

Exponent®
Engineering & Scientific Consulting

Jason Clevenger, Ph.D.

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Professional Profile

Jason Clevenger, Ph.D., is a principal scientist and director of the Biomedical Engineering & Sciences practice at Exponent. He has over 20 years of experience in medical devices, pharmaceuticals, and advanced materials. He specializes in materials characterization, pharmaceutical CMC consulting, medical device failure analysis, and combination drug/device product development across regulated life sciences industries.

Dr. Clevenger's expertise focuses on materials characterization and process development for specialty manufacturing, with a particular emphasis on products regulated by the U.S. Food and Drug Administration, such as medical devices, combination products, and pharmaceuticals. Dr. Clevenger's physical chemistry experience is applicable to problems involving materials such as semiconductors, MEMS, metal films, dielectrics, polymers, materials processing, materials characterization, pharmaceutical process chemistry, identification of trace contaminants including organics and particulates, and corrosion processes.

Medical devices, combination products, and pharmaceuticals consulting

Dr. Clevenger's medical device experience includes method development for regulatory submissions, product development and manufacturing support, and technology due diligence assessment. His pharmaceutical experience includes process development and optimization for transdermal and solid oral formulations, regulatory compliance and CMC (Chemistry, Manufacturing, and Controls) related issues involving root-cause analysis, corrective and preventive action plans, and quality assurance. He also has experience in the development of combination drug/device products, as well as litigation matters involving patent infringement, contract manufacturing, and business disputes for regulated products.

Materials characterization for advanced manufacturing

Dr. Clevenger's materials characterization background encompasses a broad range of advanced technologies and techniques, with applications in biomedical, semiconductor, and consumer electronics manufacturing. He has extensive experience with plasma chemistry and spectroscopy, thin film metrology and reliability, high-vacuum technology, and semiconductor processing, as well as the following analytical capabilities.

Analytical capabilities

- Laser spectroscopy
- X-ray photoelectron spectroscopy (XPS)
- Auger spectroscopy

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- Raman spectroscopy
- Fourier-transform infrared spectroscopy (FTIR)
- Solid/liquid-nuclear magnetic resonance (NMR) spectroscopy
- Gas and liquid chromatography (GC/LC) with mass spectrometry (MS)
- Optical emission/absorption spectroscopy
- Energy dispersive spectroscopy (EDS)
- White-light interferometry
- Spectroscopic ellipsometry
- Atomic force microscopy (AFM)
- Secondary-ion mass spectrometry (SIMS)

Government life sciences investigations

Dr. Clevenger has participated in a variety of government investigations involving life sciences companies and regulated products, including those involving FDA and the Department of Justice under the False Claims Act. He has conducted site visits at manufacturing facilities in the U.S. and Europe to facilitate investigations.

Process development for manufacturing and R&D

Dr. Clevenger has applied his experience in applying process development tools such as Design of Experiments (DoE) for challenging, multi-factorial problems related to semiconductor, consumer product, and medical product manufacturing. He has performed a number of site visits to manufacturing facilities in North America, Europe, and Asia for mitigation of quality deviations and due diligence investigations.

Academic Credentials & Professional Honors

Ph.D., Physical Chemistry, Massachusetts Institute of Technology (MIT), 2002

B.A., Chemistry, Vanderbilt University, 1995

Phi Beta Kappa and Omicron Delta Kappa

Barry M. Goldwater Foundation Scholarship, Goldwater Excellence in Education Foundation, (1994)

Prior Experience

Process Technologist (Etch and CVD), Applied Materials, Inc. (2002-2004)

Professional Affiliations

American Association of Pharmaceutical Scientists—AAPS

American Chemical Society—ACS

Patents

United States Patent – US 9,744,353 B2. Detection of Presence and Alignment of a Therapeutic Agent in an Iontophoretic Drug Delivery Device, Issued August 29, 2017 (with R. Mann and D. Saar)

Publications

Coombs, C. Rodriguez-Quijada, J.O. Clevenger, A.F. Sauer-Budge. 2023. Current Understanding of Potential Linkages between Biocide Tolerance and Antibiotic Cross-Resistance. Microorganisms 11(8): 2000.

Kou PM, Clevenger JO. A coat for all weathers: A survey of the hydrophilic coatings market. Med Device Develop 2012; May.

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Ibarreta A, Davis S, Clevenger JO. Flammability of electrical crimp connectors subjected to heating. Proceedings, Fire and Materials 10th International Conference, 2007.

Kay JJ, Byun DS, Clevenger JO, Jiang X, Petrovic VS, Seiler R, Barchi JR, Merer AJ, Field RW. "Spectrum-only" assignment of core-penetrating and core-nonpenetrating Rydberg states of calcium monofluoride. Can J Chem 2004; 82(6):791-803.

Brooks CB, Anderson RB, Clevenger JO, Collard C, Halim M, Sahin T, Mak, AW. Optimization of chrome dry etch in Tetra II using asymmetrically loaded patterns. Proceedings, SPIE-The International Society for Optical Engineering, 2003, 5256 (Pt. 2, 23rd Annual BACUS Symposium on Photomask Technology, 2003), pp. 749-757.

