U.S. Food and Drug Administration (FDA)
Code of Federal Regulation (CFR)

Title 21 Part 11

Compliance Report

of

As at date – 16 May 2019

Prepared By:

Riskpro India
www.riskpro.in

B-44 Glaxo Building, Near Mt. Mary's Steps,
Bandra West Mumbai – India 400 050

16 May 2019

To,
The Management,
iNDX Technology,
21580 Stevens Creek Blvd, #204,
Cupertino, CA 95014, USA

21 CFR Part 11 Compliance

Scope

Riskpro India was engaged to perform a Gap Assessment to evaluate compliance of iNDX Technology's (d/b/a iNDX.Ai) software products with 21 CFR Part 11 requirements set forth in United States (U.S.) Food and Drug Administration (FDA) Code of Federal Regulation (CFR) Title 21 Part 11, to the extent applicable to the company.

The regulatory scope of this letter is limited to 21 CFR Part 11 requirements.

Title 21 of the Code of Federal Regulations Part 11 ("Part 11"), entitled "Electronic Records; Electronic Signatures", defines

- Electronic Records as any combination of text, graphics, data, audio, pictorial, or other information representation in digital form that is created, modified, maintained, archived, retrieved, or distributed by a computer system.

- Electronic Signatures as a computer data compilation of any symbol or series of symbols executed, adopted, or authorized by an individual to be the legally binding equivalent of the individual's handwritten signature.

FDA regulated clients of iNDX Technology use its products to capture, store or transmit electronic records containing data regulated by the FDA.

Assessment Process

1. Riskpro conducted a Gap assessment to review implementation of applicable requirements and related technical controls, Standard Operating Procedures, Installation Qualification and Operational Qualification of software products developed and released by iNDX Technology.
2. Riskpro submitted
    a. a detailed Gap assessment document.
    b. this letter of compliance based on the Gap assessment document.

Compliance Status

Based on Gap assessment results, Riskpro confirms that iNDX Technology's software products for the FDA regulated industry are in compliance with applicable 21 CFR Part 11 requirements.

Manoj Jain
Founder & Director

Disclaimer: This letter is intended only for information purpose and should not be considered as an absolute audit report. It is an independent review and reporting of our findings to provide assurance to end clients about the 21 CFR Part 11 readiness of our client.

Compliance Report Notes

iNDX Technology may accept, reference and/or distribute this letter to any third party and agrees and accepts that:

1. The sole purpose of this letter is to document facts leading to iNDX.Ai's level of compliance to CFR 21 Part 11 effective on the above date of confirmation.
2. The information provided in this letter is subject to change due to new laws, regulations, or FDA policies issued after the above confirmation date.
3. While the information presented in this letter are good-faith interpretations made by Riskpro based on publicly accessible information; The Food and Drug Administration is the sole and final authority that defines CFR 21 Part 11 policies.
4. This letter does not modify any signed contracts or agreements iNDX Technology has signed with Riskpro nor does it create any Riskpro representations, warranties, guarantees or covenants for any matter other than confirmation of iNDX Technology's compliance to 21 CFR Part 11 as on the confirmation date.
5. That certain activities such as certification of electronic signatures to the FDA, and related Standard Operating Procedures are responsibility of iNDX Technology's Customer or End-Client who use iNDX Technology's products and services.