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Engineering & Scientific Consulting

Jason Ryans, Ph.D.

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Professional Profile

Jason Ryans, Ph.D., is a senior associate in Exponent's Biomedical Engineering & Sciences practice with over 8 years of experience in FDA regulatory affairs, medical device policy, and regulatory compliance. As a former Regulatory Policy Analyst at the FDA Center for Devices and Radiological Health (CDRH), he advises medical device manufacturers, legal teams, and healthcare companies on the interpretation and application of FDA statutes, regulations, guidance documents, and policy. His expertise focuses on FDA regulatory strategy, quality systems and postmarket compliance, and medical device litigation and regulatory disputes.

FDA Regulatory Strategy

Dr. Ryans advises medical device manufacturers on FDA regulatory pathways and premarket strategies across the total product lifecycle, including 510(k), De Novo, and Premarket Approval (PMA) pathways. He evaluates device classification, intended use, technological characteristics, predicate considerations, and applicable special controls to help clients develop well-supported regulatory strategies.

Drawing on seven years of experience as a Regulatory Policy Analyst at the FDA Center for Devices and Radiological Health (CDRH) advising review staff and industry, Dr. Ryans provides practical insight into the interpretation and application of FDA statutes, regulations, guidance documents, and policy. He translates complex, evolving regulatory requirements into actionable recommendations that help clients identify potential issues, prepare for FDA interactions, and align product-development and submission strategies with current agency expectations.

Medical Device Litigation & Regulatory Dispute Support

Dr. Ryans supports law firms, manufacturers, and in-house counsel in litigation and dispute matters involving FDA-regulated medical devices. He assists legal teams in evaluating FDA regulatory issues that arise in product liability, contract dispute, false advertising, and compliance-related matters.

His analyses focus on the interpretation and application of FDA statutes, regulations, guidance documents, and regulatory policy, as well as the regulatory significance of evidence commonly encountered in litigation and disputes, including:

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- **Premarket Regulatory Evidence**: regulatory pathway determinations; marketing submissions (510(k), De Novo, & PMA); Q-Submissions; FDA correspondence

- **Postmarket Regulatory Evidence**: complaints files and Medical Device Reports (MDRs); recalls, corrections, and removals; product lifecycle management activities and regulatory change assessments

- **Compliance and Enforcement Evidence**: quality management system documentation and records; corrective and preventative action (CAPA) activities; complaint handling and adverse event reporting processes; FDA inspection information including Form 483 observations and classification; warning letters and other enforcement actions

When called upon as an expert witness, Dr. Ryans provides independent opinions regarding FDA regulatory requirements and the interpretation of regulatory evidence relevant to the issues in dispute.

Quality Systems & Postmarket Compliance

Dr. Ryans advises medical device manufacturers on quality management system (QMS) requirements, FDA compliance risk, and postmarket compliance requirements throughout the product lifecycle. He helps organizations evaluate the effectiveness of their quality systems, identify compliance vulnerabilities, and develop strategies to address evolving FDA expectations.

His experience includes FDA's Quality Management System Regulation (QMSR), alignment with ISO 13485, CAPA systems, complaint handling, adverse event reporting under MDR regulations, and postmarket surveillance. He helps manufacturers build and maintain compliance programs that satisfy both FDA expectations and international quality standards. Dr. Ryans assists clients in understanding how FDA requirements are interpreted and applied in practice and how quality system decisions may affect regulatory, operational, and business risks.

Academic Credentials & Professional Honors

Ph.D., Biomedical Engineering, Tulane University, 2018

M.S.E., Biomedical Engineering, Mercer University, 2012

B.S.E., Biomedical Engineering, Mercer University, 2012

Prior Experience

Regulatory Policy Analyst, US FDA, CDRH, 2018-2025

Professional Affiliations

Food and Drug Law Institute (FDLI)

Publications

Ryans J, Fujioka H, Gaver D. Micro-scale to Meso-scale analysis of parenchymal tethering: the effect of heterogeneous alveolar pressures on the pulmonary mechanics of compliant airways. Journal of Applied Physiology 2019.

