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21 CFR Webinar (Transcript)

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Mary Kay Lofurno: Hi! I'm Mary Kay Lofurno, and I just want to welcome you to the second in a series of webinars on compliance and validation topics, put on by Veracord and its division, 21 CFR Consulting. This series is sponsored by SyberWorks, Inc. Veracord and its division, 21 CFR Consulting, is headquartered in San Jose, California, and serves the FDA Regulated Life Science industry, which includes pharmaceutical, biotechnology, and medical device companies. Veracord offers compliance consulting services nationwide, specializing in validation, IT compliance, clinical, medical, and regulatory affairs. SyberWorks specializes in custom e-learning solutions, and learning management systems in the FDA regulated compliant industries.

My name is Mary Kay Lofurno. I'm the Marketing Director for SyberWorks, and your host today. We're really glad to have you. Today, I'd like to go ahead and introduce our speaker David Park Schutz, Veracord Founder and CEO, currently heads Veracord's global sales, serving Fortune 100 clients in the validation compliance sectors.

Under Mr. Schutz's leadership and vision, Veracord's clients now include leading pharmaceutical, biotechnology, and medical device companies. Veracord remains the premier vendor for three of the top 10 global medical device companies. Park's unwavering business development efforts have strengthened Veracord's signature in the industry, as a company with integrity and uncommon commitment to clients.

After the presentation, we will be having a question and answer session. Please feel free to email us your questions. Park will do his best to answer all of those, but don't worry if we don't get to your question during the question and answer period. We will be sending out an email with a write-up of all the submitted questions and answers in the days following the webinar today. So, without any further delay, I'll turn the conference over to Park.

David Park Schutz: Hello, everybody. Thank you very much for joining our conference today. Again, my name is Park. I'm the President/Founder of Veracord. We're a San Jose, California-based provider of validation and compliance consulting services, and are fortunate enough to have a number of prominent companies as our clients, for whom we are very grateful. The purpose of this presentation is to share Veracord's viewpoints and provide an overview of 21 CFR Part 11, but a bit of emphasis on its applicability.

21 CFR Part 11 affects every life science organization, or LSO, and by that, I mean, pharmaceutical, biotech, or medical device companies, or any combination thereof. As we know, there's biopharmas and there's medpharmas, and etc. There's all kinds of combinations these days. All these, that are governed by the FDA. There are risks and penalties if systems are found to be non-compliant.

I don't want to go over the groans in the audience, because I'm not going to spend too much time on the background, but I did just want to touch on it lightly. The FDA has always been concerned with product that is ingested, digested, or introduced into the cellular structure of any people. Therefore, it stands to reason, that anything involved from the production to the person should fall under control and scrutiny. Especially, these days, the need for these controls and vigilances has never been so great, as with the current issues relating to terrorism, and etc.

Do you guys remember reading the book by Upton Sinclair entitled "The Jungle?" It was an exposé of the Chicago meatpacking industry, and contributed to the rising awareness of the need for regulations for public safety. Well, that book and that whole situation that it exposed was part of what led historically to the formation of the FDA. The significant milestone here is that, after a variety of different issues, we have one of our first predicate rules or sort of