From: Stat-Ease, Inc.
To: Whom it may concern
Re: Statement on FDA 21 CFR Part 11 compliance

The FDA Title 21 Code of Federal Regulations, Part 11, ruling relates to the use of electronic records and electronic signatures in pharmaceutical manufacturing in accordance with Good Manufacturing Practices (GMP). Our Design-Expert® software helps scientists design experiments for purposes of product and process development, primarily in an industrial research setting. They do not capture or retain GMP data on durable media. Furthermore, they do not support electronic signatures or incorporate actions intended to replace a hand-written signature. Therefore, the FDA's 21 CFR Part 11 ruling does not apply to Design-Expert software.

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August 2021

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