- Quality Management
- Receiving
- Supply Chain Planning
- Procurement for Supply Chain Management
- Order Management
- Manufacturing
- Inventory Management
- Logistics
- Maintenance
- Adaptive Intelligent Apps for Manufacturing
- Production Monitoring
- Intelligent Track and Trace

REPORT SUMMARY

In its report, USDM Life Sciences determined that "The internal processes and methods for software development and services operations instituted by Oracle and reviewed by USDM are designed to accommodate controls required for compliance with FDA Electronic Records; Electronic Signatures (ERES) Rule: 21 CFR 11 and general GxP applicability" (*Vendor Assurance Report*, page 3).

WHERE TO FIND THIS REPORT

The USDM Life Sciences *Vendor Assurance Report* is available to Oracle life science customers via the My Oracle Support (MOS) portal. The report can be accessed directly on MOS by searching for *Resources for Oracle Supply Chain and Manufacturing (SCM) Life Science Customers in the Context of FDA 21 CFR 11* (Doc ID 2650767.1) which is available at https://support.oracle.com/CSP/main/article?cmd=show&type=NOT&id=2650767.1 .