Ryans J, Fujioka H, Halpern D, Gaver D. Reduced-dimension modeling approach for simulating recruitment/de-recruitment dynamics in the lung. Annals of Biomedical Engineering 2016; 44(12):3619–3631.

Fujioka H, Halpern D, Ryans J, Gaver D. Reduced-dimension mode of liquid plug propagation in tubes. Physical Review Fluids 2016; 1(5):053201.

Presentations

Ryans J, Fujioka H, Halpern D, Gaver D. A computationally tractable model of alveolar/airway interactions in the entire lung. 2017 BMES Annual Meeting, October 2017.

Ryans J, Fujioka H, Halpern D, Gaver D. Multi-scale modeling of parenchymal/airway interactions. 2016 BMES Annual Meeting, October 2016.

Ryans J, Fujioka H, Halpern D, Gaver D. Multi-scale modeling of liquid obstruction formation and clearance in the lung. 2015 BMES Annual Meeting, October 2015.

Ryans J, Fujioka H, Halpern D, Gaver D. Multi-scale modeling of liquid plug formation and clearance in the lung. Computational Fluid Dynamics (CFD) in Medicine and Biology II an ECI Conference Series, August 2015.

Ryans J, Fujioka H, Halpern D, Gaver D. Dynamic multi-scale model of the lung. 2014 BMES Annual Meeting, October 2014.

Ryans J, Fujioka H, Halpern D, Gaver D. Dynamic multi-scale model of the lung. 2014 World Congress of Biomechanics, July 2014.

Glindmeyer IV H, Ryans J, Pillert J, Smith B, Gaver D. Quantifying stress-induced pulmonary epithelial damage during airway reopening. 2013 BMES Annual Meeting, September 2013.

Ryans J, Welch B, Hyun S, Zhang Z, Kleinstreuer C. Variations in tracheobronchial airway morphology for different age groups. ASME 2010 Summer Bioengineering Conference, June 2010.

Project Experience

FDA Regulatory Strategy

- Regulatory Due Diligence for a Consumer Wearable: Advised a startup developing a consumer wearable on FDA product classification and regulatory strategy, evaluating whether the product could be marketed as a general wellness product or would be regulated as a medical device. Provided recommendations regarding regulatory risk, claims, labeling, and commercialization timelines and cost.
- 510(k) Regulatory Strategy and FDA Interaction Support: Advised a medical device manufacturer during FDA review of a 510(k) submission following receipt of an Additional Information (AI) request. Assessed FDA's information requests in the context of applicable regulatory requirements, guidance documents, and least burdensome principles and provided strategic recommendations regarding response options, regulatory risk, and agency engagement.

Medical Device Litigation & Regulatory Dispute Support

- Medical Device Product Liability: Supported litigation, including multidistrict litigation (MDL), involving FDA-regulated medical devices by analyzing FDA regulatory requirements, publicly available FDA databases, and regulatory evidence, including adverse event reports, recalls, and enforcement actions. Provided substantial support in the development of expert opinions and expert report materials regarding the interpretation and regulatory significance of FDA-related evidence.
- Contract Dispute Involving Regulatory Approval Milestones: Supported litigation arising from a corporate acquisition dispute in which FDA regulatory approval was a key factor in determining whether contractual obligations had been satisfied. Conducted analyses of FDA-related evidence, including regulatory submissions, agency communications, and applicable regulatory requirements, and provided substantial support in the development of expert opinions and expert report materials.

Quality Systems & Postmarket Compliance

- Complaint Handling Process Evaluation and SOP Enhancement: Advised a medical device manufacturer on complaint handling compliance by assessing complaint management processes and associated quality system procedures. Identified areas for improvement relative to FDA requirements and supported the development and revision of SOPs to strengthen complaint evaluation, documentation, investigation, and escalation practices.