Collard C, Anderson SA, Anderson RB, Clevenger JO, Halim M, Brooks CB, Buie MJ, Sahin T. Examination of various endpoint methods for chrome mask etch. Proceedings, SPIE-The International Society for Optical Engineering, 2003) 5256 (Pt. 2, 23rd Annual BACUS Symposium on Photomask Technology, 2003), pp. 744-748.

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Anderson SA, Anderson RB, Buie MJ, Chandrachood M, Clevenger JO, Lee Y, Sandlin NL; Ding J. Optimization of a 65-nm alternating phase-shift quartz etch process. Proceedings, SPIE-The International Society for Optical Engineering, 2003, 5256 (Pt. 1, 23rd Annual BACUS Symposium on Photomask Technology, 2003), pp. 66-75.

Clevenger JO, Buie MJ, Sandlin NL. Effect of chamber seasoning on the chrome dry etch process. Proceedings, SPIE-The International Society for Optical Engineering, 2003, 5130 (Photomask and Next-Generation Lithography Mask Technology X), pp. 92-100.

Li L, Dai X, Liu Y, Clevenger JO, Field RW, Jeung GH, Geum N, Lyyra AM. The Predissociation of 13S g State of 7Li2. J Molecul Spectrosc 2001; 205(1):139-145.

Dai X, Clevenger JO, Liu Y, Song M, Shang J, Chen D, Field RW; Li L. The 23 Dg State of 7Li2. J Molecul Spectrosc 2000; 200(1):120-122.

Clevenger JO, Harris NA, Field RW, Li J. The predissociation mechanism for 2S + Rydberg states of CaCl. J Molecul Spectrosc 1999; 193(2):412-417.

Clevenger JO, Tellinghuisen, J. The *B*(1/2 2P3/2) - *X*(1/2 2S +) transition in XeBr. J Chem Phys 1995; 103(22):9611-9620.

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Radzykewycz DT, Littlejohn CD, Carter MB, Clevenger JO, Purvis JH, Tellinghuisen J. The D1- A1 transition in IBr: A deperturbation analysis. J Molecul Spectrosc 1994; 166(2):287-303.

Project Experience

Medical devices, combination products, and pharmaceuticals consulting

- Led an eight-year consulting engagement for a drug-led iontophoretic drug delivery system that spanned from clinical trial support to U.S. regulatory approval and commercialization. Served as a technical due diligence representative on behalf of the sponsor. Developed non-standardized test methods to answer FDA review questions. Co-invented a patented safety system for iontophoretic drug delivery as part of this project that facilitated revised approval of sponsor's New Drug Application by the U.S. FDA.
- Led a CMC-based engagement for a U.S.-based pharmaceutical distributor to evaluate product integrity for hundreds of individual pharmaceutical products following storage temperature excursions. These evaluations led, in some cases, to product recalls by the distributor.
- Provided consulting support and litigation testimony regarding presence of nitrosamine species in multiple pharmaceutical formulations over a multi-year period.
- Co-retained in a contract research (CRO) business dispute for an experimental pre-clinical gene therapy candidate.
- Co-led a consulting engagement for a multi-billion-dollar business dispute regarding FDA approval timelines for a CAR-T cell therapy drug.
- Performed multiple insurance-based investigations of drug product viability due to freezer failures.
- Led a multi-year engagement for a medical device implant manufacturer with unique battery power requirements and a history of complex FDA regulatory interactions. Exponent generated data that alleviated regulatory concerns regarding the form factor of the rechargeable cell used in the implant, leading to premarketing authorization (PMA) approval for the implant.

Materials characterization for FDA-regulated products

- Provided consulting support and expert testimony at deposition and trial for the analysis and characterization of dietary supplement formulations.
- Co-retained in a matter involving analysis and investigation of dietary supplement formulations for potential infringement of a patented manufacturing process for the primary ingredient, resulting in removal of misbranded competing products from the U.S. marketplace.
- Performed an analysis of final products and constituent components for potential infringement of a synthetic urine product.
- Developed complementary physical and chemical approaches for multiple root-cause investigations of pharmaceutical manufacturing batch failures and out-of-specification (OOS) results for various solid oral and transdermal drug formulations.
- Led supply chain due diligence investigations for key excipients of drug formulations, including laboratory analysis and conducting manufacturer site visits.
- Submitted declarations to the U.S. Patent and Trademark Office (USPTO) for *inter partes* patent reexamination of rapid-dissolving-film-based drug delivery systems.

Government life sciences investigations

- Served as principal in charge and co-technical lead for investigations facilitated by outside counsel for various medical device companies following whistleblower complaints and self-disclosure to the U.S. Food and Drug Administration (FDA) and the Department of Justice (DoJ).
- Conducted international site visits to various contract manufacturers of a medical device company involved in the self-disclosure process to the U.S. DoJ.

Process development for manufacturing and R&D

- Supported client quality teams for consumer electronic device manufacturers involving vendor qualification and performing site visits for process review and troubleshooting.
- Utilized and conducted design-of-experiment (DoE) methodology for process parameter optimization in diverse applications ranging from laser-texturing of polyurethane synthetic leather to medical device manufacturing.
- Developed and built on-site laboratory capabilities for client manufacturing support at Exponent’s Hong Kong office as the founding office director.
- Performed failure analysis and process optimization for parylene-based coatings used in RF MEMS switch packaging as part of a multi-year DARPA sub-contract.